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Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

Submission number	10808931	
Application number	EP15180327.7	
Date of receipt	30 March 2022	
Receiving Office	European Patent Office, The Hague	
Your reference	255.0051G1 et al.	
Applicant	All applicants as on file	
Documents submitted	package-data.xml epf1038.pdf (2 p.)	ep-sfd-request.xml
Submitted by	CN=Korbinian Kopf 47644	
Method of submission	Online	
Date and time receipt generated	30 March 2022, 16:57 (CEST)	
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Letter accompanying subsequently filed items

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The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

Application number	15180327.7
Applicant's or representative's reference	255.0051G1 et al.

	Description of document	Original file name	Assigned file name

	Payment	
1	Method of payment	Not specified

Annotations

Receipt confirmation(Korbinian Kopf; 30.03.2022)
1. Remark(Annotate)
Receipt of the following communications is herewith confirmed:

EP15180327.7
Communication dated 25.03.2022
Our ref. 255.0051G1

EP13766222.7
Communication dated 24.03.2022
Our ref. 600.1095EP-OPP

EP11817336.8
Communicaton dated 30.03.2022
Our ref. 600.1121EP-OPP

Signatures

Place:	**Munich**
Date:	**30 March 2022**
Signed by:	**Korbinian Kopf 47644**

Association:	**LKGLOBAL | Lorenz & Kopf PartG mbB Patentanwälte**
Representative name:	**Korbinian Kopf**
Capacity:	**(Representative)**

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Date
25-03-2022

Reference		Application No./Patent No.
272.0046OP	OPPO 02	15180327.7 - 1126 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

EPA/EPO/OEB Formblatt/Form/Formulaire : 2310

Empfangsbescheinigung über den Zugang des vorstehend bezeichneten Schriftstücks
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Récépissé du document spécifié ci-dessus

Unter Bezugnahme auf die Mitteilung im ABl EPA 7/2010, 377 wird gebeten, die Empfangsbescheinigung mit Empfangsdatum und Unterschrift zu versehen und **umgehend** an das EPA zurückzusenden:

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28. März 2022

238337

Date
25-03-2022

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor: Edwards Lifesciences PVT, Inc.	

EPA/EPO/OEB Formblatt/Form/Formulaire : 2310

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Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 5
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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Date
25-03-2022

Reference	OPPO 02	Application No./Patent No.
272.0046OP		15180327.7 - 1126 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

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Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 6
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC
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Provisional non-binding opinion of the opposition division

1 With the notice of opposition, both opponents requested the revocation of the contested patent in its entirety based on Art. 100(a) EPC on the grounds of novelty (Art. 54(1) EPC) and inventive step (Art. 56 EPC), based on Art. 100(b) EPC on the ground of insufficiency of disclosure and based on Art. 100(c) EPC on the ground of added subject-matter. As an auxiliary measure, oral proceedings according to Article 116 EPC were requested.

The following evidence has been submitted within the opposition period and is in the following renumbered to form a consolidated list:

EPO	CITATIONS	P	OP1	OP2
P1	US 10/883,575		E1a	
A1	EP 2 982 337 A1		E1c	
B1	EP 2 982 337 B1		E1d	
D1	US 5,258,023 A		D1	WBH1
D2	FR 2 337 543		D2	WBH2
D2a	US 4,106,129		D2a	
D3	WO 00/64380 A1		D3	WBH3
D4	FR 2 815 844 A1		D4	WBH4
D5	EP 2 537 487 A1		D5	WBH5
D5a	US 2005/137688		D5a	
D5b	US 2005/137698		D5b	WBH11
D6	WO 01/56512 A1		D6	
D7	US 6,454,799 B1		D7	WBH7
D8	US 2003/153974 A1		D8	WBH9

D9	DE 26 13 575 A1		D9	
D10	WO 03/053287 A1		D10	WBH17
D11	US 6,729,356 B1		D11	
D12	US 2004/0082989 A1		D12	
D13	Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)		D13	
D14	WO 03/039613 A1		D14	
D15 A1p	WO 2006/005015 A2 (publication of the parent application)		E1b	
D16	US 5,554,184 A			WBH6
D17	US 6,638,257 B2			WBH8
D18	WO 2006/089236 A1			WBH10
D19	WO 2004/082527 A2			WBH12
D20	WO 01/54625 A1			WBH13
D21	WO 01/76510 A2			WBH14
D22	US 2004/0210304 A1			WBH15
D23	US 5,855,601 A			WBH16
D24	US 2002/0052649 A1			WBH18
D25	Patent Assignment			Annex 3

The publication of the parent application as filed is in the following referred to as

A1p: **WO2006/005015 A2**

2 It seems that since the opposition was filed in due time and in proper form and is supported by reasoned statements, the opposition is admissible under Article 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

3 Added subject-matter (Article 100(c) EPC)

The following points regarding added subject-matter have been brought up in the procedure and will be discussed during the oral proceedings:

The requirements of added subject-matter are discussed below with reference to the publication of the parent application **A1p**. As the description of the application of the patent in suit corresponds to the description as filed of the parent application with the claims added as clauses, the below argumentation holds for both the requirements of Art. 76(1) EPC and Art. 123(2) EPC.

3.1 *Claim 1*

It is agreed upon that basis for **claim 1** as granted might be found in **claim 27** of **A1p** and the embodiment of Fig. 22 and description thereof.

3.1.1 The opponents argue that **claim 1** extends in subject-matter for the following reasons:

a) Omission of the feature of original **claim 27** that the compressible material is adapted for expansion after deployment.

b) Addition of the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

c) Omission of a feature of original **claim 27** that the valvular structure provides a flexible conduit.

d) Addition that the compressible material forms a sleeve.

3.1.2 re a)

The opposition division considers that the deleted feature of **claim 27** of **A1p** that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel limits the claimed materials to those able to fill the gaps due to its expansion properties. Also the description limits the layer of material in the same way (par. [00145]). In contrast thereto, **claim 1** as granted seems to encompass a layer of material only minimally expanding after delivery but filling the gaps by an increased bulk thickness at the positions of the gaps, e.g. the commissures, thus extending in scope over what has been originally disclosed.

3.1.3 re b)

It seems that the closest basis for feature b) might indeed be found in **claim 29** of **A1p**. There, a plurality of outward extending fibers are disclosed in combination with a growth factor disposed along the compressible material and the compressible material being formed of PET (**claim 28**). The opposition division preliminarily considers that the technical function of the outwardly extending fibres, namely to provide an increased active surface for encouraging coagulation (pars. [00055], [00142], [00145]), is linked to the geometry of the fibers and not to the chemistry of the material. The same holds for the presence of a tissue growth factor in the layer of material itself. As the description in par. [00145] clearly mentions both features of PET and the growth factor to be optional, the opposition division considers the omission of these features from original **claim 29** an allowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.1.4 re c)

It will be discussed during oral proceeding whether the valvular structure of **claim 1** implicitly defines a flexible conduit, so that the omission of an explicit definition seems allowable.

In this respect the opposition division considers that a valvular structure formed of a pliant material as claimed is necessarily flexible.

Preliminarily, it seems that even in case of three separate leaflets only connected to each other at the commissures the resulting structure might be called a "conduit", in particular as the only characteristic of a conduit mentioned in the application is that it has an inlet and an outlet. At present, the opposition division thus cannot conceive of a valvular structure for a heart valve prosthesis formed of three valve leaflets of pliant material in a form different from a flexible conduit, i.e. conveying blood from an inlet to an outlet. The omission of an explicit definition thus seems allowable.

3.1.5 re d)

OP2 argues that a layer of material in the form of a sleeve as disclosed in par. [00145] might also be provided spaced apart from the stent structure, while the claimed sleeve of a stent structure would provide covering and protection and thus be more limiting. The opposition division currently sees this as a rather linguistic approach and is currently of the opinion that a layer of material in the form of a sleeve necessarily also forms a sleeve.

In any way, the division sees par. [00145] to disclose a layer of compressible material disposed along an outer surface of the whole stent structure. This, however, seems to encompass the function of covering and protection, and thus equates the scope of the claimed sleeve.

3.1.6 Preliminarily, the opposition division thus considers solely to omission of a feature towards the compressible material being adapted for expansion after deployment to fill gaps in **claim 1** to extend in subject-matter over the original disclosure of the parent application.

3.2 *Claim 2*

The opponents argue that there is no direct and unambiguous disclosure of a sleeve surrounding an inflow end of the stent structure.

The description is silent on the position of the sleeve and the opposition division preliminarily considers that the person skilled in the art would also not immediately recognize a technical function of the position of the sleeve in Fig. 22, in particular as no technical link such as a position of the gap with respect to the stent and/or its longitudinal axis is apparent from the description. It might therefore even be considered that the inflow end of the stent in Fig. 22 is covered by the sleeve merely due to the whim of the artist and not due to a technical consideration. Thus the person skilled in the art would not be able to deduce the position of the sleeve relative to the stent's end from Fig. 22 or the description. Preliminarily, the subject-matter of **claim 2** seems to extend beyond the content of the (parent) application as filed.

3.3 *Claim 3*

The opponents argue that the thickness defined in **claim 3** is only originally disclosed together with the material PET. It seems that the only disclosure of a thickness ranging from 1-5mm as defined in **claim 3** is in par. [00145], which also discloses that the material is PET. No other material is disclosed for the embodiment of Fig. 22. The thickness of the layer and the material it is made of are functionally related as the ability to expand to fill gaps is not only due to thickness of the layer but also due to the materials expansion properties, softness, swellability etc. Therefore the opposition division preliminarily considers that the person skilled in the art would be surprised to see the claimed thickness for a generic compressible material. Preliminarily, the omission of a feature towards the material being PET seems to constitute a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.4 *Claim 4*

The opponents argue that a cloth or fabric is only disclosed in the context of the compressible material resembling a cloth or fabric (par. [00145]) and having small fibers extending from its surface so that the omission of the underlined features constitutes a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

The opposition division is of the preliminary opinion that the disclosure of par. [00145] of the compressible material resembling a cloth or fabric having small fibers extending form the surface of the material together with par. [0055] of the background of the invention relating to the same embodiment and disclosing a compressible material "*such as clot or fabric*" is sufficient basis for the material being cloth or fabric. In that respect, the opposition division considers that the word "clot" in this passage can only mean cloth, as also used in par. [00145].

Regarding the term "small", generic fibers are not only disclosed in par. [0055] but also in **claim 29** as filed, so that its omission seems unproblematic.

3.5 *Claim 5*

The additional feature of **claim 5** is disclosed in original **claim 29** together with the feature of the compressible material including a plurality of fibers that is already part of **claim 1** as granted. **Claim 5** is thus not seen as adding problems of extension of subject-matter.

3.6 *Claims 6, 7*

The additional features of **claims 6 and 7** are disclosed word by word in par. [00145] as respective optional features. **Claims 6 and 7** are thus not seen as adding problems of extension of subject-matter.

3.7 *Claim 8*

The opponent argues that the omission of a feature towards the compressible material being adapted for expansion into the gaps after deployment would extend its subject-matter. The opposition division preliminarily considers that gaps between a prosthetic valve and the body channel can only occur after deployment, and thus a compressible material configured to expand into these gaps necessarily is configured to do so after deployment. **Claim 8** is thus not seen as adding problems of extension of subject-matter.

3.8 *Claim 9*

The opposition division considers that there is no direct and unambiguous disclosure of the compressible material adjusting to the shape of a cavity existing between the valve and the vessel wall. There is merely a disclosure of the compressible material expanding into the gaps. This, however, also includes situations where the expanded shape of the material layer is pre-formed to correspond to the shape of the gaps or also where a material layer expands uniformly and seals the gaps by deforming the surrounding vessel wall. There seems thus no disclosure towards the more limited situation defined in **claim 9**, i.e. the subject-matter of **claim 9** as granted is seen as an unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.9 *Figures*

Opponent 2 argues that Fig. 22 of the parent as originally filed depicts a blank outer surface of the compressible material without any further structure, whereas Fig. 22 of the patent shows a surface comprising small elements irregularly distributed. The proprietor argues that Fig. 22 as filed seems to depict similar small structures in the vicinity of the left edge of the sleeve. To the opposition division, however, these structures are not clearly discernible and might also be scanning artefacts, i.e. no information can be derived from them.

In order to establish whether the addition of the small elements to Fig. 22 of the patent extends the subject-matter disclosed, it has to be established what the person skilled in the art would be able to derive from the figure. In this respect, the opposition division considers that the person skilled in the art only recognizes elements with a technical function immediately apparent, either from the drawing on its own or from the teaching of the description (see Case Law of the Boards of Appeal II-E-1.13). The opposition division considers that no technical function of the small elements can be deduced from the drawing on its own. The description, on the other hand, discloses only a single option for elements on the surface of the compressible material 256, namely fibers. Thus the person skilled in the art is would immediately recognize those fibers in the the elements of Fig. 22. The opposition division is unable to see how this could present any new information to the person skilled in the art over what was originally disclosed in the parent application as a whole.

Regarding the disclosure of the other figures, the opposition division considers that in the absence of a detailed argumentation on which features should be seen as extending over the content of the parent application no such extension is present, with the same reasoning as above for Fig. 22.

3.10 For the above reasons, the opposition division thus preliminarily considers the subject-matter of **claims 1, 2, 3** and **9** to extend beyond the content of the parent application.

4 Novelty (Article 100(a) EPC in connection with Art. 54(1) EPC)

The opponents argue that the priority of the patent is not validly claimed. Following from that, they argue that the subject-matter of **claim 1** is not novel over prior art documents **D5b**, **D6**, **D8**, **D14, D18-D23** (Art. 54(1) EPC).

4.1 *Priority*

The opposition division is of the preliminary opinion that the priority of **claim 1** is not valid as the priority document **P1** does not comprise the embodiment of Fig. 22, i.e. there is no disclosure of the claimed features of a prosthetic valve with a layer of compressible material forming a sleeve and including a plurality of fibers extending outward from the outer surface (Art. 87(1) EPC).

The question of whether the priority is invalid due to formal reasons will only be discussed and decided upon if necessary. At present it seems this will not be the case.

4.2 *Prior art document D5b (Art. 54(2) EPC)*

Prior art document **D5b** published on 23 June 2005 is preliminarily considered as prior art under Art. 54(2) EPC as the priority of **claim 1** of the patent seems not valid.

It discloses a prosthetic valve with an outer seal in the form of a sleeve and made of thin, elastic polymer or any other type of fabric (Figs. 8A-8C, par. [0071]).

The opposition division preliminarily considers a fabric material as a compressible material. This is also in line with the disclosure of the patent in suit (compare par. [0055] of **A1p**). Therefore feature F4 seems disclosed by **D5b**.

In the absence of convincing evidence to the contrary, the opposition division does not agree with the opponent's assertion that any fabric inevitably comprises outwardly extending fibers. In particular it seems that a fabric of monofilament fibers cannot comprise such outwardly extending fibers at all. Thus feature F6 seems not implicitly disclosed in prior art document **D5b** so that the subject-matter of **claim 1** is preliminarily found novel over this document (compare Case Law of the Boards of Appeal I-C-4.3).

4.3 *Prior art document D6 (Art. 54(2) EPC)*

Prior art document **D6** discloses a prosthetic heart valve 10A/10M with an umbrella-like frame structure 20 formed from four U-shaped elements 30, i.e. eight spokes, to which a dome-shaped valve membrane 22 is attached forming several leaflets (page 8, lines 7-21; page 11, lines 14-30). An outer band 40 is circumferentially attached to the frame forming a sleeve and may be made of velour (page 9, line 23 -28; page 11, lines 6-13).

The opposition division preliminarily considers the umbrella-like frame structure 20 of D6 not to be a substantially cylindrical stent structure, as by attaching the U-shaped struts in their respective middle parts to each other the stent structure is clearly closed at one end, while a cylindrical structure must be tubular with two open ends. Therefore feature F2 seems not disclosed in **D6**.

While the opposition division preliminarily considers that the flaps of **D6** might be validly considered as leaflets as they comprise commissures and open and close to regulate the blood flow, **D6** does not disclose a tri-cuspid valve.

While the description of prior art document **D6** does not explicitly disclose the number of attachment points 56 of the dome shaped valve membrane 22 (page 12, line 24 - page 13, line 5), it seems that the person skilled in the art looking at Fig. 3 will immediately recognize the symmetry of the eight struts and thus also four attachment points. In the preliminary opinion of the opposition division, the mere possibility to use more or less U-shaped struts 30 (page 8, lines 18-21) is not a direct and unambiguous disclosure of exactly three attachment points, in particular since there is no disclosure about how the attachment points should be distributed among the struts. Thus also feature F3 is preliminarily seen as not disclosed by **D6**.

The outer band 40 may be made from woven velour (page 11, lines 6-13). The opposition division considers it common general knowledge that velour is manufactured by cutting across (looped) threads and is thus a fabric that inevitably comprises outwardly extending fibers as it (feature F6). As set out

above, any fabric is considered as a compressible material (feature F4), but even more so if it is comprises outwardly extending fibers that can be compressed against its surface. Therefore features F4 and F6 seem preliminarily disclosed in **D6**.

For the above reasons, the opposition division is currently of the opinion that the subject-matter of **claim 1** is novel over **D6** as features F2 and F3 are not disclosed (Art. 54(2) EPC).

4.4 *Prior art document D8 (Art. 54(2) EPC)*

Prior art document **D8** discloses a prosthetic valve where a valve assembly made of PET material is rolled over the inlet end of the stent to form an outer sleeve, this sleeve enhancing sealing (Figs. 1, 2, par. [0112]).

While the opposition division is of the preliminary opinion that a fabric material might be considered as compressible, since the spacing of the fibers allows them to be compacted under pressure, prior art document **D8** does not explicitly disclose how the PET material is formed, i.e. it might also be in the form of a membrane, which is not compressible. Thus it seems at present that feature F4 is not disclosed.

There is no explicit disclosure of outwardly extending fibers in **D8** and with the argumentation of above, the opposition division preliminarily considers feature F6 also not implicitly disclosed.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D8** (Art. 54(2) EPC).

4.5 *Prior art document D14 (Art. 54(2) EPC)*

Prior art document **D14** relates to vascular prostheses and inter alia to heart valves (page 6, lines 9-17). It also discloses the use of a velour material (page 7, lines 3-14).

This document is completely silent on the structure of the prosthetic heart valve used. Since heart valves are known that

- do not comprise cylindrical stent structures (stentless valves, valves comprising rigid anchoring rings, non cylindrical stents- compare **D6**) (feature F2),
- have one, two or more than three leaflets (feature F3), and

- where the velour material may be used in other configurations than a sleeve (e.g. patches of material) (feature F4)

the opposition division is of the preliminary opinion that none of the features F2-F4 of **claim 1** are directly and unambiguously disclosed in **D14**.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D14** (Art. 54(2) EPC).

4.6 *Prior art document D18 (Art. 54(3) EPC)*

Prior art document **D18** was published on 24 August 2006 has a priority date of 18 February 2005 that is earlier than the filing date of the patent in suit. As the priority of the patent in suit seems not valid, while the priority of the relevant embodiment of **D18** seems valid (see below), **D18** is preliminarily considered as prior art under Art. 54(3) EPC.

Prior art document **D18** discloses in Figs. 1-11 a prosthetic bi-leaflet valve and in the embodiment of Fig. 12 a prosthetic tri-leaflet valve. The embodiments of Figs. 1-11 comprise a support member 40 and a layer of biocompatible material 50 covering the entire outer circumference of the support member 40 and thus forming a sleeve (page 6, lines 10-18) (feature F4).

The outer covering 50 may be made from woven velours (**D18**: page 6, lines 3-8). As set out above, the opposition division considers this a direct and unambiguous disclosure of a compressible material with outwardly extending fibers (features F4, F6).

The proprietor argues that the embodiment of Fig. 12, which is the relevant embodiment as it discloses a tri-leaflet valve, does not comprise an outer sleeve. In contrast thereto, the opposition division preliminarily considers that the valve of Fig. 12 is disclosed to be "*similar, except whereas described*" to the previous embodiments (page 21, lines 14-17), thus also featuring the sleeve 50.

In particular Fig. 12 comprises reference signs 40/46/60 related to the same support member as that of Figs. 1-11 where this support member is covered by member 50. Moreover, wing members 60 are sketched as opaque in Fig. 12, indicating the presence of a covering material on the stent frame. The opposition division thus considers layer 50 of biocompatible material covering the support member is also directly and unambiguously disclosed for the embodiment of Fig. 12.

Regarding the validity of priority of **D18**, the above reasoning also holds for the priority document **D18a=US 60/654,725**, which is attached to the present summons. Fig. 7 of this document corresponds to Fig. 12 of **D18** and the corresponding description mentions that a tri-leaflet valve is used in "the apparatus 10", thus referring back to the previous embodiments (**D18a**: page 13, line 17). Also, valve 12' is disclosed as functioning "as described above with regard to the previous embodiments", which in the preliminary opinion of the opposition division also includes layer 50 (**D18a**: page 13, line 22 - page 14, line 2). In all other relevant aspects, the disclosure of **D18a** is the same as that of **D18**. Therefore the priority of **D18** is valid and it is considered as prior art under Art.54(3) EPC.

For the above reasons, **claim 1** is preliminarily considered not novel over prior art document **D18** under Art. 54(3) EPC.

4.7 *Prior art documents D19-D23*

The argumentation of the opponents with regard to prior art documents **D19-D23** relies on the point that any fabric would comprise fibers extending outward from the outer surface and thus feature F6 would be implicitly disclosed in each of these documents. For the reasons given above in section 4.2, the opposition division preliminarily does not consider this argumentation convincing so that the subject-matter of **claim 1** as granted is preliminarily considered novel over **D19-D23** (Art. 54(1) EPC).

4.8 For all of the above reasons, the opposition division is preliminarily of the opinion that the subject-matter of **claim 1** is not novel over prior art document **D18** (Art. 54(3) EPC) but is novel over **D5b**, **D6**, **D8**, **D14, D19-D23** (Art. 54(1) EPC).

5 Inventive step (Article 100(a) EPC in connection with Art. 56 EPC)

The opponents argue inventive step with the following combinations of documents:

- **D1** together with either **D4**, **D5a, D5b**, **D7, D8**.
- **D3** together with either **D1 or D9.**
- **D8** or any of **D19-D23** together with either **D10** or **D24**.
- **D10, D11 or D12** together with **D13.**

In the oral proceedings, the opposition division would like to determine as a first step the closest prior art, taking into account not only the features disclosed but also whether a similar purpose is apparent. Preliminarily, the opposition division considers that the purpose of the claimed device is to seal gaps/prevent paravalvular leakage occurring around an expandable heart valve.

The opposition division considers that a document requiring a change in the main purpose and use of the device would not be a promising starting point (compare Case Law of the Boards of Appeal I-C-3.2). This means that the devices of

- **D1** that is not for percutaneous implantation,
- **D10-D12** that are no prosthetic valves but stent-grafts,

are preliminarily not considered good starting points.

In **D8**, the sealing layer is formed of the same material as the leaflets (par. [0112]), which require a smooth surface not prone to blood clotting. Thus **D8** teaches away from adding fibres to the sealing layer and does not seem a promising starting point.

The opposition division considers that documents **D20** and **D21** do not mention the purpose of the outer sheath as sealing against paravalvular leakage or being compressible/expandable, thus they also seem less promising starting points.

While prior art documents **D19** and **D23** seem to disclose sealing elements, they do not explicitly disclose those to be expandable or compressible and thus it seems questionable whether the person skilled in the art would actually add outwardly extending fibers, i.e. bulk to those systems.

In contrast, prior art documents **D3** and **D22** seem to disclose the concept of an expandable/deformable sealing ring to seal against paravalvular leakage (**D3**: see below, **D22**: pars. [0026], [0121]). **D22** seems not to add anything over **D3**, so prior art document **D3** will be discussed in the following.

Preliminarily, prior art document **D3** seems a good starting point, as it discloses a balloon-expandable stent-like band 110 (Fig. 1, page 5, lines 13-28, compare Fig. 6) to which is fitted a porcine tissue valve, i.e. a tri-leaflet valve (page 5, lines 34-35). It also discloses that the outer walls of the band 110 may comprise a gasket-like material that "*conforms to the existing tissue annulus and seals the new valve to the tissue annulus to protect against leakage around, or through, band 110* ". Prior art document **D3** is thus concerned with the purpose of the invention, namely preventing paravalvular leakage. It also discloses that the

gasket-like material may be formed from a soft, deformable material, such as polyurethane or also Dacron, which is a fabric material and thus in the form of a layer forming a sleeve.

It thus seems that **D3** discloses all features apart from fibers extending outwardly from the outer surface of the layer of compressible material.

Preliminarily, the opposition division considers that the technical effect and problem solved by this feature should be determined starting from the disclosure of the patent in suit. There it is stated that "*fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage*" (pars. [0046] and [0109] of **B1**) and where par. [0106] discloses that coagulation is enhanced by the fibers increasing the active surface. The opposition division thus preliminarily considers that the technical effect of the fibers is to provide an increased surface and where this solves the technical problem of encouraging coagulation to improve sealing. Preliminarily, it seems that prior art documents **D10** and **D24** are the only documents dealing with this problem.

It seems that prior art document **D10** discloses that tufts of fibrous material, i.e. outwardly extending fibers, are used in order to encourage blood clotting and adhesion (page 1, lines 18-20) and that the use of a circumferential band of such material improves sealing (page 3, lines 26-30). The opposition division preliminarily considers that the person skilled in the art would take the above teaching and incorporate a plurality of outwardly extending fibers into the gasket material of **D3** thus arriving at the claimed subject-matter in an obvious manner, contrary to the requirements of Art. 56 EPC.

The proprietor's argument that the person skilled in the art would not add bulk to the sealing element seems not applicable in this respect as the whole purpose of the sealing gasket of **D3** is to provide bulk in the form of an expandable/ compressible element.

Also prior art document **D24** seems to disclose that in order to encourage tissue attachment and improve sealing, areas of increased surface such as terry cloth with outwardly extending looped filaments might be used (par. [0032]-[0035]). Also this document seems to render the claimed subject-matter obvious when starting from **D3**.

On a preliminary basis, it thus seems that the subject-matter of **claim 1** as granted does not involve an inventive step (Art. 56 EPC).

6 Sufficiency of disclosure (Article 100(b) EPC)

OP1 argues that feature F4 defines an outer surface of the stent structure and the fibers in feature F6 extend outwardly from "*the outer surface*", i.e. the outer surface of the stent structure, but that there is no teaching how to attach fibers to the outer surface of the stent structure, because there is only a disclosure of the fibers being attached to the fabric (see par. [0109] of **B1**).

The opposition division preliminarily considers that the claim clearly defines that the compressible material includes a plurality of fibers, so that these fibers can technically only extend from the surface of the material. Thus the person skilled in the art would be immediately aware that the backwards reference to the outer surface of the stent is erroneous and nothing else than the surface of the material can be meant. This is also supported by the disclosure of the description (par. [0109]). If at all, the argument of OP1 is thus rather seen as a problem of clarity under Art. 84 EPC.

OP2 argues that since the compressible material creates a seal that prevents paravalvular leakage, the fibers are compressed against the material in use and are thus not extending outwardly. The opposition division firstly considers that even in a compressed state the fibers will still extend outwards to a certain degree. Secondly, the opposition division considers that the claimed structure defines the prosthetic heart valve in its rest state where the fibers unarguably extend outwards.

The opposition division therefore preliminarily considers that the arguments of the opponents do not equate to serious doubts, substantiated by verifiable facts, but that the person skilled in the art using his common general knowledge would gather enough information from the disclosure of the invention, in particular from pars. [0046], [0109] and Fig. 22, to be able to set the invention into practice.

7 AUXILIARY REQUESTS

7.1 *Auxiliary request 1*

In auxiliary request 1 **claim 1** has been amended by adding the feature of the the valvular structure providing a flexible conduit of **claim 27** of **A1p**.

It will have to be discussed if this feature limits the claim (see above 3.1.4). If not, the requirements of Rule 80 EPC might not be found to be met.

In any event, it seems that this feature might not be able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC) nor solve the issues of added subject-matter addressed above (Art. 76(1)EPC).

7.2 *Auxiliary request 2*

In auxiliary request 2 **claim 1** has been amended by adding the feature of the layer of compressible material being adapted for expansion after deployment to fill gaps (basis: **claim 27** and par. [0145] of **A1p**).

This amendment seems to solve the problem of added subject-matter of **claim 1**, however not of the dependent claims (Art. 76(1) EPC).

As the patent in suit is silent on what makes a compressible material "*adapted for expansion after deployment*", it is assumed that this feature is inherent in any compressible material and thus also in the materials of the prior art, in particular fabric, velour and terry material. Therefore this feature is preliminarily seen as not able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC).

7.3 *Auxiliary request 3*

In auxiliary request 3 **claim 3** has been amended by adding the feature of the compressible material being formed of PET from par. [0145] of **A1p**. It solves the issue of added subject-matter set out above in section 3.3. All other issues discussed with respect to the main request remain.

7.4 *Auxiliary request 4*

In auxiliary request 4 **claim 8** has been amended by aligning the wording of the feature of the compressible material expanding into the gaps with the wording of par. [0145] of **A1p**. The requirements or Art. 76(1) EPC seem to be met for this amendment. All other issues discussed with respect to the main request remain.

7.5 *Auxiliary request 5*

In auxiliary request 5 **claim 9** has been deleted, thus solving the problems under Art. 76(1) EPC of this claim (see above under 3.8). All other issues discussed with respect to the main request remain.

7.6 *Auxiliary request 6*

In auxiliary request 6 **claim 1** has been amended to define that the stent structure is configured for radial expansion using a balloon catheter from par. [0145] . It seems that since the stent of **claim 1** is already defined as configured

for radial expansion, the omission of a feature towards the stent structure being made from a deformable material is considered allowable. The other issues of Art. 76(1) EPC set out with respect to the main request remain.

Regarding novelty, prior art document **D18** discloses that the prosthetic valve is expanded using a balloon catheter (page 19, line 7 - page 20, line 12), thus the subject-matter of **claim 1** seems not novel over this document (Art. 54(3) EPC).

Also prior art document **D3** discloses the use of a balloon catheter to expand the stent structure (see e.g. Fig. 1 and description thereof), so that the subject-matter of **claim 1** seems not inventive for the same reasons as given for the main request.

7.7 *Auxiliary request 7*

In auxiliary request 7 **claim 1** has been amended by defining the prosthetic heart valve to be a cardiac valve. This feature seems to be originally disclosed in pars. [0001] and [0087].

As prior art documents **D18** and **D3** both relate to cardiac valves, the novelty and inventive step argumentation of the main request also applies here. Also all other issues discussed with respect to the main request remain.

7.8 *Auxiliary request 8*

In auxiliary request 8 all amendments of auxiliary requests 1-7 have been incorporated. The above reasoning applies.

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Europäisches Patentamt
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Wichtige Hinweise zur mündlichen Verhandlung	Important information concerning oral proceedings	Tres important Procédure orale
Das Europäische Patentamt verfügt über keine eigenen Dolmetscher. Diese müssen im Bedarfsfall von außerhalb, teilweise sogar aus anderen Ländern, beigezogen werden, was mit einem hohen Aufwand an Kosten und organisatorischen Vorbereitungen verbunden ist. Muss ein Verhandlungstermin kurzfristig abberaumt werden, können Kosten für bestellte Dolmetscher nicht mehr vermieden werden.	The European Patent Office has no interpreters of its own. When interpreters are needed they have to be brought in from outside, sometimes even from other countries, which is costly and involves considerable organisation. If oral proceedings have to be cancelled at short notice, the cost of interpreters already engaged still has to be borne.'	L'Office européen des brevets ne dispose pas de son propre service d'interprètes. Aussi faut-il appel le cas échéant à des interprètes de l'extérieur, qui viennent même parfois de l'étranger, ce qui occasionne des frais élevés et demande un grand travail d'organisation. Si la date d'une procédure orale doit être annulée au dernier moment, il n'est plus possible d'éviter les frais d'interprètes.
Es wird daher gebeten, eine Simultanübersetzung nur bei wirklichem Bedarf in Anspruch zu nehmen. Es wäre wünschenswert, wenn sich die Beteiligten (zweckmäßigerweise gleichzeitig mit der Terminabstimmung) auf die Benutzung einer Amtssprache einigen könnten. Bei Verständigungsschwierigkeiten sind die Mitglíeder der Einspruchsabteilung bereit zu helfen.	Please therefore make use of simultaneous interpreting facilities only where strictly necessary. If possible the parties should agree on an official language for the proceedings, preferably at the time when they arrange a date. The members of the Opposition Division witl be willing to help should any communication problems arise.'	Les parties à une procédure sont donc priées de ne demander une traduction simultanée qu'en cas de réel besoin. Il serait souhaitable qu'elles puissent se mettre d'accord en même temps qu'elles conviennent de la date sur l'utilisation d'une langue officielle comme langue des débats. Si les parties éprouvent des diffícultés de compréhensíon lors des débats, les membres de la división d'oppositíon sont disposés à leur prêter leur assistance.
Nachstehend führen wir den Zeitpunkt auf, bis zu dem die Verfahrensbeteiligten aus organisatorischen Gründen gebeten werden, ihre bevorzugte (abgestimmte) Verhandlungssprache mitzuteilen. Bis dahin bitten wir auch bei Bedarf eine Simultanübersetzung zu beantragen. Regel 4 (1) EPÜ bleibt hiervon unberührt.	For organisational reasons, we ask parties to inform us by the date specified below of their preferred (agreed) language for the oral proceedings. We also ask them to request any simultaneous interpreting required by the same date. This does not affect application of Rule 4(1) EPC.	Est indiquée ci-dessous la date jusqu'à laquelle, pour des raisons d'organisation, les parties sont priées de communiquer leur langue préférée (sur laquelle elles se sont préalablement mises d'accord). Les parties sont également priées, le cas échéant, de demander une interprétation simultanée avant cette date. La règle 4(1) CBE ne s'en trouve pas affectée.
☐ Verfahrenssprache ist **Deutsch**	☒ Language of the proceedings is **English**	☐ La langue de la procédure est le **français**
Von der/dem/den Einsprechenden wurde	The language used by the opponent/s was	La langue utilisée par l'opposant/les opposants était
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möglichst bis	if possible by	si possible jusqu'au
Datum 20.01.23	Date 20.01.23	Date 20.01.23

1. welche Sprache(n) Sie in der mündlichen Verhandlung verwenden (**Sprechen**)	1. which language(s) you intend to use during the oral proceedings (**Speaking**)	1. quelle(s) langue(s) vous utiliserez au cours de la procédure orale (**pour parler**)
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Sollten Sie Ihren Antrag auf mündliche Verhandlung zurückziehen oder zum anberaumten Verhandlungstermin nicht erscheinen wollen bzw. aus wichtigem Grund daran gehindert sein, werden Sie gebeten,

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- **in dringenden Fällen**(weniger als 1 Monat vor dem Verhandlungstermin) zusätzlich **auch dem/die anderen Verfahrensbeteiligten**bzw. ihre(n) Vertreter auf schnellstem Weg **direkt zu unterrichten.**

In jedem solchen Fall obliegt der Einspruchsabteilung die Entscheidung, ob die Verhandlung durchgeführt oder abberaumt wird. Es wird jedoch darauf hingewiesen, dass einem Verfahrensbeteiligten, der eine nicht rechtzeitige oder unterbliebene Benachrichtigung zu verantworten hat, die dadurch den anderen Beteiligten verursachten Kosten auferiegt werden können (Art. 104 EPÜ).

Hinweis auf Regel 4 EPÜ

Regel 4
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(1) Jeder an einem mündlichen Verfahren vor dem Europäischen Patentamt Beteiligte kann sich anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen, sofern er dies dem Europäischen Patentamt spätestens einen Monat vor dem angesetzten Termin mitgeteilt hat oder selbst tür die Übersetzung in die Verfahrenssprache sorgt. Jeder Beteiligte kann sich einer Amtssprache eines Vertragsstaats bedienen, sofern er selbst für die Übersetzung in die Verfahrenssprache sorgt. Von diesen Vorschriften kann das Europäische Patentamt Ausnahmen zulassen.

Should you decide to withdraw your request for oral proceedings or not wish to attend on the date set, or if for some special reason you are unable to do so, you are requested

- **to notify the EPO immediately, where possible by Online Filing (OLF), marking the document clearly with the words "Urgent, oral proceedings on ..." or similar**

- **in urgent cases** (less than one month before the date set for the proceedings), additionally to **notify the other party/parties** and/or their representative(s) **direct as rapidly as possible.**

In all such cases the Opposition Division will decide whether the proceedings are to go ahead or be cancelled. You should however note that costs incurred by the other parties may be charged to a party who either fails to notify them or does not do so in good time (Article 104 EPC).

Attention is drawn to Rule 4 EPC

Rule 4
Language in oral proceedings

(1) Any party to oral proceedings before the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings, if such party gives notice to the European Patent Office at least one month before the date of such oral proceedings or provides for interpretation into the language of the proceedings. Any party may use an official language of a Contracting State, if he provides for interpretation into the language of the proceedings. The European Patent Office may permit derogations from these provisions.

Si vous retirez votre requête tendant à recourir à la procédure orale ou si vous ne souhaitez pas vous présenter à la date fixée pour la procédure orale ou ne pouvez vous y présenter pour une raison sérieuse, veuillez

- **en faire avis sans retard à l'Office, par dépôt en ligne (OLF) si possible, en partant sur votre communication clairement la mention "Urgent, procédure orale le..." ou une indication similaire;**

- **dans les cas urgents** (moins d'un mois avant la date fixée pour la procédure orale) **en faire avis également directement** pas la voie la plus rapide à **autre/aux autres partie(s)** ou bien à son/leurs mandataire(s).

Il appartient alors à la division d'opposition de décider si la procédure orale aura lieu ou non. Il est néanmoins souligné que les frais causés aux autres parties par une partie qui est responsable de l'omission d'un tel avis ou de ce que cet avis n'a pas été fait en temps utile peuvent être mis à la charge de cette partie (art. 104 CBE).

Rappel de la Règle 4 CBE

Règle 4
Langues admissibles lors de la procédure orale

(1) Toute partie à une procédure orale devant l'Office européen des brevets peut utiliser une langue - officielle de l'Office européen des brevets autre que la langue de la procédure, à condition soit d'en aviser l'Office européen des brevets un mois au moins avant la date de la procédure orale, soit d'assurer l'interprétation dans la langue de la procédure. Toute partie peut utiliser une langue officielle de l'un des Etats contractants à condition d'assurer l'interprétation dans la langue de la procédure. L'Office européen des brevets peut autoriser des dérogations aux présentes dispositions.

(2) Die Bediensteten des Europäischen Patentamts können sich im mündlichen Verfahren anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen.

(2) In the course of oral proceedings, employees of the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings

(2) Au cours de la procédure orale, les agents de l'Office européen des brevets peuvent utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure.

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(3) Where evidence is taken, any party, witness or expert to be heard who is unable to express himself adequately in an official language of the European Patent Office or of a Contracting State may use another language. Where evidence is taken upon request of a party, parties, witnesses or experts expressing themselves in a language other than an official language of the European Patent Office shall be heard only if that party provides for interpretation into the language of the proceedings. The European Patent Office may, however, permit interpretation into one of its other official languages.

(3) Lors de l'instruction, les parties, témoins ou experts appelés à être entendus, qui ne possédent pas une maîtrise suffisante d'une langue officielle de l'Office européen des brevets ou d'un Etat contractant, peuvent utiliser une autre langue. Si la mesure d'instruction est ordonnée sur requête d'une partie, les parties, témoins ou experts qui s'expriment dans une langue autre qu'une langue officielle de l'Office européen des brevets ne sont entendus que si cette partie assure l'interprétation dans la langue de la procédure. L'Office européen des brevets peut toutefois autoriser l'interprétation dans l'une de ses autres langues officielles.

(4) Mit Einverständnis aller Beteiligten und des Europäischen Patentamts kann jede Sprache verwendet werden.

(4) If the parties and the European Patent Office agree, any language may be used.

(4) Sous réserve de l'accord des parties et de l'Office européen des brevets, toute langue peut être utilisée.

(5) Das Europäische Patentamt übernimmt, soweit erforderlich, auf seine Kosten die Übersetzung in die Verfahrenssprache und gegebenenfalls in seine anderen Amtssprachen, sofern ein Beteiligter nicht seibst für die Übersetzung zu sorgen hat.

(5) The European Patent Office shall, if necessary, provide at its own expense interpretation into the language of the proceedings, or, where appropriate, into its other official languages, unless such interpretation is the responsibility of one of the parties.

(5) L'Office européen des brevets assure à ses frais, en tant que de besoin, l'interprétation dans la langue de la procédure, ou, le cas échéant, dans ses autres langues officielles, à moins que cette interpretation ne doive être assurée par l'une des parties.

(6) Erklärungen von Bediensteten des Europäischen Patentamts, Beteiligten, Zeugen und Sachverständigen, die in einer Amtssprache des Europäischen Patentamts abgegeben werden, werden in dieser Sprache in die Niederschrift aufgenommen. Erklärungen in einer anderen Sprache werden in der Amtssprache aufgenommen, in die sie übersetzt worden sind. Änderungen einer europäischen Patentanmeldung oder eines europäischen Patents werden in der Verfahrenssprache in die Niederschrift aufgenommen.

(6) Statements by employees of the European Patent Office, parties, witnesses or experts, made in an official language of the European Patent Office, shall be entered in the minutes in that language. Statements made in any other language shall be entered in the official language into which they are translated. Amendments to a European patent application or European patent shall be entered in the minutes in the language of the proceedings.

(6) Les interventions des agents de l'Office européen des brevets, des parties, témoins et experts faites dans une langue officielle de l'Office européen des brevets sont consignées au procès-verbal dans cette langue. Les interventions faites dans une autre langue sont consignées dans la langue officielle dans laquelle elles sont traduites. Les modifications apportées à une demande de brevet européen ou à un brevet européen sont consignées au procès verbal dans la langue de la procédure.

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Date
25-03-2022

Reference	Application No./Patent No.
272.0046OP OPPO 02	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will be public, will take place before the opposition division

on 22.03.23 at 09.00 hrs

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 1/2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC).

Your attention is drawn to Rule 4 EPC, regarding the language of the oral proceedings, and to the Special edition No. 3 OJ EPO 2007, 128, concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

The final date for making written submissions and/or amendments (R. 116 EPC) is 20.01.23.

* The parties will be informed on the form of oral proceedings nearer to the scheduled date.

1st Examiner:
Prechtel, Anja-Katri

2nd Examiner:
Ebbinghaus, Maximili

Chairman:
Anscombe, Marcel

For the Opposition Division

Annexes:
Confirmation of receipt (Form 2936)
Rule 4 EPC (EPC Form 2043)
Communication (EPO Form 2906)

Registered Letter

to EPO postal service: 22.03.22

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80298 MUNICH
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Questions about this communication?
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ALLEMAGNE

Date
25-03-2022

Reference	Application No./Patent No.
255.0051G1 OPPO 01	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

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Date
25-03-2022

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

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Formalities officer
Penney, Karen

Date
25-03-2022

Reference	Application No./Patent No.
272.0046OP OPPO 02	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

EPA/EPO/OEB Formblatt/Form/Formulaire : 2310

Empfangsbescheinigung über den Zugang des vorstehend bezeichneten Schriftstücks
Acknowledgement of receipt of the document specified above
Récépissé du document spécifié ci-dessus

Unter Bezugnahme auf die Mitteilung im ABl EPA 7/2010, 377 wird gebeten, die Empfangsbescheinigung mit Empfangsdatum und Unterschrift zu versehen und **umgehend** an das EPA zurückzusenden:

With reference to the Notice in OJ EPO 7/2010, 377, you are requested to date and sign the acknowledgement of receipt and return it to the EPO **immediately**:

Conformément au communiqué paru au JO OEB 7/2010, 377, vous êtes prié d'indiquer sur le récépissé la date de réception du document, de signer le récépissé et de le renvoyer **sans délai** à l' OEB:

- **über die Online-Dienste des EPA** (als Anlage zu EPA Form 1038) / **through EPO Online Services** (as annex to EPO Form 1038) / **par les services en ligne de l'OEB** (en tant que pièce jointe au formulaire OEB 1038),
- **per Fax / by fax / par téléfax (+49 (0) 89 2399-4465 or +31 (0) 70 340-3016)**
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Provisional non-binding opinion of the opposition division

1 With the notice of opposition, both opponents requested the revocation of the contested patent in its entirety based on Art. 100(a) EPC on the grounds of novelty (Art. 54(1) EPC) and inventive step (Art. 56 EPC), based on Art. 100(b) EPC on the ground of insufficiency of disclosure and based on Art. 100(c) EPC on the ground of added subject-matter. As an auxiliary measure, oral proceedings according to Article 116 EPC were requested.

The following evidence has been submitted within the opposition period and is in the following renumbered to form a consolidated list:

EPO	CITATIONS	P	OP1	OP2
P1	US 10/883,575		E1a	
A1	EP 2 982 337 A1		E1c	
B1	EP 2 982 337 B1		E1d	
D1	US 5,258,023 A		D1	WBH1
D2	FR 2 337 543		D2	WBH2
D2a	US 4,106,129		D2a	
D3	WO 00/64380 A1		D3	WBH3
D4	FR 2 815 844 A1		D4	WBH4
D5	EP 2 537 487 A1		D5	WBH5
D5a	US 2005/137688		D5a	
D5b	US 2005/137698		D5b	WBH11
D6	WO 01/56512 A1		D6	
D7	US 6,454,799 B1		D7	WBH7
D8	US 2003/153974 A1		D8	WBH9

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D9	DE 26 13 575 A1		D9	
D10	WO 03/053287 A1		D10	WBH17
D11	US 6,729,356 B1		D11	
D12	US 2004/0082989 A1		D12	
D13	Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)		D13	
D14	WO 03/039613 A1		D14	
D15 A1p	WO 2006/005015 A2 (publication of the parent application)		E1b	
D16	US 5,554,184 A			WBH6
D17	US 6,638,257 B2			WBH8
D18	WO 2006/089236 A1			WBH10
D19	WO 2004/082527 A2			WBH12
D20	WO 01/54625 A1			WBH13
D21	WO 01/76510 A2			WBH14
D22	US 2004/0210304 A1			WBH15
D23	US 5,855,601 A			WBH16
D24	US 2002/0052649 A1			WBH18
D25	Patent Assignment			Annex 3

The publication of the parent application as filed is in the following referred to as

A1p: **WO2006/005015 A2**

2 It seems that since the opposition was filed in due time and in proper form and is supported by reasoned statements, the opposition is admissible under Article 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

3 Added subject-matter (Article 100(c) EPC)

The following points regarding added subject-matter have been brought up in the procedure and will be discussed during the oral proceedings:

The requirements of added subject-matter are discussed below with reference to the publication of the parent application **A1p**. As the description of the application of the patent in suit corresponds to the description as filed of the parent application with the claims added as clauses, the below argumentation holds for both the requirements of Art. 76(1) EPC and Art. 123(2) EPC.

3.1 *Claim 1*

It is agreed upon that basis for **claim 1** as granted might be found in **claim 27** of **A1p** and the embodiment of Fig. 22 and description thereof.

3.1.1 The opponents argue that **claim 1** extends in subject-matter for the following reasons:

a) Omission of the feature of original **claim 27** that the compressible material is adapted for expansion after deployment.

b) Addition of the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

c) Omission of a feature of original **claim 27** that the valvular structure provides a flexible conduit.

d) Addition that the compressible material forms a sleeve.

3.1.2 re a)

The opposition division considers that the deleted feature of **claim 27** of **A1p** that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel limits the claimed materials to those able to fill the gaps due to its expansion properties. Also the description limits the layer of material in the same way (par. [00145]). In contrast thereto, **claim 1** as granted seems to encompass a layer of material only minimally expanding after delivery but filling the gaps by an increased bulk thickness at the positions of the gaps, e.g. the commissures, thus extending in scope over what has been originally disclosed.

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3.1.3 re b)

It seems that the closest basis for feature b) might indeed be found in **claim 29** of **A1p**. There, a plurality of outward extending fibers are disclosed in combination with a growth factor disposed along the compressible material and the compressible material being formed of PET (**claim 28**). The opposition division preliminarily considers that the technical function of the outwardly extending fibres, namely to provide an increased active surface for encouraging coagulation (pars. [00055], [00142], [00145]), is linked to the geometry of the fibers and not to the chemistry of the material. The same holds for the presence of a tissue growth factor in the layer of material itself. As the description in par. [00145] clearly mentions both features of PET and the growth factor to be optional, the opposition division considers the omission of these features from original **claim 29** an allowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.1.4 re c)

It will be discussed during oral proceeding whether the valvular structure of **claim 1** implicitly defines a flexible conduit, so that the omission of an explicit definition seems allowable.

In this respect the opposition division considers that a valvular structure formed of a pliant material as claimed is necessarily flexible.

Preliminarily, it seems that even in case of three separate leaflets only connected to each other at the commissures the resulting structure might be called a "conduit", in particular as the only characteristic of a conduit mentioned in the application is that it has an inlet and an outlet. At present, the opposition division thus cannot conceive of a valvular structure for a heart valve prosthesis formed of three valve leaflets of pliant material in a form different from a flexible conduit, i.e. conveying blood from an inlet to an outlet. The omission of an explicit definition thus seems allowable.

3.1.5 re d)

OP2 argues that a layer of material in the form of a sleeve as disclosed in par. [00145] might also be provided spaced apart from the stent structure, while the claimed sleeve of a stent structure would provide covering and protection and thus be more limiting. The opposition division currently sees this as a rather linguistic approach and is currently of the opinion that a layer of material in the form of a sleeve necessarily also forms a sleeve.

In any way, the division sees par. [00145] to disclose a layer of compressible material disposed along an outer surface of the whole stent structure. This, however, seems to encompass the function of covering and protection, and thus equates the scope of the claimed sleeve.

3.1.6 Preliminarily, the opposition division thus considers solely to omission of a feature towards the compressible material being adapted for expansion after deployment to fill gaps in **claim 1** to extend in subject-matter over the original disclosure of the parent application.

3.2 *Claim 2*

The opponents argue that there is no direct and unambiguous disclosure of a sleeve surrounding an inflow end of the stent structure.

The description is silent on the position of the sleeve and the opposition division preliminarily considers that the person skilled in the art would also not immediately recognize a technical function of the position of the sleeve in Fig. 22, in particular as no technical link such as a position of the gap with respect to the stent and/or its longitudinal axis is apparent from the description. It might therefore even be considered that the inflow end of the stent in Fig. 22 is covered by the sleeve merely due to the whim of the artist and not due to a technical consideration. Thus the person skilled in the art would not be able to deduce the position of the sleeve relative to the stent's end from Fig. 22 or the description. Preliminarily, the subject-matter of **claim 2** seems to extend beyond the content of the (parent) application as filed.

3.3 *Claim 3*

The opponents argue that the thickness defined in **claim 3** is only originally disclosed together with the material PET. It seems that the only disclosure of a thickness ranging from 1-5mm as defined in **claim 3** is in par. [00145], which also discloses that the material is PET. No other material is disclosed for the embodiment of Fig. 22. The thickness of the layer and the material it is made of are functionally related as the ability to expand to fill gaps is not only due to thickness of the layer but also due to the materials expansion properties, softness, swellability etc. Therefore the opposition division preliminarily considers that the person skilled in the art would be surprised to see the claimed thickness for a generic compressible material. Preliminarily, the omission of a feature towards the material being PET seems to constitute a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.4 *Claim 4*

The opponents argue that a cloth or fabric is only disclosed in the context of the compressible material resembling a cloth or fabric (par. [00145]) and having small fibers extending from its surface so that the omission of the underlined features constitutes a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

The opposition division is of the preliminary opinion that the disclosure of par. [00145] of the compressible material resembling a cloth or fabric having small fibers extending form the surface of the material together with par. [0055] of the background of the invention relating to the same embodiment and disclosing a compressible material "*such as clot or fabric*" is sufficient basis for the material being cloth or fabric. In that respect, the opposition division considers that the word "clot" in this passage can only mean cloth, as also used in par. [00145].

Regarding the term "small", generic fibers are not only disclosed in par. [0055] but also in **claim 29** as filed, so that its omission seems unproblematic.

3.5 *Claim 5*

The additional feature of **claim 5** is disclosed in original **claim 29** together with the feature of the compressible material including a plurality of fibers that is already part of **claim 1** as granted. **Claim 5** is thus not seen as adding problems of extension of subject-matter.

3.6 *Claims 6, 7*

The additional features of **claims 6 and 7** are disclosed word by word in par. [00145] as respective optional features. **Claims 6 and 7** are thus not seen as adding problems of extension of subject-matter.

3.7 *Claim 8*

The opponent argues that the omission of a feature towards the compressible material being adapted for expansion into the gaps after deployment would extend its subject-matter. The opposition division preliminarily considers that gaps between a prosthetic valve and the body channel can only occur after deployment, and thus a compressible material configured to expand into these gaps necessarily is configured to do so after deployment. **Claim 8** is thus not seen as adding problems of extension of subject-matter.

3.8 *Claim 9*

The opposition division considers that there is no direct and unambiguous disclosure of the compressible material adjusting to the shape of a cavity existing between the valve and the vessel wall. There is merely a disclosure of the compressible material expanding into the gaps. This, however, also includes situations where the expanded shape of the material layer is pre-formed to correspond to the shape of the gaps or also where a material layer expands uniformly and seals the gaps by deforming the surrounding vessel wall. There seems thus no disclosure towards the more limited situation defined in **claim 9**, i.e. the subject-matter of **claim 9** as granted is seen as an unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.9 *Figures*

Opponent 2 argues that Fig. 22 of the parent as originally filed depicts a blank outer surface of the compressible material without any further structure, whereas Fig. 22 of the patent shows a surface comprising small elements irregularly distributed. The proprietor argues that Fig. 22 as filed seems to depict similar small structures in the vicinity of the left edge of the sleeve. To the opposition division, however, these structures are not clearly discernible and might also be scanning artefacts, i.e. no information can be derived from them.

In order to establish whether the addition of the small elements to Fig. 22 of the patent extends the subject-matter disclosed, it has to be established what the person skilled in the art would be able to derive from the figure. In this respect, the opposition division considers that the person skilled in the art only recognizes elements with a technical function immediately apparent, either from the drawing on its own or from the teaching of the description (see Case Law of the Boards of Appeal II-E-1.13). The opposition division considers that no technical function of the small elements can be deduced from the drawing on its own. The description, on the other hand, discloses only a single option for elements on the surface of the compressible material 256, namely fibers. Thus the person skilled in the art is would immediately recognize those fibers in the the elements of Fig. 22. The opposition division is unable to see how this could present any new information to the person skilled in the art over what was originally disclosed in the parent application as a whole.

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Regarding the disclosure of the other figures, the opposition division considers that in the absence of a detailed argumentation on which features should be seen as extending over the content of the parent application no such extension is present, with the same reasoning as above for Fig. 22.

3.10 For the above reasons, the opposition division thus preliminarily considers the subject-matter of **claims 1, 2, 3** and **9** to extend beyond the content of the parent application.

4 Novelty (Article 100(a) EPC in connection with Art. 54(1) EPC)

The opponents argue that the priority of the patent is not validly claimed. Following from that, they argue that the subject-matter of **claim 1** is not novel over prior art documents **D5b**, **D6**, **D8**, **D14, D18-D23** (Art. 54(1) EPC).

4.1 *Priority*

The opposition division is of the preliminary opinion that the priority of **claim 1** is not valid as the priority document **P1** does not comprise the embodiment of Fig. 22, i.e. there is no disclosure of the claimed features of a prosthetic valve with a layer of compressible material forming a sleeve and including a plurality of fibers extending outward from the outer surface (Art. 87(1) EPC).

The question of whether the priority is invalid due to formal reasons will only be discussed and decided upon if necessary. At present it seems this will not be the case.

4.2 *Prior art document D5b (Art. 54(2) EPC)*

Prior art document **D5b** published on 23 June 2005 is preliminarily considered as prior art under Art. 54(2) EPC as the priority of **claim 1** of the patent seems not valid.

It discloses a prosthetic valve with an outer seal in the form of a sleeve and made of thin, elastic polymer or any other type of fabric (Figs. 8A-8C, par. [0071]).

The opposition division preliminarily considers a fabric material as a compressible material. This is also in line with the disclosure of the patent in suit (compare par. [0055] of **A1p**). Therefore feature F4 seems disclosed by **D5b**.

In the absence of convincing evidence to the contrary, the opposition division does not agree with the opponent's assertion that any fabric inevitably comprises outwardly extending fibers. In particular it seems that a fabric of monofilament fibers cannot comprise such outwardly extending fibers at all. Thus feature F6 seems not implicitly disclosed in prior art document **D5b** so that the subject-matter of **claim 1** is preliminarily found novel over this document (compare Case Law of the Boards of Appeal I-C-4.3).

4.3 *Prior art document D6 (Art. 54(2) EPC)*

Prior art document **D6** discloses a prosthetic heart valve 10A/10M with an umbrella-like frame structure 20 formed from four U-shaped elements 30, i.e. eight spokes, to which a dome-shaped valve membrane 22 is attached forming several leaflets (page 8, lines 7-21; page 11, lines 14-30). An outer band 40 is circumferentially attached to the frame forming a sleeve and may be made of velour (page 9, line 23 -28; page 11, lines 6-13).

The opposition division preliminarily considers the umbrella-like frame structure 20 of D6 not to be a substantially cylindrical stent structure, as by attaching the U-shaped struts in their respective middle parts to each other the stent structure is clearly closed at one end, while a cylindrical structure must be tubular with two open ends. Therefore feature F2 seems not disclosed in **D6**.

While the opposition division preliminarily considers that the flaps of **D6** might be validly considered as leaflets as they comprise commissures and open and close to regulate the blood flow, **D6** does not disclose a tri-cuspid valve.

While the description of prior art document **D6** does not explicitly disclose the number of attachment points 56 of the dome shaped valve membrane 22 (page 12, line 24 - page 13, line 5), it seems that the person skilled in the art looking at Fig. 3 will immediately recognize the symmetry of the eight struts and thus also four attachment points. In the preliminary opinion of the opposition division, the mere possibility to use more or less U-shaped struts 30 (page 8, lines 18-21) is not a direct and unambiguous disclosure of exactly three attachment points, in particular since there is no disclosure about how the attachment points should be distributed among the struts. Thus also feature F3 is preliminarily seen as not disclosed by **D6**.

The outer band 40 may be made from woven velour (page 11, lines 6-13). The opposition division considers it common general knowledge that velour is manufactured by cutting across (looped) threads and is thus a fabric that inevitably comprises outwardly extending fibers as it (feature F6). As set out

above, any fabric is considered as a compressible material (feature F4), but even more so if it is comprises outwardly extending fibers that can be compressed against its surface. Therefore features F4 and F6 seem preliminarily disclosed in **D6**.

For the above reasons, the opposition division is currently of the opinion that the subject-matter of **claim 1** is novel over **D6** as features F2 and F3 are not disclosed (Art. 54(2) EPC).

4.4 *Prior art document D8 (Art. 54(2) EPC)*

Prior art document **D8** discloses a prosthetic valve where a valve assembly made of PET material is rolled over the inlet end of the stent to form an outer sleeve, this sleeve enhancing sealing (Figs. 1, 2, par. [0112]).

While the opposition division is of the preliminary opinion that a fabric material might be considered as compressible, since the spacing of the fibers allows them to be compacted under pressure, prior art document **D8** does not explicitly disclose how the PET material is formed, i.e. it might also be in the form of a membrane, which is not compressible. Thus it seems at present that feature F4 is not disclosed.

There is no explicit disclosure of outwardly extending fibers in **D8** and with the argumentation of above, the opposition division preliminarily considers feature F6 also not implicitly disclosed.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D8** (Art. 54(2) EPC).

4.5 *Prior art document D14 (Art. 54(2) EPC)*

Prior art document **D14** relates to vascular prostheses and inter alia to heart valves (page 6, lines 9-17). It also discloses the use of a velour material (page 7, lines 3-14).

This document is completely silent on the structure of the prosthetic heart valve used. Since heart valves are known that

- do not comprise cylindrical stent structures (stentless valves, valves comprising rigid anchoring rings, non cylindrical stents- compare **D6**) (feature F2),
- have one, two or more than three leaflets (feature F3), and

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- where the velour material may be used in other configurations than a sleeve (e.g. patches of material) (feature F4)

the opposition division is of the preliminary opinion that none of the features F2-F4 of **claim 1** are directly and unambiguously disclosed in **D14**.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D14** (Art. 54(2) EPC).

4.6 *Prior art document D18 (Art. 54(3) EPC)*

Prior art document **D18** was published on 24 August 2006 has a priority date of 18 February 2005 that is earlier than the filing date of the patent in suit. As the priority of the patent in suit seems not valid, while the priority of the relevant embodiment of **D18** seems valid (see below), **D18** is preliminarily considered as prior art under Art. 54(3) EPC.

Prior art document **D18** discloses in Figs. 1-11 a prosthetic bi-leaflet valve and in the embodiment of Fig. 12 a prosthetic tri-leaflet valve. The embodiments of Figs. 1-11 comprise a support member 40 and a layer of biocompatible material 50 covering the entire outer circumference of the support member 40 and thus forming a sleeve (page 6, lines 10-18) (feature F4).

The outer covering 50 may be made from woven velours (**D18**: page 6, lines 3-8). As set out above, the opposition division considers this a direct and unambiguous disclosure of a compressible material with outwardly extending fibers (features F4, F6).

The proprietor argues that the embodiment of Fig. 12, which is the relevant embodiment as it discloses a tri-leaflet valve, does not comprise an outer sleeve. In contrast thereto, the opposition division preliminarily considers that the valve of Fig. 12 is disclosed to be "*similar, except whereas described*" to the previous embodiments (page 21, lines 14-17), thus also featuring the sleeve 50.

In particular Fig. 12 comprises reference signs 40/46/60 related to the same support member as that of Figs. 1-11 where this support member is covered by member 50. Moreover, wing members 60 are sketched as opaque in Fig. 12, indicating the presence of a covering material on the stent frame. The opposition division thus considers layer 50 of biocompatible material covering the support member is also directly and unambiguously disclosed for the embodiment of Fig. 12.

Regarding the validity of priority of **D18**, the above reasoning also holds for the priority document **D18a=US 60/654,725**, which is attached to the present summons. Fig. 7 of this document corresponds to Fig. 12 of **D18** and the corresponding description mentions that a tri-leaflet valve is used in "the apparatus 10", thus referring back to the previous embodiments (**D18a**: page 13, line 17). Also, valve 12' is disclosed as functioning "as described above with regard to the previous embodiments", which in the preliminary opinion of the opposition division also includes layer 50 (**D18a**: page 13, line 22 - page 14, line 2). In all other relevant aspects, the disclosure of **D18a** is the same as that of **D18**. Therefore the priority of **D18** is valid and it is considered as prior art under Art.54(3) EPC.

For the above reasons, **claim 1** is preliminarily considered not novel over prior art document **D18** under Art. 54(3) EPC.

4.7 *Prior art documents D19-D23*

The argumentation of the opponents with regard to prior art documents **D19-D23** relies on the point that any fabric would comprise fibers extending outward from the outer surface and thus feature F6 would be implicitly disclosed in each of these documents. For the reasons given above in section 4.2, the opposition division preliminarily does not consider this argumentation convincing so that the subject-matter of **claim 1** as granted is preliminarily considered novel over **D19-D23** (Art. 54(1) EPC).

4.8 For all of the above reasons, the opposition division is preliminarily of the opinion that the subject-matter of **claim 1** is not novel over prior art document **D18** (Art. 54(3) EPC) but is novel over **D5b**, **D6**, **D8**, **D14, D19-D23** (Art. 54(1) EPC).

5 Inventive step (Article 100(a) EPC in connection with Art. 56 EPC)

The opponents argue inventive step with the following combinations of documents:

- **D1** together with either **D4**, **D5a, D5b**, **D7, D8**.
- **D3** together with either **D1 or D9.**
- **D8** or any of **D19-D23** together with either **D10** or **D24**.
- **D10, D11 or D12** together with **D13.**

In the oral proceedings, the opposition division would like to determine as a first step the closest prior art, taking into account not only the features disclosed but also whether a similar purpose is apparent. Preliminarily, the opposition division considers that the purpose of the claimed device is to seal gaps/prevent paravalvular leakage occurring around an expandable heart valve.

The opposition division considers that a document requiring a change in the main purpose and use of the device would not be a promising starting point (compare Case Law of the Boards of Appeal I-C-3.2). This means that the devices of

- **D1** that is not for percutaneous implantation,
- **D10-D12** that are no prosthetic valves but stent-grafts,

are preliminarily not considered good starting points.

In **D8**, the sealing layer is formed of the same material as the leaflets (par. [0112]), which require a smooth surface not prone to blood clotting. Thus **D8** teaches away from adding fibres to the sealing layer and does not seem a promising starting point.

The opposition division considers that documents **D20** and **D21** do not mention the purpose of the outer sheath as sealing against paravalvular leakage or being compressible/expandable, thus they also seem less promising starting points.

While prior art documents **D19** and **D23** seem to disclose sealing elements, they do not explicitly disclose those to be expandable or compressible and thus it seems questionable whether the person skilled in the art would actually add outwardly extending fibers, i.e. bulk to those systems.

In contrast, prior art documents **D3** and **D22** seem to disclose the concept of an expandable/deformable sealing ring to seal against paravalvular leakage (**D3**: see below, **D22**: pars. [0026], [0121]). **D22** seems not to add anything over **D3**, so prior art document **D3** will be discussed in the following.

Preliminarily, prior art document **D3** seems a good starting point, as it discloses a balloon-expandable stent-like band 110 (Fig. 1, page 5, lines 13-28, compare Fig. 6) to which is fitted a porcine tissue valve, i.e. a tri-leaflet valve (page 5, lines 34-35). It also discloses that the outer walls of the band 110 may comprise a gasket-like material that "*conforms to the existing tissue annulus and seals the new valve to the tissue annulus to protect against leakage around, or through, band 110* ". Prior art document **D3** is thus concerned with the purpose of the invention, namely preventing paravalvular leakage. It also discloses that the

gasket-like material may be formed from a soft, deformable material, such as polyurethane or also Dacron, which is a fabric material and thus in the form of a layer forming a sleeve.

It thus seems that **D3** discloses all features apart from fibers extending outwardly from the outer surface of the layer of compressible material.

Preliminarily, the opposition division considers that the technical effect and problem solved by this feature should be determined starting from the disclosure of the patent in suit. There it is stated that "*fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage*" (pars. [0046] and [0109] of **B1**) and where par. [0106] discloses that coagulation is enhanced by the fibers increasing the active surface. The opposition division thus preliminarily considers that the technical effect of the fibers is to provide an increased surface and where this solves the technical problem of encouraging coagulation to improve sealing. Preliminarily, it seems that prior art documents **D10** and **D24** are the only documents dealing with this problem.

It seems that prior art document **D10** discloses that tufts of fibrous material, i.e. outwardly extending fibers, are used in order to encourage blood clotting and adhesion (page 1, lines 18-20) and that the use of a circumferential band of such material improves sealing (page 3, lines 26-30). The opposition division preliminarily considers that the person skilled in the art would take the above teaching and incorporate a plurality of outwardly extending fibers into the gasket material of **D3** thus arriving at the claimed subject-matter in an obvious manner, contrary to the requirements of Art. 56 EPC.

The proprietor's argument that the person skilled in the art would not add bulk to the sealing element seems not applicable in this respect as the whole purpose of the sealing gasket of **D3** is to provide bulk in the form of an expandable/ compressible element.

Also prior art document **D24** seems to disclose that in order to encourage tissue attachment and improve sealing, areas of increased surface such as terry cloth with outwardly extending looped filaments might be used (par. [0032]-[0035]). Also this document seems to render the claimed subject-matter obvious when starting from **D3**.

On a preliminary basis, it thus seems that the subject-matter of **claim 1** as granted does not involve an inventive step (Art. 56 EPC).

6 Sufficiency of disclosure (Article 100(b) EPC)

OP1 argues that feature F4 defines an outer surface of the stent structure and the fibers in feature F6 extend outwardly from "*the outer surface*", i.e. the outer surface of the stent structure, but that there is no teaching how to attach fibers to the outer surface of the stent structure, because there is only a disclosure of the fibers being attached to the fabric (see par. [0109] of **B1**).

The opposition division preliminarily considers that the claim clearly defines that the compressible material includes a plurality of fibers, so that these fibers can technically only extend from the surface of the material. Thus the person skilled in the art would be immediately aware that the backwards reference to the outer surface of the stent is erroneous and nothing else than the surface of the material can be meant. This is also supported by the disclosure of the description (par. [0109]). If at all, the argument of OP1 is thus rather seen as a problem of clarity under Art. 84 EPC.

OP2 argues that since the compressible material creates a seal that prevents paravalvular leakage, the fibers are compressed against the material in use and are thus not extending outwardly. The opposition division firstly considers that even in a compressed state the fibers will still extend outwards to a certain degree. Secondly, the opposition division considers that the claimed structure defines the prosthetic heart valve in its rest state where the fibers unarguably extend outwards.

The opposition division therefore preliminarily considers that the arguments of the opponents do not equate to serious doubts, substantiated by verifiable facts, but that the person skilled in the art using his common general knowledge would gather enough information from the disclosure of the invention, in particular from pars. [0046], [0109] and Fig. 22, to be able to set the invention into practice.

7 AUXILIARY REQUESTS

7.1 *Auxiliary request 1*

In auxiliary request 1 **claim 1** has been amended by adding the feature of the the valvular structure providing a flexible conduit of **claim 27** of **A1p**.

It will have to be discussed if this feature limits the claim (see above 3.1.4). If not, the requirements of Rule 80 EPC might not be found to be met.

In any event, it seems that this feature might not be able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC) nor solve the issues of added subject-matter addressed above (Art. 76(1)EPC).

7.2 *Auxiliary request 2*

In auxiliary request 2 **claim 1** has been amended by adding the feature of the layer of compressible material being adapted for expansion after deployment to fill gaps (basis: **claim 27** and par. [0145] of **A1p**).

This amendment seems to solve the problem of added subject-matter of **claim 1**, however not of the dependent claims (Art. 76(1) EPC).

As the patent in suit is silent on what makes a compressible material "*adapted for expansion after deployment*", it is assumed that this feature is inherent in any compressible material and thus also in the materials of the prior art, in particular fabric, velour and terry material. Therefore this feature is preliminarily seen as not able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC).

7.3 *Auxiliary request 3*

In auxiliary request 3 **claim 3** has been amended by adding the feature of the compressible material being formed of PET from par. [0145] of **A1p**. It solves the issue of added subject-matter set out above in section 3.3. All other issues discussed with respect to the main request remain.

7.4 *Auxiliary request 4*

In auxiliary request 4 **claim 8** has been amended by aligning the wording of the feature of the compressible material expanding into the gaps with the wording of par. [0145] of **A1p**. The requirements or Art. 76(1) EPC seem to be met for this amendment. All other issues discussed with respect to the main request remain.

7.5 *Auxiliary request 5*

In auxiliary request 5 **claim 9** has been deleted, thus solving the problems under Art. 76(1) EPC of this claim (see above under 3.8). All other issues discussed with respect to the main request remain.

7.6 *Auxiliary request 6*

In auxiliary request 6 **claim 1** has been amended to define that the stent structure is configured for radial expansion using a balloon catheter from par. [0145] . It seems that since the stent of **claim 1** is already defined as configured

for radial expansion, the omission of a feature towards the stent structure being made from a deformable material is considered allowable. The other issues of Art. 76(1) EPC set out with respect to the main request remain.

Regarding novelty, prior art document **D18** discloses that the prosthetic valve is expanded using a balloon catheter (page 19, line 7 - page 20, line 12), thus the subject-matter of **claim 1** seems not novel over this document (Art. 54(3) EPC).

Also prior art document **D3** discloses the use of a balloon catheter to expand the stent structure (see e.g. Fig. 1 and description thereof), so that the subject-matter of **claim 1** seems not inventive for the same reasons as given for the main request.

7.7 *Auxiliary request 7*

In auxiliary request 7 **claim 1** has been amended by defining the prosthetic heart valve to be a cardiac valve. This feature seems to be originally disclosed in pars. [0001] and [0087].

As prior art documents **D18** and **D3** both relate to cardiac valves, the novelty and inventive step argumentation of the main request also applies here. Also all other issues discussed with respect to the main request remain.

7.8 *Auxiliary request 8*

In auxiliary request 8 all amendments of auxiliary requests 1-7 have been incorporated. The above reasoning applies.

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Europäisches Patentamt
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Wichtige Hinweise zur mündlichen Verhandlung	Important information concerning oral proceedings	Tres important Procédure orale
Das Europäische Patentamt verfügt über keine eigenen Dolmetscher. Diese müssen im Bedarfsfall von außerhalb, teilweise sogar aus anderen Ländern, beigezogen werden, was mit einem hohen Aufwand an Kosten und organisatorischen Vorbereitungen verbunden ist. Muss ein Verhandlungstermin kurzfristig abberaumt werden, können Kosten für bestellte Dolmetscher nicht mehr vermieden werden.	The European Patent Office has no interpreters of its own. When interpreters are needed they have to be brought in from outside, sometimes even from other countries, which is costly and involves considerable organisation. If oral proceedings have to be cancelled at short notice, the cost of interpreters already engaged still has to be borne.'	L'Office européen des brevets ne dispose pas de son propre service d'interprètes. Aussi faut-il appel le cas échéant à des interprètes de l'extérieur, qui viennent même parfois de l'étranger, ce qui occasionne des frais élevés et demande un grand travail d'organisation. Si la date d'une procédure orale doit être annulée au dernier moment, il n'est plus possible d'éviter les frais d'interprètes.
Es wird daher gebeten, eine Simultanübersetzung nur bei wirklichem Bedarf in Anspruch zu nehmen. Es wäre wünschenswert, wenn sich die Beteiligten (zweckmäßigerweise gleichzeitig mit der Terminabstimmung) auf die Benutzung einer Amtssprache einigen könnten. Bei Verständigungsschwierigkeiten sind die Mitglíeder der Einspruchsabteilung bereit zu helfen.	Please therefore make use of simultaneous interpreting facilities only where strictly necessary. If possible the parties should agree on an official language for the proceedings, preferably at the time when they arrange a date. The members of the Opposition Division witl be willing to help should any communication problems arise.'	Les parties à une procédure sont donc priées de ne demander une traduction simultanée qu'en cas de réel besoin. Il serait souhaitable qu'elles puissent se mettre d'accord en même temps qu'elles conviennent de la date sur l'utilisation d'une langue officielle comme langue des débats. Si les parties éprouvent des diffícultés de compréhensíon lors des débats, les membres de la división d'opposition sont disposés à leur prêter leur assistance.
Nachstehend führen wir den Zeitpunkt auf, bis zu dem die Verfahrensbeteiligten aus organisatorischen Gründen gebeten werden, ihre bevorzugte (abgestimmte) Verhandlungssprache mitzuteilen. Bis dahin bitten wir auch bei Bedarf eine Simultanübersetzung zu beantragen. Regel 4 (1) EPÜ bleibt hiervon unberührt.	For organisational reasons, we ask parties to inform us by the date specified below of their preferred (agreed) language for the oral proceedings. We also ask them to request any simultaneous interpreting required by the same date. This does not affect application of Rule 4(1) EPC.	Est indiquée ci-dessous la date jusqu'à laquelle, pour des raisons d'organisation, les parties sont priées de communiquer leur langue préférée (sur laquelle elles se sont préalablement mises d'accord). Les parties sont également priées, le cas échéant, de demander une interprétation simultanée avant cette date. La règle 4(1) CBE ne s'en trouve pas affectée.
☐ Verfahrenssprache ist **Deutsch**	☒ Language of the proceedings is **English**	☐ La langue de la procédure est le **français**
Von der/dem/den Einsprechenden wurde	The language used by the opponent/s was	La langue utilisée par l'opposant/les opposants était
☐ Englisch	☐ German ✗ English	☐ l'allemand
☐ Französisch benutzt.	☐ French.	☐ l'anglais.
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möglichst bis	if possible by	si possible jusqu'au
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1. welche Sprache(n) Sie in der mündlichen Verhandlung verwenden (**Sprechen**)	1. which language(s) you intend to use during the oral proceedings (**Speaking**)	1. quelle(s) langue(s) vous utiliserez au cours de la procédure orale (**pour parler**)
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Hinweis auf Regel 4 EPÜ

Regel 4
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Attention is drawn to Rule 4 EPC

Rule 4
Language in oral proceedings

(1) Any party to oral proceedings before the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings, if such party gives notice to the European Patent Office at least one month before the date of such oral proceedings or provides for interpretation into the language of the proceedings. Any party may use an official language of a Contracting State, if he provides for interpretation into the language of the proceedings. The European Patent Office may permit derogations from these provisions.

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Rappel de la Règle 4 CBE

Règle 4
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(2) Au cours de la procédure orale, les agents de l'Office européen des brevets peuvent utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure.

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(5) The European Patent Office shall, if necessary, provide at its own expense interpretation into the language of the proceedings, or, where appropriate, into its other official languages, unless such interpretation is the responsibility of one of the parties.

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25-03-2022

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

EPA/EPO/OEB Formblatt/Form/Formulaire : 2310

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Unter Bezugnahme auf die Mitteilung im ABl EPA 7/2010, 377 wird gebeten, die Empfangsbescheinigung mit Empfangsdatum und Unterschrift zu versehen und **umgehend** an das EPA zurückzusenden:

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Date
25-03-2022

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will be public, will take place before the opposition division

on 22.03.23 at 09.00 hrs *

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 1/2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC).

Your attention is drawn to Rule 4 EPC, regarding the language of the oral proceedings, and to the Special edition No. 3 OJ EPO 2007, 128, concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

The final date for making written submissions and/or amendments (R. 116 EPC) is 20.01.23.

* The parties will be informed on the form of oral proceedings nearer to the scheduled date.

1st Examiner:
Prechtel, Anja-Katri

2nd Examiner:
Ebbinghaus, Maximili

Chairman:
Anscombe, Marcel

For the Opposition Division

Annexes:
Confirmation of receipt (Form 2936)
Rule 4 EPC (EPC Form 2043)
Communication (EPO Form 2906)

Registered Letter

to EPO postal service: 22.03.22

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Provisional non-binding opinion of the opposition division

1 With the notice of opposition, both opponents requested the revocation of the contested patent in its entirety based on Art. 100(a) EPC on the grounds of novelty (Art. 54(1) EPC) and inventive step (Art. 56 EPC), based on Art. 100(b) EPC on the ground of insufficiency of disclosure and based on Art. 100(c) EPC on the ground of added subject-matter. As an auxiliary measure, oral proceedings according to Article 116 EPC were requested.

The following evidence has been submitted within the opposition period and is in the following renumbered to form a consolidated list:

EPO	CITATIONS	P	OP1	OP2
P1	US 10/883,575		E1a	
A1	EP 2 982 337 A1		E1c	
B1	EP 2 982 337 B1		E1d	
D1	US 5,258,023 A		D1	WBH1
D2	FR 2 337 543		D2	WBH2
D2a	US 4,106,129		D2a	
D3	WO 00/64380 A1		D3	WBH3
D4	FR 2 815 844 A1		D4	WBH4
D5	EP 2 537 487 A1		D5	WBH5
D5a	US 2005/137688		D5a	
D5b	US 2005/137698		D5b	WBH11
D6	WO 01/56512 A1		D6	
D7	US 6,454,799 B1		D7	WBH7
D8	US 2003/153974 A1		D8	WBH9

D9	DE 26 13 575 A1		D9	
D10	WO 03/053287 A1		D10	WBH17
D11	US 6,729,356 B1		D11	
D12	US 2004/0082989 A1		D12	
D13	Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)		D13	
D14	WO 03/039613 A1		D14	
D15 A1p	WO 2006/005015 A2 (publication of the parent application)		E1b	
D16	US 5,554,184 A			WBH6
D17	US 6,638,257 B2			WBH8
D18	WO 2006/089236 A1			WBH10
D19	WO 2004/082527 A2			WBH12
D20	WO 01/54625 A1			WBH13
D21	WO 01/76510 A2			WBH14
D22	US 2004/0210304 A1			WBH15
D23	US 5,855,601 A			WBH16
D24	US 2002/0052649 A1			WBH18
D25	Patent Assignment			Annex 3

The publication of the parent application as filed is in the following referred to as

A1p: **WO2006/005015 A2**

2 It seems that since the opposition was filed in due time and in proper form and is supported by reasoned statements, the opposition is admissible under Article 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

3 Added subject-matter (Article 100(c) EPC)

The following points regarding added subject-matter have been brought up in the procedure and will be discussed during the oral proceedings:

The requirements of added subject-matter are discussed below with reference to the publication of the parent application **A1p**. As the description of the application of the patent in suit corresponds to the description as filed of the parent application with the claims added as clauses, the below argumentation holds for both the requirements of Art. 76(1) EPC and Art. 123(2) EPC.

3.1 *Claim 1*

It is agreed upon that basis for **claim 1** as granted might be found in **claim 27** of **A1p** and the embodiment of Fig. 22 and description thereof.

3.1.1 The opponents argue that **claim 1** extends in subject-matter for the following reasons:

a) Omission of the feature of original **claim 27** that the compressible material is adapted for expansion after deployment.

b) Addition of the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

c) Omission of a feature of original **claim 27** that the valvular structure provides a flexible conduit.

d) Addition that the compressible material forms a sleeve.

3.1.2 re a)

The opposition division considers that the deleted feature of **claim 27** of **A1p** that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel limits the claimed materials to those able to fill the gaps due to its expansion properties. Also the description limits the layer of material in the same way (par. [00145]). In contrast thereto, **claim 1** as granted seems to encompass a layer of material only minimally expanding after delivery but filling the gaps by an increased bulk thickness at the positions of the gaps, e.g. the commissures, thus extending in scope over what has been originally disclosed.

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3.1.3 re b)

It seems that the closest basis for feature b) might indeed be found in **claim 29** of **A1p**. There, a plurality of outward extending fibers are disclosed in combination with a growth factor disposed along the compressible material and the compressible material being formed of PET (**claim 28**). The opposition division preliminarily considers that the technical function of the outwardly extending fibres, namely to provide an increased active surface for encouraging coagulation (pars. [00055], [00142], [00145]), is linked to the geometry of the fibers and not to the chemistry of the material. The same holds for the presence of a tissue growth factor in the layer of material itself. As the description in par. [00145] clearly mentions both features of PET and the growth factor to be optional, the opposition division considers the omission of these features from original **claim 29** an allowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.1.4 re c)

It will be discussed during oral proceeding whether the valvular structure of **claim 1** implicitly defines a flexible conduit, so that the omission of an explicit definition seems allowable.

In this respect the opposition division considers that a valvular structure formed of a pliant material as claimed is necessarily flexible.

Preliminarily, it seems that even in case of three separate leaflets only connected to each other at the commissures the resulting structure might be called a "conduit", in particular as the only characteristic of a conduit mentioned in the application is that it has an inlet and an outlet. At present, the opposition division thus cannot conceive of a valvular structure for a heart valve prosthesis formed of three valve leaflets of pliant material in a form different from a flexible conduit, i.e. conveying blood from an inlet to an outlet. The omission of an explicit definition thus seems allowable.

3.1.5 re d)

OP2 argues that a layer of material in the form of a sleeve as disclosed in par. [00145] might also be provided spaced apart from the stent structure, while the claimed sleeve of a stent structure would provide covering and protection and thus be more limiting. The opposition division currently sees this as a rather linguistic approach and is currently of the opinion that a layer of material in the form of a sleeve necessarily also forms a sleeve.

In any way, the division sees par. [00145] to disclose a layer of compressible material disposed along an outer surface of the whole stent structure. This, however, seems to encompass the function of covering and protection, and thus equates the scope of the claimed sleeve.

3.1.6 Preliminarily, the opposition division thus considers solely to omission of a feature towards the compressible material being adapted for expansion after deployment to fill gaps in **claim 1** to extend in subject-matter over the original disclosure of the parent application.

3.2 *Claim 2*

The opponents argue that there is no direct and unambiguous disclosure of a sleeve surrounding an inflow end of the stent structure.

The description is silent on the position of the sleeve and the opposition division preliminarily considers that the person skilled in the art would also not immediately recognize a technical function of the position of the sleeve in Fig. 22, in particular as no technical link such as a position of the gap with respect to the stent and/or its longitudinal axis is apparent from the description. It might therefore even be considered that the inflow end of the stent in Fig. 22 is covered by the sleeve merely due to the whim of the artist and not due to a technical consideration. Thus the person skilled in the art would not be able to deduce the position of the sleeve relative to the stent's end from Fig. 22 or the description. Preliminarily, the subject-matter of **claim 2** seems to extend beyond the content of the (parent) application as filed.

3.3 *Claim 3*

The opponents argue that the thickness defined in **claim 3** is only originally disclosed together with the material PET. It seems that the only disclosure of a thickness ranging from 1-5mm as defined in **claim 3** is in par. [00145], which also discloses that the material is PET. No other material is disclosed for the embodiment of Fig. 22. The thickness of the layer and the material it is made of are functionally related as the ability to expand to fill gaps is not only due to thickness of the layer but also due to the materials expansion properties, softness, swellability etc. Therefore the opposition division preliminarily considers that the person skilled in the art would be surprised to see the claimed thickness for a generic compressible material. Preliminarily, the omission of a feature towards the material being PET seems to constitute a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.4 *Claim 4*

The opponents argue that a cloth or fabric is only disclosed in the context of the compressible material resembling a cloth or fabric (par. [00145]) and having small fibers extending from its surface so that the omission of the underlined features constitutes a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

The opposition division is of the preliminary opinion that the disclosure of par. [00145] of the compressible material resembling a cloth or fabric having small fibers extending form the surface of the material together with par. [0055] of the background of the invention relating to the same embodiment and disclosing a compressible material "*such as clot or fabric*" is sufficient basis for the material being cloth or fabric. In that respect, the opposition division considers that the word "clot" in this passage can only mean cloth, as also used in par. [00145].

Regarding the term "small", generic fibers are not only disclosed in par. [0055] but also in **claim 29** as filed, so that its omission seems unproblematic.

3.5 *Claim 5*

The additional feature of **claim 5** is disclosed in original **claim 29** together with the feature of the compressible material including a plurality of fibers that is already part of **claim 1** as granted. **Claim 5** is thus not seen as adding problems of extension of subject-matter.

3.6 *Claims 6, 7*

The additional features of **claims 6 and 7** are disclosed word by word in par. [00145] as respective optional features. **Claims 6 and 7** are thus not seen as adding problems of extension of subject-matter.

3.7 *Claim 8*

The opponent argues that the omission of a feature towards the compressible material being adapted for expansion into the gaps after deployment would extend its subject-matter. The opposition division preliminarily considers that gaps between a prosthetic valve and the body channel can only occur after deployment, and thus a compressible material configured to expand into these gaps necessarily is configured to do so after deployment. **Claim 8** is thus not seen as adding problems of extension of subject-matter.

3.8 *Claim 9*

The opposition division considers that there is no direct and unambiguous disclosure of the compressible material adjusting to the shape of a cavity existing between the valve and the vessel wall. There is merely a disclosure of the compressible material expanding into the gaps. This, however, also includes situations where the expanded shape of the material layer is pre-formed to correspond to the shape of the gaps or also where a material layer expands uniformly and seals the gaps by deforming the surrounding vessel wall. There seems thus no disclosure towards the more limited situation defined in **claim 9**, i.e. the subject-matter of **claim 9** as granted is seen as an unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.9 *Figures*

Opponent 2 argues that Fig. 22 of the parent as originally filed depicts a blank outer surface of the compressible material without any further structure, whereas Fig. 22 of the patent shows a surface comprising small elements irregularly distributed. The proprietor argues that Fig. 22 as filed seems to depict similar small structures in the vicinity of the left edge of the sleeve. To the opposition division, however, these structures are not clearly discernible and might also be scanning artefacts, i.e. no information can be derived from them.

In order to establish whether the addition of the small elements to Fig. 22 of the patent extends the subject-matter disclosed, it has to be established what the person skilled in the art would be able to derive from the figure. In this respect, the opposition division considers that the person skilled in the art only recognizes elements with a technical function immediately apparent, either from the drawing on its own or from the teaching of the description (see Case Law of the Boards of Appeal II-E-1.13). The opposition division considers that no technical function of the small elements can be deduced from the drawing on its own. The description, on the other hand, discloses only a single option for elements on the surface of the compressible material 256, namely fibers. Thus the person skilled in the art is would immediately recognize those fibers in the the elements of Fig. 22. The opposition division is unable to see how this could present any new information to the person skilled in the art over what was originally disclosed in the parent application as a whole.

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Regarding the disclosure of the other figures, the opposition division considers that in the absence of a detailed argumentation on which features should be seen as extending over the content of the parent application no such extension is present, with the same reasoning as above for Fig. 22.

3.10 For the above reasons, the opposition division thus preliminarily considers the subject-matter of **claims 1, 2, 3** and **9** to extend beyond the content of the parent application.

4 Novelty (Article 100(a) EPC in connection with Art. 54(1) EPC)

The opponents argue that the priority of the patent is not validly claimed. Following from that, they argue that the subject-matter of **claim 1** is not novel over prior art documents **D5b**, **D6**, **D8**, **D14, D18-D23** (Art. 54(1) EPC).

4.1 *Priority*

The opposition division is of the preliminary opinion that the priority of **claim 1** is not valid as the priority document **P1** does not comprise the embodiment of Fig. 22, i.e. there is no disclosure of the claimed features of a prosthetic valve with a layer of compressible material forming a sleeve and including a plurality of fibers extending outward from the outer surface (Art. 87(1) EPC).

The question of whether the priority is invalid due to formal reasons will only be discussed and decided upon if necessary. At present it seems this will not be the case.

4.2 *Prior art document D5b (Art. 54(2) EPC)*

Prior art document **D5b** published on 23 June 2005 is preliminarily considered as prior art under Art. 54(2) EPC as the priority of **claim 1** of the patent seems not valid.

It discloses a prosthetic valve with an outer seal in the form of a sleeve and made of thin, elastic polymer or any other type of fabric (Figs. 8A-8C, par. [0071]).

The opposition division preliminarily considers a fabric material as a compressible material. This is also in line with the disclosure of the patent in suit (compare par. [0055] of **A1p**). Therefore feature F4 seems disclosed by **D5b**.

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In the absence of convincing evidence to the contrary, the opposition division does not agree with the opponent's assertion that any fabric inevitably comprises outwardly extending fibers. In particular it seems that a fabric of monofilament fibers cannot comprise such outwardly extending fibers at all. Thus feature F6 seems not implicitly disclosed in prior art document **D5b** so that the subject-matter of **claim 1** is preliminarily found novel over this document (compare Case Law of the Boards of Appeal I-C-4.3).

4.3 *Prior art document D6 (Art. 54(2) EPC)*

Prior art document **D6** discloses a prosthetic heart valve 10A/10M with an umbrella-like frame structure 20 formed from four U-shaped elements 30, i.e. eight spokes, to which a dome-shaped valve membrane 22 is attached forming several leaflets (page 8, lines 7-21; page 11, lines 14-30). An outer band 40 is circumferentially attached to the frame forming a sleeve and may be made of velour (page 9, line 23 -28; page 11, lines 6-13).

The opposition division preliminarily considers the umbrella-like frame structure 20 of D6 not to be a substantially cylindrical stent structure, as by attaching the U-shaped struts in their respective middle parts to each other the stent structure is clearly closed at one end, while a cylindrical structure must be tubular with two open ends. Therefore feature F2 seems not disclosed in **D6**.

While the opposition division preliminarily considers that the flaps of **D6** might be validly considered as leaflets as they comprise commissures and open and close to regulate the blood flow, **D6** does not disclose a tri-cuspid valve.

While the description of prior art document **D6** does not explicitly disclose the number of attachment points 56 of the dome shaped valve membrane 22 (page 12, line 24 - page 13, line 5), it seems that the person skilled in the art looking at Fig. 3 will immediately recognize the symmetry of the eight struts and thus also four attachment points. In the preliminary opinion of the opposition division, the mere possibility to use more or less U-shaped struts 30 (page 8, lines 18-21) is not a direct and unambiguous disclosure of exactly three attachment points, in particular since there is no disclosure about how the attachment points should be distributed among the struts. Thus also feature F3 is preliminarily seen as not disclosed by **D6**.

The outer band 40 may be made from woven velour (page 11, lines 6-13). The opposition division considers it common general knowledge that velour is manufactured by cutting across (looped) threads and is thus a fabric that inevitably comprises outwardly extending fibers as it (feature F6). As set out

above, any fabric is considered as a compressible material (feature F4), but even more so if it is comprises outwardly extending fibers that can be compressed against its surface. Therefore features F4 and F6 seem preliminarily disclosed in **D6**.

For the above reasons, the opposition division is currently of the opinion that the subject-matter of **claim 1** is novel over **D6** as features F2 and F3 are not disclosed (Art. 54(2) EPC).

4.4 *Prior art document D8 (Art. 54(2) EPC)*

Prior art document **D8** discloses a prosthetic valve where a valve assembly made of PET material is rolled over the inlet end of the stent to form an outer sleeve, this sleeve enhancing sealing (Figs. 1, 2, par. [0112]).

While the opposition division is of the preliminary opinion that a fabric material might be considered as compressible, since the spacing of the fibers allows them to be compacted under pressure, prior art document **D8** does not explicitly disclose how the PET material is formed, i.e. it might also be in the form of a membrane, which is not compressible. Thus it seems at present that feature F4 is not disclosed.

There is no explicit disclosure of outwardly extending fibers in **D8** and with the argumentation of above, the opposition division preliminarily considers feature F6 also not implicitly disclosed.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D8** (Art. 54(2) EPC).

4.5 *Prior art document D14 (Art. 54(2) EPC)*

Prior art document **D14** relates to vascular prostheses and inter alia to heart valves (page 6, lines 9-17). It also discloses the use of a velour material (page 7, lines 3-14).

This document is completely silent on the structure of the prosthetic heart valve used. Since heart valves are known that

- do not comprise cylindrical stent structures (stentless valves, valves comprising rigid anchoring rings, non cylindrical stents- compare **D6**) (feature F2),
- have one, two or more than three leaflets (feature F3), and

- where the velour material may be used in other configurations than a sleeve (e.g. patches of material) (feature F4)

the opposition division is of the preliminary opinion that none of the features F2-F4 of **claim 1** are directly and unambiguously disclosed in **D14**.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D14** (Art. 54(2) EPC).

4.6 *Prior art document D18 (Art. 54(3) EPC)*

Prior art document **D18** was published on 24 August 2006 has a priority date of 18 February 2005 that is earlier than the filing date of the patent in suit. As the priority of the patent in suit seems not valid, while the priority of the relevant embodiment of **D18** seems valid (see below), **D18** is preliminarily considered as prior art under Art. 54(3) EPC.

Prior art document **D18** discloses in Figs. 1-11 a prosthetic bi-leaflet valve and in the embodiment of Fig. 12 a prosthetic tri-leaflet valve. The embodiments of Figs. 1-11 comprise a support member 40 and a layer of biocompatible material 50 covering the entire outer circumference of the support member 40 and thus forming a sleeve (page 6, lines 10-18) (feature F4).

The outer covering 50 may be made from woven velours (**D18**: page 6, lines 3-8). As set out above, the opposition division considers this a direct and unambiguous disclosure of a compressible material with outwardly extending fibers (features F4, F6).

The proprietor argues that the embodiment of Fig. 12, which is the relevant embodiment as it discloses a tri-leaflet valve, does not comprise an outer sleeve. In contrast thereto, the opposition division preliminarily considers that the valve of Fig. 12 is disclosed to be "*similar, except whereas described*" to the previous embodiments (page 21, lines 14-17), thus also featuring the sleeve 50.

In particular Fig. 12 comprises reference signs 40/46/60 related to the same support member as that of Figs. 1-11 where this support member is covered by member 50. Moreover, wing members 60 are sketched as opaque in Fig. 12, indicating the presence of a covering material on the stent frame. The opposition division thus considers layer 50 of biocompatible material covering the support member is also directly and unambiguously disclosed for the embodiment of Fig. 12.

Regarding the validity of priority of **D18**, the above reasoning also holds for the priority document **D18a=US 60/654,725**, which is attached to the present summons. Fig. 7 of this document corresponds to Fig. 12 of **D18** and the corresponding description mentions that a tri-leaflet valve is used in "the apparatus 10", thus referring back to the previous embodiments (**D18a**: page 13, line 17). Also, valve 12' is disclosed as functioning "as described above with regard to the previous embodiments", which in the preliminary opinion of the opposition division also includes layer 50 (**D18a**: page 13, line 22 - page 14, line 2). In all other relevant aspects, the disclosure of **D18a** is the same as that of **D18**. Therefore the priority of **D18** is valid and it is considered as prior art under Art.54(3) EPC.

For the above reasons, **claim 1** is preliminarily considered not novel over prior art document **D18** under Art. 54(3) EPC.

4.7 *Prior art documents D19-D23*

The argumentation of the opponents with regard to prior art documents **D19-D23** relies on the point that any fabric would comprise fibers extending outward from the outer surface and thus feature F6 would be implicitly disclosed in each of these documents. For the reasons given above in section 4.2, the opposition division preliminarily does not consider this argumentation convincing so that the subject-matter of **claim 1** as granted is preliminarily considered novel over **D19-D23** (Art. 54(1) EPC).

4.8 For all of the above reasons, the opposition division is preliminarily of the opinion that the subject-matter of **claim 1** is not novel over prior art document **D18** (Art. 54(3) EPC) but is novel over **D5b**, **D6**, **D8**, **D14, D19-D23** (Art. 54(1) EPC).

5 Inventive step (Article 100(a) EPC in connection with Art. 56 EPC)

The opponents argue inventive step with the following combinations of documents:

- **D1** together with either **D4**, **D5a, D5b**, **D7, D8**.
- **D3** together with either **D1 or D9.**
- **D8** or any of **D19-D23** together with either **D10** or **D24**.
- **D10, D11 or D12** together with **D13.**

In the oral proceedings, the opposition division would like to determine as a first step the closest prior art, taking into account not only the features disclosed but also whether a similar purpose is apparent. Preliminarily, the opposition division considers that the purpose of the claimed device is to seal gaps/prevent paravalvular leakage occurring around an expandable heart valve.

The opposition division considers that a document requiring a change in the main purpose and use of the device would not be a promising starting point (compare Case Law of the Boards of Appeal I-C-3.2). This means that the devices of

- **D1** that is not for percutaneous implantation,
- **D10-D12** that are no prosthetic valves but stent-grafts,

are preliminarily not considered good starting points.

In **D8**, the sealing layer is formed of the same material as the leaflets (par. [0112]), which require a smooth surface not prone to blood clotting. Thus **D8** teaches away from adding fibres to the sealing layer and does not seem a promising starting point.

The opposition division considers that documents **D20** and **D21** do not mention the purpose of the outer sheath as sealing against paravalvular leakage or being compressible/expandable, thus they also seem less promising starting points.

While prior art documents **D19** and **D23** seem to disclose sealing elements, they do not explicitly disclose those to be expandable or compressible and thus it seems questionable whether the person skilled in the art would actually add outwardly extending fibers, i.e. bulk to those systems.

In contrast, prior art documents **D3** and **D22** seem to disclose the concept of an expandable/deformable sealing ring to seal against paravalvular leakage (**D3**: see below, **D22**: pars. [0026], [0121]). **D22** seems not to add anything over **D3**, so prior art document **D3** will be discussed in the following.

Preliminarily, prior art document **D3** seems a good starting point, as it discloses a balloon-expandable stent-like band 110 (Fig. 1, page 5, lines 13-28, compare Fig. 6) to which is fitted a porcine tissue valve, i.e. a tri-leaflet valve (page 5, lines 34-35). It also discloses that the outer walls of the band 110 may comprise a gasket-like material that "*conforms to the existing tissue annulus and seals the new valve to the tissue annulus to protect against leakage around, or through, band 110* ". Prior art document **D3** is thus concerned with the purpose of the invention, namely preventing paravalvular leakage. It also discloses that the

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gasket-like material may be formed from a soft, deformable material, such as polyurethane or also Dacron, which is a fabric material and thus in the form of a layer forming a sleeve.

It thus seems that **D3** discloses all features apart from fibers extending outwardly from the outer surface of the layer of compressible material.

Preliminarily, the opposition division considers that the technical effect and problem solved by this feature should be determined starting from the disclosure of the patent in suit. There it is stated that "*fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage*" (pars. [0046] and [0109] of **B1**) and where par. [0106] discloses that coagulation is enhanced by the fibers increasing the active surface. The opposition division thus preliminarily considers that the technical effect of the fibers is to provide an increased surface and where this solves the technical problem of encouraging coagulation to improve sealing. Preliminarily, it seems that prior art documents **D10** and **D24** are the only documents dealing with this problem.

It seems that prior art document **D10** discloses that tufts of fibrous material, i.e. outwardly extending fibers, are used in order to encourage blood clotting and adhesion (page 1, lines 18-20) and that the use of a circumferential band of such material improves sealing (page 3, lines 26-30). The opposition division preliminarily considers that the person skilled in the art would take the above teaching and incorporate a plurality of outwardly extending fibers into the gasket material of **D3** thus arriving at the claimed subject-matter in an obvious manner, contrary to the requirements of Art. 56 EPC.

The proprietor's argument that the person skilled in the art would not add bulk to the sealing element seems not applicable in this respect as the whole purpose of the sealing gasket of **D3** is to provide bulk in the form of an expandable/ compressible element.

Also prior art document **D24** seems to disclose that in order to encourage tissue attachment and improve sealing, areas of increased surface such as terry cloth with outwardly extending looped filaments might be used (par. [0032]-[0035]). Also this document seems to render the claimed subject-matter obvious when starting from **D3**.

On a preliminary basis, it thus seems that the subject-matter of **claim 1** as granted does not involve an inventive step (Art. 56 EPC).

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6 Sufficiency of disclosure (Article 100(b) EPC)

OP1 argues that feature F4 defines an outer surface of the stent structure and the fibers in feature F6 extend outwardly from "*the outer surface*", i.e. the outer surface of the stent structure, but that there is no teaching how to attach fibers to the outer surface of the stent structure, because there is only a disclosure of the fibers being attached to the fabric (see par. [0109] of **B1**).

The opposition division preliminarily considers that the claim clearly defines that the compressible material includes a plurality of fibers, so that these fibers can technically only extend from the surface of the material. Thus the person skilled in the art would be immediately aware that the backwards reference to the outer surface of the stent is erroneous and nothing else than the surface of the material can be meant. This is also supported by the disclosure of the description (par. [0109]). If at all, the argument of OP1 is thus rather seen as a problem of clarity under Art. 84 EPC.

OP2 argues that since the compressible material creates a seal that prevents paravalvular leakage, the fibers are compressed against the material in use and are thus not extending outwardly. The opposition division firstly considers that even in a compressed state the fibers will still extend outwards to a certain degree. Secondly, the opposition division considers that the claimed structure defines the prosthetic heart valve in its rest state where the fibers unarguably extend outwards.

The opposition division therefore preliminarily considers that the arguments of the opponents do not equate to serious doubts, substantiated by verifiable facts, but that the person skilled in the art using his common general knowledge would gather enough information from the disclosure of the invention, in particular from pars. [0046], [0109] and Fig. 22, to be able to set the invention into practice.

7 AUXILIARY REQUESTS

7.1 *Auxiliary request 1*

In auxiliary request 1 **claim 1** has been amended by adding the feature of the the valvular structure providing a flexible conduit of **claim 27** of **A1p**.

It will have to be discussed if this feature limits the claim (see above 3.1.4). If not, the requirements of Rule 80 EPC might not be found to be met.

In any event, it seems that this feature might not be able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC) nor solve the issues of added subject-matter addressed above (Art. 76(1)EPC).

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7.2 *Auxiliary request 2*

In auxiliary request 2 **claim 1** has been amended by adding the feature of the layer of compressible material being adapted for expansion after deployment to fill gaps (basis: **claim 27** and par. [0145] of **A1p**).

This amendment seems to solve the problem of added subject-matter of **claim 1**, however not of the dependent claims (Art. 76(1) EPC).

As the patent in suit is silent on what makes a compressible material "*adapted for expansion after deployment*", it is assumed that this feature is inherent in any compressible material and thus also in the materials of the prior art, in particular fabric, velour and terry material. Therefore this feature is preliminarily seen as not able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC).

7.3 *Auxiliary request 3*

In auxiliary request 3 **claim 3** has been amended by adding the feature of the compressible material being formed of PET from par. [0145] of **A1p**. It solves the issue of added subject-matter set out above in section 3.3. All other issues discussed with respect to the main request remain.

7.4 *Auxiliary request 4*

In auxiliary request 4 **claim 8** has been amended by aligning the wording of the feature of the compressible material expanding into the gaps with the wording of par. [0145] of **A1p**. The requirements or Art. 76(1) EPC seem to be met for this amendment. All other issues discussed with respect to the main request remain.

7.5 *Auxiliary request 5*

In auxiliary request 5 **claim 9** has been deleted, thus solving the problems under Art. 76(1) EPC of this claim (see above under 3.8). All other issues discussed with respect to the main request remain.

7.6 *Auxiliary request 6*

In auxiliary request 6 **claim 1** has been amended to define that the stent structure is configured for radial expansion using a balloon catheter from par. [0145] . It seems that since the stent of **claim 1** is already defined as configured

for radial expansion, the omission of a feature towards the stent structure being made from a deformable material is considered allowable. The other issues of Art. 76(1) EPC set out with respect to the main request remain.

Regarding novelty, prior art document **D18** discloses that the prosthetic valve is expanded using a balloon catheter (page 19, line 7 - page 20, line 12), thus the subject-matter of **claim 1** seems not novel over this document (Art. 54(3) EPC).

Also prior art document **D3** discloses the use of a balloon catheter to expand the stent structure (see e.g. Fig. 1 and description thereof), so that the subject-matter of **claim 1** seems not inventive for the same reasons as given for the main request.

7.7 *Auxiliary request 7*

In auxiliary request 7 **claim 1** has been amended by defining the prosthetic heart valve to be a cardiac valve. This feature seems to be originally disclosed in pars. [0001] and [0087].

As prior art documents **D18** and **D3** both relate to cardiac valves, the novelty and inventive step argumentation of the main request also applies here. Also all other issues discussed with respect to the main request remain.

7.8 *Auxiliary request 8*

In auxiliary request 8 all amendments of auxiliary requests 1-7 have been incorporated. The above reasoning applies.

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Europäisches Patentamt
European Patent Office
Office européen des brevets

Wichtige Hinweise zur mündlichen Verhandlung	Important information concerning oral proceedings	Tres important Procédure orale
Das Europäische Patentamt verfügt über keine eigenen Dolmetscher. Diese müssen im Bedarfsfall von außerhalb, teilweise sogar aus anderen Ländern, beigezogen werden, was mit einem hohen Aufwand an Kosten und organisatorischen Vorbereitungen verbunden ist. Muss ein Verhandlungstermin kurzfristig abberaumt werden, können Kosten für bestellte Dolmetscher nicht mehr vermieden werden.	The European Patent Office has no interpreters of its own. When interpreters are needed they have to be brought in from outside, sometimes even from other countries, which is costly and involves considerable organisation. If oral proceedings have to be cancelled at short notice, the cost of interpreters already engaged still has to be borne.'	L'Office européen des brevets ne dispose pas de son propre service d'interprètes. Aussi faut-il appel le cas échéant à des interprètes de l'extérieur, qui viennent même parfois de l'étranger, ce qui occasionne des frais élevés et demande un grand travail d'organisation. Si la date d'une procédure orale doit être annulée au dernier moment, il n'est plus possible d'éviter les frais d'interprètes.
Es wird daher gebeten, eine Simultanübersetzung nur bei wirklichem Bedarf in Anspruch zu nehmen. Es wäre wünschenswert, wenn sich die Beteiligten (zweckmäßigerweise gleichzeitig mit der Terminabstimmung) auf die Benutzung einer Amtssprache einigen könnten. Bei Verständigungsschwierigkeiten sind die Mitglíeder der Einspruchsabteilung bereit zu helfen.	Please therefore make use of simultaneous interpreting facilities only where strictly necessary. If possible the parties should agree on an official language for the proceedings, preferably at the time when they arrange a date. The members of the Opposition Division witl be willing to help should any communication problems arise.'	Les parties à une procédure sont donc priées de ne demander une traduction simultanée qu'en cas de réel besoin. Il serait souhaitable qu'elles puissent se mettre d'accord en même temps qu'elles conviennent de la date sur l'utilisation d'une langue officielle comme langue des débats. Si les parties éprouvent des diffícultés de compréhensíon lors des débats, les membres de la división d'opposition sont disposés à leur prêter leur assistance.
Nachstehend führen wir den Zeitpunkt auf, bis zu dem die Verfahrensbeteiligten aus organisatorischen Gründen gebeten werden, ihre bevorzugte (abgestimmte) Verhandlungssprache mitzuteilen. Bis dahin bitten wir auch bei Bedarf eine Simultanübersetzung zu beantragen. Regel 4 (1) EPÜ bleibt hiervon unberührt.	For organisational reasons, we ask parties to inform us by the date specified below of their preferred (agreed) language for the oral proceedings. We also ask them to request any simultaneous interpreting required by the same date. This does not affect application of Rule 4(1) EPC.	Est indiquée ci-dessous la date jusqu'à laquelle, pour des raisons d'organisation, les parties sont priées de communiquer leur langue préférée (sur laquelle elles se sont préalablement mises d'accord). Les parties sont également priées, le cas échéant, de demander une interprétation simultanée avant cette date. La règle 4(1) CBE ne s'en trouve pas affectée.
☐ Verfahrenssprache ist **Deutsch**	☒ Language of the proceedings is **English**	☐ La langue de la procédure est le **français**
Von der/dem/den Einsprechenden wurde	The language used by the opponent/s was	La langue utilisée par l'opposant/les opposants était
☐ Englisch	☐ German ✗ English	☐ l'allemand
☐ Französisch benutzt.	☐ French.	☐ l'anglais.
Es wird um eilige Mitteilung, möglichst per Online Filing (OLF), gebeten.	**Please inform us urgently, where possible by Online Filing (OLF).**	**Prière d'indiquer d'urgence par dépôt en ligne (OLF) si possible.**

möglichst bis	if possible by	si possible jusqu'au
Datum 20.01.23	Date 20.01.23	Date 20.01.23

1. welche Sprache(n) Sie in der mündlichen Verhandlung verwenden (**Sprechen**)	1. which language(s) you intend to use during the oral proceedings (**Speaking**)	1. quelle(s) langue(s) vous utiliserez au cours de la procédure orale (**pour parler**)
2. aus welcher Sprache Sie eine Simultanübersetzung benötigen (**Hören**).	2. from which language you need simultaneous interpretation (**Listening**).	2. à partir de quelle langue vous aurez besoin d'une traduction simultanée (**pour écouter**).

Sollten Sie Ihren Antrag auf mündliche Verhandlung zurückziehen oder zum anberaumten Verhandlungstermin nicht erscheinen wollen bzw. aus wichtigem Grund daran gehindert sein, werden Sie gebeten,

- **unverzüglich das Amt - möglichst per Online Filing (OLF) - davon zu benachrichtigen, wobei das Schriftstück mit einem deutlichen Vermerk "Dringend, mündliche Verhandlung am..." oder sinngemäß gekennzeichnet sein sollte**

- **in dringenden Fällen**(weniger als 1 Monat vor dem Verhandlungstermin) zusätzlich **auch dem/die anderen Verfahrensbeteiligten**bzw. ihre(n) Vertreter auf schnellstem Weg **direkt zu unterrichten.**

In jedem solchen Fall obliegt der Einspruchsabteilung die Entscheidung, ob die Verhandlung durchgeführt oder abberaumt wird. Es wird jedoch darauf hingewiesen, dass einem Verfahrensbeteiligten, der eine nicht rechtzeitige oder unterbliebene Benachrichtigung zu verantworten hat, die dadurch den anderen Beteiligten verursachten Kosten auferiegt werden können (Art. 104 EPÜ).

Hinweis auf Regel 4 EPÜ

Regel 4
Sprache im mündlichen Verfahren

(1) Jeder an einem mündlichen Verfahren vor dem Europäischen Patentamt Beteiligte kann sich anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen, sofern er dies dem Europäischen Patentamt spätestens einen Monat vor dem angesetzten Termin mitgeteilt hat oder selbst tür die Übersetzung in die Verfahrenssprache sorgt. Jeder Beteiligte kann sich einer Amtssprache eines Vertragsstaats bedienen, sofern er selbst für die Übersetzung in die Verfahrenssprache sorgt. Von diesen Vorschriften kann das Europäische Patentamt Ausnahmen zulassen.

Should you decide to withdraw your request for oral proceedings or not wish to attend on the date set, or if for some special reason you are unable to do so, you are requested

- **to notify the EPO immediately, where possible by Online Filing (OLF), marking the document clearly with the words "Urgent, oral proceedings on ..." or similar**

- **in urgent cases** (less than one month before the date set for the proceedings), additionally to **notify the other party/parties** and/or their representative(s) **direct as rapidly as possible.**

In all such cases the Opposition Division will decide whether the proceedings are to go ahead or be cancelled. You should however note that costs incurred by the other parties may be charged to a party who either fails to notify them or does not do so in good time (Article 104 EPC).

Attention is drawn to Rule 4 EPC

Rule 4
Language in oral proceedings

(1) Any party to oral proceedings before the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings, if such party gives notice to the European Patent Office at least one month before the date of such oral proceedings or provides for interpretation into the language of the proceedings. Any party may use an official language of a Contracting State, if he provides for interpretation into the language of the proceedings. The European Patent Office may permit derogations from these provisions.

Si vous retirez votre requête tendant à recourir à la procédure orale ou si vous ne souhaitez pas vous présenter à la date fixée pour la procédure orale ou ne pouvez vous y présenter pour une raison sérieuse, veuillez

- **en faire avis sans retard à l'Office, par dépôt en ligne (OLF) si possible, en partant sur votre communication clairement la mention "Urgent, procédure orale le..." ou une indication similaire;**

- **dans les cas urgents** (moins d'un mois avant la date fixée pour la procédure orale) **en faire avis également directement** pas la voie la plus rapide à **autre/aux autres partie(s)** ou bien à son/leurs mandataire(s).

Il appartient alors à la division d'opposition de décider si la procédure orale aura lieu ou non. Il est néanmoins souligné que les frais causés aux autres parties par une partie qui est responsable de l'omission d'un tel avis ou de ce que cet avis n'a pas été fait en temps utile peuvent être mis à la charge de cette partie (art. 104 CBE).

Rappel de la Règle 4 CBE

Règle 4
Langues admissibles lors de la procédure orale

(1) Toute partie à une procédure orale devant l'Office européen des brevets peut utiliser une langue - officielle de l'Office européen des brevets autre que la langue de la procédure, à condition soit d'en aviser l'Office européen des brevets un mois au moins avant la date de la procédure orale, soit d'assurer l'interprétation dans la langue de la procédure. Toute partie peut utiliser une langue officielle de l'un des Etats contractants à condition d'assurer l'interprétation dans la langue de la procédure. L'Office européen des brevets peut autoriser des dérogations aux présentes dispositions.

(2) Die Bediensteten des Europäischen Patentamts können sich im mündlichen Verfahren anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen.

(2) In the course of oral proceedings, employees of the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings

(2) Au cours de la procédure orale, les agents de l'Office européen des brevets peuvent utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure.

(3) In der Beweisaufnahme können sich die zu vernehmenden Beteiligten, Zeugen oder Sachverständigen, die sich in einer Amtssprache des Europäischen Patentamts oder eines Vertragsstaats nicht hinlänglich ausdrücken können, einer anderen Sprache bedienen. Erfolgt die Beweisaufnahme auf Antrag eines Beteiligten, so werden die Beteiligten, Zeugen oder Sachverständigen mit Erklärungen, die sie in einer anderen Sprache als in einer Amtssprache des Europäischen Patentamts abgeben, nur gehört, sofern dieser Beteiligte selbst für die Übersetzung in die Verfahrenssprache sorgt. Das Europäische Patentamt kann jedoch die Übersetzung in eine seiner anderen Amtssprachen zulassen.

(3) Where evidence is taken, any party, witness or expert to be heard who is unable to express himself adequately in an official language of the European Patent Office or of a Contracting State may use another language. Where evidence is taken upon request of a party, parties, witnesses or experts expressing themselves in a language other than an official language of the European Patent Office shall be heard only if that party provides for interpretation into the language of the proceedings. The European Patent Office may, however, permit interpretation into one of its other official languages.

(3) Lors de l'instruction, les parties, témoins ou experts appelés à être entendus, qui ne possédent pas une maîtrise suffisante d'une langue officielle de l'Office européen des brevets ou d'un Etat contractant, peuvent utiliser une autre langue. Si la mesure d'instruction est ordonnée sur requête d'une partie, les parties, témoins ou experts qui s'expriment dans une langue autre qu'une langue officielle de l'Office européen des brevets ne sont entendus que si cette partie assure l'interprétation dans la langue de la procédure. L'Office européen des brevets peut toutefois autoriser l'interprétation dans l'une de ses autres langues officielles.

(4) Mit Einverständnis aller Beteiligten und des Europäischen Patentamts kann jede Sprache verwendet werden.

(4) If the parties and the European Patent Office agree, any language may be used.

(4) Sous réserve de l'accord des parties et de l'Office européen des brevets, toute langue peut être utilisée.

(5) Das Europäische Patentamt übernimmt, soweit erforderlich, auf seine Kosten die Übersetzung in die Verfahrenssprache und gegebenenfalls in seine anderen Amtssprachen, sofern ein Beteiligter nicht seibst für die Übersetzung zu sorgen hat.

(5) The European Patent Office shall, if necessary, provide at its own expense interpretation into the language of the proceedings, or, where appropriate, into its other official languages, unless such interpretation is the responsibility of one of the parties.

(5) L'Office européen des brevets assure à ses frais, en tant que de besoin, l'interprétation dans la langue de la procédure, ou, le cas échéant, dans ses autres langues officielles, à moins que cette interpretation ne doive être assurée par l'une des parties.

(6) Erklärungen von Bediensteten des Europäischen Patentamts, Beteiligten, Zeugen und Sachverständigen, die in einer Amtssprache des Europäischen Patentamts abgegeben werden, werden in dieser Sprache in die Niederschrift aufgenommen. Erklärungen in einer anderen Sprache werden in der Amtssprache aufgenommen, in die sie übersetzt worden sind. Änderungen einer europäischen Patentanmeldung oder eines europäischen Patents werden in der Verfahrenssprache in die Niederschrift aufgenommen.

(6) Statements by employees of the European Patent Office, parties, witnesses or experts, made in an official language of the European Patent Office, shall be entered in the minutes in that language. Statements made in any other language shall be entered in the official language into which they are translated. Amendments to a European patent application or European patent shall be entered in the minutes in the language of the proceedings.

(6) Les interventions des agents de l'Office européen des brevets, des parties, témoins et experts faites dans une langue officielle de l'Office européen des brevets sont consignées au procès-verbal dans cette langue. Les interventions faites dans une autre langue sont consignées dans la langue officielle dans laquelle elles sont traduites. Les modifications apportées à une demande de brevet européen ou à un brevet européen sont consignées au procès verbal dans la langue de la procédure.

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Formalities officer
Penney, Karen

LKGLOBAL
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Brienner Straße 11
80333 München
ALLEMAGNE

Date
25-03-2022

Reference		Application No./Patent No.
255.0051G1	OPPO 01	15180327.7 - 1126 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

EPA/EPO/OEB Formblatt/Form/Formulaire : 2310

Empfangsbescheinigung über den Zugang des vorstehend bezeichneten Schriftstücks
Acknowledgement of receipt of the document specified above
Récépissé du document spécifié ci-dessus

Unter Bezugnahme auf die Mitteilung im ABl EPA 7/2010, 377 wird gebeten, die Empfangsbescheinigung mit Empfangsdatum und Unterschrift zu versehen und **umgehend** an das EPA zurückzusenden:

With reference to the Notice in OJ EPO 7/2010, 377, you are requested to date and sign the acknowledgement of receipt and return it to the EPO **immediately**:

Conformément au communiqué paru au JO OEB 7/2010, 377, vous êtes prié d'indiquer sur le récépissé la date de réception du document, de signer le récépissé et de le renvoyer **sans délai** à l' OEB:

- **über die Online-Dienste des EPA** (als Anlage zu EPA Form 1038) / **through EPO Online Services** (as annex to EPO Form 1038) / **par les services en ligne de l'OEB** (en tant que pièce jointe au formulaire OEB 1038),
- **per Fax / by fax / par téléfax (+49 (0) 89 2399-4465 or +31 (0) 70 340-3016)**
- oder per Post / or by post / ou par courrier.

Empfangen am / Received on / Reçu le :

Unterschrift / Signature:

Empfangsberechtigter/authorised recipient/
le destinataire ou la personne dûment mandatée

Rücksende-Adresse / Return address / Adresse de retour
(Umschlag / envelope / enveloppe ISO C4 / DL / C6/C5 / C6)

Europäisches Patentamt
80298 MUNCHEN
DEUTSCHLAND

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EPA/EPO/OEB Form 2936 08.10

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ALLEMAGNE

Date
25-03-2022

Reference	Application No./Patent No.
255.0051G1 OPPO 01	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will be public, will take place before the opposition division

on 22.03.23 at 09.00 hrs

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 1/2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC).

Your attention is drawn to Rule 4 EPC, regarding the language of the oral proceedings, and to the Special edition No. 3 OJ EPO 2007, 128, concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

The final date for making written submissions and/or amendments (R. 116 EPC) is 20.01.23.

* The parties will be informed on the form of oral proceedings nearer to the scheduled date.

1st Examiner:
Prechtel, Anja-Katri

2nd Examiner:
Ebbinghaus, Maximili

Chairman:
Anscombe, Marcel

For the Opposition Division

Annexes:
Confirmation of receipt (Form 2936)
Rule 4 EPC (EPC Form 2043)
Communication (EPO Form 2906)

Registered Letter

to EPO postal service: 22.03.22

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Provisional non-binding opinion of the opposition division

1 With the notice of opposition, both opponents requested the revocation of the contested patent in its entirety based on Art. 100(a) EPC on the grounds of novelty (Art. 54(1) EPC) and inventive step (Art. 56 EPC), based on Art. 100(b) EPC on the ground of insufficiency of disclosure and based on Art. 100(c) EPC on the ground of added subject-matter. As an auxiliary measure, oral proceedings according to Article 116 EPC were requested.

The following evidence has been submitted within the opposition period and is in the following renumbered to form a consolidated list:

EPO	CITATIONS	P	OP1	OP2
P1	US 10/883,575		E1a	
A1	EP 2 982 337 A1		E1c	
B1	EP 2 982 337 B1		E1d	
D1	US 5,258,023 A		D1	WBH1
D2	FR 2 337 543		D2	WBH2
D2a	US 4,106,129		D2a	
D3	WO 00/64380 A1		D3	WBH3
D4	FR 2 815 844 A1		D4	WBH4
D5	EP 2 537 487 A1		D5	WBH5
D5a	US 2005/137688		D5a	
D5b	US 2005/137698		D5b	WBH11
D6	WO 01/56512 A1		D6	
D7	US 6,454,799 B1		D7	WBH7
D8	US 2003/153974 A1		D8	WBH9

D9	DE 26 13 575 A1		D9	
D10	WO 03/053287 A1		D10	WBH17
D11	US 6,729,356 B1		D11	
D12	US 2004/0082989 A1		D12	
D13	Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)		D13	
D14	WO 03/039613 A1		D14	
D15 A1p	WO 2006/005015 A2 (publication of the parent application)		E1b	
D16	US 5,554,184 A			WBH6
D17	US 6,638,257 B2			WBH8
D18	WO 2006/089236 A1			WBH10
D19	WO 2004/082527 A2			WBH12
D20	WO 01/54625 A1			WBH13
D21	WO 01/76510 A2			WBH14
D22	US 2004/0210304 A1			WBH15
D23	US 5,855,601 A			WBH16
D24	US 2002/0052649 A1			WBH18
D25	Patent Assignment			Annex 3

The publication of the parent application as filed is in the following referred to as

A1p: **WO2006/005015 A2**

2 It seems that since the opposition was filed in due time and in proper form and is supported by reasoned statements, the opposition is admissible under Article 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

3 Added subject-matter (Article 100(c) EPC)

The following points regarding added subject-matter have been brought up in the procedure and will be discussed during the oral proceedings:

The requirements of added subject-matter are discussed below with reference to the publication of the parent application **A1p**. As the description of the application of the patent in suit corresponds to the description as filed of the parent application with the claims added as clauses, the below argumentation holds for both the requirements of Art. 76(1) EPC and Art. 123(2) EPC.

3.1 *Claim 1*

It is agreed upon that basis for **claim 1** as granted might be found in **claim 27** of **A1p** and the embodiment of Fig. 22 and description thereof.

3.1.1 The opponents argue that **claim 1** extends in subject-matter for the following reasons:

a) Omission of the feature of original **claim 27** that the compressible material is adapted for expansion after deployment.

b) Addition of the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

c) Omission of a feature of original **claim 27** that the valvular structure provides a flexible conduit.

d) Addition that the compressible material forms a sleeve.

3.1.2 re a)

The opposition division considers that the deleted feature of **claim 27** of **A1p** that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel limits the claimed materials to those able to fill the gaps due to its expansion properties. Also the description limits the layer of material in the same way (par. [00145]). In contrast thereto, **claim 1** as granted seems to encompass a layer of material only minimally expanding after delivery but filling the gaps by an increased bulk thickness at the positions of the gaps, e.g. the commissures, thus extending in scope over what has been originally disclosed.

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3.1.3 re b)

It seems that the closest basis for feature b) might indeed be found in **claim 29** of **A1p**. There, a plurality of outward extending fibers are disclosed in combination with a growth factor disposed along the compressible material and the compressible material being formed of PET (**claim 28**). The opposition division preliminarily considers that the technical function of the outwardly extending fibres, namely to provide an increased active surface for encouraging coagulation (pars. [00055], [00142], [00145]), is linked to the geometry of the fibers and not to the chemistry of the material. The same holds for the presence of a tissue growth factor in the layer of material itself. As the description in par. [00145] clearly mentions both features of PET and the growth factor to be optional, the opposition division considers the omission of these features from original **claim 29** an allowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.1.4 re c)

It will be discussed during oral proceeding whether the valvular structure of **claim 1** implicitly defines a flexible conduit, so that the omission of an explicit definition seems allowable.

In this respect the opposition division considers that a valvular structure formed of a pliant material as claimed is necessarily flexible.

Preliminarily, it seems that even in case of three separate leaflets only connected to each other at the commissures the resulting structure might be called a "conduit", in particular as the only characteristic of a conduit mentioned in the application is that it has an inlet and an outlet. At present, the opposition division thus cannot conceive of a valvular structure for a heart valve prosthesis formed of three valve leaflets of pliant material in a form different from a flexible conduit, i.e. conveying blood from an inlet to an outlet. The omission of an explicit definition thus seems allowable.

3.1.5 re d)

OP2 argues that a layer of material in the form of a sleeve as disclosed in par. [00145] might also be provided spaced apart from the stent structure, while the claimed sleeve of a stent structure would provide covering and protection and thus be more limiting. The opposition division currently sees this as a rather linguistic approach and is currently of the opinion that a layer of material in the form of a sleeve necessarily also forms a sleeve.

In any way, the division sees par. [00145] to disclose a layer of compressible material disposed along an outer surface of the whole stent structure. This, however, seems to encompass the function of covering and protection, and thus equates the scope of the claimed sleeve.

3.1.6 Preliminarily, the opposition division thus considers solely to omission of a feature towards the compressible material being adapted for expansion after deployment to fill gaps in **claim 1** to extend in subject-matter over the original disclosure of the parent application.

3.2 *Claim 2*

The opponents argue that there is no direct and unambiguous disclosure of a sleeve surrounding an inflow end of the stent structure.

The description is silent on the position of the sleeve and the opposition division preliminarily considers that the person skilled in the art would also not immediately recognize a technical function of the position of the sleeve in Fig. 22, in particular as no technical link such as a position of the gap with respect to the stent and/or its longitudinal axis is apparent from the description. It might therefore even be considered that the inflow end of the stent in Fig. 22 is covered by the sleeve merely due to the whim of the artist and not due to a technical consideration. Thus the person skilled in the art would not be able to deduce the position of the sleeve relative to the stent's end from Fig. 22 or the description. Preliminarily, the subject-matter of **claim 2** seems to extend beyond the content of the (parent) application as filed.

3.3 *Claim 3*

The opponents argue that the thickness defined in **claim 3** is only originally disclosed together with the material PET. It seems that the only disclosure of a thickness ranging from 1-5mm as defined in **claim 3** is in par. [00145], which also discloses that the material is PET. No other material is disclosed for the embodiment of Fig. 22. The thickness of the layer and the material it is made of are functionally related as the ability to expand to fill gaps is not only due to thickness of the layer but also due to the materials expansion properties, softness, swellability etc. Therefore the opposition division preliminarily considers that the person skilled in the art would be surprised to see the claimed thickness for a generic compressible material. Preliminarily, the omission of a feature towards the material being PET seems to constitute a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.4 *Claim 4*

The opponents argue that a cloth or fabric is only disclosed in the context of the compressible material resembling a cloth or fabric (par. [00145]) and having small fibers extending from its surface so that the omission of the underlined features constitutes a case of unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

The opposition division is of the preliminary opinion that the disclosure of par. [00145] of the compressible material resembling a cloth or fabric having small fibers extending form the surface of the material together with par. [0055] of the background of the invention relating to the same embodiment and disclosing a compressible material "*such as clot or fabric*" is sufficient basis for the material being cloth or fabric. In that respect, the opposition division considers that the word "clot" in this passage can only mean cloth, as also used in par. [00145].

Regarding the term "small", generic fibers are not only disclosed in par. [0055] but also in **claim 29** as filed, so that its omission seems unproblematic.

3.5 *Claim 5*

The additional feature of **claim 5** is disclosed in original **claim 29** together with the feature of the compressible material including a plurality of fibers that is already part of **claim 1** as granted. **Claim 5** is thus not seen as adding problems of extension of subject-matter.

3.6 *Claims 6, 7*

The additional features of **claims 6 and 7** are disclosed word by word in par. [00145] as respective optional features. **Claims 6 and 7** are thus not seen as adding problems of extension of subject-matter.

3.7 *Claim 8*

The opponent argues that the omission of a feature towards the compressible material being adapted for expansion into the gaps after deployment would extend its subject-matter. The opposition division preliminarily considers that gaps between a prosthetic valve and the body channel can only occur after deployment, and thus a compressible material configured to expand into these gaps necessarily is configured to do so after deployment. **Claim 8** is thus not seen as adding problems of extension of subject-matter.

3.8 *Claim 9*

The opposition division considers that there is no direct and unambiguous disclosure of the compressible material adjusting to the shape of a cavity existing between the valve and the vessel wall. There is merely a disclosure of the compressible material expanding into the gaps. This, however, also includes situations where the expanded shape of the material layer is pre-formed to correspond to the shape of the gaps or also where a material layer expands uniformly and seals the gaps by deforming the surrounding vessel wall. There seems thus no disclosure towards the more limited situation defined in **claim 9**, i.e. the subject-matter of **claim 9** as granted is seen as an unallowable intermediate generalisation (see Guidelines H-V 3.2.1).

3.9 *Figures*

Opponent 2 argues that Fig. 22 of the parent as originally filed depicts a blank outer surface of the compressible material without any further structure, whereas Fig. 22 of the patent shows a surface comprising small elements irregularly distributed. The proprietor argues that Fig. 22 as filed seems to depict similar small structures in the vicinity of the left edge of the sleeve. To the opposition division, however, these structures are not clearly discernible and might also be scanning artefacts, i.e. no information can be derived from them.

In order to establish whether the addition of the small elements to Fig. 22 of the patent extends the subject-matter disclosed, it has to be established what the person skilled in the art would be able to derive from the figure. In this respect, the opposition division considers that the person skilled in the art only recognizes elements with a technical function immediately apparent, either from the drawing on its own or from the teaching of the description (see Case Law of the Boards of Appeal II-E-1.13). The opposition division considers that no technical function of the small elements can be deduced from the drawing on its own. The description, on the other hand, discloses only a single option for elements on the surface of the compressible material 256, namely fibers. Thus the person skilled in the art is would immediately recognize those fibers in the the elements of Fig. 22. The opposition division is unable to see how this could present any new information to the person skilled in the art over what was originally disclosed in the parent application as a whole.

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Regarding the disclosure of the other figures, the opposition division considers that in the absence of a detailed argumentation on which features should be seen as extending over the content of the parent application no such extension is present, with the same reasoning as above for Fig. 22.

3.10 For the above reasons, the opposition division thus preliminarily considers the subject-matter of **claims 1, 2, 3** and **9** to extend beyond the content of the parent application.

4 Novelty (Article 100(a) EPC in connection with Art. 54(1) EPC)

The opponents argue that the priority of the patent is not validly claimed. Following from that, they argue that the subject-matter of **claim 1** is not novel over prior art documents **D5b**, **D6**, **D8**, **D14, D18-D23** (Art. 54(1) EPC).

4.1 *Priority*

The opposition division is of the preliminary opinion that the priority of **claim 1** is not valid as the priority document **P1** does not comprise the embodiment of Fig. 22, i.e. there is no disclosure of the claimed features of a prosthetic valve with a layer of compressible material forming a sleeve and including a plurality of fibers extending outward from the outer surface (Art. 87(1) EPC).

The question of whether the priority is invalid due to formal reasons will only be discussed and decided upon if necessary. At present it seems this will not be the case.

4.2 *Prior art document D5b (Art. 54(2) EPC)*

Prior art document **D5b** published on 23 June 2005 is preliminarily considered as prior art under Art. 54(2) EPC as the priority of **claim 1** of the patent seems not valid.

It discloses a prosthetic valve with an outer seal in the form of a sleeve and made of thin, elastic polymer or any other type of fabric (Figs. 8A-8C, par. [0071]).

The opposition division preliminarily considers a fabric material as a compressible material. This is also in line with the disclosure of the patent in suit (compare par. [0055] of **A1p**). Therefore feature F4 seems disclosed by **D5b**.

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In the absence of convincing evidence to the contrary, the opposition division does not agree with the opponent's assertion that any fabric inevitably comprises outwardly extending fibers. In particular it seems that a fabric of monofilament fibers cannot comprise such outwardly extending fibers at all. Thus feature F6 seems not implicitly disclosed in prior art document **D5b** so that the subject-matter of **claim 1** is preliminarily found novel over this document (compare Case Law of the Boards of Appeal I-C-4.3).

4.3 *Prior art document D6 (Art. 54(2) EPC)*

Prior art document **D6** discloses a prosthetic heart valve 10A/10M with an umbrella-like frame structure 20 formed from four U-shaped elements 30, i.e. eight spokes, to which a dome-shaped valve membrane 22 is attached forming several leaflets (page 8, lines 7-21; page 11, lines 14-30). An outer band 40 is circumferentially attached to the frame forming a sleeve and may be made of velour (page 9, line 23 -28; page 11, lines 6-13).

The opposition division preliminarily considers the umbrella-like frame structure 20 of D6 not to be a substantially cylindrical stent structure, as by attaching the U-shaped struts in their respective middle parts to each other the stent structure is clearly closed at one end, while a cylindrical structure must be tubular with two open ends. Therefore feature F2 seems not disclosed in **D6**.

While the opposition division preliminarily considers that the flaps of **D6** might be validly considered as leaflets as they comprise commissures and open and close to regulate the blood flow, **D6** does not disclose a tri-cuspid valve.

While the description of prior art document **D6** does not explicitly disclose the number of attachment points 56 of the dome shaped valve membrane 22 (page 12, line 24 - page 13, line 5), it seems that the person skilled in the art looking at Fig. 3 will immediately recognize the symmetry of the eight struts and thus also four attachment points. In the preliminary opinion of the opposition division, the mere possibility to use more or less U-shaped struts 30 (page 8, lines 18-21) is not a direct and unambiguous disclosure of exactly three attachment points, in particular since there is no disclosure about how the attachment points should be distributed among the struts. Thus also feature F3 is preliminarily seen as not disclosed by **D6**.

The outer band 40 may be made from woven velour (page 11, lines 6-13). The opposition division considers it common general knowledge that velour is manufactured by cutting across (looped) threads and is thus a fabric that inevitably comprises outwardly extending fibers as it (feature F6). As set out

above, any fabric is considered as a compressible material (feature F4), but even more so if it is comprises outwardly extending fibers that can be compressed against its surface. Therefore features F4 and F6 seem preliminarily disclosed in **D6**.

For the above reasons, the opposition division is currently of the opinion that the subject-matter of **claim 1** is novel over **D6** as features F2 and F3 are not disclosed (Art. 54(2) EPC).

4.4 *Prior art document D8 (Art. 54(2) EPC)*

Prior art document **D8** discloses a prosthetic valve where a valve assembly made of PET material is rolled over the inlet end of the stent to form an outer sleeve, this sleeve enhancing sealing (Figs. 1, 2, par. [0112]).

While the opposition division is of the preliminary opinion that a fabric material might be considered as compressible, since the spacing of the fibers allows them to be compacted under pressure, prior art document **D8** does not explicitly disclose how the PET material is formed, i.e. it might also be in the form of a membrane, which is not compressible. Thus it seems at present that feature F4 is not disclosed.

There is no explicit disclosure of outwardly extending fibers in **D8** and with the argumentation of above, the opposition division preliminarily considers feature F6 also not implicitly disclosed.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D8** (Art. 54(2) EPC).

4.5 *Prior art document D14 (Art. 54(2) EPC)*

Prior art document **D14** relates to vascular prostheses and inter alia to heart valves (page 6, lines 9-17). It also discloses the use of a velour material (page 7, lines 3-14).

This document is completely silent on the structure of the prosthetic heart valve used. Since heart valves are known that

- do not comprise cylindrical stent structures (stentless valves, valves comprising rigid anchoring rings, non cylindrical stents- compare **D6**) (feature F2),
- have one, two or more than three leaflets (feature F3), and

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- where the velour material may be used in other configurations than a sleeve (e.g. patches of material) (feature F4)

the opposition division is of the preliminary opinion that none of the features F2-F4 of **claim 1** are directly and unambiguously disclosed in **D14**.

Therefore the subject-matter of **claim 1** seems novel over prior art document **D14** (Art. 54(2) EPC).

4.6 *Prior art document D18 (Art. 54(3) EPC)*

Prior art document **D18** was published on 24 August 2006 has a priority date of 18 February 2005 that is earlier than the filing date of the patent in suit. As the priority of the patent in suit seems not valid, while the priority of the relevant embodiment of **D18** seems valid (see below), **D18** is preliminarily considered as prior art under Art. 54(3) EPC.

Prior art document **D18** discloses in Figs. 1-11 a prosthetic bi-leaflet valve and in the embodiment of Fig. 12 a prosthetic tri-leaflet valve. The embodiments of Figs. 1-11 comprise a support member 40 and a layer of biocompatible material 50 covering the entire outer circumference of the support member 40 and thus forming a sleeve (page 6, lines 10-18) (feature F4).

The outer covering 50 may be made from woven velours (**D18**: page 6, lines 3-8). As set out above, the opposition division considers this a direct and unambiguous disclosure of a compressible material with outwardly extending fibers (features F4, F6).

The proprietor argues that the embodiment of Fig. 12, which is the relevant embodiment as it discloses a tri-leaflet valve, does not comprise an outer sleeve. In contrast thereto, the opposition division preliminarily considers that the valve of Fig. 12 is disclosed to be "*similar, except whereas described*" to the previous embodiments (page 21, lines 14-17), thus also featuring the sleeve 50.

In particular Fig. 12 comprises reference signs 40/46/60 related to the same support member as that of Figs. 1-11 where this support member is covered by member 50. Moreover, wing members 60 are sketched as opaque in Fig. 12, indicating the presence of a covering material on the stent frame. The opposition division thus considers layer 50 of biocompatible material covering the support member is also directly and unambiguously disclosed for the embodiment of Fig. 12.

Regarding the validity of priority of **D18**, the above reasoning also holds for the priority document **D18a=US 60/654,725**, which is attached to the present summons. Fig. 7 of this document corresponds to Fig. 12 of **D18** and the corresponding description mentions that a tri-leaflet valve is used in "the apparatus 10", thus referring back to the previous embodiments (**D18a**: page 13, line 17). Also, valve 12' is disclosed as functioning "as described above with regard to the previous embodiments", which in the preliminary opinion of the opposition division also includes layer 50 (**D18a**: page 13, line 22 - page 14, line 2). In all other relevant aspects, the disclosure of **D18a** is the same as that of **D18**. Therefore the priority of **D18** is valid and it is considered as prior art under Art.54(3) EPC.

For the above reasons, **claim 1** is preliminarily considered not novel over prior art document **D18** under Art. 54(3) EPC.

4.7 *Prior art documents D19-D23*

The argumentation of the opponents with regard to prior art documents **D19-D23** relies on the point that any fabric would comprise fibers extending outward from the outer surface and thus feature F6 would be implicitly disclosed in each of these documents. For the reasons given above in section 4.2, the opposition division preliminarily does not consider this argumentation convincing so that the subject-matter of **claim 1** as granted is preliminarily considered novel over **D19-D23** (Art. 54(1) EPC).

4.8 For all of the above reasons, the opposition division is preliminarily of the opinion that the subject-matter of **claim 1** is not novel over prior art document **D18** (Art. 54(3) EPC) but is novel over **D5b**, **D6**, **D8**, **D14, D19-D23** (Art. 54(1) EPC).

5 Inventive step (Article 100(a) EPC in connection with Art. 56 EPC)

The opponents argue inventive step with the following combinations of documents:

- **D1** together with either **D4**, **D5a, D5b**, **D7, D8**.
- **D3** together with either **D1 or D9.**
- **D8** or any of **D19-D23** together with either **D10** or **D24**.
- **D10, D11 or D12** together with **D13.**

In the oral proceedings, the opposition division would like to determine as a first step the closest prior art, taking into account not only the features disclosed but also whether a similar purpose is apparent. Preliminarily, the opposition division considers that the purpose of the claimed device is to seal gaps/prevent paravalvular leakage occurring around an expandable heart valve.

The opposition division considers that a document requiring a change in the main purpose and use of the device would not be a promising starting point (compare Case Law of the Boards of Appeal I-C-3.2). This means that the devices of

- **D1** that is not for percutaneous implantation,
- **D10-D12** that are no prosthetic valves but stent-grafts,

are preliminarily not considered good starting points.

In **D8**, the sealing layer is formed of the same material as the leaflets (par. [0112]), which require a smooth surface not prone to blood clotting. Thus **D8** teaches away from adding fibres to the sealing layer and does not seem a promising starting point.

The opposition division considers that documents **D20** and **D21** do not mention the purpose of the outer sheath as sealing against paravalvular leakage or being compressible/expandable, thus they also seem less promising starting points.

While prior art documents **D19** and **D23** seem to disclose sealing elements, they do not explicitly disclose those to be expandable or compressible and thus it seems questionable whether the person skilled in the art would actually add outwardly extending fibers, i.e. bulk to those systems.

In contrast, prior art documents **D3** and **D22** seem to disclose the concept of an expandable/deformable sealing ring to seal against paravalvular leakage (**D3**: see below, **D22**: pars. [0026], [0121]). **D22** seems not to add anything over **D3**, so prior art document **D3** will be discussed in the following.

Preliminarily, prior art document **D3** seems a good starting point, as it discloses a balloon-expandable stent-like band 110 (Fig. 1, page 5, lines 13-28, compare Fig. 6) to which is fitted a porcine tissue valve, i.e. a tri-leaflet valve (page 5, lines 34-35). It also discloses that the outer walls of the band 110 may comprise a gasket-like material that "*conforms to the existing tissue annulus and seals the new valve to the tissue annulus to protect against leakage around, or through, band 110* ". Prior art document **D3** is thus concerned with the purpose of the invention, namely preventing paravalvular leakage. It also discloses that the

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gasket-like material may be formed from a soft, deformable material, such as polyurethane or also Dacron, which is a fabric material and thus in the form of a layer forming a sleeve.

It thus seems that **D3** discloses all features apart from fibers extending outwardly from the outer surface of the layer of compressible material.

Preliminarily, the opposition division considers that the technical effect and problem solved by this feature should be determined starting from the disclosure of the patent in suit. There it is stated that "*fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage*" (pars. [0046] and [0109] of **B1**) and where par. [0106] discloses that coagulation is enhanced by the fibers increasing the active surface. The opposition division thus preliminarily considers that the technical effect of the fibers is to provide an increased surface and where this solves the technical problem of encouraging coagulation to improve sealing. Preliminarily, it seems that prior art documents **D10** and **D24** are the only documents dealing with this problem.

It seems that prior art document **D10** discloses that tufts of fibrous material, i.e. outwardly extending fibers, are used in order to encourage blood clotting and adhesion (page 1, lines 18-20) and that the use of a circumferential band of such material improves sealing (page 3, lines 26-30). The opposition division preliminarily considers that the person skilled in the art would take the above teaching and incorporate a plurality of outwardly extending fibers into the gasket material of **D3** thus arriving at the claimed subject-matter in an obvious manner, contrary to the requirements of Art. 56 EPC.

The proprietor's argument that the person skilled in the art would not add bulk to the sealing element seems not applicable in this respect as the whole purpose of the sealing gasket of **D3** is to provide bulk in the form of an expandable/ compressible element.

Also prior art document **D24** seems to disclose that in order to encourage tissue attachment and improve sealing, areas of increased surface such as terry cloth with outwardly extending looped filaments might be used (par. [0032]-[0035]). Also this document seems to render the claimed subject-matter obvious when starting from **D3**.

On a preliminary basis, it thus seems that the subject-matter of **claim 1** as granted does not involve an inventive step (Art. 56 EPC).

6 Sufficiency of disclosure (Article 100(b) EPC)

OP1 argues that feature F4 defines an outer surface of the stent structure and the fibers in feature F6 extend outwardly from "*the outer surface*", i.e. the outer surface of the stent structure, but that there is no teaching how to attach fibers to the outer surface of the stent structure, because there is only a disclosure of the fibers being attached to the fabric (see par. [0109] of **B1**).

The opposition division preliminarily considers that the claim clearly defines that the compressible material includes a plurality of fibers, so that these fibers can technically only extend from the surface of the material. Thus the person skilled in the art would be immediately aware that the backwards reference to the outer surface of the stent is erroneous and nothing else than the surface of the material can be meant. This is also supported by the disclosure of the description (par. [0109]). If at all, the argument of OP1 is thus rather seen as a problem of clarity under Art. 84 EPC.

OP2 argues that since the compressible material creates a seal that prevents paravalvular leakage, the fibers are compressed against the material in use and are thus not extending outwardly. The opposition division firstly considers that even in a compressed state the fibers will still extend outwards to a certain degree. Secondly, the opposition division considers that the claimed structure defines the prosthetic heart valve in its rest state where the fibers unarguably extend outwards.

The opposition division therefore preliminarily considers that the arguments of the opponents do not equate to serious doubts, substantiated by verifiable facts, but that the person skilled in the art using his common general knowledge would gather enough information from the disclosure of the invention, in particular from pars. [0046], [0109] and Fig. 22, to be able to set the invention into practice.

7 AUXILIARY REQUESTS

7.1 *Auxiliary request 1*

In auxiliary request 1 **claim 1** has been amended by adding the feature of the the valvular structure providing a flexible conduit of **claim 27** of **A1p**.

It will have to be discussed if this feature limits the claim (see above 3.1.4). If not, the requirements of Rule 80 EPC might not be found to be met.

In any event, it seems that this feature might not be able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC) nor solve the issues of added subject-matter addressed above (Art. 76(1)EPC).

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7.2 *Auxiliary request 2*

In auxiliary request 2 **claim 1** has been amended by adding the feature of the layer of compressible material being adapted for expansion after deployment to fill gaps (basis: **claim 27** and par. [0145] of **A1p**).

This amendment seems to solve the problem of added subject-matter of **claim 1**, however not of the dependent claims (Art. 76(1) EPC).

As the patent in suit is silent on what makes a compressible material "*adapted for expansion after deployment*", it is assumed that this feature is inherent in any compressible material and thus also in the materials of the prior art, in particular fabric, velour and terry material. Therefore this feature is preliminarily seen as not able to establish novelty or inventive step (Art. 54(2) EPC, Art. 56 EPC).

7.3 *Auxiliary request 3*

In auxiliary request 3 **claim 3** has been amended by adding the feature of the compressible material being formed of PET from par. [0145] of **A1p**. It solves the issue of added subject-matter set out above in section 3.3. All other issues discussed with respect to the main request remain.

7.4 *Auxiliary request 4*

In auxiliary request 4 **claim 8** has been amended by aligning the wording of the feature of the compressible material expanding into the gaps with the wording of par. [0145] of **A1p**. The requirements or Art. 76(1) EPC seem to be met for this amendment. All other issues discussed with respect to the main request remain.

7.5 *Auxiliary request 5*

In auxiliary request 5 **claim 9** has been deleted, thus solving the problems under Art. 76(1) EPC of this claim (see above under 3.8). All other issues discussed with respect to the main request remain.

7.6 *Auxiliary request 6*

In auxiliary request 6 **claim 1** has been amended to define that the stent structure is configured for radial expansion using a balloon catheter from par. [0145] . It seems that since the stent of **claim 1** is already defined as configured

for radial expansion, the omission of a feature towards the stent structure being made from a deformable material is considered allowable. The other issues of Art. 76(1) EPC set out with respect to the main request remain.

Regarding novelty, prior art document **D18** discloses that the prosthetic valve is expanded using a balloon catheter (page 19, line 7 - page 20, line 12), thus the subject-matter of **claim 1** seems not novel over this document (Art. 54(3) EPC).

Also prior art document **D3** discloses the use of a balloon catheter to expand the stent structure (see e.g. Fig. 1 and description thereof), so that the subject-matter of **claim 1** seems not inventive for the same reasons as given for the main request.

7.7 *Auxiliary request 7*

In auxiliary request 7 **claim 1** has been amended by defining the prosthetic heart valve to be a cardiac valve. This feature seems to be originally disclosed in pars. [0001] and [0087].

As prior art documents **D18** and **D3** both relate to cardiac valves, the novelty and inventive step argumentation of the main request also applies here. Also all other issues discussed with respect to the main request remain.

7.8 *Auxiliary request 8*

In auxiliary request 8 all amendments of auxiliary requests 1-7 have been incorporated. The above reasoning applies.

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Wichtige Hinweise zur mündlichen Verhandlung	Important information concerning oral proceedings	Tres important Procédure orale
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Hinweis auf Regel 4 EPÜ

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Attention is drawn to Rule 4 EPC

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Rappel de la Règle 4 CBE

Règle 4
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(2) Au cours de la procédure orale, les agents de l'Office européen des brevets peuvent utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure.

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Date
25.10.2021

Reference	OPPO 01	Application No./Patent No.
255.0051G1		15180327.7 - 1126 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

BRIEF COMMUNICATION

Subject:
- ☐ Your letter of
- ☐ Our telephone conversation of
- ☒ Communication of 10.6.2021
- ☐

Enclosure(s):
- ☒ Letter from the proprietor of the patent of 20.10.2021
- ☐ Letter from the opponent of
- ☒ Copy (copies) auxiliary requests 1-8

Communication:

☐ The documents specified as patent documents and as non-patent literature in this letter are available for inspection via the European Patent Register at **www.epo.org/register.** Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2020, A106).

☐

For the Opposition Division

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Munich, October 20, 2021

European Patent 2 982 337 (EP No. 15 180 327.7)
EDWARDS LIFESCIENCES PVT, Inc.
Our Ref.: 238 337 t2
Opponent O1: Abbott Cardiovascular Systems, Inc.
Opponent O2: Neovasc Tiara Inc.

With reference to the Communication of notices of opposition dated June 10, 2021, we respond as follows to the oppositions filed to the above referenced patent by Abbott Cardiovascular Systems, Inc. ("Opponent O1") and Neovasc Tiara Inc. ("Opponent O2").

A Requests

We request

a) that the oppositions be rejected;

b) in case the request according to a) is not granted, that the patent be maintained on the basis of amended claims according to one of the enclosed auxiliary requests; and

c) that oral proceedings be arranged in case the Opposition Division considers taking any decision adverse to the Proprietor.

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B No inadmissible extension - Art. 100(c) EPC

To demonstrate that the opposed patent does not extend beyond the contents of the application as filed, we will refer to the A1 publication of the parent application of the opposed patent, WO 2006/005015 A1 ("**D15**" according to the EPO's consolidated list).

B.1 General remark regarding claim 1

In general terms, the granted claim 1 of the opposed patent is derived from Figure 22 of the parent application and the associated text, including (but not restricted to) paragraph [00145], as well as claims 27-29 of the parent application.

Opponent O1 refers to claims 27-29 of the parent application (**D15**) and finds that "several features are missing in the subject-matter of claim 1 of the opposed patent so that the subject-matter surely extends beyond the content of the claims as originally filed". We understand this reference to "missing" features to mean that the granted claim 1 does not include all features of claims 27-29 of **D15**. In a separate step, O1 refers to the description of **D15** and argues that based "on the description, the subject-matter of claim 1 of the patent cannot be directly and unambiguously achieved" (point 2.1.2 of the notice of opposition).

However, Art. 100(c) EPC refers to the content of *the application as filed*. When considered *in its entirety*, **D15** clearly and unambiguously discloses a prosthetic valve according to the granted claim 1 of the opposed patent. This will be demonstrated in detail below.

B.2 Claim 1 – "flexible conduit"

Both Opponents refer to the fact that claim 27 of **D15** specifies a valvular structure "providing a flexible conduit having an inlet and an outlet", whereas the granted claim 1 of the opposed patent does not expressly include the words "providing a flexible conduit".

However, this deviation in wording between the granted claim 1 and claim 27 of **D15** does not result in an inadmissible extension.

On the one hand, **D15** does not even refer to a "flexible conduit" when describing the prosthetic valve in Figure 22. Neither paragraph [00145] which closely relates to this Figure, nor the remaining text passages disclosing various features of the prosthetic valve refer to a "flexible conduit".

On the other hand, according to the granted claim 1, the valvular structure still has "an inlet and an outlet", is "formed of a pliant material attached to the stent structure" and

forms "three valve leaflets", and it is part of a prosthetic valve for implantation in a body channel. For a skilled reader of claim 1, it is immediately clear from these claim features that the valvular structure - like any valvular structure of a prosthetic valve of this kind - is configured to convey blood from the inlet to the outlet thereof and through the said body channel. This in turn is precisely the function of a conduit[1]. Therefore, a structure with the features of claim 1 necessarily provides a flexible conduit, and thus the skilled person understands that this feature is implicitly included in the claim. The granted claim 1 does therefore not extend beyond the original disclosure.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 1 which further addresses this point.

B.3a Claim 1 – "sleeve"

The claimed prosthetic valve is characterized by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

O1 states that the features relating to this sleeve result in an inadmissible extension of claim 1 because **D15** rather discloses a "layer of compressible material 256" which "is disposed along an outer surface of the stent structure 252", wherein the material may extend "entirely around the stent structure, such as in the form of a sleeve" (paragraph [00145]).

In an attempt to explain why this disclosure in paragraph [00145] does not support claim 1, O1 argues that it is disclosed in **D15** that *the material* extends entirely around the stent structure *and not a sleeve* as in claim 1. O1 further argues that claim 1 requires the sleeve as a "distinct structural component", the presence of which is not disclosed in **D15** and thus inadmissibly extends the subject matter.

O2 provides a slightly different explanation for basically the same objection: a material which forms a sleeve (claim 1) "is required to engage with the stent structure to provide covering and protection functionalities", whereas a material *in the form of a sleeve* ([00145]) "may be provided spaced apart from the stent structure, for example". In O2's view, it is not derivable from **D15** that the material actually forms a sleeve (provides cover and protection) beyond just being *in the form of a sleeve*.

The relevant comparison is not between *material* on the one hand ([00145]) and *a sleeve* on the other hand (claim 1) which would extend around the stent structure, as argued by O1. The comparison is also not between a *material in the form of a sleeve* ([00145]) and a *material which forms a sleeve* (claim 1), as argued by O2. The relevant

[1] cf. e.g. the definition of a conduit as a "natural or artificial channel through which something (such as a fluid) is conveyed" (per Merriam-Webster, see m-w.com)

comparison is between material *extending around the stent structure in the form of a sleeve* ([00145]) and material *which forms a sleeve extending around the stent structure* (claim 1). There is no difference whatsoever *in substance* between the two. One cannot possibly think of any material e*xtending around the stent structure in the form of a sleeve* which would not also *form a sleeve extending around the stent structure*, and vice versa.

In conclusion, we submit that the disclosure of material *extending around the stent structure in the form of a sleeve* in paragraph [00145] of **D15** does amount up to a clear and unambiguous disclosure of material *which forms a sleeve extending around the stent structure* according to the granted claim 1.

B.3b Claim 1 – "for expansion"

The granted claim 1 relates to the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.

For the Opponents, claim 1 extends beyond the contents of **D15** because the original description ([00145]) and claims in the Opponents' view only disclose compressible materials adapted *for expansion* after deployment to fill gaps between the prosthetic valve and the body channel, whereas granted claim 1 is in the Opponents' view not restricted accordingly.

Also in this regard, the granted claim 1 does not extend beyond the contents of **D15** though: The claim specifies the compressible material as being adapted after deployment to fill gaps between the prosthetic valve and the body channel. This in turn is precisely how the skilled person understands the prosthetic valve illustrated in Figure 22 of **D15** to be configured, which has the layer of compressible material 256 in the form of a sleeve: Being attached to the stent structure, this compressible material is crimped or folded when the stent structure is crimped. After deployment of the stent structure, the material fills gaps between the prosthetic valve and the body channel.

The claim feature as to the compressible material being "adapted after deployment to fill gaps between the prosthetic valve and the body channel" is therefore closely in line with the disclosure in paragraph [00145] and Figure 22 of **D15**.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 2 which further addresses this point.

B.4 Claim 1 – "plurality of fibers" without "tissue growth factor" or "PET"

According to the last feature of claim 1, the compressible material includes a plurality of fibers extending outward from the outer surface.

This feature is literally disclosed in claim 29 of **D15**. The Opponents point out that this claim includes a further feature relating to a "tissue growth factor" and is dependent on claim 28 of **D15**, according to which "the compressible material is formed of polyethylene terephthalate". The Opponents argue that these features are missing in the granted claim 1, resulting in an intermediate generalization.

However, **D15** clearly and unambiguously discloses a prosthetic valve in which the compressible material includes a plurality of fibers extending outward from the outer surface, entirely irrespective of any tissue growth factor and irrespective of whether the compressible material is formed of polyethylene terephthalate. Paragraph [00145] of **D15** confirms that

- "*In one preferred embodiment*, the compressible material is formed of PET and has a thickness ranging from about 1 to 5 mm";
- "*In certain configurations*, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material"; and
- "*In an alternative configuration*, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps" (emphases added).

The feature relating to the fibers is disclosed here without any close structural or functional relationship to the feature of the prosthetic valve further comprising a tissue growth factor disposed along the compressible material and the compressible material being formed of polyethylene terephthalate.

B.5 The dependent claims

O1 also objects to all of the dependent claims under Art. 100(c) EPC. O2 only objects to claims 2, 3, 4 and 9. However, as will be demonstrated below, the combinations of features of the dependent claims are clearly and unambiguously disclosed in **D15**.

Claim 2:

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

The additional feature of claim 2 is disclosed in Figure 22 of **D15** in view of the text in paragraph [00145] which confirms that the sleeve extends entirely around the stent structure. Also according to paragraph [0055] of **D15**, "a compressible material, such as a clot *(sic[2])* or fabric, extends around an exterior portion of the stent". The fact that it is

[2] The skilled person would understand that this is a reference to "cloth".

the *inflow* end of the stent structure which is surrounded by the sleeve is immediately apparent to the skilled reader of the application (the flow direction through the valve in Figure 22 – from the bottom of the page to the top of the page - is clear to the skilled person).

Claim 3:

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5 mm.

This feature is literally disclosed in paragraph [00145] of **D15**. O1 points out that the thickness range is disclosed here *only for PET material*. However, **D15** repeatedly confirms that PET is only one possible compressible material. The skilled reader therefore understands the statement in paragraph [00145] to mean that the thickness indicated therein is irrespective of whether PET or another suitable material is used.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 3 which further addresses this point.

Claim 4:

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

This additional feature finds literal support in paragraph [0055] of **D15**: "such as a clot[h] or fabric". Further support is in [00145] of **D15**: "may resemble a cloth or fabric having small fibers".

Claim 5:

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

The clear and unambiguous disclosure of the tissue growth factor also without other features has been shown above in the context of claim 1.

Claim 6:

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

This wording is literally supported by paragraph [00145] of **D15**. While the feature is disclosed here in the form of a method step, the step of applying the growth factor along the outer surface of the compressible material certainly results in a prosthetic valve which has the growth factor applied along the outer surface of the compressible material, and therefore, this original disclosure relates to the device as well as to the method.

Claim 7

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

This wording is literally supported by paragraph [00145] of **D15**. It is obvious for the skilled reader that the "fibers" referred to in this paragraph are the same fibers as in other parts of the original disclosure, including claim 29 of **D15**. It is not apparent why a further "pointer in the description" should be necessary to combine the various statements as to the fibers, as implied by O1.

Claim 8:

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

This additional feature finds support in original paragraphs [0055] ("The compressible material may be formed of PET and is configured to expand into the gaps.") and [00145] ("The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.").

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 4 which further addresses this point.

Claim 9:

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

This additional feature finds support in claim 1 of **D15** which literally mentions "cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole".

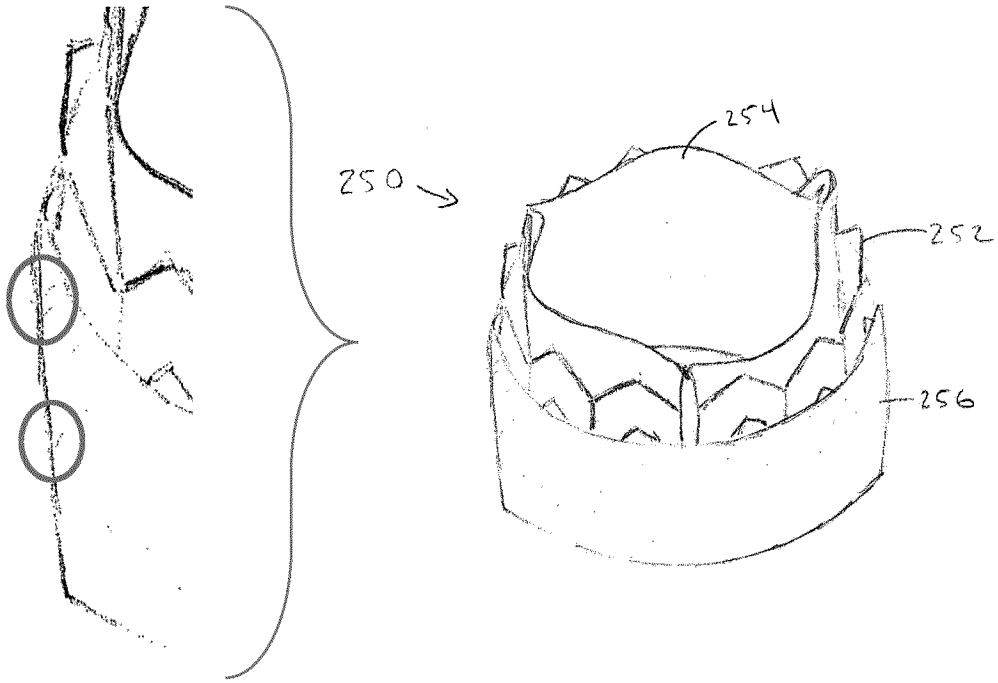
To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 5 which further addresses this point.

B.6 The drawings

O2 argues that Figure 22 of the granted patent extends beyond the contents of **D15** because fibers are not depicted in the corresponding provisional drawing in **D15**, wherein O2 refers to the provisional drawings available via the online register of the EPO.

Figure 22 of the granted patent does not add anything to the original disclosure though.

A closer examination of the provisional Figure 22 in the register shows that fibers are in fact (albeit faintly) illustrated therein:



Furthermore, the fibers are clearly and unambiguously described in the associated text in **D15**. Therefore, ***D15*** *as a whole* discloses the valve prosthesis of Figure 22 *including the fibers*, and Figure 22 of the patent does therefore not extend beyond the contents of **D15**.

O2 argues that "similar objections" as to Figure 22 also apply to a series of other Figures in the granted patent. However, while the O2's objection to Figure 22 relates to the

illustration or not of fibers, most of the further drawings do not show any fibers at all, and it is therefore not apparent how "similar objections" should apply to them. The formal drawings in the granted patent differ from the original provisional drawings only in that they have been redrawn as it is commonly the case with this type of patent drawings. The proprietor can hardly be expected to speculate at this point as to which deviations between the two sets of drawings might in the Opponent's view result in an inadmissible extension.

C Sufficiency of disclosure - Art. 100(b) EPC

According to the last feature of claim 1, the compressible material includes a plurality of fibers extending outward from the outer surface.

O1 states that the only outer surface previously mentioned in the claim is the outer surface of the stent structure. In O1's view, the skilled person would therefore read the claim so that "the fibers must start on the stent and then extend outwardly therefrom". At the same time, O1 confirms that "According to the teaching of the patent, it seems intended to encourage coagulation of blood at the fibers outside of the compressible material". To reconcile these two concepts, O1 suggests that "the fibers would have to extend from the stent structure through the compressible material outwardly", and as there is no disclosure in the patent as to how fibers might be integrated into the compressible material so as to extend *from the stent through the material and outwardly of it* to encourage coagulation of blood, the Opponent finds the invention to be insufficiently disclosed in the patent.

These objections are unfounded:

A skilled reader would not interpret claim 1 so that the "outer surface" referred to at the very end thereof is the outer surface *of the stent structure*. In fact, the compressible material which is disposed along an outer surface of the stent structure necessarily also has an outer surface, and according to the only reasonable interpretation, the outer surface in the last feature of claim 1 is actually the outer surface of the compressible material (i.e. claim 1 would be read to end with "the compressible material includes a plurality of fibers extending outward from the outer surface [thereof]"). This understanding is also supported by the granted dependent claim 6 which refers to "the outer surface of the compressible material" (thereby also implying that there is an antecedent basis for this outer surface which would then be in claim 1). The description is also in line with this understanding, as becomes clear from e.g. the wording in paragraph [0064] of the patent: "The compressible material 256 resembles a cloth or fabric having small fibers extending from the surface *of the material.*" (emphasis added)

To the extent that the alleged ambiguous reference to the "outer surface" results in a potential lack of clarity of the claim, we note that a potential unclarity is not a Ground for opposition.

O2 makes a different argument, stating that claim 1 contradicts the description because claim 1 calls for the fibers to extend outwardly from the outer surface, whereas the description implies that the fibers are compressed against the native anatomy.

This alleged contradiction does of course not exist either. The claim relates to the prosthesis in the free air in which the fibers are extending outwardly. In the implanted state, the fibers may or may not be compressed to some extent against the native anatomy.

The claimed invention is therefore certainly disclosed in the patent in a manner sufficiently clear and complete for it to be carried out by the skilled person.

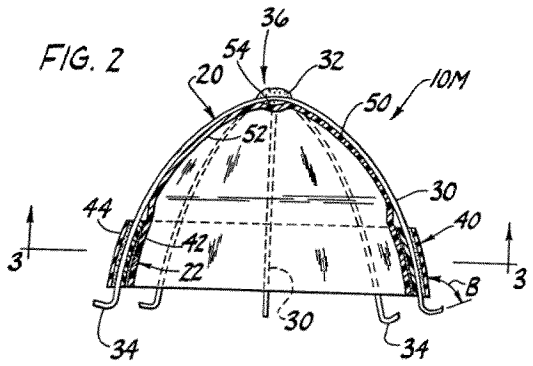
D Novelty (claim 1) - Art. 100(a) EPC and Art. 54 EPC

*D.1 WO 01/56512 A1 (**D6**)*

O1 refers to the drawings of **D6** for a disclosure of different artificial heart valves, and specifically to a prosthetic aortic valve 10A in Figure 5 and a prosthetic mitral valve 10M in Figure 2 of **D6**. A band 40 of the mitral valve prosthesis in Figure 2 is said to permit "the frame elements 30 to be pushed together so that the flexibly resilient frame 20 can be collapsed" to the configuration shown in Figures 4 and 5. An "exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth" (page 11, lines 6 to 11).

The prosthesis of **D6** has a valve element 22 which can be longitudinally pleated (page 12 lines 17 to 23). The upstream side 50 of the flexible valve element 22 has an apex 54 which is attached to the frame 20 at the junction 32 of the frame elements 30 (page 11, line 24). The valve element can be attached to the frame at attachment points 56 so as to form flaps 58, see page 12, last lines, and claim 7 of **D6**. Each of the flaps 58 and a corresponding portion of the band 40 defines an opening 60 through the valve when the valve element 22 moves to the open position. The valve 10M in Figures 2 and 3 comprises four attachment points 56, and the valve element 22 thereof forms four such flaps 58.

Using the wording of the granted claim 1, the claimed prosthetic valve (250) differs from the disclosure of **D6** at least in that it comprises a substantially cylindrical stent structure. The stent structure of the prosthetic valve of **D6** is essentially dome shaped, with frame elements 30 meeting at a junction 32:



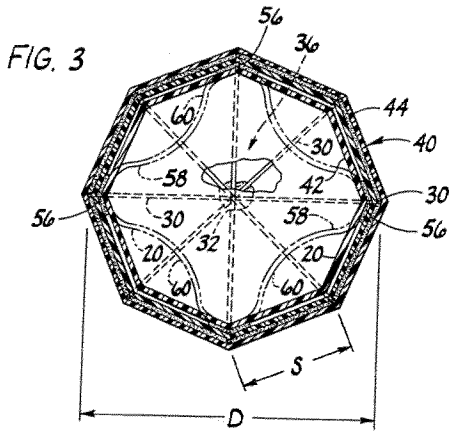
Already for this reason, claim 1 is novel over **D6**.

There are further claim features which are not disclosed in **D6**:

- the valvular structure forms <u>three valve leaflets</u> - the valve element 22 of **D6** is a continuous structure attached to the frame elements 30 so as to form flaps 58, wherein "Each of the flaps 58 and a corresponding portion of the band 40 extending between adjacent attachment points 56 defines an opening 60 through the valve when the valve element 22 moves to the open position" (**D6**, page 13, lines 1-5), whereas leaflets would be pushed open to allow blood flow and then close together to seal and prevent backflow;

- a layer of <u>compressible</u> material - no mention is made in D6 as to the material of the band 40 being compressible;

- a layer of compressible material forms a sleeve disposed along <u>an outer surface of the stent structure</u> - the prosthetic valve of **D6** has individual frame elements 30, and the band 40 rather extends from one frame element 30 to the next (or "between each of the frame elements 30", **D6**, page 9, lines 24-25):



- and the compressible material includes <u>a plurality of fibers extending outward from the outer surface</u>. It seems needless to say that **D6** does not explicitly or implicitly disclose such fibers. The Opponent refers to the mentioning of "Dacron

velour material" and "porous PTFE felt" in **D6**, but "Dacron velour material" and "porous PTFE felt" do not amount to a clear and unambiguous disclosure of a plurality of fibers extending outward from the outer surface. In fact, *porous* felt would be characterized in having voids for promoting tissue ingrowth, i.e. the opposite of fibers extending outwardly.

*D.2 WO 03/039613 A1 (**D14**)*

D14 discloses a synthetic vascular prosthesis in the form of *e.g.* a vascular graft or an artificial heart valve (**D14**, claim 11). The prosthesis is formed from a basic structure and contains an active substance to stimulate the ingrowth of vascular cells into the prosthesis.

O1 refers to the disclosure on page 7 of **D14** of a prosthesis containing a basic structure comprising voids, wherein the basic structure can *e.g.* be made from a double-velours type material. The basic structure may be constructed of fibres (e.g. a woven or knitted material), see **D14**, page 7, lines 17-21.

D14 hardly anticipates *any* of the features of claim 1 of the opposed patent. **D14** mentions the possible use of the prosthesis as an artificial heart valve (claim 11) but fails to disclose a substantially cylindrical stent structure configured for radial expansion; a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets; or a layer of compressible material, which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure. The double-velours type material in **D14** which is referred to by the Opponent *forms the basic structure of the prosthesis*; it does not form a sleeve disposed along an outer surface of a stent structure of a prosthetic heart valve.

*D.3 WO 2006/089236 A1 (**D18** or WBH10)*

According to O2, **D18** forms part of the prior art according to Art. 54(3) EPC. However, this document does not anticipate claim 1:

The text of **D18** refers, on the one hand, to an apparatus 10 for replacing a dysfunctional mitral valve 14, including "an expandable support member 40 (Fig. 2)" "and the prosthetic valve 12" (page 5, lines 23-25). The prosthetic valve 12 of this embodiment has two leaflets, as is apparent from the existence of two commissural sections 47 in Figure 2 - similar as the native mitral valve 14 which has two leaflets, too.

O2 refers to Figure 4. In **D18**, Figure 4 is said to illustrate "another alternative embodiment of the apparatus shown in Figure 2" (**D18**, page 4, lines 14 and 15). Figure 7 shows the same embodiment and also clearly illustrates the two leaflets. Already for

this reason, the embodiment of Figures 2-8 does not anticipate claim 1 of the opposed patent - what is claimed is a valvular structure forming *three* valve leaflets.

Further in relation to its Figures 2-8, **D18** also fails to disclose the last feature of claim 1: The apparatus 10 of Figure 2 may further include a layer 50 of biocompatible material to which O2 refers for an alleged anticipation of the "compressible material" of granted claim 1. According to **D18**, the biocompatible material may *e.g.* be made from woven velour, which for the Opponent means that it "comprises a plurality of fibers" and thereby anticipates the claim feature. This conclusion is incorrect - the claim does not only require a plurality of fibers but a plurality of fibers *extending outward from the outer surface*; the mere mentioning of woven velour does not amount to a clear and unambiguous disclosure of such outwardly extending fibers. Also for this reason, claim 1 is novel over **D18** (Figures 2-8).

O2 further refers to Figure 12 of **D18** which shows a different embodiment. The text beginning on page 21 confirms that "The apparatus 10_b of Fig. 12 is identically constructed as the apparatus 10 of Figs. 2-8, except whereas described below. … As shown in Fig. 21, the apparatus 10_b comprises a tri-leaflet prosthetic valve 12_b." (this text passage thereby further confirms that the previous embodiment of Figures 2-8 does *not* comprise a tri-leaflet valve). While the embodiment in Figure 12 has three leaflets, it does not comprise the layer 50 of biocompatible material and therefore already lacks a compressible (or any) material forming a sleeve disposed along an outer surface of the stent structure as required by claim 1. In any event, the embodiment in Figure 12 does not disclose a "compressible material having outwardly extending fibers" for the reasons set out above.

In conclusion, the granted claim 1 is novel over the embodiment of Figures 2-8 of **D18** in view of at least the three valve leaflets, novel over the embodiment of Figure 12 **D18** in view of at least the compressible material forming a sleeve, and novel over both these embodiments of **D18** in view of the compressible material having outwardly extending fibers.

*D.4 US 2005/0137698 A1 (**D5b** or WBH11)*

D5b describes a valve prosthesis comprising a seal extending about the outer circumference of a stent thereof, wherein the seal can bunch up upon deployment and create pleats. The seal can be composed of a thin, elastic polymer or any other type of fabric.

D5b fails to disclose at least the essential characterizing features of claim 1:

D5b does not disclose any layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure. The properties associated with the seal in **D5b** - a thin, elastic polymer or any other type of fabric - do not include compressibility.

Also, in **D5b**, the material forming the seal does not have a plurality of fibers extending outward from the outer surface thereof. O2 points out that a "fabric" regularly comprises a plurality of fibers and that some of these fibers are "always extending outward from the outer surface", which is certainly not correct.

*D.5 WO 2004/082527 A2 (**D19** or WBH12)*

Similar considerations apply to **D19** - leaving other aspects aside, **D19** discloses a fabric made from PET which according to the Opponent O2 forms a layer of compressible material and "must comprise fibers, some of which extend outward from the outer surface". The Opponent's interpretation clearly goes beyond what is actually disclosed in **D19**.

*D.6 WO 01/54625 A1 (**D20** or WBH13)*

D20 mentions "a textured surface or any other treated surface that facilitates relative affixation of the device in its location". This is not a clear and unambiguous disclosure of a layer of compressible material and/or of outwardly extending fibers.

*D.7 WO 01/76510 (**D21** or WBH14)*

Leaving other points aside, we submit that also **D21** does not clearly and unambiguously disclose a compressible material having outwardly extending fibers. **D21** merely mentions a fabric section 34 "formed of PTFE or other suitable biocompatible sheet material".

*D.8 US 2004/0210304 A1 (**D22** or WBH15)*

D22, too, provides only a general disclosure of sealing means made from polyester or tissue and does not clearly and unambiguously disclose a compressible material having outwardly extending fibers.

*D.9 US 5,855,601 (**D23** or WBH16)*

The disclosure in **D23** does not go beyond a cuff portion 37 from e.g. PTFE, polyester or the like. **D23** does not clearly and unambiguously disclose a compressible material having outwardly extending fibers.

*D.10 US 2003/0153974 A1 (**D8** or WBH9)*

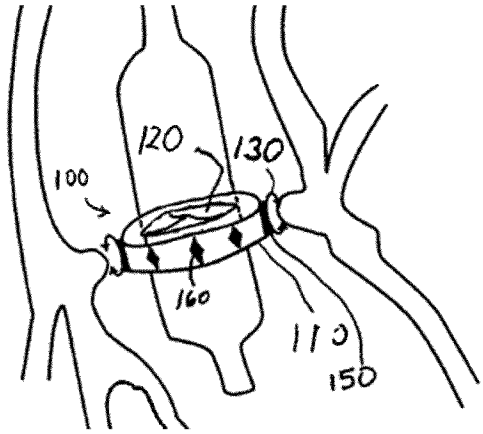
D8 is acknowledged in the prior art section of the opposed patent. The document mentions a sleeve made from PET but fails to disclose a layer of compressible material or any outwardly extending fibers.

E Inventive Step (claim 1) - Art. 100(a) EPC and Art. 56 EPC

*E.1 WO 00/64380 A1 (**D3**) in combination with either DE 26 13 575 A1 (**D9**) or US 5,258,023 (**D1**)*

D3 discloses a valve apparatus for deploying in, and securing to, a tissue annulus. FIG. 1 shows an artificial heart valve 100 having a balloon expandable connector band 110 with a one-way valve portion 120 integrated within connector band 110. In an embodiment, a separate gasket 150 (shown in FIG. 1) may be attached around band 110.

The document was discussed extensively during prosecution, wherein the Examiner considered the gasket 150 of the apparatus shown in Figure 1 of **D3** to anticipate a "sleeve" in terms of claim 1.



O1 agrees, though, that the last feature of claim 1 (the compressible material includes a plurality of fibers extending outward from the outer surface) is not disclosed in **D3**.

According to O1, the technical effect of providing such fibers is "to promote ingrowth of tissue on the surface" (of the compressible material).

However, in the patent, the effect of "promoting the growth of tissue into the material" is presented as an effect of the tissue growth factor (patent, [0064]). Fibers are rather said to increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing ([0061]). The effect of protein adhesion in turn

resides in that blood protein preferably adheres to the compressible material, thereby causing coagulation for further leak prevention. Coagulation and leak prevention / sealing therefore result from protein adhesion.

The technical effect of the above defined distinguishing feature is therefore to increase the active surface of the compressible material, thus increasing the effect of protein adhesion.

Further to O1, the objective technical problem to be solved when starting from **D3** is "to provide a graft material which facilitates formation of tissue on surfaces thereof without impeding the flow of blood therethrough". However, according to the established practice, the objective technical problem is defined in view of the technical effect of the distinguishing feature(s), which in turn result from a comparison of the claim with the closest prior art. Seeing as neither **D3** nor the opposed patent even remotely relate to graft materials, it is not apparent why the objective technical problem to be solved when starting from **D3** should be to provide *a graft material*. The only document in this line of argumentation which does relate to grafts is **D9**, which the Opponent would like the skilled person to combine with **D3** in what is obviously a hindsight approach (see below).

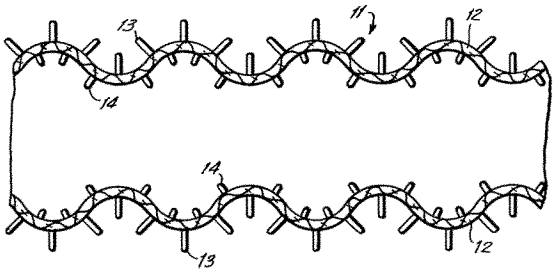
In view of the above technical effect set out in the opposed patent, an objective technical problem to be solved by the skilled person, starting from **D3**, is rather to increase the effect of protein adhesion to the gasket or compressible material of **D3**.

This problem is solved by the combination of features of claim 1 of the opposed patent, including the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

The claimed solution is not rendered obvious by the prior art:

O1 refers to **D9** as a secondary reference. **D9**, published in 1977, discloses a synthetic vascular graft of the type configured to replace a portion of an artery (cf. e.g. the paragraph bridging pages 7 and 8 of **D9**: "die Wand des Gefäßes, das durch das Transplantat ersetzt wird, ..." ("the wall of the vessel which is replaced by the graft ...")). The vascular graft is in the form of a double velour warp knitted fabric made of a material to which cell tissue can adhere, characterized by a tubular lattice work 12 which is provided with a large number of knitted thread loops 13, 14 (*Fadenschlingen*) which extend from the surface of the lattice work outwards as well as inwards and form a pile of thread-like material on the outer and inner surface of the latticework, which is receptive to ingrown cell tissue, the loops 13, 15 effectively improving the growth rate of cell tissue into the graft (**D9**, claim 1).

FIG. 2



The skilled person, starting from **D3** and being faced with the above defined objective technical problem (or, for the sake of argument, with the objective technical problem as defined by O1), does not arrive in an obvious manner at what is claimed:

First of all, it is not apparent, and O1 has also not provided any explanations in this regard, why the skilled person aiming at improving on an artificial heart valve (i.e. the one of **D3**) and specifically on a gasket thereof should revert to a document relating to vascular grafts in the first place, let alone vascular grafts configured to replace a portion of a native artery.

O1 has also not provided any explanations why the claimed solution should be obvious from **D3** and **D9**. O1 just points out that "a skilled person would have no problems to achieve the claimed subject-matter" – however, not having any problems would at best confirm that the skilled person *could* arrive at the claimed solution, whereas O1 would have to show that the skilled person *would* arrive at the claimed solution without being inventive. O1 further explains that "The skilled person would have to apply the method of preparing a graft as in **D9** when providing the sleeve made of Dacron material as known in **D3**", but beyond this mere statement of what the skilled person would have to do, the Opponent stays silent as to *why* this would be an *obvious* measure for the skilled person to take.

In addition, the teaching of **D9** is not as readily compatible with **D3** from a technical point of view as O1 would like to make us believe. O1 basically argues that the skilled person would use a portion of the graft of **D9** to form the gasket of the prosthesis of **D3**. However, the gasket or sleeve of **D3** is extending about the circumference of a metallic stent structure, whereas in **D9**, a tubular framework is provided with thread loops 13, 14. Assuming that the skilled person would consider making use of the teaching of **D9** to improve on the prosthesis of **D3**, they would hardly replace the gasket 150 of the prosthesis of **D3** by a part of a graft such as the one of **D9**, since this would mean to attach a second framework to the already existing stent structure of **D3**. To the extent that O1 argues that a possible way to combine the teaching of the two documents is to provide the metallic stent structure of **D3** with the thread loops of **D9** in an attempt to obtain the effect described in **D9** also with the prosthesis of **D3**. However, if so, the

skilled person would use the threaded loops *instead of* the gasket 150 in the prosthesis of **D3**, and the result would not be what is claimed.

Summing up, the skilled person would not revert to **D9** in the first place to solve the problem with **D3**, and if reverting to **D9**, the skilled person would not combine the two documents in the manner suggested by the O1, i.e. use a part of the graft of **D9** to form the gasket of the prosthesis of **D3**.

The mere fact that Dacron is mentioned in both documents, i.e. as the material of the gasket in **D3** and as the material of the yarns constituting the graft in **D9**, does not lead to a different result - the skilled person does not replace a gasket by a graft just because both happen to be made from the same basic material. By the way, **D9** confirms that a double velours material made from Dacron yarns does not include any fibers extending outward from the surface thereof - the thread loops 13, 14 are deliberately added to the double velours in order to create such outwardly extending fibers.

D1, which was also considered during prosecution, is briefly mentioned by O1 as an alternative secondary reference to be combined with **D3**. According to O1, "the skilled person knows from **D1** that a Dacron velour would be a suitable material for covering a stent structure of a stented heart valve." However, as previously pointed out by O1, Dacron is also mentioned in **D3** proper as a possible material of the gasket. **D1** would then not add anything to what is known from **D3**.

*E.2 Any one of **D5a**, **D5b**, **D7** and **D8** with **D9** or **D1***

For similar reasons as when starting from **D3**, O1's asserted combinations of any one of **D5a**, **D5b**, **D7** and **D8** (all disclosing prosthetic heart valve) with **D9** or **D1** do not result in an obvious manner at what is claimed.

*E.3 **D1** in combination with any one of **D4**, **D5a**, **D5b**, **D7**, or **D8***

D1 is considered by O1 not only in combination with **D3** (see above), but also as a possible starting point in the prior art. The document discloses a prosthetic heart valve 10 comprising a heart valve leaflet apparatus 20 and a heart valve leaflet supporting stent 30.

Claim 1 differs from **D1** in that the claimed prosthesis is *for percutaneous implantation*, as confirmed by O1. However, it was not obvious for the skilled person to modify the prosthesis of **D1** so as to be implantable by means of a catheter. Prostheses for percutaneous implantation may have been known *per se*, however, the mere fact that these were known does certainly not make it obvious for the skilled person to drastically modify the prosthesis of **D1**.

Moreover, claim 1 differs from **D1** in further features.

For an alleged disclosure in **D1** of a "compressible material forming a sleeve" in terms of claim 1, O1 apparently refers (using statements made by the Examiner during prosecution) to item 150 in **D1**, which is a cylindrical seamless section 150 of material such as a continuous knit comprising Dacron velour, covering a frame 110 (see e.g. Figure 3 of **D1**).

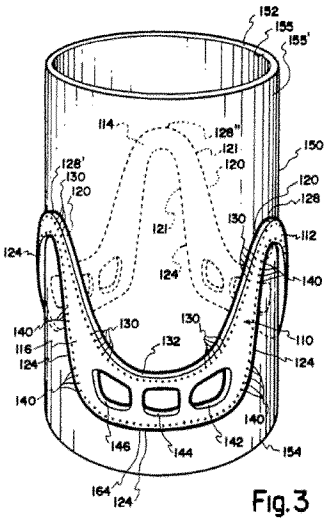


Fig.3

O1 assumes that a compressible material including a plurality of fibers extending outward from the outer surface is "at least implicitly" disclosed in **D1** due to a mentioning of Dacron velours. However, as explicitly confirmed by e.g. **D9**, Dacron velours as such does not necessarily include such outwardly extending fibers.

Furthermore, if element 150 was assumed to anticipate a "sleeve disposed along an outer surface of a stent structure and extending entirely around the stent structure" as claimed, then the frame 110 of the prosthesis of **D1** would have to be equated with the claimed "stent structure". Claim 1 calls for a *substantially cylindrical* stent structure though, and the frame 110 of **D1** is obviously not substantially cylindrical.

*E.4 WO 03/053287 A1 (**D10**) in combination with **D13***

D10 relates to a tubular graft 1 having a band of fibrous material 13 on the outer surface of the proximal end 9 and/or the distal end of the graft 1.

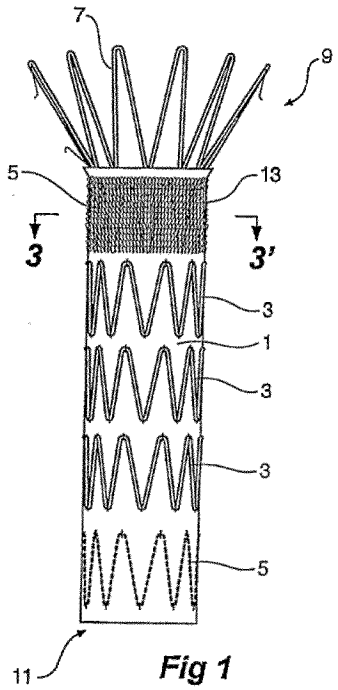


Fig 1

Also disclosed is a stent graft comprising such a tubular graft and stents disposed thereon. As an example, Figure 1 of **D10** shows a stent graft which includes stents 3 disposed on a tubular graft 1 as well as self-expanding stents 5 at each end inside the graft 1. A proximally extending stent 7 is also provided. The stent graft is adapted for insertion into an internal lumen of a patient to be incorporated therein (**D10**, page 2, lines 22-23).

For an alleged disclosure of a compressible material including a plurality of fibers extending outward from the outer surface, O1 further refers to claims 4 to 8 of **D10**, which all relate to the band of fibrous material 13:

- The band 13 may include "fibres woven or knitted into material of said graft" (claim 7). In this case, individual fibres would be added directly into the framework of the graft, i.e. there is no layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

- Similarly, the band 13 may comprise "brushed raised fibers of said graft material", i.e. fibers of the graft material proper may be made to raise from the framework of the graft to constitute the band. Also in this case, there is no layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

- According to claims 4-6 of **D10**, the band 13 may include velour material, specifically "a loop pile velour material" (claim 5) or "a cut pile velour material" (claim 6).

  These claims depend on claim 1 of **D10**, though, and claim 1 describes a stent graft in which at least one expandable stent is disposed on said tubular graft, and the band of fibrous material extends circumferentially around *said graft* and not around the at least one expandable stent. The band of claim 1 is therefore not a sleeve disposed along an outer surface *of the stent structure* and extending entirely around the stent structure, contrary to what is required by granted claim 1.

  Also Figure 1 confirms that the band 13 does not form a sleeve disposed along an outer surface *of the stent structure (stent 5)*, but at best a sleeve disposed along an outer surface *of the graft 1.*

The claims of **D10** referred to by O1 do therefore not disclose a sleeve in terms of claim 1.

This all being said, the clear difference between claim 1 and **D10** is that **D10** does not disclose a prosthetic valve.

O1 claims that it would be obvious for the skilled person to re-work the stent graft of **D10** into a prosthetic valve.

O1 refers to **D13** to confirm that prosthetic valves were originally developed from stent grafts. O1 reads **D13** so as "to provide a stented graft with a valve". This is not correct though. **D13** is a preliminary study relating to a *stent valve*, i.e. a stent to which a valve is sewn. The stent valve of **D13** does not include a graft. Also, it is immediately apparent to the skilled person that the stent structure used for the stent valve of **D13** must be

very different from the individual stents 3, 5, 7 of the stented graft of **D10** - a stented valve must have a stronger stent than a stented graft.

D13 is therefore far from suggesting that a valve could be added to a stented graft such as the one of **D10**.

Other documents disclosing prosthetic heart valves per se also do not provide a hint for the skilled person to add valve leaflets to the stent graft of **D10**.

*E.5 Starting from **D11** or **D12***

D11 relates to methods and apparatus for the endoluminal placement of tubular prostheses, such as grafts, for repairing aneurysms or other vascular defects in humans and animals. "Aneurysms are discrete dilations of the arterial wall, caused by weakening of the arterial wall. One of the most common, and among the most life threatening, is an aneurysm of the abdominal aorta between the renal and iliac arteries." (**D11**, column 1, lines 6-15)

In its introductory portion, **D11** confirms that one method to treat aneurysms "is provided by direct surgical intervention, in which the defective vessel may be bypassed or replaced using a prosthetic device such as a synthetic graft. [...] In recent years a less invasive method of treatment has evolved through a series of inventions. The details vary, but, conventionally, a resilient tubular conduit fashioned from flexible fabric (herein referred to as a 'graft') is introduced into the defective vessel by means of catheters introduced into the femoral artery. The graft is attached to the nondilated or slightly dilated arteries above and below the aneurysm using expandable metallic cylinders (herein referred to as 'attachment systems') which may include barbs or hooks to enhance attachment to the vascular wall" (**D11**, column 1, lines 18-34).

D11 discloses various different embodiments of grafts of the latter type, i.e. grafts configured to be introduced into a defective vessel by means of catheters.

Figure 1 of **D11** exemplifies a proximal end portion of one embodiment of a graft 30 positioned within a vessel 32 of a patient. The vessel 32 is shown to expand from a relatively narrow diameter healthy section to a dilated section where the tissue is diseased. The improved graft 30 comprises a tubular member 34 having a proximal end 36 and distal end (not shown in FIG. 1), at least one expandable attachment system 38, and a generally frustrum shaped sealing member 40 supported by a biasing member 44. The attachment system 38 is connected to the tubular member 34 adjacent the proximal end 36 of the graft 30 (**D11**, column 4, lines 42-52).

O1 refers to alternative embodiments in Figures 20 and 21 of **D11** in which a sealing member made from tufted yarn 932 is attached to an outer wall of the tubular member

934 of the graft 931. In the embodiment of Figure 21, the tufted yarn 932 is attached to the graft 931 in the area of an attachment system 938 which could arguably qualify as a stent structure.

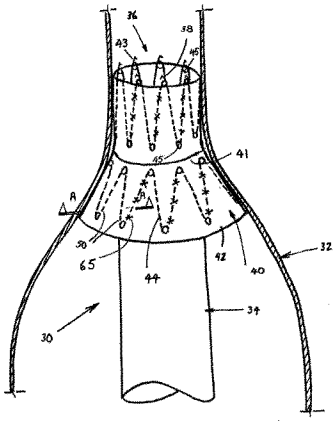


Fig. 1

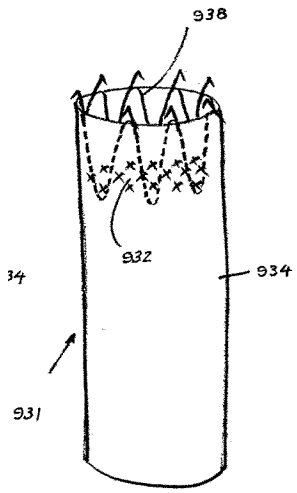


Fig. 21

Using the wording of the granted claim 1, Figure 21 of **D11** would disclose a substantially cylindrical stent structure 938 configured for radial expansion, and a layer of material (the graft) 931, which forms a sleeve disposed along an outer surface of the stent structure 938 and extending entirely around the stent structure, wherein the material 931 includes a plurality of fibers 932 extending outward from the outer surface.

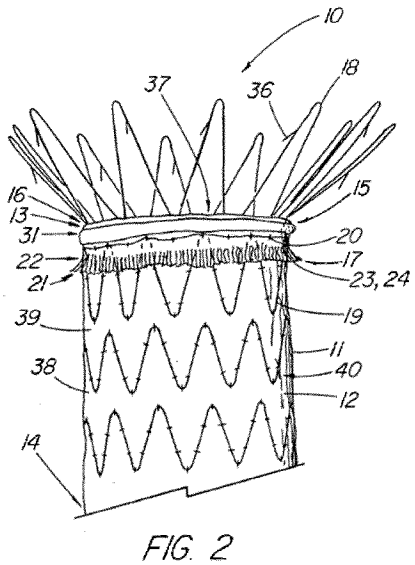


FIG. 2

D12, which the Opponent O1 presents as an alternative starting point, describes an intraluminal graft prosthesis for being placed in e.g. the aorta (**D12**, [0003]). The graft prosthesis 10 comprising a graft portion 11 having a main body 12, and a supporting structure (stent structure) 40 including a top supporting stent 19. O1 refers to paragraph [0009] according to which the top end of the graft is folded onto itself, forming a cuff portion with a frayed region that extends outward from the graft. Such a cuff portion 15 having a frayed portion 22 is also illustrated e.g. in Figure 2 of **D12**. We understand O1 to claim that the cuff portion 15 forms a sleeve disposed along an outer surface of the stent structure 19 and extending entirely around the stent structure 19.

The granted claim 1 differs from **D11** and **D12** in that it relates to a prosthetic valve for percutaneous implantation in a body channel, comprising a valvular structure having an

inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets.

O1 argues that the skilled person starting from **D11** or **D12** arrives at what is claimed by "simply [!] adding a three-leaflet valve to the stented graft already including a sleeve of compressible material having fibers extending therefrom". However, no explanations whatsoever are presented as to why it should be obvious for the skilled person to do that. None of the references cited remotely suggests adding a three-leaflet valve (or, for that matter, any valve) to a stented graft. Adding a three-leaflet valve to the stented graft of **D11** and **D12** is neither obvious from **D11** or **D12** as such, nor from any of the other references cited.

*E.6 Any of **D8** and **D19-D23** with WO 03/053287 A1 (**D10** or WBH17) or US 2002/0052649 A1 (**D24** or WBH18)*

O2 considers any of the above discussed documents **D8** (WBH9) and **D19-D23** (WBH12-16) to form suitable starting points in the prior art to assess the inventive step of claim 1 of the opposed patent.

Working on the assumption that the claim differs from any one of these documents in that the compressible material includes a plurality of fibers extending outward from the outer surface, O2 refers to paragraphs [0011], [0025] and [0064] of the opposed patent and claims that the effect is "directed to the mitigation of paravalvular leakage". O2 further argues that the skilled person would then turn to **D10** or **D24** and find a solution to this problem.

D10 is discussed in section E.4 further above; O1 had asserted it as a possible starting point in the prior art. O2 in turn refers to Figure 4 of **D10** when asserting **D10** as a secondary reference to be combined with one of **D8** or **D19-D23**.

D10 relates to stent grafts though. If the technical effect, and therefore the objective technical problem to be solved by the skilled person starting from one of **D8** (WBH9) or **D19-D23** (WBH12-16), is "directed to the mitigation of para*valvular* leakage", why would the skilled person then refer to **D10** which does not even mention a valve?

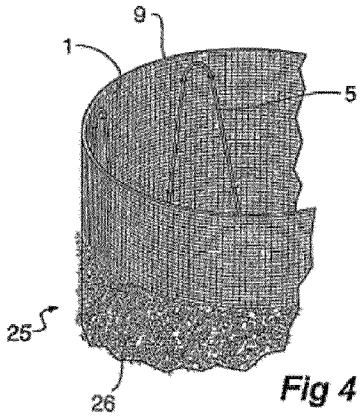


Fig 4

What is more, in the embodiment in Figure 4 of **D10** to which O2 refers, the band of fibrous material 25 provided by raising fibers 26 from the graft material does not even surround the stent structure ("proximal stent") 5.

In summary, O2 argues that the skilled person aiming to mitigate paravalvular leakage in **D8** or **D19**-**D23** *would* refer to **D10** even though **D10** does not even disclose a valve, let alone address paravalvular leakage; *would* isolate from **D10** the teaching as to fibers 26 extending outward from the surface of a graft, notably in an area where the graft is not even supported by a stent; and *would* provide such outwardly extending fibers to the sleeve of the valve prosthesis of the respective closest prior art document (**D8** or **D19**-**D23**), all without exercising an inventive activity. Such an argumentation can only be based on inadmissible hindsight considerations.

Similarly, **D24** (O2's alternative secondary reference for **D8** or **D19**-**D23**) relates to a stent graft typically used to treat a vascular aneurysm in an artery (**D24**, [0023]).

By way of example, Figure 1 of **D24** shows a vascular stent graft 10 typically used to treat a vascular aneurysm 12 in an artery 14. Aneurysm 12 comprises a region of artery 14 wherein the wall 16 is weakened and dilated. Rupture of an aneurysm can be fatal, and treatment consists of replacing the weakened region of the vessel with the stent graft 10. The stent graft may be implanted by means of a catheter or by more invasive surgical techniques (**D1**, [0023]).

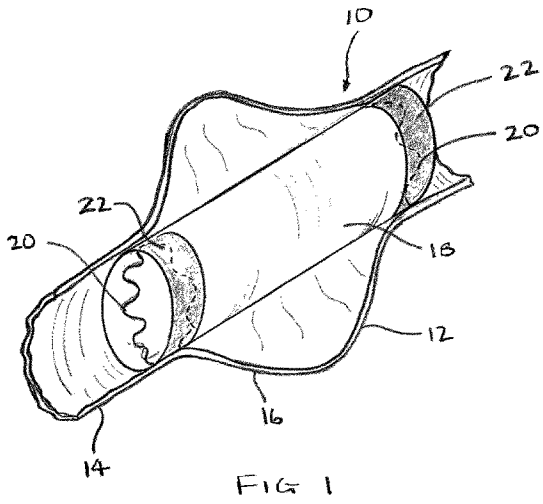


FIG 1

At each end of substrate 18 are attachment regions 22 engageable with the living tissue of the artery, the attachment regions having means for promoting growth of the tissue across the attachment region to form a biological attachment and a seal between the graft 10 and the tissue comprising the artery wall 16. The means for promoting growth of the tissue across regions 22 have several embodiments (**D1**, [0025]).

In one embodiment to which O2 refers, said regions 22 are provided with a textured surface 23 having an increased surface area preferably comprising loops 28 which extend outwardly from the substrate 18. "The areas of increased surface area comprising regions 22 provide a region which promotes the ingrowth of living animal tissue for attaching and sealing the vessel to the graft." See paragraph [0032] and Figure 4 of **D24**.

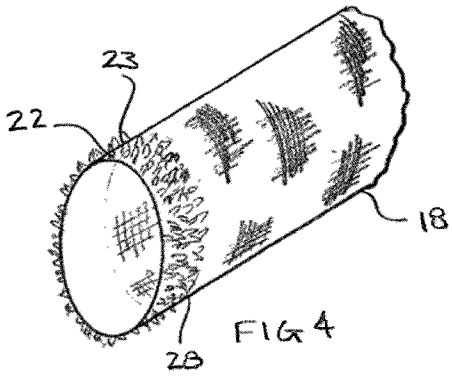


FIG 4

O2 states that being faced with the objective technical problem to mitigate paravalvular leakage in the prosthetic valve of one of **D8** (WBH9) or **D19-D23** (WBH12-16), "the skilled person would thus provide fibers according to feature 1.4 to the valve prostheses of WBH9/WBH12-WBH16, therefore arriving at the subject-matter of Claim 1 of the opposed patent without inventive activity". O2 leaves it at this mere allegation; specifically, O2 fails to explain why the skilled person would refer to **D24** in the first place to address paravalvular leakage, even though **D24** does not even mention a valve. There is no paravalvular leakage problem in vascular lumina, and grafts for being placed in arteries are subject to different challenges than prosthetic valves like the ones of **D8** and **D19-D23**, configured to be placed in the heart itself. The blood pressure acting on the valve results in stresses which are not only larger than the ones acting on a graft but also different in nature.

Regarding the above asserted combinations of **D8** or **D19-D23** with **D10** or **D24**, we further note that **D8** and **D19-D23** were all filed between 1996 and 2004. At that time, first attempts were made to provide prosthetic heart valves which could be delivered by a catheter. In a prosthetic heart valve, the valve leaflets are attached within the frame of the device and add to the size of the device, which is why the research and development of prosthetic valves focused very much on the minimum achievable size of the device in the crimped state. The modifications to the valves of D8 and D19-D23 proposed by O2 would all *add* bulk to the prosthetic valve, which would be considered undesirable by the skilled person. A skilled practitioner aiming at improving on a prosthetic valve at that time would have realized that adding further material to the outer circumference of the device would inevitably further add to the bulk of the device and would therefore have worked contrary to the ongoing attempts for size reduction. For this reason, the skilled person would have refrained from using a sleeve with outwardly extending fibers in the valve prostheses of **D8** or **D19-D23**.

F Novelty and inventive step - the dependent claims

It has been demonstrated that the subject matter of the independent claim 1 of the opposed patent is granted is novel and inventive. Therefore, we refrain from commenting on the dependent claims for the time being.

G Amended claims (Auxiliary Requests)

G.1 Auxiliary Request 1

In the set of claims according to Auxiliary Request 1, claim 1 specifies a valvular structure (254) *providing a flexible conduit* having an inlet and an outlet.

Figure 22 of **D15** shows "an elongated valvular structure in the form of a conduit", as also confirmed by Opponent O2. Support for the amendment is also in claim 27 of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.2 Auxiliary Request 2

In the set of claims according to Auxiliary Request 2, claim 1 specifies the compressible material as being adapted *for expansion* after deployment to fill gaps between the prosthetic valve and the body channel.

Support for the amendment is in paragraph [00145] of **D15** ("The compressible material expands after deployment at a treatment site") and also in claim 27 of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.3 Auxiliary Request 3

In the set of claims according to Auxiliary Request 3, claim 3 reads that the compressible material *is formed of polyethylene terephthalate (PET) and* has a thickness ranging from 1 to 5mm.

Support for the amendment is in paragraph [00145] of the application as filed.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.4 Auxiliary Request 4

In the set of claims according to Auxiliary Request 3, claim 8 states that the compressible material is configured to expand after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

Support for the amendment is in paragraph [00145] of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.5 Auxiliary Request 5

In the set of claims according to Auxiliary Request 3, claim 9 is omitted.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.6 Auxiliary Request 6

In the set of claims according to Auxiliary Request 6, claim 1 recites a substantially cylindrical stent structure (252) configured for radial expansion *using a balloon catheter*.

Support for the amendment is throughout **D15**, specifically in paragraph [00144] thereof.

The amendment further restricts the claim against the prior art.

G.7 Auxiliary Request 7

In the set of claims according to Auxiliary Request 7, the claims relate to a prosthetic *cardiac* valve.

Support for the amendments is throughout **D15**, e.g. in paragraphs [0001] and [0087] thereof.

The amendment further restricts the claim against the prior art.

G.8 Auxiliary Request 8

In the set of claims according to Auxiliary Request 8, all amendments according to Auxiliary Requests 1-7 are combined.

G.9 Further possible Auxiliary Requests

We reserve the right to file further Auxiliary Requests at a later stage in which some, but not all amendments according to Auxiliary Requests 1-7 are combined.



/SCHÖN, Anne/
European Patent Attorney
Hoffmann Eitle
(Association No. 151)

Enclosures
Sets of claims according to eight Auxiliary Requests.

Auxiliary Request 1

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 2

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 3

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible

material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 4

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand ~~into~~after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 5

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

~~9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of~~

~~the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.~~

Auxiliary Request 6

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion using a balloon catheter;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 7

1. A prosthetic cardiac valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 8

1. A prosthetic cardiac valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion using a balloon catheter;

a valvular structure (254) providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand ~~into~~after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

~~9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.~~

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25.10.2021

Reference		Application No./Patent No.
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Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

BRIEF COMMUNICATION

Subject:
- ☐ Your letter of
- ☐ Our telephone conversation of
- ☒ Communication of 10.6.2021
- ☐

Enclosure(s):
- ☒ Letter from the proprietor of the patent of 20.10.2021
- ☐ Letter from the opponent of
- ☒ Copy (copies) auxiliary requests 1-8

Communication:

☐ The documents specified as patent documents and as non-patent literature in this letter are available for inspection via the European Patent Register at **www.epo.org/register.** Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2020, A106).

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European Patent 2 982 337 (EP No. 15 180 327.7)
EDWARDS LIFESCIENCES PVT, Inc.
Our Ref.: 238 337 t2
Opponent O1: Abbott Cardiovascular Systems, Inc.
Opponent O2: Neovasc Tiara Inc.

With reference to the Communication of notices of opposition dated June 10, 2021, we respond as follows to the oppositions filed to the above referenced patent by Abbott Cardiovascular Systems, Inc. ("Opponent O1") and Neovasc Tiara Inc. ("Opponent O2").

A Requests

We request

a) that the oppositions be rejected;

b) in case the request according to a) is not granted, that the patent be maintained on the basis of amended claims according to one of the enclosed auxiliary requests; and

c) that oral proceedings be arranged in case the Opposition Division considers taking any decision adverse to the Proprietor.

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B No inadmissible extension - Art. 100(c) EPC

To demonstrate that the opposed patent does not extend beyond the contents of the application as filed, we will refer to the A1 publication of the parent application of the opposed patent, WO 2006/005015 A1 ("**D15**" according to the EPO's consolidated list).

B.1 General remark regarding claim 1

In general terms, the granted claim 1 of the opposed patent is derived from Figure 22 of the parent application and the associated text, including (but not restricted to) paragraph [00145], as well as claims 27-29 of the parent application.

Opponent O1 refers to claims 27-29 of the parent application (**D15**) and finds that "several features are missing in the subject-matter of claim 1 of the opposed patent so that the subject-matter surely extends beyond the content of the claims as originally filed". We understand this reference to "missing" features to mean that the granted claim 1 does not include all features of claims 27-29 of **D15**. In a separate step, O1 refers to the description of **D15** and argues that based "on the description, the subject-matter of claim 1 of the patent cannot be directly and unambiguously achieved" (point 2.1.2 of the notice of opposition).

However, Art. 100(c) EPC refers to the content of *the application as filed*. When considered *in its entirety*, **D15** clearly and unambiguously discloses a prosthetic valve according to the granted claim 1 of the opposed patent. This will be demonstrated in detail below.

B.2 Claim 1 – "flexible conduit"

Both Opponents refer to the fact that claim 27 of **D15** specifies a valvular structure "providing a flexible conduit having an inlet and an outlet", whereas the granted claim 1 of the opposed patent does not expressly include the words "providing a flexible conduit".

However, this deviation in wording between the granted claim 1 and claim 27 of **D15** does not result in an inadmissible extension.

On the one hand, **D15** does not even refer to a "flexible conduit" when describing the prosthetic valve in Figure 22. Neither paragraph [00145] which closely relates to this Figure, nor the remaining text passages disclosing various features of the prosthetic valve refer to a "flexible conduit".

On the other hand, according to the granted claim 1, the valvular structure still has "an inlet and an outlet", is "formed of a pliant material attached to the stent structure" and

forms "three valve leaflets", and it is part of a prosthetic valve for implantation in a body channel. For a skilled reader of claim 1, it is immediately clear from these claim features that the valvular structure - like any valvular structure of a prosthetic valve of this kind - is configured to convey blood from the inlet to the outlet thereof and through the said body channel. This in turn is precisely the function of a conduit[1]. Therefore, a structure with the features of claim 1 necessarily provides a flexible conduit, and thus the skilled person understands that this feature is implicitly included in the claim. The granted claim 1 does therefore not extend beyond the original disclosure.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 1 which further addresses this point.

B.3a Claim 1 – "sleeve"

The claimed prosthetic valve is characterized by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

O1 states that the features relating to this sleeve result in an inadmissible extension of claim 1 because **D15** rather discloses a "layer of compressible material 256" which "is disposed along an outer surface of the stent structure 252", wherein the material may extend "entirely around the stent structure, such as in the form of a sleeve" (paragraph [00145]).

In an attempt to explain why this disclosure in paragraph [00145] does not support claim 1, O1 argues that it is disclosed in **D15** that *the material* extends entirely around the stent structure *and not a sleeve* as in claim 1. O1 further argues that claim 1 requires the sleeve as a "distinct structural component", the presence of which is not disclosed in **D15** and thus inadmissibly extends the subject matter.

O2 provides a slightly different explanation for basically the same objection: a material which forms a sleeve (claim 1) "is required to engage with the stent structure to provide covering and protection functionalities", whereas a material *in the form of a sleeve* ([00145]) "may be provided spaced apart from the stent structure, for example". In O2's view, it is not derivable from **D15** that the material actually forms a sleeve (provides cover and protection) beyond just being *in the form of a sleeve*.

The relevant comparison is not between *material* on the one hand ([00145]) and *a sleeve* on the other hand (claim 1) which would extend around the stent structure, as argued by O1. The comparison is also not between a *material in the form of a sleeve* ([00145]) and a *material which forms a sleeve* (claim 1), as argued by O2. The relevant

[1] cf. e.g. the definition of a conduit as a "natural or artificial channel through which something (such as a fluid) is conveyed" (per Merriam-Webster, see m-w.com)

comparison is between material *extending around the stent structure in the form of a sleeve* ([00145]) and material *which forms a sleeve extending around the stent structure* (claim 1). There is no difference whatsoever *in substance* between the two. One cannot possibly think of any material e*xtending around the stent structure in the form of a sleeve* which would not also *form a sleeve extending around the stent structure*, and vice versa.

In conclusion, we submit that the disclosure of material *extending around the stent structure in the form of a sleeve* in paragraph [00145] of **D15** does amount up to a clear and unambiguous disclosure of material *which forms a sleeve extending around the stent structure* according to the granted claim 1.

B.3b Claim 1 – "for expansion"

The granted claim 1 relates to the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.

For the Opponents, claim 1 extends beyond the contents of **D15** because the original description ([00145]) and claims in the Opponents' view only disclose compressible materials adapted *for expansion* after deployment to fill gaps between the prosthetic valve and the body channel, whereas granted claim 1 is in the Opponents' view not restricted accordingly.

Also in this regard, the granted claim 1 does not extend beyond the contents of **D15** though: The claim specifies the compressible material as being adapted after deployment to fill gaps between the prosthetic valve and the body channel. This in turn is precisely how the skilled person understands the prosthetic valve illustrated in Figure 22 of **D15** to be configured, which has the layer of compressible material 256 in the form of a sleeve: Being attached to the stent structure, this compressible material is crimped or folded when the stent structure is crimped. After deployment of the stent structure, the material fills gaps between the prosthetic valve and the body channel.

The claim feature as to the compressible material being "adapted after deployment to fill gaps between the prosthetic valve and the body channel" is therefore closely in line with the disclosure in paragraph [00145] and Figure 22 of **D15**.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 2 which further addresses this point.

B.4 Claim 1 – "plurality of fibers" without "tissue growth factor" or "PET"

According to the last feature of claim 1, the compressible material includes a plurality of fibers extending outward from the outer surface.

This feature is literally disclosed in claim 29 of **D15**. The Opponents point out that this claim includes a further feature relating to a "tissue growth factor" and is dependent on claim 28 of **D15**, according to which "the compressible material is formed of polyethylene terephthalate". The Opponents argue that these features are missing in the granted claim 1, resulting in an intermediate generalization.

However, **D15** clearly and unambiguously discloses a prosthetic valve in which the compressible material includes a plurality of fibers extending outward from the outer surface, entirely irrespective of any tissue growth factor and irrespective of whether the compressible material is formed of polyethylene terephthalate. Paragraph [00145] of **D15** confirms that

- "*In one preferred embodiment*, the compressible material is formed of PET and has a thickness ranging from about 1 to 5 mm";
- "*In certain configurations*, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material"; and
- "*In an alternative configuration*, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps" (emphases added).

The feature relating to the fibers is disclosed here without any close structural or functional relationship to the feature of the prosthetic valve further comprising a tissue growth factor disposed along the compressible material and the compressible material being formed of polyethylene terephthalate.

B.5 The dependent claims

O1 also objects to all of the dependent claims under Art. 100(c) EPC. O2 only objects to claims 2, 3, 4 and 9. However, as will be demonstrated below, the combinations of features of the dependent claims are clearly and unambiguously disclosed in **D15**.

Claim 2:

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

The additional feature of claim 2 is disclosed in Figure 22 of **D15** in view of the text in paragraph [00145] which confirms that the sleeve extends entirely around the stent structure. Also according to paragraph [0055] of **D15**, "a compressible material, such as a clot *(sic[2])* or fabric, extends around an exterior portion of the stent". The fact that it is

[2] The skilled person would understand that this is a reference to "cloth".

the *inflow* end of the stent structure which is surrounded by the sleeve is immediately apparent to the skilled reader of the application (the flow direction through the valve in Figure 22 – from the bottom of the page to the top of the page - is clear to the skilled person).

Claim 3:

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5 mm.

This feature is literally disclosed in paragraph [00145] of **D15**. O1 points out that the thickness range is disclosed here *only for PET material*. However, **D15** repeatedly confirms that PET is only one possible compressible material. The skilled reader therefore understands the statement in paragraph [00145] to mean that the thickness indicated therein is irrespective of whether PET or another suitable material is used.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 3 which further addresses this point.

Claim 4:

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

This additional feature finds literal support in paragraph [0055] of **D15**: "such as a clot[h] or fabric". Further support is in [00145] of **D15**: "may resemble a cloth or fabric having small fibers".

Claim 5:

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

The clear and unambiguous disclosure of the tissue growth factor also without other features has been shown above in the context of claim 1.

Claim 6:

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

This wording is literally supported by paragraph [00145] of **D15**. While the feature is disclosed here in the form of a method step, the step of applying the growth factor along the outer surface of the compressible material certainly results in a prosthetic valve which has the growth factor applied along the outer surface of the compressible material, and therefore, this original disclosure relates to the device as well as to the method.

Claim 7

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

This wording is literally supported by paragraph [00145] of **D15**. It is obvious for the skilled reader that the "fibers" referred to in this paragraph are the same fibers as in other parts of the original disclosure, including claim 29 of **D15**. It is not apparent why a further "pointer in the description" should be necessary to combine the various statements as to the fibers, as implied by O1.

Claim 8:

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

This additional feature finds support in original paragraphs [0055] ("The compressible material may be formed of PET and is configured to expand into the gaps.") and [00145] ("The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.").

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 4 which further addresses this point.

Claim 9:

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

This additional feature finds support in claim 1 of **D15** which literally mentions "cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole".

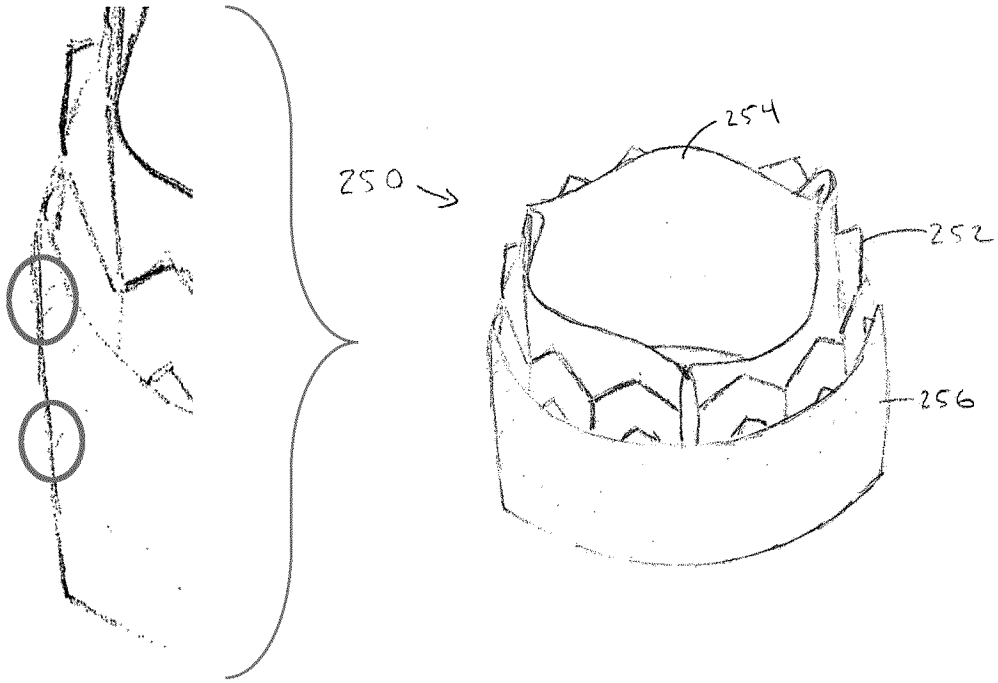
To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 5 which further addresses this point.

B.6 The drawings

O2 argues that Figure 22 of the granted patent extends beyond the contents of **D15** because fibers are not depicted in the corresponding provisional drawing in **D15**, wherein O2 refers to the provisional drawings available via the online register of the EPO.

Figure 22 of the granted patent does not add anything to the original disclosure though.

A closer examination of the provisional Figure 22 in the register shows that fibers are in fact (albeit faintly) illustrated therein:



Furthermore, the fibers are clearly and unambiguously described in the associated text in **D15**. Therefore, ***D15*** *as a whole* discloses the valve prosthesis of Figure 22 *including the fibers*, and Figure 22 of the patent does therefore not extend beyond the contents of **D15**.

O2 argues that "similar objections" as to Figure 22 also apply to a series of other Figures in the granted patent. However, while the O2's objection to Figure 22 relates to the

illustration or not of fibers, most of the further drawings do not show any fibers at all, and it is therefore not apparent how "similar objections" should apply to them. The formal drawings in the granted patent differ from the original provisional drawings only in that they have been redrawn as it is commonly the case with this type of patent drawings. The proprietor can hardly be expected to speculate at this point as to which deviations between the two sets of drawings might in the Opponent's view result in an inadmissible extension.

C Sufficiency of disclosure - Art. 100(b) EPC

According to the last feature of claim 1, the compressible material includes a plurality of fibers extending outward from the outer surface.

O1 states that the only outer surface previously mentioned in the claim is the outer surface of the stent structure. In O1's view, the skilled person would therefore read the claim so that "the fibers must start on the stent and then extend outwardly therefrom". At the same time, O1 confirms that "According to the teaching of the patent, it seems intended to encourage coagulation of blood at the fibers outside of the compressible material". To reconcile these two concepts, O1 suggests that "the fibers would have to extend from the stent structure through the compressible material outwardly", and as there is no disclosure in the patent as to how fibers might be integrated into the compressible material so as to extend *from the stent through the material and outwardly of it* to encourage coagulation of blood, the Opponent finds the invention to be insufficiently disclosed in the patent.

These objections are unfounded:

A skilled reader would not interpret claim 1 so that the "outer surface" referred to at the very end thereof is the outer surface *of the stent structure*. In fact, the compressible material which is disposed along an outer surface of the stent structure necessarily also has an outer surface, and according to the only reasonable interpretation, the outer surface in the last feature of claim 1 is actually the outer surface of the compressible material (i.e. claim 1 would be read to end with "the compressible material includes a plurality of fibers extending outward from the outer surface [thereof]"). This understanding is also supported by the granted dependent claim 6 which refers to "the outer surface of the compressible material" (thereby also implying that there is an antecedent basis for this outer surface which would then be in claim 1). The description is also in line with this understanding, as becomes clear from e.g. the wording in paragraph [0064] of the patent: "The compressible material 256 resembles a cloth or fabric having small fibers extending from the surface *of the material.*" (emphasis added)

To the extent that the alleged ambiguous reference to the "outer surface" results in a potential lack of clarity of the claim, we note that a potential unclarity is not a Ground for opposition.

O2 makes a different argument, stating that claim 1 contradicts the description because claim 1 calls for the fibers to extend outwardly from the outer surface, whereas the description implies that the fibers are compressed against the native anatomy.

This alleged contradiction does of course not exist either. The claim relates to the prosthesis in the free air in which the fibers are extending outwardly. In the implanted state, the fibers may or may not be compressed to some extent against the native anatomy.

The claimed invention is therefore certainly disclosed in the patent in a manner sufficiently clear and complete for it to be carried out by the skilled person.

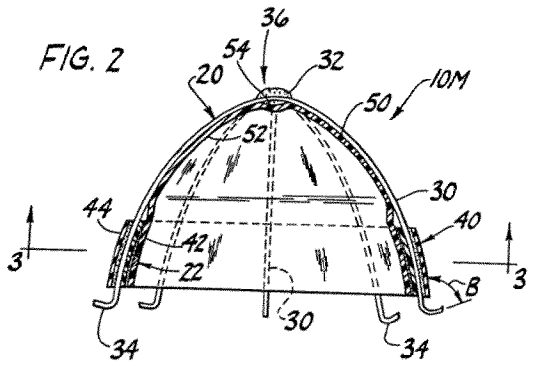
D Novelty (claim 1) - Art. 100(a) EPC and Art. 54 EPC

*D.1 WO 01/56512 A1 (**D6**)*

O1 refers to the drawings of **D6** for a disclosure of different artificial heart valves, and specifically to a prosthetic aortic valve 10A in Figure 5 and a prosthetic mitral valve 10M in Figure 2 of **D6**. A band 40 of the mitral valve prosthesis in Figure 2 is said to permit "the frame elements 30 to be pushed together so that the flexibly resilient frame 20 can be collapsed" to the configuration shown in Figures 4 and 5. An "exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth" (page 11, lines 6 to 11).

The prosthesis of **D6** has a valve element 22 which can be longitudinally pleated (page 12 lines 17 to 23). The upstream side 50 of the flexible valve element 22 has an apex 54 which is attached to the frame 20 at the junction 32 of the frame elements 30 (page 11, line 24). The valve element can be attached to the frame at attachment points 56 so as to form flaps 58, see page 12, last lines, and claim 7 of **D6**. Each of the flaps 58 and a corresponding portion of the band 40 defines an opening 60 through the valve when the valve element 22 moves to the open position. The valve 10M in Figures 2 and 3 comprises four attachment points 56, and the valve element 22 thereof forms four such flaps 58.

Using the wording of the granted claim 1, the claimed prosthetic valve (250) differs from the disclosure of **D6** at least in that it comprises a substantially cylindrical stent structure. The stent structure of the prosthetic valve of **D6** is essentially dome shaped, with frame elements 30 meeting at a junction 32:



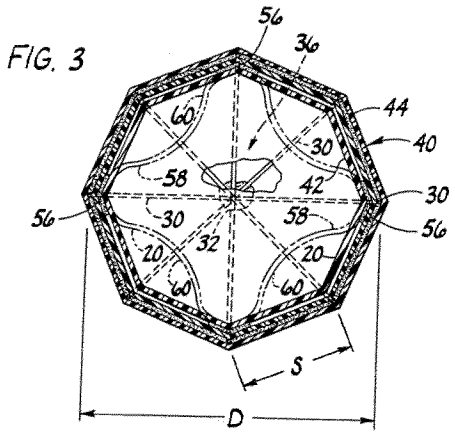
Already for this reason, claim 1 is novel over **D6**.

There are further claim features which are not disclosed in **D6**:

- the valvular structure forms three valve leaflets - the valve element 22 of **D6** is a continuous structure attached to the frame elements 30 so as to form flaps 58, wherein "Each of the flaps 58 and a corresponding portion of the band 40 extending between adjacent attachment points 56 defines an opening 60 through the valve when the valve element 22 moves to the open position" (**D6**, page 13, lines 1-5), whereas leaflets would be pushed open to allow blood flow and then close together to seal and prevent backflow;

- a layer of compressible material - no mention is made in D6 as to the material of the band 40 being compressible;

- a layer of compressible material forms a sleeve disposed along an outer surface of the stent structure - the prosthetic valve of **D6** has individual frame elements 30, and the band 40 rather extends from one frame element 30 to the next (or "between each of the frame elements 30", **D6**, page 9, lines 24-25):



- and the compressible material includes a plurality of fibers extending outward from the outer surface. It seems needless to say that **D6** does not explicitly or implicitly disclose such fibers. The Opponent refers to the mentioning of "Dacron

velour material" and "porous PTFE felt" in **D6**, but "Dacron velour material" and "porous PTFE felt" do not amount to a clear and unambiguous disclosure of a plurality of fibers extending outward from the outer surface. In fact, *porous* felt would be characterized in having voids for promoting tissue ingrowth, i.e. the opposite of fibers extending outwardly.

*D.2 WO 03/039613 A1 (**D14**)*

D14 discloses a synthetic vascular prosthesis in the form of *e.g.* a vascular graft or an artificial heart valve (**D14**, claim 11). The prosthesis is formed from a basic structure and contains an active substance to stimulate the ingrowth of vascular cells into the prosthesis.

O1 refers to the disclosure on page 7 of **D14** of a prosthesis containing a basic structure comprising voids, wherein the basic structure can *e.g.* be made from a double-velours type material. The basic structure may be constructed of fibres (e.g. a woven or knitted material), see **D14**, page 7, lines 17-21.

D14 hardly anticipates *any* of the features of claim 1 of the opposed patent. **D14** mentions the possible use of the prosthesis as an artificial heart valve (claim 11) but fails to disclose a substantially cylindrical stent structure configured for radial expansion; a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets; or a layer of compressible material, which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure. The double-velours type material in **D14** which is referred to by the Opponent *forms the basic structure of the prosthesis*; it does not form a sleeve disposed along an outer surface of a stent structure of a prosthetic heart valve.

*D.3 WO 2006/089236 A1 (**D18** or WBH10)*

According to O2, **D18** forms part of the prior art according to Art. 54(3) EPC. However, this document does not anticipate claim 1:

The text of **D18** refers, on the one hand, to an apparatus 10 for replacing a dysfunctional mitral valve 14, including "an expandable support member 40 (Fig. 2)" "and the prosthetic valve 12" (page 5, lines 23-25). The prosthetic valve 12 of this embodiment has two leaflets, as is apparent from the existence of two commissural sections 47 in Figure 2 - similar as the native mitral valve 14 which has two leaflets, too.

O2 refers to Figure 4. In **D18**, Figure 4 is said to illustrate "another alternative embodiment of the apparatus shown in Figure 2" (**D18**, page 4, lines 14 and 15). Figure 7 shows the same embodiment and also clearly illustrates the two leaflets. Already for

this reason, the embodiment of Figures 2-8 does not anticipate claim 1 of the opposed patent - what is claimed is a valvular structure forming *three* valve leaflets.

Further in relation to its Figures 2-8, **D18** also fails to disclose the last feature of claim 1: The apparatus 10 of Figure 2 may further include a layer 50 of biocompatible material to which O2 refers for an alleged anticipation of the "compressible material" of granted claim 1. According to **D18**, the biocompatible material may *e.g.* be made from woven velour, which for the Opponent means that it "comprises a plurality of fibers" and thereby anticipates the claim feature. This conclusion is incorrect - the claim does not only require a plurality of fibers but a plurality of fibers *extending outward from the outer surface*; the mere mentioning of woven velour does not amount to a clear and unambiguous disclosure of such outwardly extending fibers. Also for this reason, claim 1 is novel over **D18** (Figures 2-8).

O2 further refers to Figure 12 of **D18** which shows a different embodiment. The text beginning on page 21 confirms that "The apparatus 10_b of Fig. 12 is identically constructed as the apparatus 10 of Figs. 2-8, except whereas described below. … As shown in Fig. 21, the apparatus 10_b comprises a tri-leaflet prosthetic valve 12_b." (this text passage thereby further confirms that the previous embodiment of Figures 2-8 does *not* comprise a tri-leaflet valve). While the embodiment in Figure 12 has three leaflets, it does not comprise the layer 50 of biocompatible material and therefore already lacks a compressible (or any) material forming a sleeve disposed along an outer surface of the stent structure as required by claim 1. In any event, the embodiment in Figure 12 does not disclose a "compressible material having outwardly extending fibers" for the reasons set out above.

In conclusion, the granted claim 1 is novel over the embodiment of Figures 2-8 of **D18** in view of at least the three valve leaflets, novel over the embodiment of Figure 12 **D18** in view of at least the compressible material forming a sleeve, and novel over both these embodiments of **D18** in view of the compressible material having outwardly extending fibers.

*D.4 US 2005/0137698 A1 (**D5b** or WBH11)*

D5b describes a valve prosthesis comprising a seal extending about the outer circumference of a stent thereof, wherein the seal can bunch up upon deployment and create pleats. The seal can be composed of a thin, elastic polymer or any other type of fabric.

D5b fails to disclose at least the essential characterizing features of claim 1:

D5b does not disclose any layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure. The properties associated with the seal in **D5b** - a thin, elastic polymer or any other type of fabric - do not include compressibility.

Also, in **D5b**, the material forming the seal does not have a plurality of fibers extending outward from the outer surface thereof. O2 points out that a "fabric" regularly comprises a plurality of fibers and that some of these fibers are "always extending outward from the outer surface", which is certainly not correct.

*D.5 WO 2004/082527 A2 (**D19** or WBH12)*

Similar considerations apply to **D19** - leaving other aspects aside, **D19** discloses a fabric made from PET which according to the Opponent O2 forms a layer of compressible material and "must comprise fibers, some of which extend outward from the outer surface". The Opponent's interpretation clearly goes beyond what is actually disclosed in **D19**.

*D.6 WO 01/54625 A1 (**D20** or WBH13)*

D20 mentions "a textured surface or any other treated surface that facilitates relative affixation of the device in its location". This is not a clear and unambiguous disclosure of a layer of compressible material and/or of outwardly extending fibers.

*D.7 WO 01/76510 (**D21** or WBH14)*

Leaving other points aside, we submit that also **D21** does not clearly and unambiguously disclose a compressible material having outwardly extending fibers. **D21** merely mentions a fabric section 34 "formed of PTFE or other suitable biocompatible sheet material".

*D.8 US 2004/0210304 A1 (**D22** or WBH15)*

D22, too, provides only a general disclosure of sealing means made from polyester or tissue and does not clearly and unambiguously disclose a compressible material having outwardly extending fibers.

*D.9 US 5,855,601 (**D23** or WBH16)*

The disclosure in **D23** does not go beyond a cuff portion 37 from e.g. PTFE, polyester or the like. **D23** does not clearly and unambiguously disclose a compressible material having outwardly extending fibers.

*D.10 US 2003/0153974 A1 (**D8** or WBH9)*

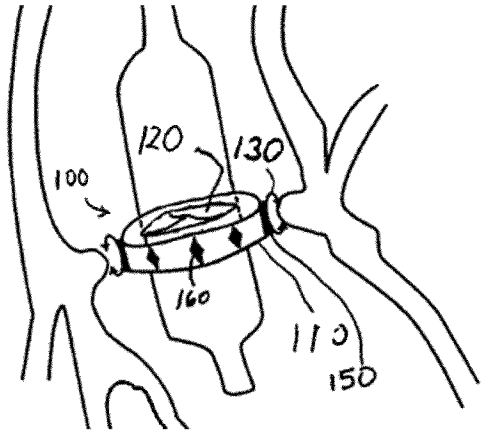
D8 is acknowledged in the prior art section of the opposed patent. The document mentions a sleeve made from PET but fails to disclose a layer of compressible material or any outwardly extending fibers.

E Inventive Step (claim 1) - Art. 100(a) EPC and Art. 56 EPC

*E.1 WO 00/64380 A1 (**D3**) in combination with either DE 26 13 575 A1 (**D9**) or US 5,258,023 (**D1**)*

D3 discloses a valve apparatus for deploying in, and securing to, a tissue annulus. FIG. 1 shows an artificial heart valve 100 having a balloon expandable connector band 110 with a one-way valve portion 120 integrated within connector band 110. In an embodiment, a separate gasket 150 (shown in FIG. 1) may be attached around band 110.

The document was discussed extensively during prosecution, wherein the Examiner considered the gasket 150 of the apparatus shown in Figure 1 of **D3** to anticipate a "sleeve" in terms of claim 1.



O1 agrees, though, that the last feature of claim 1 (the compressible material includes a plurality of fibers extending outward from the outer surface) is not disclosed in **D3**.

According to O1, the technical effect of providing such fibers is "to promote ingrowth of tissue on the surface" (of the compressible material).

However, in the patent, the effect of "promoting the growth of tissue into the material" is presented as an effect of the tissue growth factor (patent, [0064]). Fibers are rather said to increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing ([0061]). The effect of protein adhesion in turn

resides in that blood protein preferably adheres to the compressible material, thereby causing coagulation for further leak prevention. Coagulation and leak prevention / sealing therefore result from protein adhesion.

The technical effect of the above defined distinguishing feature is therefore to increase the active surface of the compressible material, thus increasing the effect of protein adhesion.

Further to O1, the objective technical problem to be solved when starting from **D3** is "to provide a graft material which facilitates formation of tissue on surfaces thereof without impeding the flow of blood therethrough". However, according to the established practice, the objective technical problem is defined in view of the technical effect of the distinguishing feature(s), which in turn result from a comparison of the claim with the closest prior art. Seeing as neither **D3** nor the opposed patent even remotely relate to graft materials, it is not apparent why the objective technical problem to be solved when starting from **D3** should be to provide *a graft material*. The only document in this line of argumentation which does relate to grafts is **D9**, which the Opponent would like the skilled person to combine with **D3** in what is obviously a hindsight approach (see below).

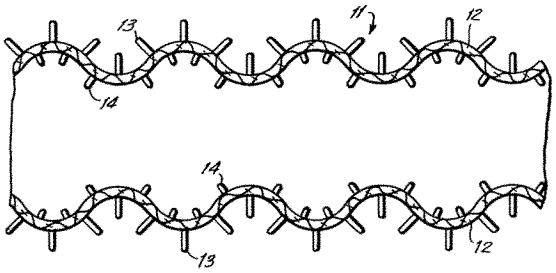
In view of the above technical effect set out in the opposed patent, an objective technical problem to be solved by the skilled person, starting from **D3**, is rather to increase the effect of protein adhesion to the gasket or compressible material of **D3**.

This problem is solved by the combination of features of claim 1 of the opposed patent, including the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

The claimed solution is not rendered obvious by the prior art:

O1 refers to **D9** as a secondary reference. **D9**, published in 1977, discloses a synthetic vascular graft of the type configured to replace a portion of an artery (cf. e.g. the paragraph bridging pages 7 and 8 of **D9**: "die Wand des Gefäßes, das durch das Transplantat ersetzt wird, ..." ("the wall of the vessel which is replaced by the graft ...")). The vascular graft is in the form of a double velour warp knitted fabric made of a material to which cell tissue can adhere, characterized by a tubular lattice work 12 which is provided with a large number of knitted thread loops 13, 14 (*Fadenschlingen*) which extend from the surface of the lattice work outwards as well as inwards and form a pile of thread-like material on the outer and inner surface of the latticework, which is receptive to ingrown cell tissue, the loops 13, 15 effectively improving the growth rate of cell tissue into the graft (**D9**, claim 1).

FIG. 2



The skilled person, starting from **D3** and being faced with the above defined objective technical problem (or, for the sake of argument, with the objective technical problem as defined by O1), does not arrive in an obvious manner at what is claimed:

First of all, it is not apparent, and O1 has also not provided any explanations in this regard, why the skilled person aiming at improving on an artificial heart valve (i.e. the one of **D3**) and specifically on a gasket thereof should revert to a document relating to vascular grafts in the first place, let alone vascular grafts configured to replace a portion of a native artery.

O1 has also not provided any explanations why the claimed solution should be obvious from **D3** and **D9**. O1 just points out that "a skilled person would have no problems to achieve the claimed subject-matter" – however, not having any problems would at best confirm that the skilled person *could* arrive at the claimed solution, whereas O1 would have to show that the skilled person *would* arrive at the claimed solution without being inventive. O1 further explains that "The skilled person would have to apply the method of preparing a graft as in **D9** when providing the sleeve made of Dacron material as known in **D3**", but beyond this mere statement of what the skilled person would have to do, the Opponent stays silent as to *why* this would be an *obvious* measure for the skilled person to take.

In addition, the teaching of **D9** is not as readily compatible with **D3** from a technical point of view as O1 would like to make us believe. O1 basically argues that the skilled person would use a portion of the graft of **D9** to form the gasket of the prosthesis of **D3**. However, the gasket or sleeve of **D3** is extending about the circumference of a metallic stent structure, whereas in **D9**, a tubular framework is provided with thread loops 13, 14. Assuming that the skilled person would consider making use of the teaching of **D9** to improve on the prosthesis of **D3**, they would hardly replace the gasket 150 of the prosthesis of **D3** by a part of a graft such as the one of **D9**, since this would mean to attach a second framework to the already existing stent structure of **D3**. To the extent that O1 argues that a possible way to combine the teaching of the two documents is to provide the metallic stent structure of **D3** with the thread loops of **D9** in an attempt to obtain the effect described in **D9** also with the prosthesis of **D3**. However, if so, the

skilled person would use the threaded loops *instead of* the gasket 150 in the prosthesis of **D3**, and the result would not be what is claimed.

Summing up, the skilled person would not revert to **D9** in the first place to solve the problem with **D3**, and if reverting to **D9**, the skilled person would not combine the two documents in the manner suggested by the O1, i.e. use a part of the graft of **D9** to form the gasket of the prosthesis of **D3**.

The mere fact that Dacron is mentioned in both documents, i.e. as the material of the gasket in **D3** and as the material of the yarns constituting the graft in **D9**, does not lead to a different result - the skilled person does not replace a gasket by a graft just because both happen to be made from the same basic material. By the way, **D9** confirms that a double velours material made from Dacron yarns does not include any fibers extending outward from the surface thereof - the thread loops 13, 14 are deliberately added to the double velours in order to create such outwardly extending fibers.

D1, which was also considered during prosecution, is briefly mentioned by O1 as an alternative secondary reference to be combined with **D3**. According to O1, "the skilled person knows from **D1** that a Dacron velour would be a suitable material for covering a stent structure of a stented heart valve." However, as previously pointed out by O1, Dacron is also mentioned in **D3** proper as a possible material of the gasket. **D1** would then not add anything to what is known from **D3**.

*E.2 Any one of **D5a**, **D5b**, **D7** and **D8** with **D9** or **D1***

For similar reasons as when starting from **D3**, O1's asserted combinations of any one of **D5a**, **D5b**, **D7** and **D8** (all disclosing prosthetic heart valve) with **D9** or **D1** do not result in an obvious manner at what is claimed.

*E.3 **D1** in combination with any one of **D4**, **D5a**, **D5b**, **D7**, or **D8***

D1 is considered by O1 not only in combination with **D3** (see above), but also as a possible starting point in the prior art. The document discloses a prosthetic heart valve 10 comprising a heart valve leaflet apparatus 20 and a heart valve leaflet supporting stent 30.

Claim 1 differs from **D1** in that the claimed prosthesis is *for percutaneous implantation*, as confirmed by O1. However, it was not obvious for the skilled person to modify the prosthesis of **D1** so as to be implantable by means of a catheter. Prostheses for percutaneous implantation may have been known *per se*, however, the mere fact that these were known does certainly not make it obvious for the skilled person to drastically modify the prosthesis of **D1**.

Moreover, claim 1 differs from **D1** in further features.

For an alleged disclosure in **D1** of a "compressible material forming a sleeve" in terms of claim 1, O1 apparently refers (using statements made by the Examiner during prosecution) to item 150 in **D1**, which is a cylindrical seamless section 150 of material such as a continuous knit comprising Dacron velour, covering a frame 110 (see e.g. Figure 3 of **D1**).

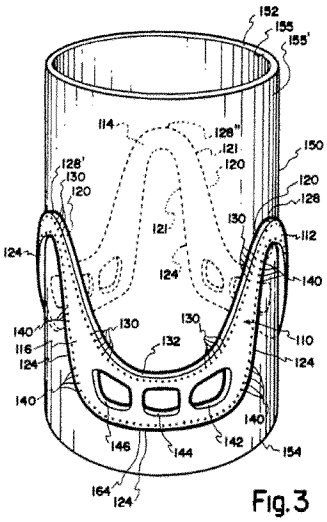


Fig.3

O1 assumes that a compressible material including a plurality of fibers extending outward from the outer surface is "at least implicitly" disclosed in **D1** due to a mentioning of Dacron velours. However, as explicitly confirmed by e.g. **D9**, Dacron velours as such does not necessarily include such outwardly extending fibers.

Furthermore, if element 150 was assumed to anticipate a "sleeve disposed along an outer surface of a stent structure and extending entirely around the stent structure" as claimed, then the frame 110 of the prosthesis of **D1** would have to be equated with the claimed "stent structure". Claim 1 calls for a *substantially cylindrical* stent structure though, and the frame 110 of **D1** is obviously not substantially cylindrical.

*E.4 WO 03/053287 A1 (**D10**) in combination with **D13***

D10 relates to a tubular graft 1 having a band of fibrous material 13 on the outer surface of the proximal end 9 and/or the distal end of the graft 1.

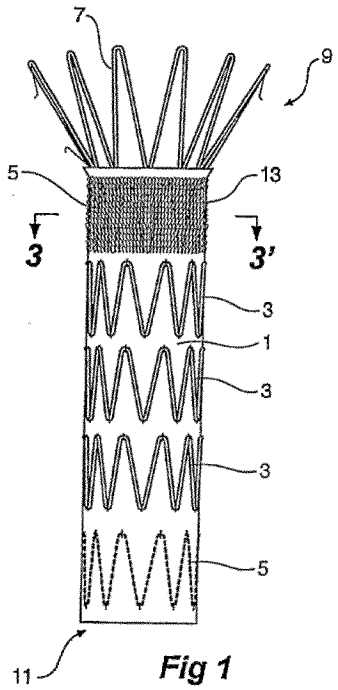


Fig 1

Also disclosed is a stent graft comprising such a tubular graft and stents disposed thereon. As an example, Figure 1 of **D10** shows a stent graft which includes stents 3 disposed on a tubular graft 1 as well as self-expanding stents 5 at each end inside the graft 1. A proximally extending stent 7 is also provided. The stent graft is adapted for insertion into an internal lumen of a patient to be incorporated therein (**D10**, page 2, lines 22-23).

For an alleged disclosure of a compressible material including a plurality of fibers extending outward from the outer surface, O1 further refers to claims 4 to 8 of **D10**, which all relate to the band of fibrous material 13:

- The band 13 may include "fibres woven or knitted into material of said graft" (claim 7). In this case, individual fibres would be added directly into the framework of the graft, i.e. there is no layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

- Similarly, the band 13 may comprise "brushed raised fibers of said graft material", i.e. fibers of the graft material proper may be made to raise from the framework of the graft to constitute the band. Also in this case, there is no layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

- According to claims 4-6 of **D10**, the band 13 may include velour material, specifically "a loop pile velour material" (claim 5) or "a cut pile velour material" (claim 6).

  These claims depend on claim 1 of **D10**, though, and claim 1 describes a stent graft in which at least one expandable stent is disposed on said tubular graft, and the band of fibrous material extends circumferentially around *said graft* and not around the at least one expandable stent. The band of claim 1 is therefore not a sleeve disposed along an outer surface *of the stent structure* and extending entirely around the stent structure, contrary to what is required by granted claim 1.

  Also Figure 1 confirms that the band 13 does not form a sleeve disposed along an outer surface *of the stent structure (stent 5)*, but at best a sleeve disposed along an outer surface *of the graft 1.*

The claims of **D10** referred to by O1 do therefore not disclose a sleeve in terms of claim 1.

This all being said, the clear difference between claim 1 and **D10** is that **D10** does not disclose a prosthetic valve.

O1 claims that it would be obvious for the skilled person to re-work the stent graft of **D10** into a prosthetic valve.

O1 refers to **D13** to confirm that prosthetic valves were originally developed from stent grafts. O1 reads **D13** so as "to provide a stented graft with a valve". This is not correct though. **D13** is a preliminary study relating to a *stent valve*, i.e. a stent to which a valve is sewn. The stent valve of **D13** does not include a graft. Also, it is immediately apparent to the skilled person that the stent structure used for the stent valve of **D13** must be

very different from the individual stents 3, 5, 7 of the stented graft of **D10** - a stented valve must have a stronger stent than a stented graft.

D13 is therefore far from suggesting that a valve could be added to a stented graft such as the one of **D10**.

Other documents disclosing prosthetic heart valves per se also do not provide a hint for the skilled person to add valve leaflets to the stent graft of **D10**.

*E.5 Starting from **D11** or **D12***

D11 relates to methods and apparatus for the endoluminal placement of tubular prostheses, such as grafts, for repairing aneurysms or other vascular defects in humans and animals. "Aneurysms are discrete dilations of the arterial wall, caused by weakening of the arterial wall. One of the most common, and among the most life threatening, is an aneurysm of the abdominal aorta between the renal and iliac arteries." (**D11**, column 1, lines 6-15)

In its introductory portion, **D11** confirms that one method to treat aneurysms "is provided by direct surgical intervention, in which the defective vessel may be bypassed or replaced using a prosthetic device such as a synthetic graft. [...] In recent years a less invasive method of treatment has evolved through a series of inventions. The details vary, but, conventionally, a resilient tubular conduit fashioned from flexible fabric (herein referred to as a 'graft') is introduced into the defective vessel by means of catheters introduced into the femoral artery. The graft is attached to the nondilated or slightly dilated arteries above and below the aneurysm using expandable metallic cylinders (herein referred to as 'attachment systems') which may include barbs or hooks to enhance attachment to the vascular wall" (**D11**, column 1, lines 18-34).

D11 discloses various different embodiments of grafts of the latter type, i.e. grafts configured to be introduced into a defective vessel by means of catheters.

Figure 1 of **D11** exemplifies a proximal end portion of one embodiment of a graft 30 positioned within a vessel 32 of a patient. The vessel 32 is shown to expand from a relatively narrow diameter healthy section to a dilated section where the tissue is diseased. The improved graft 30 comprises a tubular member 34 having a proximal end 36 and distal end (not shown in FIG. 1), at least one expandable attachment system 38, and a generally frustrum shaped sealing member 40 supported by a biasing member 44. The attachment system 38 is connected to the tubular member 34 adjacent the proximal end 36 of the graft 30 (**D11**, column 4, lines 42-52).

O1 refers to alternative embodiments in Figures 20 and 21 of **D11** in which a sealing member made from tufted yarn 932 is attached to an outer wall of the tubular member

934 of the graft 931. In the embodiment of Figure 21, the tufted yarn 932 is attached to the graft 931 in the area of an attachment system 938 which could arguably qualify as a stent structure.

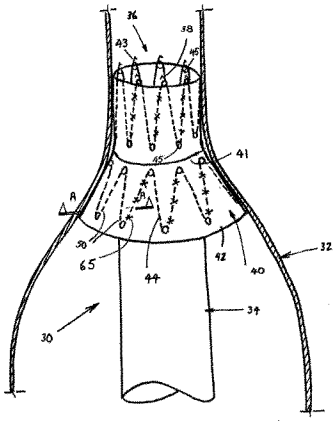


Fig. 1

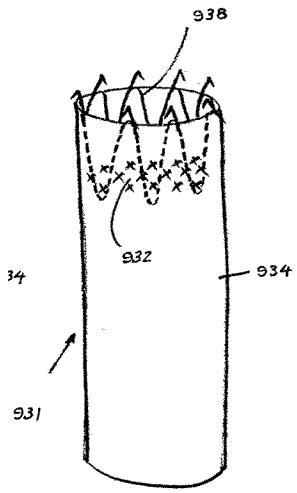


Fig. 21

Using the wording of the granted claim 1, Figure 21 of **D11** would disclose a substantially cylindrical stent structure 938 configured for radial expansion, and a layer of material (the graft) 931, which forms a sleeve disposed along an outer surface of the stent structure 938 and extending entirely around the stent structure, wherein the material 931 includes a plurality of fibers 932 extending outward from the outer surface.

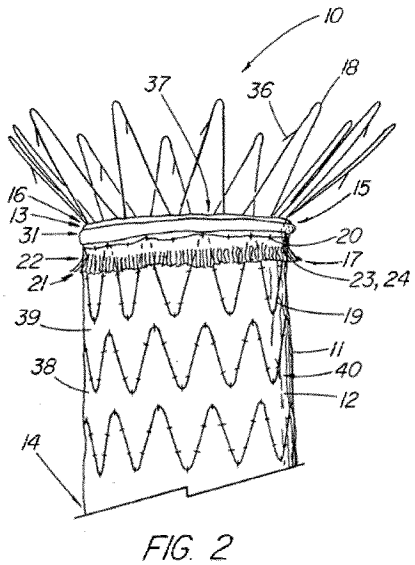


FIG. 2

D12, which the Opponent O1 presents as an alternative starting point, describes an intraluminal graft prosthesis for being placed in e.g. the aorta (**D12**, [0003]). The graft prosthesis 10 comprising a graft portion 11 having a main body 12, and a supporting structure (stent structure) 40 including a top supporting stent 19. O1 refers to paragraph [0009] according to which the top end of the graft is folded onto itself, forming a cuff portion with a frayed region that extends outward from the graft. Such a cuff portion 15 having a frayed portion 22 is also illustrated e.g. in Figure 2 of **D12**. We understand O1 to claim that the cuff portion 15 forms a sleeve disposed along an outer surface of the stent structure 19 and extending entirely around the stent structure 19.

The granted claim 1 differs from **D11** and **D12** in that it relates to a prosthetic valve for percutaneous implantation in a body channel, comprising a valvular structure having an

inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets.

O1 argues that the skilled person starting from **D11** or **D12** arrives at what is claimed by "simply [!] adding a three-leaflet valve to the stented graft already including a sleeve of compressible material having fibers extending therefrom". However, no explanations whatsoever are presented as to why it should be obvious for the skilled person to do that. None of the references cited remotely suggests adding a three-leaflet valve (or, for that matter, any valve) to a stented graft. Adding a three-leaflet valve to the stented graft of **D11** and **D12** is neither obvious from **D11** or **D12** as such, nor from any of the other references cited.

*E.6 Any of **D8** and **D19-D23** with WO 03/053287 A1 (**D10** or WBH17) or US 2002/0052649 A1 (**D24** or WBH18)*

O2 considers any of the above discussed documents **D8** (WBH9) and **D19-D23** (WBH12-16) to form suitable starting points in the prior art to assess the inventive step of claim 1 of the opposed patent.

Working on the assumption that the claim differs from any one of these documents in that the compressible material includes a plurality of fibers extending outward from the outer surface, O2 refers to paragraphs [0011], [0025] and [0064] of the opposed patent and claims that the effect is "directed to the mitigation of paravalvular leakage". O2 further argues that the skilled person would then turn to **D10** or **D24** and find a solution to this problem.

D10 is discussed in section E.4 further above; O1 had asserted it as a possible starting point in the prior art. O2 in turn refers to Figure 4 of **D10** when asserting **D10** as a secondary reference to be combined with one of **D8** or **D19-D23**.

D10 relates to stent grafts though. If the technical effect, and therefore the objective technical problem to be solved by the skilled person starting from one of **D8** (WBH9) or **D19-D23** (WBH12-16), is "directed to the mitigation of para*valvular* leakage", why would the skilled person then refer to **D10** which does not even mention a valve?

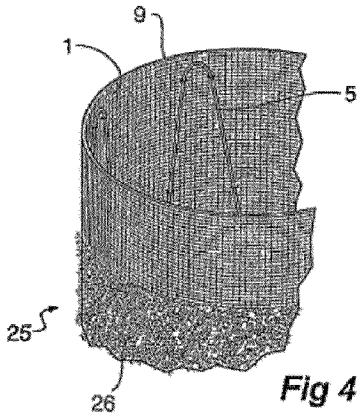


Fig 4

What is more, in the embodiment in Figure 4 of **D10** to which O2 refers, the band of fibrous material 25 provided by raising fibers 26 from the graft material does not even surround the stent structure ("proximal stent") 5.

In summary, O2 argues that the skilled person aiming to mitigate paravalvular leakage in **D8** or **D19**-**D23** *would* refer to **D10** even though **D10** does not even disclose a valve, let alone address paravalvular leakage; *would* isolate from **D10** the teaching as to fibers 26 extending outward from the surface of a graft, notably in an area where the graft is not even supported by a stent; and *would* provide such outwardly extending fibers to the sleeve of the valve prosthesis of the respective closest prior art document (**D8** or **D19**-**D23**), all without exercising an inventive activity. Such an argumentation can only be based on inadmissible hindsight considerations.

Similarly, **D24** (O2's alternative secondary reference for **D8** or **D19**-**D23**) relates to a stent graft typically used to treat a vascular aneurysm in an artery (**D24**, [0023]).

By way of example, Figure 1 of **D24** shows a vascular stent graft 10 typically used to treat a vascular aneurysm 12 in an artery 14. Aneurysm 12 comprises a region of artery 14 wherein the wall 16 is weakened and dilated. Rupture of an aneurysm can be fatal, and treatment consists of replacing the weakened region of the vessel with the stent graft 10. The stent graft may be implanted by means of a catheter or by more invasive surgical techniques (**D1**, [0023]).

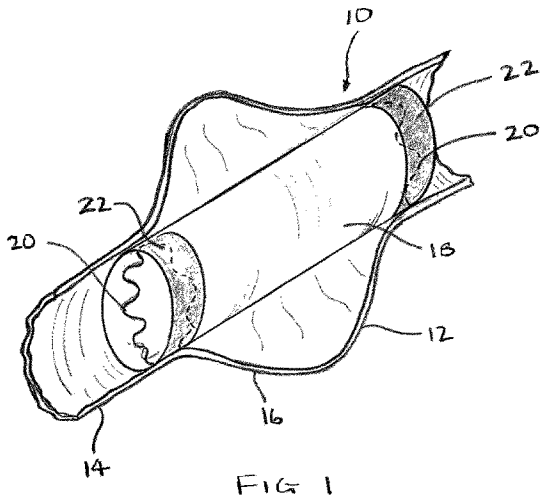


FIG 1

At each end of substrate 18 are attachment regions 22 engageable with the living tissue of the artery, the attachment regions having means for promoting growth of the tissue across the attachment region to form a biological attachment and a seal between the graft 10 and the tissue comprising the artery wall 16. The means for promoting growth of the tissue across regions 22 have several embodiments (**D1**, [0025]).

In one embodiment to which O2 refers, said regions 22 are provided with a textured surface 23 having an increased surface area preferably comprising loops 28 which extend outwardly from the substrate 18. "The areas of increased surface area comprising regions 22 provide a region which promotes the ingrowth of living animal tissue for attaching and sealing the vessel to the graft." See paragraph [0032] and Figure 4 of **D24**.

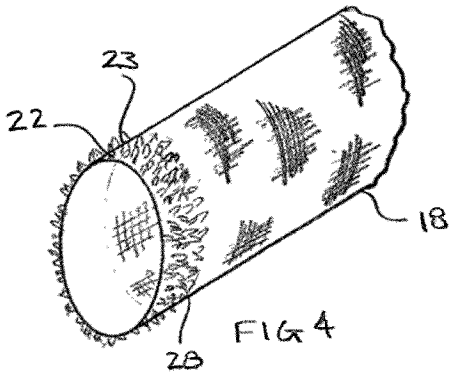


FIG 4

O2 states that being faced with the objective technical problem to mitigate paravalvular leakage in the prosthetic valve of one of **D8** (WBH9) or **D19-D23** (WBH12-16), "the skilled person would thus provide fibers according to feature 1.4 to the valve prostheses of WBH9/WBH12-WBH16, therefore arriving at the subject-matter of Claim 1 of the opposed patent without inventive activity". O2 leaves it at this mere allegation; specifically, O2 fails to explain why the skilled person would refer to **D24** in the first place to address paravalvular leakage, even though **D24** does not even mention a valve. There is no paravalvular leakage problem in vascular lumina, and grafts for being placed in arteries are subject to different challenges than prosthetic valves like the ones of **D8** and **D19-D23**, configured to be placed in the heart itself. The blood pressure acting on the valve results in stresses which are not only larger than the ones acting on a graft but also different in nature.

Regarding the above asserted combinations of **D8** or **D19-D23** with **D10** or **D24**, we further note that **D8** and **D19-D23** were all filed between 1996 and 2004. At that time, first attempts were made to provide prosthetic heart valves which could be delivered by a catheter. In a prosthetic heart valve, the valve leaflets are attached within the frame of the device and add to the size of the device, which is why the research and development of prosthetic valves focused very much on the minimum achievable size of the device in the crimped state. The modifications to the valves of D8 and D19-D23 proposed by O2 would all *add* bulk to the prosthetic valve, which would be considered undesirable by the skilled person. A skilled practitioner aiming at improving on a prosthetic valve at that time would have realized that adding further material to the outer circumference of the device would inevitably further add to the bulk of the device and would therefore have worked contrary to the ongoing attempts for size reduction. For this reason, the skilled person would have refrained from using a sleeve with outwardly extending fibers in the valve prostheses of **D8** or **D19-D23**.

F Novelty and inventive step - the dependent claims

It has been demonstrated that the subject matter of the independent claim 1 of the opposed patent is granted is novel and inventive. Therefore, we refrain from commenting on the dependent claims for the time being.

G Amended claims (Auxiliary Requests)

G.1 Auxiliary Request 1

In the set of claims according to Auxiliary Request 1, claim 1 specifies a valvular structure (254) *providing a flexible conduit* having an inlet and an outlet.

Figure 22 of **D15** shows "an elongated valvular structure in the form of a conduit", as also confirmed by Opponent O2. Support for the amendment is also in claim 27 of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.2 Auxiliary Request 2

In the set of claims according to Auxiliary Request 2, claim 1 specifies the compressible material as being adapted *for expansion* after deployment to fill gaps between the prosthetic valve and the body channel.

Support for the amendment is in paragraph [00145] of **D15** ("The compressible material expands after deployment at a treatment site") and also in claim 27 of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.3 Auxiliary Request 3

In the set of claims according to Auxiliary Request 3, claim 3 reads that the compressible material *is formed of polyethylene terephthalate (PET) and* has a thickness ranging from 1 to 5mm.

Support for the amendment is in paragraph [00145] of the application as filed.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.4 Auxiliary Request 4

In the set of claims according to Auxiliary Request 3, claim 8 states that the compressible material is configured to expand after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

Support for the amendment is in paragraph [00145] of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.5 Auxiliary Request 5

In the set of claims according to Auxiliary Request 3, claim 9 is omitted.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.6 Auxiliary Request 6

In the set of claims according to Auxiliary Request 6, claim 1 recites a substantially cylindrical stent structure (252) configured for radial expansion *using a balloon catheter*.

Support for the amendment is throughout **D15**, specifically in paragraph [00144] thereof.

The amendment further restricts the claim against the prior art.

G.7 Auxiliary Request 7

In the set of claims according to Auxiliary Request 7, the claims relate to a prosthetic *cardiac* valve.

Support for the amendments is throughout **D15**, e.g. in paragraphs [0001] and [0087] thereof.

The amendment further restricts the claim against the prior art.

G.8 Auxiliary Request 8

In the set of claims according to Auxiliary Request 8, all amendments according to Auxiliary Requests 1-7 are combined.

G.9 Further possible Auxiliary Requests

We reserve the right to file further Auxiliary Requests at a later stage in which some, but not all amendments according to Auxiliary Requests 1-7 are combined.



/SCHÖN, Anne/
European Patent Attorney
Hoffmann Eitle
(Association No. 151)

Enclosures
Sets of claims according to eight Auxiliary Requests.

Auxiliary Request 1

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 2

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 3

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible

material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 4

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand ~~into~~after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 5

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

~~9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of~~

~~the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.~~

Auxiliary Request 6

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion using a balloon catheter;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 7

1. A prosthetic cardiac valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 8

1. A prosthetic cardiac valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion using a balloon catheter;

a valvular structure (254) providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand ~~into~~after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

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Acknowledgement of receipt

We hereby acknowledge receipt of the following submission by the proprietor:

Submission number	10309373
Application number	EP15180327.7
Patent number	EP2982337
Date of receipt	20 October 2021
Your reference	238 337 t2/aka
Proprietor	EDWARDS LIFESCIENCES CORPORATION
Title	Paravalvular leak detection, sealing and prevention

Documents submitted	
package-data.xml	ep-opposition-data.xml
ep-oppo.pdf (2 p.)	OBSO3.pdf\Response to oppositions, EP '337 - Oct. 20, 2021.pdf (27 p.)
AUXREQ-1.pdf\Auxiliary Request 1 - "flexible conduit" - Oct. 20, 2021.pdf (2 p.)	AUXREQ-2.pdf\Auxiliary Request 2 - "for expansion" - Oct. 20, 2021.pdf (2 p.)
AUXREQ-3.pdf\Auxiliary Request 3 - claim 3 revised - Oct. 20, 2021.pdf (2 p.)	AUXREQ-4.pdf\Auxiliary Request 4 - claim 8 revised - Oct. 20, 2021.pdf (2 p.)
AUXREQ-5.pdf\Auxiliary Request 5 - claim 9 omitted - Oct. 20, 2021.pdf (2 p.)	AUXREQ-6.pdf\Auxiliary Request 6 - "balloon expandable" - Oct. 20, 2021.pdf (2 p.)
AUXREQ-7.pdf\Auxiliary Request 7 - "prosthetic cardiac valve" - Oct. 20, 2021.pdf (2 p.)	AUXREQ-8.pdf\Auxiliary Request 8 - all amendments combined - Oct. 20, 2021.pdf (2 p.)

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Auxiliary Request 1

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 2

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 3

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible

material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 4

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand ~~into~~after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 5

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

~~9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of~~

~~the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.~~

Auxiliary Request 6

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion using a balloon catheter;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 7

1. A prosthetic cardiac valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion;

a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of

the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Auxiliary Request 8

1. A prosthetic cardiac valve (250) for percutaneous implantation in a body channel, comprising:

a substantially cylindrical stent structure (252) configured for radial expansion using a balloon catheter;

a valvular structure (254) providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

characterized by

a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel,

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve of claim 1, further comprising a tissue growth factor disposed along the compressible material.

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand ~~into~~after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

~~9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.~~

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Submission in opposition proceedings

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Proprietor/representative's reference	238 337 t2/aka

The information given below is pertaining to the following patent in opposition proceedings:

Patent No.	EP2982337
Application No.	EP15180327.7
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	26 August 2020
Title of the invention	Paravalvular leak detection, sealing and prevention
Proprietor of the patent	EDWARDS LIFESCIENCES CORPORATION

Documents attached:

	Description of document	Original file name	Assigned file name
1	Reply of the patent proprietor to the notice(s) of opposition	Response to oppositions, EP '337 - Oct. 20, 2021.pdf	OBSO3.pdf
2	Auxiliary request in opposition	Auxiliary Request 1 - "flexible conduit" - Oct. 20, 2021.pdf	AUXREQ-1.pdf
3	Auxiliary request in opposition	Auxiliary Request 2 - "for expansion" - Oct. 20, 2021.pdf	AUXREQ-2.pdf
4	Auxiliary request in opposition	Auxiliary Request 3 - claim 3 revised - Oct. 20, 2021.pdf	AUXREQ-3.pdf
5	Auxiliary request in opposition	Auxiliary Request 4 - claim 8 revised - Oct. 20, 2021.pdf	AUXREQ-4.pdf
6	Auxiliary request in opposition	Auxiliary Request 5 - claim 9 omitted - Oct. 20, 2021.pdf	AUXREQ-5.pdf
7	Auxiliary request in opposition	Auxiliary Request 6 - "balloon	AUXREQ-6.pdf

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 202
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

		expandable" - Oct. 20, 2021.pdf	
8	Auxiliary request in opposition	Auxiliary Request 7 - "prosthetic cardiac valve" - Oct. 20, 2021.pdf	AUXREQ-7.pdf
9	Auxiliary request in opposition	Auxiliary Request 8 - all amendments combined - Oct. 20, 2021.pdf	AUXREQ-8.pdf

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Signatures

Place:	**München**
Date:	**20 October 2021**
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European Patent 2 982 337 (EP No. 15 180 327.7)
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Opponent O1: Abbott Cardiovascular Systems, Inc.
Opponent O2: Neovasc Tiara Inc.

With reference to the Communication of notices of opposition dated June 10, 2021, we respond as follows to the oppositions filed to the above referenced patent by Abbott Cardiovascular Systems, Inc. ("Opponent O1") and Neovasc Tiara Inc. ("Opponent O2").

A Requests

We request

a) that the oppositions be rejected;

b) in case the request according to a) is not granted, that the patent be maintained on the basis of amended claims according to one of the enclosed auxiliary requests; and

c) that oral proceedings be arranged in case the Opposition Division considers taking any decision adverse to the Proprietor.

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B No inadmissible extension - Art. 100(c) EPC

To demonstrate that the opposed patent does not extend beyond the contents of the application as filed, we will refer to the A1 publication of the parent application of the opposed patent, WO 2006/005015 A1 ("**D15**" according to the EPO's consolidated list).

B.1 General remark regarding claim 1

In general terms, the granted claim 1 of the opposed patent is derived from Figure 22 of the parent application and the associated text, including (but not restricted to) paragraph [00145], as well as claims 27-29 of the parent application.

Opponent O1 refers to claims 27-29 of the parent application (**D15**) and finds that "several features are missing in the subject-matter of claim 1 of the opposed patent so that the subject-matter surely extends beyond the content of the claims as originally filed". We understand this reference to "missing" features to mean that the granted claim 1 does not include all features of claims 27-29 of **D15**. In a separate step, O1 refers to the description of **D15** and argues that based "on the description, the subject-matter of claim 1 of the patent cannot be directly and unambiguously achieved" (point 2.1.2 of the notice of opposition).

However, Art. 100(c) EPC refers to the content of *the application as filed*. When considered *in its entirety*, **D15** clearly and unambiguously discloses a prosthetic valve according to the granted claim 1 of the opposed patent. This will be demonstrated in detail below.

B.2 Claim 1 – "flexible conduit"

Both Opponents refer to the fact that claim 27 of **D15** specifies a valvular structure "providing a flexible conduit having an inlet and an outlet", whereas the granted claim 1 of the opposed patent does not expressly include the words "providing a flexible conduit".

However, this deviation in wording between the granted claim 1 and claim 27 of **D15** does not result in an inadmissible extension.

On the one hand, **D15** does not even refer to a "flexible conduit" when describing the prosthetic valve in Figure 22. Neither paragraph [00145] which closely relates to this Figure, nor the remaining text passages disclosing various features of the prosthetic valve refer to a "flexible conduit".

On the other hand, according to the granted claim 1, the valvular structure still has "an inlet and an outlet", is "formed of a pliant material attached to the stent structure" and

forms "three valve leaflets", and it is part of a prosthetic valve for implantation in a body channel. For a skilled reader of claim 1, it is immediately clear from these claim features that the valvular structure - like any valvular structure of a prosthetic valve of this kind - is configured to convey blood from the inlet to the outlet thereof and through the said body channel. This in turn is precisely the function of a conduit[1]. Therefore, a structure with the features of claim 1 necessarily provides a flexible conduit, and thus the skilled person understands that this feature is implicitly included in the claim. The granted claim 1 does therefore not extend beyond the original disclosure.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 1 which further addresses this point.

B.3a Claim 1 – "sleeve"

The claimed prosthetic valve is characterized by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

O1 states that the features relating to this sleeve result in an inadmissible extension of claim 1 because **D15** rather discloses a "layer of compressible material 256" which "is disposed along an outer surface of the stent structure 252", wherein the material may extend "entirely around the stent structure, such as in the form of a sleeve" (paragraph [00145]).

In an attempt to explain why this disclosure in paragraph [00145] does not support claim 1, O1 argues that it is disclosed in **D15** that *the material* extends entirely around the stent structure *and not a sleeve* as in claim 1. O1 further argues that claim 1 requires the sleeve as a "distinct structural component", the presence of which is not disclosed in **D15** and thus inadmissibly extends the subject matter.

O2 provides a slightly different explanation for basically the same objection: a material which forms a sleeve (claim 1) "is required to engage with the stent structure to provide covering and protection functionalities", whereas a material *in the form of a sleeve* ([00145]) "may be provided spaced apart from the stent structure, for example". In O2's view, it is not derivable from **D15** that the material actually forms a sleeve (provides cover and protection) beyond just being *in the form of a sleeve*.

The relevant comparison is not between *material* on the one hand ([00145]) and *a sleeve* on the other hand (claim 1) which would extend around the stent structure, as argued by O1. The comparison is also not between a *material in the form of a sleeve* ([00145]) and a *material which forms a sleeve* (claim 1), as argued by O2. The relevant

[1] cf. e.g. the definition of a conduit as a "natural or artificial channel through which something (such as a fluid) is conveyed" (per Merriam-Webster, see m-w.com)

comparison is between material *extending around the stent structure in the form of a sleeve* ([00145]) and material *which forms a sleeve extending around the stent structure* (claim 1). There is no difference whatsoever *in substance* between the two. One cannot possibly think of any material e*xtending around the stent structure in the form of a sleeve* which would not also *form a sleeve extending around the stent structure*, and vice versa.

In conclusion, we submit that the disclosure of material *extending around the stent structure in the form of a sleeve* in paragraph [00145] of **D15** does amount up to a clear and unambiguous disclosure of material *which forms a sleeve extending around the stent structure* according to the granted claim 1.

B.3b Claim 1 – "for expansion"

The granted claim 1 relates to the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.

For the Opponents, claim 1 extends beyond the contents of **D15** because the original description ([00145]) and claims in the Opponents' view only disclose compressible materials adapted *for expansion* after deployment to fill gaps between the prosthetic valve and the body channel, whereas granted claim 1 is in the Opponents' view not restricted accordingly.

Also in this regard, the granted claim 1 does not extend beyond the contents of **D15** though: The claim specifies the compressible material as being adapted after deployment to fill gaps between the prosthetic valve and the body channel. This in turn is precisely how the skilled person understands the prosthetic valve illustrated in Figure 22 of **D15** to be configured, which has the layer of compressible material 256 in the form of a sleeve: Being attached to the stent structure, this compressible material is crimped or folded when the stent structure is crimped. After deployment of the stent structure, the material fills gaps between the prosthetic valve and the body channel.

The claim feature as to the compressible material being "adapted after deployment to fill gaps between the prosthetic valve and the body channel" is therefore closely in line with the disclosure in paragraph [00145] and Figure 22 of **D15**.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 2 which further addresses this point.

B.4 Claim 1 – "plurality of fibers" without "tissue growth factor" or "PET"

According to the last feature of claim 1, the compressible material includes a plurality of fibers extending outward from the outer surface.

This feature is literally disclosed in claim 29 of **D15**. The Opponents point out that this claim includes a further feature relating to a "tissue growth factor" and is dependent on claim 28 of **D15**, according to which "the compressible material is formed of polyethylene terephthalate". The Opponents argue that these features are missing in the granted claim 1, resulting in an intermediate generalization.

However, **D15** clearly and unambiguously discloses a prosthetic valve in which the compressible material includes a plurality of fibers extending outward from the outer surface, entirely irrespective of any tissue growth factor and irrespective of whether the compressible material is formed of polyethylene terephthalate. Paragraph [00145] of **D15** confirms that

- "*In one preferred embodiment*, the compressible material is formed of PET and has a thickness ranging from about 1 to 5 mm";
- "*In certain configurations*, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material"; and
- "*In an alternative configuration*, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps" (emphases added).

The feature relating to the fibers is disclosed here without any close structural or functional relationship to the feature of the prosthetic valve further comprising a tissue growth factor disposed along the compressible material and the compressible material being formed of polyethylene terephthalate.

B.5 The dependent claims

O1 also objects to all of the dependent claims under Art. 100(c) EPC. O2 only objects to claims 2, 3, 4 and 9. However, as will be demonstrated below, the combinations of features of the dependent claims are clearly and unambiguously disclosed in **D15**.

Claim 2:

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

The additional feature of claim 2 is disclosed in Figure 22 of **D15** in view of the text in paragraph [00145] which confirms that the sleeve extends entirely around the stent structure. Also according to paragraph [0055] of **D15**, "a compressible material, such as a clot *(sic[2])* or fabric, extends around an exterior portion of the stent". The fact that it is

[2] The skilled person would understand that this is a reference to "cloth".

the *inflow* end of the stent structure which is surrounded by the sleeve is immediately apparent to the skilled reader of the application (the flow direction through the valve in Figure 22 – from the bottom of the page to the top of the page - is clear to the skilled person).

Claim 3:

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5 mm.

This feature is literally disclosed in paragraph [00145] of **D15**. O1 points out that the thickness range is disclosed here *only for PET material*. However, **D15** repeatedly confirms that PET is only one possible compressible material. The skilled reader therefore understands the statement in paragraph [00145] to mean that the thickness indicated therein is irrespective of whether PET or another suitable material is used.

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 3 which further addresses this point.

Claim 4:

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

This additional feature finds literal support in paragraph [0055] of **D15**: "such as a clot[h] or fabric". Further support is in [00145] of **D15**: "may resemble a cloth or fabric having small fibers".

Claim 5:

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

The clear and unambiguous disclosure of the tissue growth factor also without other features has been shown above in the context of claim 1.

Claim 6:

6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

This wording is literally supported by paragraph [00145] of **D15**. While the feature is disclosed here in the form of a method step, the step of applying the growth factor along the outer surface of the compressible material certainly results in a prosthetic valve which has the growth factor applied along the outer surface of the compressible material, and therefore, this original disclosure relates to the device as well as to the method.

Claim 7

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

This wording is literally supported by paragraph [00145] of **D15**. It is obvious for the skilled reader that the "fibers" referred to in this paragraph are the same fibers as in other parts of the original disclosure, including claim 29 of **D15**. It is not apparent why a further "pointer in the description" should be necessary to combine the various statements as to the fibers, as implied by O1.

Claim 8:

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

This additional feature finds support in original paragraphs [0055] ("The compressible material may be formed of PET and is configured to expand into the gaps.") and [00145] ("The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.").

To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 4 which further addresses this point.

Claim 9:

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

This additional feature finds support in claim 1 of **D15** which literally mentions "cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole".

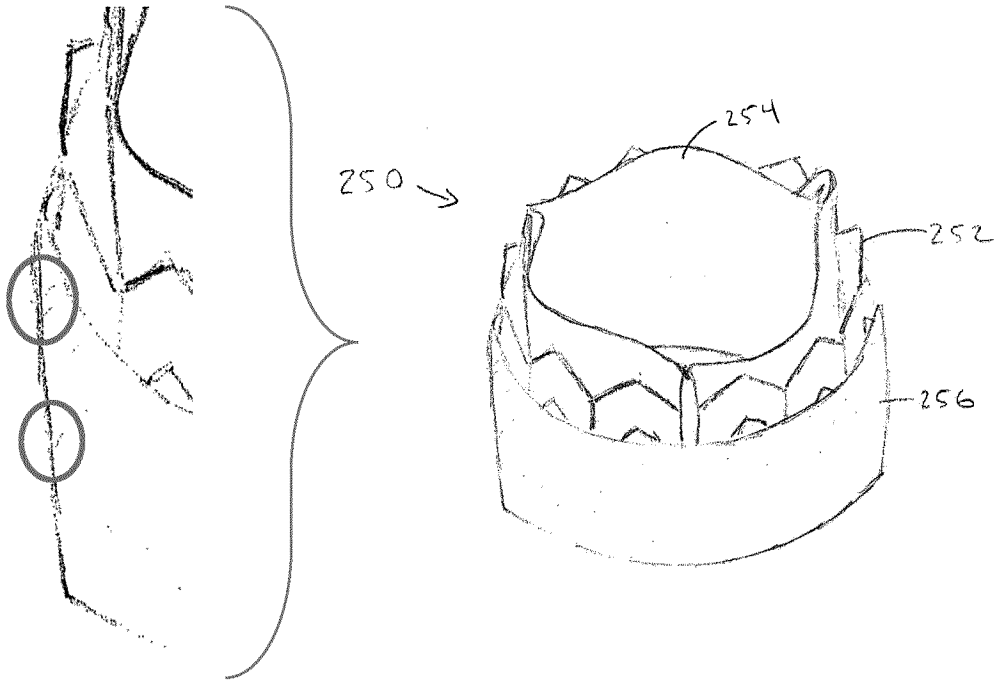
To the extent that the Opposition Division does not agree with the Patentee, we submit Auxiliary Request 5 which further addresses this point.

B.6 The drawings

O2 argues that Figure 22 of the granted patent extends beyond the contents of **D15** because fibers are not depicted in the corresponding provisional drawing in **D15**, wherein O2 refers to the provisional drawings available via the online register of the EPO.

Figure 22 of the granted patent does not add anything to the original disclosure though.

A closer examination of the provisional Figure 22 in the register shows that fibers are in fact (albeit faintly) illustrated therein:



Furthermore, the fibers are clearly and unambiguously described in the associated text in **D15**. Therefore, ***D15*** *as a whole* discloses the valve prosthesis of Figure 22 *including the fibers*, and Figure 22 of the patent does therefore not extend beyond the contents of **D15**.

O2 argues that "similar objections" as to Figure 22 also apply to a series of other Figures in the granted patent. However, while the O2's objection to Figure 22 relates to the

illustration or not of fibers, most of the further drawings do not show any fibers at all, and it is therefore not apparent how "similar objections" should apply to them. The formal drawings in the granted patent differ from the original provisional drawings only in that they have been redrawn as it is commonly the case with this type of patent drawings. The proprietor can hardly be expected to speculate at this point as to which deviations between the two sets of drawings might in the Opponent's view result in an inadmissible extension.

C Sufficiency of disclosure - Art. 100(b) EPC

According to the last feature of claim 1, the compressible material includes a plurality of fibers extending outward from the outer surface.

O1 states that the only outer surface previously mentioned in the claim is the outer surface of the stent structure. In O1's view, the skilled person would therefore read the claim so that "the fibers must start on the stent and then extend outwardly therefrom". At the same time, O1 confirms that "According to the teaching of the patent, it seems intended to encourage coagulation of blood at the fibers outside of the compressible material". To reconcile these two concepts, O1 suggests that "the fibers would have to extend from the stent structure through the compressible material outwardly", and as there is no disclosure in the patent as to how fibers might be integrated into the compressible material so as to extend *from the stent through the material and outwardly of it* to encourage coagulation of blood, the Opponent finds the invention to be insufficiently disclosed in the patent.

These objections are unfounded:

A skilled reader would not interpret claim 1 so that the "outer surface" referred to at the very end thereof is the outer surface *of the stent structure*. In fact, the compressible material which is disposed along an outer surface of the stent structure necessarily also has an outer surface, and according to the only reasonable interpretation, the outer surface in the last feature of claim 1 is actually the outer surface of the compressible material (i.e. claim 1 would be read to end with "the compressible material includes a plurality of fibers extending outward from the outer surface [thereof]"). This understanding is also supported by the granted dependent claim 6 which refers to "the outer surface of the compressible material" (thereby also implying that there is an antecedent basis for this outer surface which would then be in claim 1). The description is also in line with this understanding, as becomes clear from e.g. the wording in paragraph [0064] of the patent: "The compressible material 256 resembles a cloth or fabric having small fibers extending from the surface *of the material.*" (emphasis added)

To the extent that the alleged ambiguous reference to the "outer surface" results in a potential lack of clarity of the claim, we note that a potential unclarity is not a Ground for opposition.

O2 makes a different argument, stating that claim 1 contradicts the description because claim 1 calls for the fibers to extend outwardly from the outer surface, whereas the description implies that the fibers are compressed against the native anatomy.

This alleged contradiction does of course not exist either. The claim relates to the prosthesis in the free air in which the fibers are extending outwardly. In the implanted state, the fibers may or may not be compressed to some extent against the native anatomy.

The claimed invention is therefore certainly disclosed in the patent in a manner sufficiently clear and complete for it to be carried out by the skilled person.

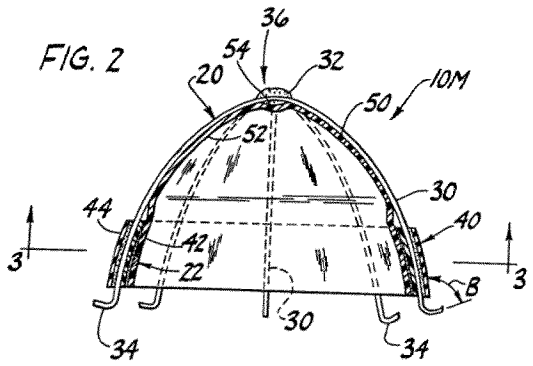
D Novelty (claim 1) - Art. 100(a) EPC and Art. 54 EPC

*D.1 WO 01/56512 A1 (**D6**)*

O1 refers to the drawings of **D6** for a disclosure of different artificial heart valves, and specifically to a prosthetic aortic valve 10A in Figure 5 and a prosthetic mitral valve 10M in Figure 2 of **D6**. A band 40 of the mitral valve prosthesis in Figure 2 is said to permit "the frame elements 30 to be pushed together so that the flexibly resilient frame 20 can be collapsed" to the configuration shown in Figures 4 and 5. An "exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth" (page 11, lines 6 to 11).

The prosthesis of **D6** has a valve element 22 which can be longitudinally pleated (page 12 lines 17 to 23). The upstream side 50 of the flexible valve element 22 has an apex 54 which is attached to the frame 20 at the junction 32 of the frame elements 30 (page 11, line 24). The valve element can be attached to the frame at attachment points 56 so as to form flaps 58, see page 12, last lines, and claim 7 of **D6**. Each of the flaps 58 and a corresponding portion of the band 40 defines an opening 60 through the valve when the valve element 22 moves to the open position. The valve 10M in Figures 2 and 3 comprises four attachment points 56, and the valve element 22 thereof forms four such flaps 58.

Using the wording of the granted claim 1, the claimed prosthetic valve (250) differs from the disclosure of **D6** at least in that it comprises a substantially cylindrical stent structure. The stent structure of the prosthetic valve of **D6** is essentially dome shaped, with frame elements 30 meeting at a junction 32:



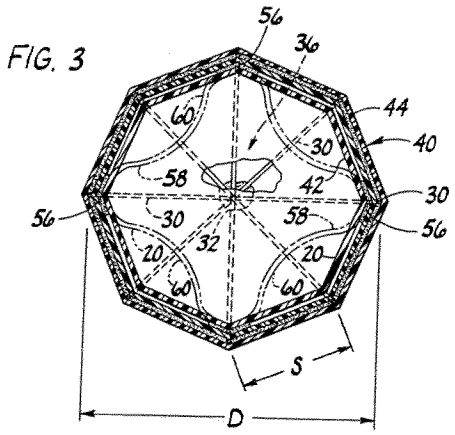
Already for this reason, claim 1 is novel over **D6**.

There are further claim features which are not disclosed in **D6**:

- the valvular structure forms <u>three valve leaflets</u> - the valve element 22 of **D6** is a continuous structure attached to the frame elements 30 so as to form flaps 58, wherein "Each of the flaps 58 and a corresponding portion of the band 40 extending between adjacent attachment points 56 defines an opening 60 through the valve when the valve element 22 moves to the open position" (**D6**, page 13, lines 1-5), whereas leaflets would be pushed open to allow blood flow and then close together to seal and prevent backflow;

- a layer of <u>compressible</u> material - no mention is made in D6 as to the material of the band 40 being compressible;

- a layer of compressible material forms a sleeve disposed along <u>an outer surface of the stent structure</u> - the prosthetic valve of **D6** has individual frame elements 30, and the band 40 rather extends from one frame element 30 to the next (or "between each of the frame elements 30", **D6**, page 9, lines 24-25):



- and the compressible material includes <u>a plurality of fibers extending outward from the outer surface</u>. It seems needless to say that **D6** does not explicitly or implicitly disclose such fibers. The Opponent refers to the mentioning of "Dacron

velour material" and "porous PTFE felt" in **D6**, but "Dacron velour material" and "porous PTFE felt" do not amount to a clear and unambiguous disclosure of a plurality of fibers extending outward from the outer surface. In fact, *porous* felt would be characterized in having voids for promoting tissue ingrowth, i.e. the opposite of fibers extending outwardly.

*D.2 WO 03/039613 A1 (**D14**)*

D14 discloses a synthetic vascular prosthesis in the form of *e.g.* a vascular graft or an artificial heart valve (**D14**, claim 11). The prosthesis is formed from a basic structure and contains an active substance to stimulate the ingrowth of vascular cells into the prosthesis.

O1 refers to the disclosure on page 7 of **D14** of a prosthesis containing a basic structure comprising voids, wherein the basic structure can *e.g.* be made from a double-velours type material. The basic structure may be constructed of fibres (e.g. a woven or knitted material), see **D14**, page 7, lines 17-21.

D14 hardly anticipates *any* of the features of claim 1 of the opposed patent. **D14** mentions the possible use of the prosthesis as an artificial heart valve (claim 11) but fails to disclose a substantially cylindrical stent structure configured for radial expansion; a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets; or a layer of compressible material, which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure. The double-velours type material in **D14** which is referred to by the Opponent *forms the basic structure of the prosthesis*; it does not form a sleeve disposed along an outer surface of a stent structure of a prosthetic heart valve.

*D.3 WO 2006/089236 A1 (**D18** or WBH10)*

According to O2, **D18** forms part of the prior art according to Art. 54(3) EPC. However, this document does not anticipate claim 1:

The text of **D18** refers, on the one hand, to an apparatus 10 for replacing a dysfunctional mitral valve 14, including "an expandable support member 40 (Fig. 2)" "and the prosthetic valve 12" (page 5, lines 23-25). The prosthetic valve 12 of this embodiment has two leaflets, as is apparent from the existence of two commissural sections 47 in Figure 2 - similar as the native mitral valve 14 which has two leaflets, too.

O2 refers to Figure 4. In **D18**, Figure 4 is said to illustrate "another alternative embodiment of the apparatus shown in Figure 2" (**D18**, page 4, lines 14 and 15). Figure 7 shows the same embodiment and also clearly illustrates the two leaflets. Already for

this reason, the embodiment of Figures 2-8 does not anticipate claim 1 of the opposed patent - what is claimed is a valvular structure forming *three* valve leaflets.

Further in relation to its Figures 2-8, **D18** also fails to disclose the last feature of claim 1: The apparatus 10 of Figure 2 may further include a layer 50 of biocompatible material to which O2 refers for an alleged anticipation of the "compressible material" of granted claim 1. According to **D18**, the biocompatible material may *e.g.* be made from woven velour, which for the Opponent means that it "comprises a plurality of fibers" and thereby anticipates the claim feature. This conclusion is incorrect - the claim does not only require a plurality of fibers but a plurality of fibers *extending outward from the outer surface*; the mere mentioning of woven velour does not amount to a clear and unambiguous disclosure of such outwardly extending fibers. Also for this reason, claim 1 is novel over **D18** (Figures 2-8).

O2 further refers to Figure 12 of **D18** which shows a different embodiment. The text beginning on page 21 confirms that "The apparatus 10_b of Fig. 12 is identically constructed as the apparatus 10 of Figs. 2-8, except whereas described below. … As shown in Fig. 21, the apparatus 10_b comprises a tri-leaflet prosthetic valve 12_b." (this text passage thereby further confirms that the previous embodiment of Figures 2-8 does *not* comprise a tri-leaflet valve). While the embodiment in Figure 12 has three leaflets, it does not comprise the layer 50 of biocompatible material and therefore already lacks a compressible (or any) material forming a sleeve disposed along an outer surface of the stent structure as required by claim 1. In any event, the embodiment in Figure 12 does not disclose a "compressible material having outwardly extending fibers" for the reasons set out above.

In conclusion, the granted claim 1 is novel over the embodiment of Figures 2-8 of **D18** in view of at least the three valve leaflets, novel over the embodiment of Figure 12 **D18** in view of at least the compressible material forming a sleeve, and novel over both these embodiments of **D18** in view of the compressible material having outwardly extending fibers.

*D.4 US 2005/0137698 A1 (**D5b** or WBH11)*

D5b describes a valve prosthesis comprising a seal extending about the outer circumference of a stent thereof, wherein the seal can bunch up upon deployment and create pleats. The seal can be composed of a thin, elastic polymer or any other type of fabric.

D5b fails to disclose at least the essential characterizing features of claim 1:

D5b does not disclose any layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure. The properties associated with the seal in **D5b** - a thin, elastic polymer or any other type of fabric - do not include compressibility.

Also, in **D5b**, the material forming the seal does not have a plurality of fibers extending outward from the outer surface thereof. O2 points out that a "fabric" regularly comprises a plurality of fibers and that some of these fibers are "always extending outward from the outer surface", which is certainly not correct.

*D.5 WO 2004/082527 A2 (**D19** or WBH12)*

Similar considerations apply to **D19** - leaving other aspects aside, **D19** discloses a fabric made from PET which according to the Opponent O2 forms a layer of compressible material and "must comprise fibers, some of which extend outward from the outer surface". The Opponent's interpretation clearly goes beyond what is actually disclosed in **D19**.

*D.6 WO 01/54625 A1 (**D20** or WBH13)*

D20 mentions "a textured surface or any other treated surface that facilitates relative affixation of the device in its location". This is not a clear and unambiguous disclosure of a layer of compressible material and/or of outwardly extending fibers.

*D.7 WO 01/76510 (**D21** or WBH14)*

Leaving other points aside, we submit that also **D21** does not clearly and unambiguously disclose a compressible material having outwardly extending fibers. **D21** merely mentions a fabric section 34 "formed of PTFE or other suitable biocompatible sheet material".

*D.8 US 2004/0210304 A1 (**D22** or WBH15)*

D22, too, provides only a general disclosure of sealing means made from polyester or tissue and does not clearly and unambiguously disclose a compressible material having outwardly extending fibers.

*D.9 US 5,855,601 (**D23** or WBH16)*

The disclosure in **D23** does not go beyond a cuff portion 37 from e.g. PTFE, polyester or the like. **D23** does not clearly and unambiguously disclose a compressible material having outwardly extending fibers.

*D.10 US 2003/0153974 A1 (**D8** or WBH9)*

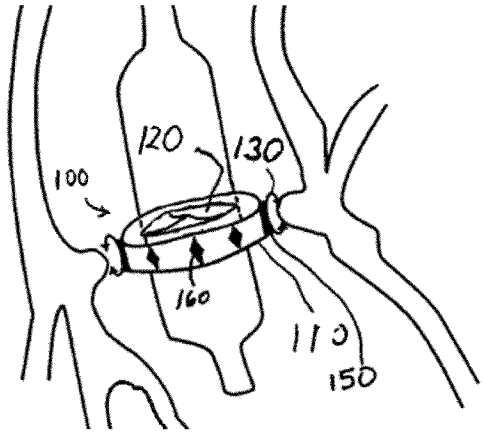
D8 is acknowledged in the prior art section of the opposed patent. The document mentions a sleeve made from PET but fails to disclose a layer of compressible material or any outwardly extending fibers.

E Inventive Step (claim 1) - Art. 100(a) EPC and Art. 56 EPC

*E.1 WO 00/64380 A1 (**D3**) in combination with either DE 26 13 575 A1 (**D9**) or US 5,258,023 (**D1**)*

D3 discloses a valve apparatus for deploying in, and securing to, a tissue annulus. FIG. 1 shows an artificial heart valve 100 having a balloon expandable connector band 110 with a one-way valve portion 120 integrated within connector band 110. In an embodiment, a separate gasket 150 (shown in FIG. 1) may be attached around band 110.

The document was discussed extensively during prosecution, wherein the Examiner considered the gasket 150 of the apparatus shown in Figure 1 of **D3** to anticipate a "sleeve" in terms of claim 1.



O1 agrees, though, that the last feature of claim 1 (the compressible material includes a plurality of fibers extending outward from the outer surface) is not disclosed in **D3**.

According to O1, the technical effect of providing such fibers is "to promote ingrowth of tissue on the surface" (of the compressible material).

However, in the patent, the effect of "promoting the growth of tissue into the material" is presented as an effect of the tissue growth factor (patent, [0064]). Fibers are rather said to increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing ([0061]). The effect of protein adhesion in turn

resides in that blood protein preferably adheres to the compressible material, thereby causing coagulation for further leak prevention. Coagulation and leak prevention / sealing therefore result from protein adhesion.

The technical effect of the above defined distinguishing feature is therefore to increase the active surface of the compressible material, thus increasing the effect of protein adhesion.

Further to O1, the objective technical problem to be solved when starting from **D3** is "to provide a graft material which facilitates formation of tissue on surfaces thereof without impeding the flow of blood therethrough". However, according to the established practice, the objective technical problem is defined in view of the technical effect of the distinguishing feature(s), which in turn result from a comparison of the claim with the closest prior art. Seeing as neither **D3** nor the opposed patent even remotely relate to graft materials, it is not apparent why the objective technical problem to be solved when starting from **D3** should be to provide *a graft material*. The only document in this line of argumentation which does relate to grafts is **D9**, which the Opponent would like the skilled person to combine with **D3** in what is obviously a hindsight approach (see below).

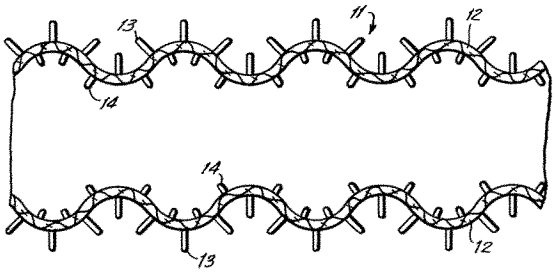
In view of the above technical effect set out in the opposed patent, an objective technical problem to be solved by the skilled person, starting from **D3**, is rather to increase the effect of protein adhesion to the gasket or compressible material of **D3**.

This problem is solved by the combination of features of claim 1 of the opposed patent, including the feature that the compressible material includes a plurality of fibers extending outward from the outer surface.

The claimed solution is not rendered obvious by the prior art:

O1 refers to **D9** as a secondary reference. **D9**, published in 1977, discloses a synthetic vascular graft of the type configured to replace a portion of an artery (cf. e.g. the paragraph bridging pages 7 and 8 of **D9**: "die Wand des Gefäßes, das durch das Transplantat ersetzt wird, ..." ("the wall of the vessel which is replaced by the graft ...")). The vascular graft is in the form of a double velour warp knitted fabric made of a material to which cell tissue can adhere, characterized by a tubular lattice work 12 which is provided with a large number of knitted thread loops 13, 14 (*Fadenschlingen*) which extend from the surface of the lattice work outwards as well as inwards and form a pile of thread-like material on the outer and inner surface of the latticework, which is receptive to ingrown cell tissue, the loops 13, 15 effectively improving the growth rate of cell tissue into the graft (**D9**, claim 1).

FIG. 2



The skilled person, starting from **D3** and being faced with the above defined objective technical problem (or, for the sake of argument, with the objective technical problem as defined by O1), does not arrive in an obvious manner at what is claimed:

First of all, it is not apparent, and O1 has also not provided any explanations in this regard, why the skilled person aiming at improving on an artificial heart valve (i.e. the one of **D3**) and specifically on a gasket thereof should revert to a document relating to vascular grafts in the first place, let alone vascular grafts configured to replace a portion of a native artery.

O1 has also not provided any explanations why the claimed solution should be obvious from **D3** and **D9**. O1 just points out that "a skilled person would have no problems to achieve the claimed subject-matter" – however, not having any problems would at best confirm that the skilled person *could* arrive at the claimed solution, whereas O1 would have to show that the skilled person *would* arrive at the claimed solution without being inventive. O1 further explains that "The skilled person would have to apply the method of preparing a graft as in **D9** when providing the sleeve made of Dacron material as known in **D3**", but beyond this mere statement of what the skilled person would have to do, the Opponent stays silent as to *why* this would be an *obvious* measure for the skilled person to take.

In addition, the teaching of **D9** is not as readily compatible with **D3** from a technical point of view as O1 would like to make us believe. O1 basically argues that the skilled person would use a portion of the graft of **D9** to form the gasket of the prosthesis of **D3**. However, the gasket or sleeve of **D3** is extending about the circumference of a metallic stent structure, whereas in **D9**, a tubular framework is provided with thread loops 13, 14. Assuming that the skilled person would consider making use of the teaching of **D9** to improve on the prosthesis of **D3**, they would hardly replace the gasket 150 of the prosthesis of **D3** by a part of a graft such as the one of **D9**, since this would mean to attach a second framework to the already existing stent structure of **D3**. To the extent that O1 argues that a possible way to combine the teaching of the two documents is to provide the metallic stent structure of **D3** with the thread loops of **D9** in an attempt to obtain the effect described in **D9** also with the prosthesis of **D3**. However, if so, the

skilled person would use the threaded loops *instead of* the gasket 150 in the prosthesis of **D3**, and the result would not be what is claimed.

Summing up, the skilled person would not revert to **D9** in the first place to solve the problem with **D3**, and if reverting to **D9**, the skilled person would not combine the two documents in the manner suggested by the O1, i.e. use a part of the graft of **D9** to form the gasket of the prosthesis of **D3**.

The mere fact that Dacron is mentioned in both documents, i.e. as the material of the gasket in **D3** and as the material of the yarns constituting the graft in **D9**, does not lead to a different result - the skilled person does not replace a gasket by a graft just because both happen to be made from the same basic material. By the way, **D9** confirms that a double velours material made from Dacron yarns does not include any fibers extending outward from the surface thereof - the thread loops 13, 14 are deliberately added to the double velours in order to create such outwardly extending fibers.

D1, which was also considered during prosecution, is briefly mentioned by O1 as an alternative secondary reference to be combined with **D3**. According to O1, "the skilled person knows from **D1** that a Dacron velour would be a suitable material for covering a stent structure of a stented heart valve." However, as previously pointed out by O1, Dacron is also mentioned in **D3** proper as a possible material of the gasket. **D1** would then not add anything to what is known from **D3**.

*E.2 Any one of **D5a**, **D5b**, **D7** and **D8** with **D9** or **D1***

For similar reasons as when starting from **D3**, O1's asserted combinations of any one of **D5a**, **D5b**, **D7** and **D8** (all disclosing prosthetic heart valve) with **D9** or **D1** do not result in an obvious manner at what is claimed.

*E.3 **D1** in combination with any one of **D4**, **D5a**, **D5b**, **D7**, or **D8***

D1 is considered by O1 not only in combination with **D3** (see above), but also as a possible starting point in the prior art. The document discloses a prosthetic heart valve 10 comprising a heart valve leaflet apparatus 20 and a heart valve leaflet supporting stent 30.

Claim 1 differs from **D1** in that the claimed prosthesis is *for percutaneous implantation*, as confirmed by O1. However, it was not obvious for the skilled person to modify the prosthesis of **D1** so as to be implantable by means of a catheter. Prostheses for percutaneous implantation may have been known *per se*, however, the mere fact that these were known does certainly not make it obvious for the skilled person to drastically modify the prosthesis of **D1**.

Moreover, claim 1 differs from **D1** in further features.

For an alleged disclosure in **D1** of a "compressible material forming a sleeve" in terms of claim 1, O1 apparently refers (using statements made by the Examiner during prosecution) to item 150 in **D1**, which is a cylindrical seamless section 150 of material such as a continuous knit comprising Dacron velour, covering a frame 110 (see e.g. Figure 3 of **D1**).

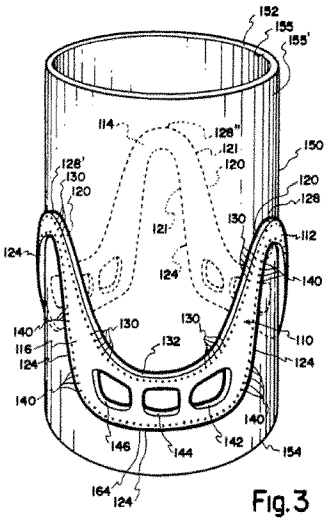


Fig.3

O1 assumes that a compressible material including a plurality of fibers extending outward from the outer surface is "at least implicitly" disclosed in **D1** due to a mentioning of Dacron velours. However, as explicitly confirmed by e.g. **D9**, Dacron velours as such does not necessarily include such outwardly extending fibers.

Furthermore, if element 150 was assumed to anticipate a "sleeve disposed along an outer surface of a stent structure and extending entirely around the stent structure" as claimed, then the frame 110 of the prosthesis of **D1** would have to be equated with the claimed "stent structure". Claim 1 calls for a *substantially cylindrical* stent structure though, and the frame 110 of **D1** is obviously not substantially cylindrical.

*E.4 WO 03/053287 A1 (**D10**) in combination with **D13***

D10 relates to a tubular graft 1 having a band of fibrous material 13 on the outer surface of the proximal end 9 and/or the distal end of the graft 1.

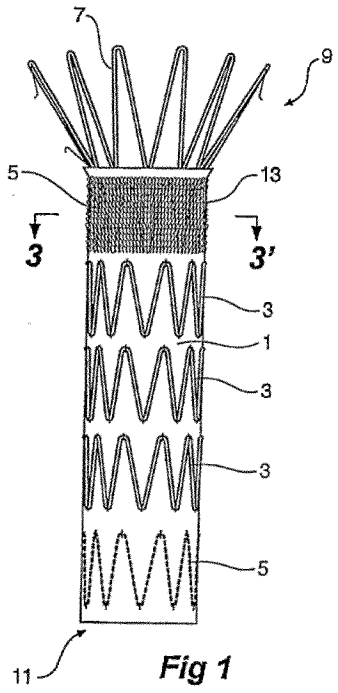


Fig 1

Also disclosed is a stent graft comprising such a tubular graft and stents disposed thereon. As an example, Figure 1 of **D10** shows a stent graft which includes stents 3 disposed on a tubular graft 1 as well as self-expanding stents 5 at each end inside the graft 1. A proximally extending stent 7 is also provided. The stent graft is adapted for insertion into an internal lumen of a patient to be incorporated therein (**D10**, page 2, lines 22-23).

For an alleged disclosure of a compressible material including a plurality of fibers extending outward from the outer surface, O1 further refers to claims 4 to 8 of **D10**, which all relate to the band of fibrous material 13:

- The band 13 may include "fibres woven or knitted into material of said graft" (claim 7). In this case, individual fibres would be added directly into the framework of the graft, i.e. there is no layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

- Similarly, the band 13 may comprise "brushed raised fibers of said graft material", i.e. fibers of the graft material proper may be made to raise from the framework of the graft to constitute the band. Also in this case, there is no layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure.

- According to claims 4-6 of **D10**, the band 13 may include velour material, specifically "a loop pile velour material" (claim 5) or "a cut pile velour material" (claim 6).

  These claims depend on claim 1 of **D10**, though, and claim 1 describes a stent graft in which at least one expandable stent is disposed on said tubular graft, and the band of fibrous material extends circumferentially around *said graft* and not around the at least one expandable stent. The band of claim 1 is therefore not a sleeve disposed along an outer surface *of the stent structure* and extending entirely around the stent structure, contrary to what is required by granted claim 1.

  Also Figure 1 confirms that the band 13 does not form a sleeve disposed along an outer surface *of the stent structure (stent 5)*, but at best a sleeve disposed along an outer surface *of the graft 1.*

The claims of **D10** referred to by O1 do therefore not disclose a sleeve in terms of claim 1.

This all being said, the clear difference between claim 1 and **D10** is that **D10** does not disclose a prosthetic valve.

O1 claims that it would be obvious for the skilled person to re-work the stent graft of **D10** into a prosthetic valve.

O1 refers to **D13** to confirm that prosthetic valves were originally developed from stent grafts. O1 reads **D13** so as "to provide a stented graft with a valve". This is not correct though. **D13** is a preliminary study relating to a *stent valve*, i.e. a stent to which a valve is sewn. The stent valve of **D13** does not include a graft. Also, it is immediately apparent to the skilled person that the stent structure used for the stent valve of **D13** must be

very different from the individual stents 3, 5, 7 of the stented graft of **D10** - a stented valve must have a stronger stent than a stented graft.

D13 is therefore far from suggesting that a valve could be added to a stented graft such as the one of **D10**.

Other documents disclosing prosthetic heart valves per se also do not provide a hint for the skilled person to add valve leaflets to the stent graft of **D10**.

*E.5 Starting from **D11** or **D12***

D11 relates to methods and apparatus for the endoluminal placement of tubular prostheses, such as grafts, for repairing aneurysms or other vascular defects in humans and animals. "Aneurysms are discrete dilations of the arterial wall, caused by weakening of the arterial wall. One of the most common, and among the most life threatening, is an aneurysm of the abdominal aorta between the renal and iliac arteries." (**D11**, column 1, lines 6-15)

In its introductory portion, **D11** confirms that one method to treat aneurysms "is provided by direct surgical intervention, in which the defective vessel may be bypassed or replaced using a prosthetic device such as a synthetic graft. [...] In recent years a less invasive method of treatment has evolved through a series of inventions. The details vary, but, conventionally, a resilient tubular conduit fashioned from flexible fabric (herein referred to as a 'graft') is introduced into the defective vessel by means of catheters introduced into the femoral artery. The graft is attached to the nondilated or slightly dilated arteries above and below the aneurysm using expandable metallic cylinders (herein referred to as 'attachment systems') which may include barbs or hooks to enhance attachment to the vascular wall" (**D11**, column 1, lines 18-34).

D11 discloses various different embodiments of grafts of the latter type, i.e. grafts configured to be introduced into a defective vessel by means of catheters.

Figure 1 of **D11** exemplifies a proximal end portion of one embodiment of a graft 30 positioned within a vessel 32 of a patient. The vessel 32 is shown to expand from a relatively narrow diameter healthy section to a dilated section where the tissue is diseased. The improved graft 30 comprises a tubular member 34 having a proximal end 36 and distal end (not shown in FIG. 1), at least one expandable attachment system 38, and a generally frustrum shaped sealing member 40 supported by a biasing member 44. The attachment system 38 is connected to the tubular member 34 adjacent the proximal end 36 of the graft 30 (**D11**, column 4, lines 42-52).

O1 refers to alternative embodiments in Figures 20 and 21 of **D11** in which a sealing member made from tufted yarn 932 is attached to an outer wall of the tubular member

934 of the graft 931. In the embodiment of Figure 21, the tufted yarn 932 is attached to the graft 931 in the area of an attachment system 938 which could arguably qualify as a stent structure.

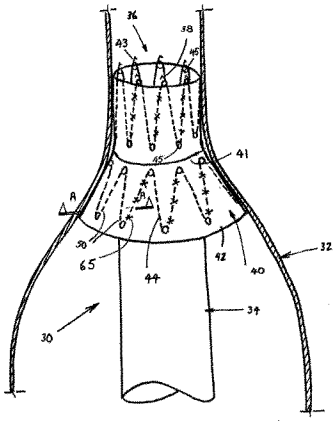


Fig. 1

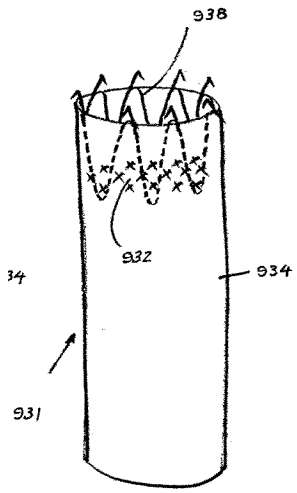


Fig. 21

Using the wording of the granted claim 1, Figure 21 of **D11** would disclose a substantially cylindrical stent structure 938 configured for radial expansion, and a layer of material (the graft) 931, which forms a sleeve disposed along an outer surface of the stent structure 938 and extending entirely around the stent structure, wherein the material 931 includes a plurality of fibers 932 extending outward from the outer surface.

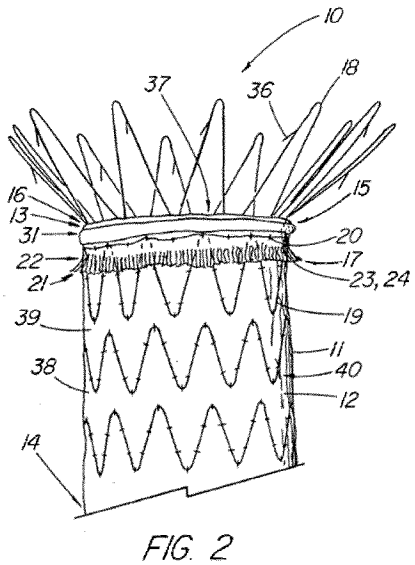


FIG. 2

D12, which the Opponent O1 presents as an alternative starting point, describes an intraluminal graft prosthesis for being placed in e.g. the aorta (**D12**, [0003]). The graft prosthesis 10 comprising a graft portion 11 having a main body 12, and a supporting structure (stent structure) 40 including a top supporting stent 19. O1 refers to paragraph [0009] according to which the top end of the graft is folded onto itself, forming a cuff portion with a frayed region that extends outward from the graft. Such a cuff portion 15 having a frayed portion 22 is also illustrated e.g. in Figure 2 of **D12**. We understand O1 to claim that the cuff portion 15 forms a sleeve disposed along an outer surface of the stent structure 19 and extending entirely around the stent structure 19.

The granted claim 1 differs from **D11** and **D12** in that it relates to a prosthetic valve for percutaneous implantation in a body channel, comprising a valvular structure having an

inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets.

O1 argues that the skilled person starting from **D11** or **D12** arrives at what is claimed by "simply [!] adding a three-leaflet valve to the stented graft already including a sleeve of compressible material having fibers extending therefrom". However, no explanations whatsoever are presented as to why it should be obvious for the skilled person to do that. None of the references cited remotely suggests adding a three-leaflet valve (or, for that matter, any valve) to a stented graft. Adding a three-leaflet valve to the stented graft of **D11** and **D12** is neither obvious from **D11** or **D12** as such, nor from any of the other references cited.

*E.6 Any of **D8** and **D19-D23** with WO 03/053287 A1 (**D10** or WBH17) or US 2002/0052649 A1 (**D24** or WBH18)*

O2 considers any of the above discussed documents **D8** (WBH9) and **D19-D23** (WBH12-16) to form suitable starting points in the prior art to assess the inventive step of claim 1 of the opposed patent.

Working on the assumption that the claim differs from any one of these documents in that the compressible material includes a plurality of fibers extending outward from the outer surface, O2 refers to paragraphs [0011], [0025] and [0064] of the opposed patent and claims that the effect is "directed to the mitigation of paravalvular leakage". O2 further argues that the skilled person would then turn to **D10** or **D24** and find a solution to this problem.

D10 is discussed in section E.4 further above; O1 had asserted it as a possible starting point in the prior art. O2 in turn refers to Figure 4 of **D10** when asserting **D10** as a secondary reference to be combined with one of **D8** or **D19-D23**.

D10 relates to stent grafts though. If the technical effect, and therefore the objective technical problem to be solved by the skilled person starting from one of **D8** (WBH9) or **D19-D23** (WBH12-16), is "directed to the mitigation of para*valvular* leakage", why would the skilled person then refer to **D10** which does not even mention a valve?

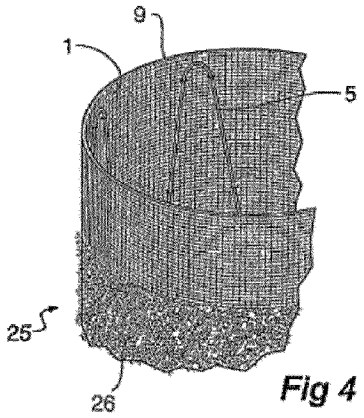


Fig 4

What is more, in the embodiment in Figure 4 of **D10** to which O2 refers, the band of fibrous material 25 provided by raising fibers 26 from the graft material does not even surround the stent structure ("proximal stent") 5.

In summary, O2 argues that the skilled person aiming to mitigate paravalvular leakage in **D8** or **D19**-**D23** *would* refer to **D10** even though **D10** does not even disclose a valve, let alone address paravalvular leakage; *would* isolate from **D10** the teaching as to fibers 26 extending outward from the surface of a graft, notably in an area where the graft is not even supported by a stent; and *would* provide such outwardly extending fibers to the sleeve of the valve prosthesis of the respective closest prior art document (**D8** or **D19**-**D23**), all without exercising an inventive activity. Such an argumentation can only be based on inadmissible hindsight considerations.

Similarly, **D24** (O2's alternative secondary reference for **D8** or **D19**-**D23**) relates to a stent graft typically used to treat a vascular aneurysm in an artery (**D24**, [0023]).

By way of example, Figure 1 of **D24** shows a vascular stent graft 10 typically used to treat a vascular aneurysm 12 in an artery 14. Aneurysm 12 comprises a region of artery 14 wherein the wall 16 is weakened and dilated. Rupture of an aneurysm can be fatal, and treatment consists of replacing the weakened region of the vessel with the stent graft 10. The stent graft may be implanted by means of a catheter or by more invasive surgical techniques (**D1**, [0023]).

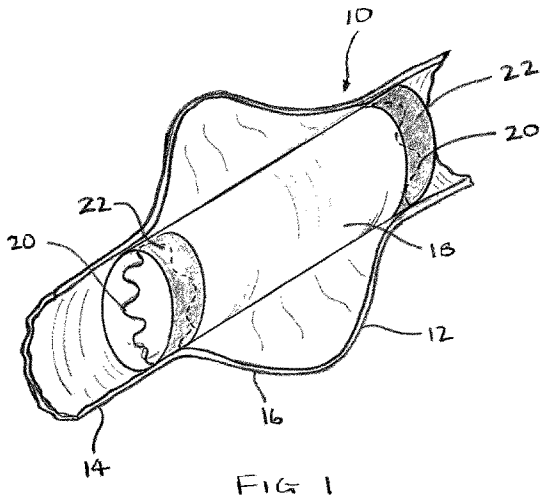


FIG 1

At each end of substrate 18 are attachment regions 22 engageable with the living tissue of the artery, the attachment regions having means for promoting growth of the tissue across the attachment region to form a biological attachment and a seal between the graft 10 and the tissue comprising the artery wall 16. The means for promoting growth of the tissue across regions 22 have several embodiments (**D1**, [0025]).

In one embodiment to which O2 refers, said regions 22 are provided with a textured surface 23 having an increased surface area preferably comprising loops 28 which extend outwardly from the substrate 18. "The areas of increased surface area comprising regions 22 provide a region which promotes the ingrowth of living animal tissue for attaching and sealing the vessel to the graft." See paragraph [0032] and Figure 4 of **D24**.

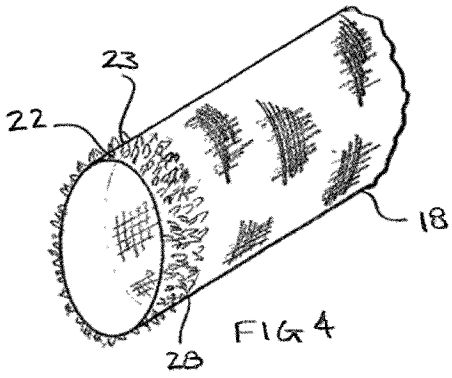


FIG 4

O2 states that being faced with the objective technical problem to mitigate paravalvular leakage in the prosthetic valve of one of **D8** (WBH9) or **D19**-**D23** (WBH12-16), "the skilled person would thus provide fibers according to feature 1.4 to the valve prostheses of WBH9/WBH12-WBH16, therefore arriving at the subject-matter of Claim 1 of the opposed patent without inventive activity". O2 leaves it at this mere allegation; specifically, O2 fails to explain why the skilled person would refer to **D24** in the first place to address paravalvular leakage, even though **D24** does not even mention a valve. There is no paravalvular leakage problem in vascular lumina, and grafts for being placed in arteries are subject to different challenges than prosthetic valves like the ones of **D8** and **D19**-**D23**, configured to be placed in the heart itself. The blood pressure acting on the valve results in stresses which are not only larger than the ones acting on a graft but also different in nature.

Regarding the above asserted combinations of **D8** or **D19**-**D23** with **D10** or **D24**, we further note that **D8** and **D19**-**D23** were all filed between 1996 and 2004. At that time, first attempts were made to provide prosthetic heart valves which could be delivered by a catheter. In a prosthetic heart valve, the valve leaflets are attached within the frame of the device and add to the size of the device, which is why the research and development of prosthetic valves focused very much on the minimum achievable size of the device in the crimped state. The modifications to the valves of D8 and D19-D23 proposed by O2 would all *add* bulk to the prosthetic valve, which would be considered undesirable by the skilled person. A skilled practitioner aiming at improving on a prosthetic valve at that time would have realized that adding further material to the outer circumference of the device would inevitably further add to the bulk of the device and would therefore have worked contrary to the ongoing attempts for size reduction. For this reason, the skilled person would have refrained from using a sleeve with outwardly extending fibers in the valve prostheses of **D8** or **D19**-**D23**.

F Novelty and inventive step - the dependent claims

It has been demonstrated that the subject matter of the independent claim 1 of the opposed patent is granted is novel and inventive. Therefore, we refrain from commenting on the dependent claims for the time being.

G Amended claims (Auxiliary Requests)

G.1 Auxiliary Request 1

In the set of claims according to Auxiliary Request 1, claim 1 specifies a valvular structure (254) *providing a flexible conduit* having an inlet and an outlet.

Figure 22 of **D15** shows "an elongated valvular structure in the form of a conduit", as also confirmed by Opponent O2. Support for the amendment is also in claim 27 of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.2 Auxiliary Request 2

In the set of claims according to Auxiliary Request 2, claim 1 specifies the compressible material as being adapted *for expansion* after deployment to fill gaps between the prosthetic valve and the body channel.

Support for the amendment is in paragraph [00145] of **D15** ("The compressible material expands after deployment at a treatment site") and also in claim 27 of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.3 Auxiliary Request 3

In the set of claims according to Auxiliary Request 3, claim 3 reads that the compressible material *is formed of polyethylene terephthalate (PET) and* has a thickness ranging from 1 to 5mm.

Support for the amendment is in paragraph [00145] of the application as filed.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.4 Auxiliary Request 4

In the set of claims according to Auxiliary Request 3, claim 8 states that the compressible material is configured to expand after deployment at a treatment site, wherein, as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue to create a mechanical seal that prevents paravalvular leakage.

Support for the amendment is in paragraph [00145] of **D15**.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.5 Auxiliary Request 5

In the set of claims according to Auxiliary Request 3, claim 9 is omitted.

The amendment addresses one of the Opponents' objections under Art. 100(c) EPC.

G.6 Auxiliary Request 6

In the set of claims according to Auxiliary Request 6, claim 1 recites a substantially cylindrical stent structure (252) configured for radial expansion *using a balloon catheter*.

Support for the amendment is throughout **D15**, specifically in paragraph [00144] thereof.

The amendment further restricts the claim against the prior art.

G.7 Auxiliary Request 7

In the set of claims according to Auxiliary Request 7, the claims relate to a prosthetic *cardiac* valve.

Support for the amendments is throughout **D15**, e.g. in paragraphs [0001] and [0087] thereof.

The amendment further restricts the claim against the prior art.

G.8 Auxiliary Request 8

In the set of claims according to Auxiliary Request 8, all amendments according to Auxiliary Requests 1-7 are combined.

G.9 Further possible Auxiliary Requests

We reserve the right to file further Auxiliary Requests at a later stage in which some, but not all amendments according to Auxiliary Requests 1-7 are combined.



/SCHÖN, Anne/
European Patent Attorney
Hoffmann Eitle
(Association No. 151)

Enclosures
Sets of claims according to eight Auxiliary Requests.

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Date
25.08.2021

Reference	OPPO 01	Application No./Patent No.
255.0051G1		15180327.7 - 1126 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

BRIEF COMMUNICATION

Subject:
- ☐ Your letter of
- ☐ Our telephone conversation of
- ☐ Communication of
- ☐

Enclosure(s):
- ☒ Letter from the proprietor of the patent of 17.8.2021
- ☐ Letter from the opponent of
- ☒ Copy (copies) EPO Form 2548

Communication:

☐ The documents specified as patent documents and as non-patent literature in this letter are available for inspection via the European Patent Register at **www.epo.org/register.** Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2020, A106).

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17 August 2021

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Dear Sirs

European Patent No. 2982337
(European Patent Application No. 15180327.7)
Edwards Lifesciences PVT, Inc.

We hereby resign our representation for the above patent which is under opposition.

Please record the new representatives who are:

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81925 Munich
Germany

Fax: +49 (89) 918356
Phone: +49 (89) 92409-0
e-mail: pm@HoffmannEitle.com

Please direct all future communications to the new representatives, indicating their file reference **238337 t2**.

Yours faithfully

EKE, Philippa Dianne
Authorised Representative

CC. Hoffmann Eitle PatmbB

Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München
ALLEMAGNE

Date
23.08.21

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of amended entries concerning the representative (R. 143(1)(h) EPC)

As requested, for the above-mentioned European patent application / European patent the entries concerning the representative have been amended as follows:

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München
DE

The amendment will be recorded in the Register of European Patents.

Important note for EPO deposit account holders

If you would like to have fee refunds credited to a deposit account held with the EPO, you should ensure that you provide clear and up-to-date refund instructions to this effect, using one of the permitted electronic means of filing (see Arrangements for deposit accounts).

For the Opposition Division

Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Formalities officer
Heim, Patrick

WBH Wachenhausen Patentanwälte PartG mbB
Müllerstraße 40
80469 München
ALLEMAGNE

Date 25.08.2021

Reference		Application No./Patent No.
272.0046OP	OPPO 02	15180327.7 - 1126 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

BRIEF COMMUNICATION

Subject:
- ☐ Your letter of
- ☐ Our telephone conversation of
- ☐ Communication of
- ☐

Enclosure(s):
- ☒ Letter from the proprietor of the patent of 17.8.2021
- ☐ Letter from the opponent of
- ☒ Copy (copies) EPO Form 2548

Communication:

☐ The documents specified as patent documents and as non-patent literature in this letter are available for inspection via the European Patent Register at **www.epo.org/register.** Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2020, A106).

☐

For the Opposition Division

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☐ **Registered letter**

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Est 1969

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WD18 0JU
United Kingdom

T: +44 (0)1923 238311
F: +44 (0)1923 246491
info@dolleymores.com

BY E-FILING

17 August 2021

Your Ref:

Our Ref:
P/14624.EPWD1:PE:
SD

Dear Sirs

European Patent No. 2982337
(European Patent Application No. 15180327.7)
Edwards Lifesciences PVT, Inc.

We hereby resign our representation for the above patent which is under opposition.

Please record the new representatives who are:

Hoffmann Eitle PartmbB
Arabellastrasse 30
81925 Munich
Germany

Fax: +49 (89) 918356
Phone: +49 (89) 92409-0
e-mail: pm@HoffmannEitle.com

Please direct all future communications to the new representatives, indicating their file reference **238337 t2**.

Yours faithfully

EKE, Philippa Dianne
Authorised Representative

CC. Hoffmann Eitle PatmbB

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European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY

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Contact Customer Services at www.epo.org/contact

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München
ALLEMAGNE

Date
23.08.21

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of amended entries concerning the representative (R. 143(1)(h) EPC)

As requested, for the above-mentioned European patent application / European patent the entries concerning the representative have been amended as follows:

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München
DE

The amendment will be recorded in the Register of European Patents.

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80298 MUNICH
GERMANY

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Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München
ALLEMAGNE

Date
23.08.21

Reference	Application No./Patent No.
238837 t2	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of amended entries concerning the representative (R. 143(1)(h) EPC)

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For the Opposition Division

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European Patent Office
Office européen des brevets

Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

Submission number	10104521
Application number	EP15180327.7
Date of receipt	17 August 2021
Receiving Office	European Patent Office, The Hague
Your reference	P/14624.EPWD1:PE
Applicant	All applicants as on file
Documents submitted	package-data.xml epf1038.pdf (1 p.) ep-sfd-request.xml CDAPPR-CHOR-1.pdf\21.08.17 - EPO.pdf (1 p.)
Submitted by	CN=John Kensett 2118
Method of submission	Online
Date and time receipt generated	17 August 2021, 14:10 (CEST)
Message Digest	CE:DC:6C:C8:D3:AA:B6:47:C9:62:CD:77:25:D5:80:0B:01:8C:AF:1C

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F: +44 (0)1923 246491
info@dolleymores.com

European Patent Office
D-80298 München
Germany

BY E-FILING

17 August 2021

Your Ref:

Our Ref:
P/14624.EPWD1:PE:
SD

Dear Sirs

European Patent No. 2982337
(European Patent Application No. 15180327.7)
Edwards Lifesciences PVT, Inc.

We hereby resign our representation for the above patent which is under opposition.

Please record the new representatives who are:

Hoffmann Eitle PartmbB
Arabellastrasse 30
81925 Munich
Germany

Fax: +49 (89) 918356
Phone: +49 (89) 92409-0
e-mail: pm@HoffmannEitle.com

Please direct all future communications to the new representatives, indicating their file reference **238337 t2**.

Yours faithfully

EKE, Philippa Dianne
Authorised Representative

CC. Hoffmann Eitle PatmbB

Europäisches Patentamt
European Patent Office
Office européen des brevets

Letter accompanying subsequently filed items

Representative:

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573
9 Rickmansworth Road
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Netherlands
Tel. +31(0)70 340-2040 | Fax -3016

10958 Berlin
Germany
Tel. +49(0)30 25901-0 | Fax -840

The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

Application number	15180327.7
Applicant's or representative's reference	P/14624.EPWD1:PE

	Description of document	Original file name	Assigned file name
1	Request for change of representative	21.08.17 - EPO.pdf	CDAPPR-CHOR-1.pdf

	Payment	
1	Method of payment	Not specified

Signatures

Place:	**Watford**
Date:	**17 August 2021**
Signed by:	**John Kensett 2118**
Association:	**Dolleymores**
Representative name:	**John Hinton Kensett**
Capacity:	**(Representative)**

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 240
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Formalities officer
Heim, Patrick

Dolleymores
9 Rickmansworth Road
Watford, Hertfordshire WD18 0JU
ROYAUME UNI

Date
10.06.2021

Reference	Application No./Patent No.
P/14624EPWD1:RK	15180327.7 - 1122 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of notices of opposition (R. 79(1) EPC)

Notices of opposition have been filed within the opposition period by:

01.
Abbott Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054
ETATS-UNIS D'AMERIQUE
02.
Neovasc Tiara Inc.
13562 Maycrest Way, Suite 5138
Richmond, BC V6V 2J7
CANADA

The notices of opposition indicated above have already been communicated to you.

You are requested to file your observations within a period of **four months** from notification of this communication.

You may also file amendments, where appropriate, to the description, claims and drawings within the period specified. One set of these documents is to be filed.

If you introduced documents which have not yet been mentioned during the proceedings, your attention is drawn to Rule 83 EPC.

Enclosures:

For the Opposition Division

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 241
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Formalities officer
Heim, Patrick

LKGLOBAL
Lorenz & Kopf PartG mbB Patentanwälte
Brienner Straße 11
80333 München
ALLEMAGNE

Date
10.06.2021

Reference		Application No./Patent No.
255.0051G1	OPPO01	15180327.7 - 1122 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

Communication of further notices of opposition pursuant to Rule 79(2) EPC

You are hereby informed pursuant to Rule 79(2) EPC of further notices of opposition. The documents specified as patent documents and as non-patent literature in the notice of opposition are available for inspection via the European Patent Register at **www.epo.org/register**. Should you wish to receive any citations in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (see OJ EPO 2020, A106).

If oral proceedings are to take place, parties are advised to check the electronic file via the European Patent Register in advance of the hearing to ensure they are in possession of all relevant documents.

A copy of the communication pursuant to Rule 79(1) EPC sent to the proprietor of the patent is also enclosed for your information.

The observations of the patent proprietor on the notice of opposition will be communicated to the opponents without delay. A time limit for reply will be fixed if the Opposition Division considers this expedient.

If no reply to a communication is received within the time limit set, the proceedings will be continued. Your attention is drawn to Article 114(2) EPC.

For the Opposition Division

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Enclosures: copy of the communication pursuant to Rule 79(1) EPC (Form 2317A)

O2 Neovasc Tiara Inc + annex

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 242
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Formalities officer
Heim, Patrick

Dolleymores
9 Rickmansworth Road
Watford, Hertfordshire WD18 0JU
ROYAUME UNI

Date
10.06.2021

Reference	Application No./Patent No.
P/14624EPWD1:RK	15180327.7 - 1122 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of notices of opposition (R. 79(1) EPC)

Notices of opposition have been filed within the opposition period by:

01.
Abbott Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054
ETATS-UNIS D'AMERIQUE
02.
Neovasc Tiara Inc.
13562 Maycrest Way, Suite 5138
Richmond, BC V6V 2J7
CANADA

The notices of opposition indicated above have already been communicated to you.

You are requested to file your observations within a period of **four months** from notification of this communication.

You may also file amendments, where appropriate, to the description, claims and drawings within the period specified. One set of these documents is to be filed.

If you introduced documents which have not yet been mentioned during the proceedings, your attention is drawn to Rule 83 EPC.

Enclosures:

For the Opposition Division

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 243
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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Notice of opposition to a European patent

I. Patent opposed

Patent No.	EP2982337
Application No.	EP15180327.7
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	26 August 2020
Title of the invention	PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

II. Proprietor of the patent

first named in the patent specification	Edwards Lifesciences PVT, Inc.
Opponent's or representative's reference	272.0046OP

III. Opponent

Name	Neovasc Tiara Inc.
Address:	13562 Maycrest Way Suite 5138 Richmond British Columbia V6V 2J7 Canada
State of residence or of principal place of business	Canada
Multiple opponents (see additional sheet)	☐

IV. Authorisation

1. Representative

	WBH Wachenhausen Patentanwälte PartG mbB	
Association No.:	786	
Address of place of business	Müllerstraße 40 80469 Munich Germany	
Telephone/Fax	+49 (0)89 9545370 30	+49 (0)89 9545370 31
E-mail:	office@wachenhausen.com	

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 244
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Additional representative(s) on additional sheet/see authorisation ☐

Authorisation(s)

is/are enclosed ☐

has/have been registered under No. ☐

V. Opposition is filed against

the patent as a whole ☒

claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

- it is not new (Art. 52(1); Art. 54 EPC) ☒
- it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒
- patentability is excluded on other grounds, namely articles ☐

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on an attached document ☒

VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 245
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

IX. Evidence presented

WBH1	Patent document	US5,258,023 (A) , 02.11.1993 original file name: WBH1_US5258023A.pdf attached as: Published-Evidence-1.pdf
WBH10	Patent document	WO2006/089236 (A1) , 24.08.2006 original file name: WBH10_WO2006089236A1.pdf attached as: Published-Evidence-10.pdf
WBH11	Patent document	US2005/0137698 (A1) , 23.06.2005 original file name: WBH11_US20050137698A1.pdf attached as: Published-Evidence-11.pdf
WBH12	Patent document	WO2004/082527 (A2) , 30.09.2004 original file name: WBH12_WO2004082527A2.pdf attached as: Published-Evidence-12.pdf
WBH13	Patent document	WO01/54625 (A1) , 02.08.2001 original file name: WBH13_WO01054625A1.pdf attached as: Published-Evidence-13.pdf
WBH14	Patent document	WO01/76510 (A2) , 18.10.2001 original file name: WBH14_WO01076510A2.pdf attached as: Published-Evidence-14.pdf
WBH15	Patent document	US2004/0210304 (A1) , 21.10.2004 original file name: WBH15_US20040210304A1.pdf attached as: Published-Evidence-15.pdf
WBH16	Patent document	US5,855,601 (A) , 05.01.1999 original file name: WBH16_US5855601A.pdf attached as: Published-Evidence-16.pdf
WBH17	Patent document	WO 03/053287 (A1) , 03.07.2003 original file name: WBH17_WO03053287A1.pdf attached as: Published-Evidence-17.pdf
WBH18	Patent document	US2002/0052649 (A1) , 02.05.2002 original file name: WBH18_US20020052649A1.pdf attached as: Published-Evidence-18.pdf
WBH2	Patent document	FR2337543 (A) , 05.08.1977 original file name: WBH2_FR2337543A1.pdf attached as: Published-Evidence-2.pdf
WBH3	Patent document	WO00/64380 (A1) , 02.11.2000 original file name: WBH3_WO0064380A1.pdf attached as: Published-Evidence-3.pdf
WBH4	Patent document	FR2815844 (A1) , 03.05.2002 original file name: WBH4_FR2815844A1.pdf attached as: Published-Evidence-4.pdf
WBH5	Patent document	EP2537487 (A1) , 26.12.2012 original file name: WBH5_EP2537487A1.pdf

		attached as: Published-Evidence-5.pdf
WBH6	Patent document	US5,554,184 (A) , 10.09.1996 original file name: WBH6_US5554184A.pdf attached as: Published-Evidence-6.pdf
WBH7	Patent document	US6,454,799 (B1) , 24.09.2002 original file name: WBH7_US6454799B1.pdf attached as: Published-Evidence-7.pdf
WBH8	Patent document	US6,638,257 (B2) , 28.10.2003 original file name: WBH8_US6638257B2.pdf attached as: Published-Evidence-8.pdf
WBH9	Patent document	US2003/0153974 (A1) , 14.08.2003 original file name: WBH9_US20030153974A1.pdf attached as: Published-Evidence-9.pdf

X. Payment

Method of payment: Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated in the fees section below.

Currency: EUR

Deposit account number: 28003089

Account holder: WBH Wachenhausen Patentanwälte PartG mbB

Refunds

Any refunds should be made to EPO deposit account: 28003089

Account holder: WBH Wachenhausen Patentanwälte PartG mbB

Fees	Factor applied	Fee schedule	Amount to be paid
010 Opposition fee	1	815.00	815.00
Total:		EUR	815.00

A Forms	Details:	System file name:
A-1 Form for notice of opposition		ep-oppo.pdf

B Attached document files	Original file name:	System file name:
B-1 1. Facts and arguments	20210525_Annex 1_Facts and Arguments_272.0046OP.pdf	OPPO.pdf
B-2 1. Any annexes (other than citation) to an opposition letter - Annex 3_Assignment	Annex 3_Assignment.pdf	OTHER-2.pdf
B-3 2. Any annexes (other than citation) to an opposition letter - Annex 2_Feature Analysis	20210525_Annex 2_Feature Analysis_272.0046OP.pdf	OTHER-1.pdf

C Attached evidence files	Original file name:	System file name:
C-1 1. Patent document	WBH3_WO0064380A1.pdf	Published-Evidence-3.pdf
C-2 2. Patent document	WBH4_FR2815844A1.pdf	Published-Evidence-4.pdf
C-3 3. Patent document	WBH5_EP2537487A1.pdf	Published-Evidence-5.pdf

C-4	4. Patent document	WBH6_US5554184A.pdf	Published-Evidence-6.pdf
C-5	5. Patent document	WBH7_US6454799B1.pdf	Published-Evidence-7.pdf
C-6	6. Patent document	WBH8_US6638257B2.pdf	Published-Evidence-8.pdf
C-7	7. Patent document	WBH9_US20030153974A1.pdf	Published-Evidence-9.pdf
C-8	8. Patent document	WBH10_WO2006089236A1.pdf	Published-Evidence-10.pdf
C-9	9. Patent document	WBH11_US20050137698A1.pdf	Published-Evidence-11.pdf
C-10	10. Patent document	WBH12_WO2004082527A2.pdf	Published-Evidence-12.pdf
C-11	11. Patent document	WBH13_WO01054625A1.pdf	Published-Evidence-13.pdf
C-12	12. Patent document	WBH14_WO01076510A2.pdf	Published-Evidence-14.pdf
C-13	13. Patent document	WBH15_US20040210304A1.pdf	Published-Evidence-15.pdf
C-14	14. Patent document	WBH16_US5855601A.pdf	Published-Evidence-16.pdf
C-15	15. Patent document	WBH17_WO03053287A1.pdf	Published-Evidence-17.pdf
C-16	16. Patent document	WBH18_US20020052649A1.pdf	Published-Evidence-18.pdf
C-17	17. Patent document	WBH1_US5258023A.pdf	Published-Evidence-1.pdf
C-18	18. Patent document	WBH2_FR2337543A1.pdf	Published-Evidence-2.pdf

Signature of opponent or representative

Place	**Munich**
Date:	**26 May 2021**
Signed by:	**Thorsten Haslinde 53075**
Association:	**WBH Wachenhausen Patentanwälte PartG mbB**
Representative name:	**Thorsten Haslinde**
Capacity:	**(Representative)**

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 249
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

WBH Wachenhausen
Patentanwälte

FACTS & ARGUMENTS

On behalf of the Neovasc Tiara Inc., 13562 Maycrest Way #5138 of Richmond, BC V6V 2J7, Canada, it is requested to revoke European Patent EP 2 982 337 B1 (in the following referred to as "opposed patent") in its entirety on the grounds of Art. 100(a) EPC, Art. 100(b) EPC and Art. 100(c) EPC. The opposed patent was granted to Edwards Lifesciences PVT, Inc., One Edwards Way, Irvine, CA 92614 (US) and is entitled "Paravalvular leak Detection, sealing, and prevention".

As an auxiliary measure, if the Patent in its entirety is not revoked on the basis of the written proceedings, oral proceedings are requested.

The opposition grounds will be substantiated in the following. The below arguments are made without prejudice to the right to adapt and supplement them in the course of the Opposition Proceedings.

1 Introduction

The opposed patent relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses (see paragraph [0001]).

The opposed patent is a first generation divisional application from the parent application with the application number EP 05769359.0 of 30 June 2005 and claims the priority of the US patent application filed on June 30, 2004 with application number US 10/883,575.

During prosecution, 5 prior art documents were cited:

WBH1	US 5,258,023 A
WBH2	FR 2 337 543 A1
WBH3	WO 00/64380 A1
WBH4	FR 2 815 844 A1
WBH5	EP 2 537 487 A1

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 250
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

The Applicant further cited the following documents in the opposed patent:

WBH6	US 5,554,184 A
WBH7	US 6,454,799 B1
WBH8	US 6,638,257 B2
WBH9	US 2003/0153974 A

In addition to the prior art documents already known from the prosecution phase, it is referred to the following documents:

WBH10	WO 2006/089236 A1
WBH11	US 2005/0137698 A1
WBH12	WO 2004/082527 A2
WBH13	WO 01/54625 A1
WBH14	WO 01/76510 A2
WBH15	US 2004/0210304 A1
WBH16	US 5,855,601 A
WBH17	WO 03/053287 A1
WBH18	US 2002/0052649 A1

2 Construction of Claim 1

The opposed patent comprises one independent device Claim 1 followed by dependent Claims 2 to 9.

Independent device Claim 1 can be structured as follows:

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 251
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

For ease of reference, the feature analysis is submitted along with this opposition brief as

Annex 2.

3 Added matter (Art. 100(c) EPC)

Applicant filed the present divisional application with a new set of claims and with the claims of the parent application as filed included as clauses at the end of the description. Applicant did not provide any kind of basis where the subject-matter of the new claims is disclosed in the parent application as filed. It appears as if Claim 1 of the opposed patent is based on Claim 27 of the parent application as filed. However, as derivable from the below marked-up version, in which Claim 1 of the opposed patent is compared to Claim 27 of the parent application as filed, Applicant has significantly amended and shifted the claims' subject-matter during prosecution of this divisional application.

Marked-up claim 1

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) ~~providing a flexible conduit~~ having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

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1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted ~~for expansion~~ after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Among other amendments, Applicant has

a) deleted that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel

b) added that the compressible material includes a plurality of fibers extending outward from the outer surface

c) deleted that the valvular structure provides a flexible conduit

d) added that the layer of compressible material forms a sleeve.

As outlined below, at least each of the amendments a)-d) add matter to the application as filed, contravening either Art. 76 EPC, Art. 123(2) EPC or both.

3.1 Amendment a): deletion of adaptation of compressible material for expansion after deployment

In Claim 27 of the parent application as filed, it is claimed that the compressible material is "*adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel*". Likewise, paragraph [0055] of the description of the parent application as filed states that the compressible material "*is configured to expand into the gaps*". The same applies to paragraph [00145] of the description of the parent application *mutatis mutandis*, stating in lines 22 to 23 that the "*compressible material expands after deployment at a treatment side. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.*"

The parent application as filed only provides support for a prosthetic valve, which comprises a compressible material adapted for expansion after

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deployment (of the cylindrical stent structure) to fill gaps between the prosthetic valve and the body channel. In other words, the parent application as filed only provides support for embodiments in which the compressible material expands to fill gaps between the prosthetic valve and the native anatomy, said expansion occurring after deployment of the prosthetic valve from the delivery device. This implies that the parent application as filed does not provide any kind of basis for a prosthetic valve with an expandable stent structure and a compressible material, the compressible material being pressed into gaps between the valve prosthesis and the native anatomy via the stent structure during deployment of the stent structure, for example.

Thus, by conducting amendment a), Applicant has deleted a feature from independent Claim 27 of the parent application, which is outlined as being essential in the parent application as filed. This constitutes a breach of Art. 123(2) EPC (see *Case Law of the Boards of Appeal, 9th edition, II-E-1.4.3*).

Furthermore, we stress that the underlying idea of Art. 123(2) EPC is that an Applicant should not be allowed to improve his/her position by adding subject-matter not disclosed in the application as filed, which would give him/her an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application (see G1/93, *Case Law of the Boards of Appeal, 9th edition, II-E-1.1*). The public may not be confronted with an extent of protection, which could not have been established by a skilled person having studied the whole content of the technical disclosure of the originally filed patent application (see e.g. T157/90 and T187/91).

As outlined in detail above, the parent application as originally filed does not provide support for a prosthetic valve having a stent, a valvular structure and a generic compressible material adapted to fill gaps between the prosthesis and the native tissue but only for such a valve prosthesis having a compressible material adapted to expand after deployment to fill said gaps between the prosthetic valve and the body channel. The latter has already been claimed in Claim 27 of the parent application as filed and the entire disclosure of the parent application does not teach any alternative. Applicant thus extended the scope

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of protection to an extent not justified by the overall disclosure damaging the legal security of third parties.

The subject-matter of Claim 1 of the opposed patent therefore contravenes the requirements of Art. 76 EPC.

3.2 Amendment b): addition that the compressible material includes a plurality of fibers extending outward from the outer surface

During prosecution, Applicant specified that the compressible material includes a plurality of fibers extending outward from the outer surface. This feature finds basis in Claim 29 of the parent application as filed but only in combination with the feature that the prosthetic valve further comprises "*a tissue growth factor disposed along the compressible material*". According to paragraph [00145] of the description of the parent application as filed, the tissue growth factor is applied to "*the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps*". This additional sealing functionality is provided by the combination of the fibers and the tissue growth factor, which are therefore functionally interlinked.

Separating the fibers from the tissue growth factor constitutes an unallowable intermediate generalization, contravening the requirements of Art. 76 EPC.

3.3 Amendments c) and d): deletion that the valvular structure provides a flexible conduit and addition that the compressible material forms a sleeve

Amendments c) and d) constitute unallowable intermediate generalizations.

Firstly, we note that the parent application as filed only provides support for a valvular structure providing a flexible conduit having an inlet and an outlet but not for a valvular structure with an inlet and an outlet having an arbitrary shape. We refer to Fig. 22 of the parent application as filed showing an elongated valvular structure in the form of a conduit. No other type of configuration of the valvular structure is disclosed in the parent application as filed.

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By deleting the feature that the valvular structure provides a flexible conduit, Applicant extended the scope of protection to an extent not justified by the overall disclosure. Amendment b) therefore contravenes the requirements of Art. 76 EPC.

Secondly, we note that the addition of the feature that the compressible material forms a sleeve constitutes an unallowable intermediate generalization. Specifically, a sleeve is only mentioned in paragraph [00145] of the parent application as filed. However, this paragraph states that the compressible material "*may extend entirely around the stent structure, such as in the form of a sleeve*". In contrast, Claim 1 of the opposed patent requires the layer of compressible material to form a sleeve.

The *Merriam Webster* dictionary defines a "*sleeve*" as "*a tubular part … designed to fit over another part*". The purpose of the sleeve is to protect the other part, i.e. the part over which it is fitted. Accordingly, a compressible material forming a sleeve of a stent structure is required to engage with the stent structure to provide covering and protection functionalities. In contrast, a compressible material in the form of a sleeve may be provided spaced apart from the stent structure, for example.

It is not directly and unambiguously derivable from the parent application that the compressible material actually forms a sleeve – that it exhibits a configuration and is adapted to the remaining parts of the prosthesis so as to provide covering and protection functionalities. In contrast, the parent application as filed merely provides support for a compressible material extending around the stent structure in the form of a sleeve but not of a compressible material which actually forms a sleeve.

Claim 1 of the opposed patent therefore contravenes the requirements of Art. 76 EPC. For the sake of completeness, we note that amending Claim 1 by specifying that the compressible material is extending around the stent in the form of a sleeve to overcome the Art. 76 EPC objection, Proprietor would broaden the scope of protection contravening the stipulations of Art. 123(3) EPC.

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3.4 Lack of basis of other parts of the disclosure

Furthermore, the subject-matter of dependent Claims 2, 3, 4 and 9 is not directly and unambiguously derivable from the parent application as filed. In detail:

- Claim 2: It is not directly and unambiguously derivable from the parent application that the sleeve may surround an inflow end of the stent structure. In fact, the term "inflow" is not used at any point in the parent application as filed. Likewise, it is not directly and unambiguously derivable from Fig. 22 of the parent application as filed that the sleeve surrounds the inflow end since the inflow of the stent structure is not visible in Fig. 22.

- Claim 3: The feature that the compressible material exhibits a thickness ranging from 1 to 5 mm is only mentioned in paragraph [00145] of the parent application. However, it is only disclosed in combination with the compressible material being formed of polyethylene terephthalate (PET). There is no teaching in the entire parent application of a compressible material having a thickness ranging from about 1 to 5 mm that is formed from any other type of material. Claim 3 of the opposed patent therefore constitutes an unallowable intermediate generalization.

- Claim 4 of the opposed patent specifies that the compressible material comprises a cloth or fabric. This feature is also only mentioned in paragraph [00145] of the parent application as filed. However, said paragraph only discloses that the compressible material resembles a cloth or fabric having small fibers extending from the surface of the material. Claim 4 of the opposed patent thus constitutes an unallowable intermediate generalization since it only requires the compressible material to comprise a cloth of fabric while the parent application as filed requires the compressible material to resemble a cloth of fabric having small fibers.

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- Claim 8 of the opposed patent specifies the compressible material to be configured to expand into gaps. However, said claim does not specify at what point in time the compressible material is configured to expand into gaps during the delivery process of the prosthetic valve. As outlined in detail under section 3.1 above, the parent application as filed merely provides basis for a compressible material being adapted for expansion after deployment to fill gaps. As the specification of the point in time for the expansion of the compressible material is lacking in Claim 8 of the opposed patent, it constitutes an unallowable intermediate generalization which contravenes Art. 76 EPC.

- Claim 9 specifies the compressible material to be configured to adjust to the shape of the cavity existing between the valve and the wall of the body vessel upon stent opening. It appears as if the subject-matter of Claim 9 is ought to be directed to an embodiment in which the compressible material is passively introduced into gaps between the prosthetic valve in the body channel via the radially expanding stent structure. We have outlined in detail under section 3.1 above that such an embodiment does not find any kind of basis in the parent application as filed. Claim 9 of the opposed patent therefore contravenes the requirements of Art. 76 EPC.

Finally, we note that the parent application was filed with a provisional set of drawings while the opposed patent was filed with a substituted set of formal drawings. The provisional drawings originally filed with the parent application and the substituted formal drawings originally filed with this divisional application deviate in multiple aspects, thereby adding subject-matter against the stipulations of Art. 76 EPC.

Specifically, as derivable from a comparison of Fig. 22 of the provisional drawings of the parent application and Fig. 22 of the substituted formal drawings of this divisional application illustrated side-by-side below, the compressible material (256, Fig. 22) of the substituted formal drawing exhibits a plurality of components, which appear to be the claimed fibes. Said components are not depicted in Fig. 22 of the provisional drawings. Instead, the compressible

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material of Fig. 22 of the provisional drawings exhibits a continuous and uniform planar outer surface. Accordingly, Fig. 22 of the opposed patent as originally filed provides the skilled person with additional information not derivable from Fig. 22 of the parent application as filed. Similar objections apply to Fig. 2B, Fig. 3, Figs. 5C and D, Figs. 8C and D, Fig. 10E, Figs. 11C and D, Figs. 13A and B, Fig. 15A, Fig. 16A, Fig. 17B, Fig. 19D, Fig. 20A as well as Figs. 20E and 20G.

Also because of these reasons, the subject-matter of the opposed patent contravenes the requirements of Art. 76 EPC.

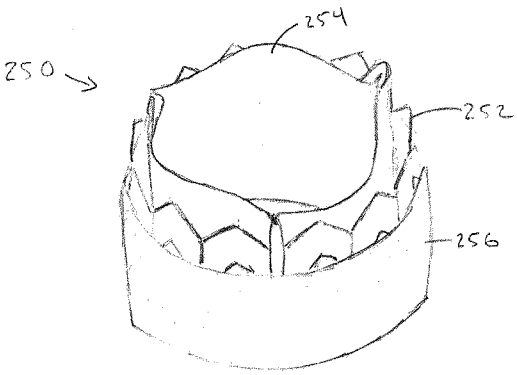


Fig 22 as filed of parent

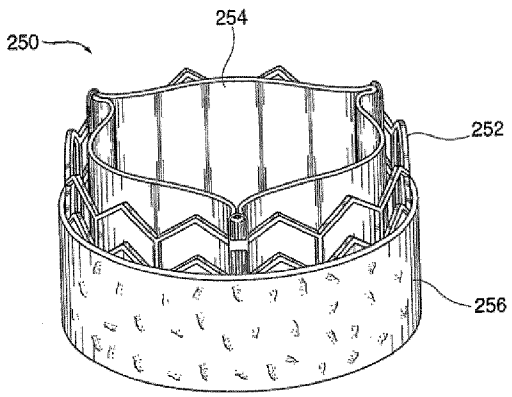


Fig. 22 as filed of divisional

4 Insufficiency (Art. 100(b) EPC)

Claim 1 of the opposed patent requires the compressible material to be adapted after deployment to fill gaps between the prosthetic valve and the body channel (feature 1.3). According to paragraph [0064] of the opposed patent, "*the compressible material creates a mechanical seal that prevents paravalvular leakage*". The skilled person therefore takes from feature 1.3 that the compressible material is compressed against the tissue of the native anatomy. At the same time, feature 1.4 of Claim 1 of the opposed patent requires the compressible material to comprise fibers extending outward from the outer surface.

The skilled person is provided with contradictory teaching. The compressible material and therefore also the fibers are supposed to be compressed against

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the native anatomy, implying that the fibers are bent to not extend outward from the outer surface. However, in contradiction with this teaching of feature 1.3, feature 1.4 requires the fibers to extend outward the outer surface.

Neither the disclosure of the opposed patent nor the common general knowledge provides the skilled person with any kind of teaching on how this contradictory teaching can be resolved and the invention can be put into practice over the whole area claimed without undue burden and without requiring inventive activity.

Due to the above, the opposed patent does not fulfil the requirements of Art. 83 EPC.

5 Lack of patentability (Art. 100(a) EPC)

The opposed patent lacks novelty over several prior art documents not considered during prosecution – inter alia since the priority of the opposed patent is not validly claimed. In addition, also some of the prior art documents cited during prosecution are prejudicial to novelty of the opposed patent. Besides, the opposed patent lacks an inventive step.

5.1 Priority not validly claimed

The opposed patent does not validly claim the priority due to formal reasons and due to the subject-matter of the claims of the opposed patent not being directly and unambiguously derivable from the priority application.

5.1.1 Priority claim invalid due to formal reasons

Pursuant to Art. 87(1) EPC, a right of priority originates in the Applicant of a first application. However, pursuant to the same provision, the right of priority may also be invoked by the "successor in title" of the person who has filed the first application. It is generally accepted that the right of priority is transferable. However, according to well established case law of the Boards of Appeal, the transfer must have occurred before the filing date of the subsequent application

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(see e.g. T 1201/14). The Boards of Appeal confirmed in T 577/11 that a succession in title that occurred after the filing date of the subsequent application was not sufficient to comply with the requirements of Art. 87(1) EPC.

The priority application of the opposed patent, US 10/883,575 filed on June 30, 2004, was filed with the Inventors as Applicant. The latter already becomes evident from the matter of fact that all US patent applications prior to the American Invents Act (AIA) in 2011 had to be filed with the Inventors as Applicant. The filing date of the opposed patent is of course the filing date of the PCT application with the publication number WO 2006/005015 from which the opposed patent's parent derives. WO 2006/005015 was filed on June 30, 2005 in the name of Edwards Lifesciences PVT, Inc. In view of the above outlined requirements, for the priority to be validly claimed, the right to priority must have been validly transferred to the Applicant of the opposed patent, i.e. Edwards Lifesciences PVT, Inc., prior to the filing date of the opposed patent.

This is not the case. As derivable from the attached assignment, which we enclose as

Annex 3,

the right to priority was only transferred from the Inventors to the predecessor in title, the proprietor of the opposed patent, in April/May 2007 and, thus, after filing of the opposed patent.

In view of the above, the opposed patent does not validly claim the priority since the Applicant/Proprietor of the opposed patent was not entitled to the priority right at the time of filing of the opposed patent.

5.1.2 Subject matter of Claim 1 not disclosed in priority application

Furthermore, we note that the subject-matter of Claim 1 of the opposed patent is not directly and unambiguously derivable from the priority document (US 10/883,575). We note that Art. 87(1) EPC stipulates that the subject-matter of a claim is only entitled to priority in respect of "the same invention" as was

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disclosed in the previous application. The Enlarged Board of Appeal has decided in the landmark decisions G 3/93 and G 2/98 that for assessing the "same invention" requirement, the "Gold standard" disclosure test must be applied. The latter implies that priority of a claim is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the priority application as a whole. This has been confirmed by the decisions of the Enlarged Board of Appeal G 1/03, G 2/03, G 2/10 and G 1/16.

The subject-matter of Claim 1 of the opposed patent relates to a prosthetic valve with a cylindrical stent structure, a valvular structure with three leaflets and a layer of compressible material having a plurality of fibers adapted to fill gaps between the prosthetic valve and a body channel. The compressible material is disposed on an outer surface of the stent structure and extends entirely around the stent structure. Only the embodiment of Fig. 22 of the opposed patent, which is described in paragraphs [0063] to [0064], relates to such a prosthetic valve having a stent, a valvular structure with three leaflets and a layer of compressible material extending around the outer surface of the stent structure. However, the configuration illustrated in Fig. 22 and described in the above listed passages of the description is missing in the priority document. In fact, if any, the priority document only shows configurations according to Figs. 1 to 19 of the opposed patent. A compressible material being provided on the outer surface of the stent, in particular a compressible material comprising a plurality of fibers, is not disclosed in the priority document whatsoever. Likewise, the priority document does not disclose a valvular structure having three leaflets.

In view of the above, for the subject-matter of the claims of the opposed patent, the priority is not validly claimed since it is not directly and unambiguously derivable from the priority document.

5.2 Lack of novelty over WO 2006/089236 A1 (WBH10)

WBH10 was filed on February 18, 2006 and validly claims a priority of February 18, 2005. Since the opposed patent does not validly claim the priority (see 5.1.1 and 5.1.2 above) and WBH10 validly entered the EP regional phase,

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WBH10 constitutes prior art according to Art. 54(3) EPC in line with Rule 165 EPC.

WBH10 relates to an apparatus (10, Fig. 4) having an expandable support member (40, Fig. 4) – a stent – and a prosthetic valve (page 5, lines 23 to 25). According to page 22, lines 8 to 11, the apparatus may be delivered "with a percutaneous approach". Furthermore, according to page 5, lines 25 to 28, the support member "*has a known stent configuration that allows it to be collapsed and expanded*" and may be made from "*shape memory materials such as Nitinol*". Accordingly, WBH10 discloses features **1** and **1.1**. Features 1 and 1.1 are also directly and unambiguously derivable from the priority document of WBH10 (see page 8, lines 1 to 6, page 14, lines 4 to 8 and Fig. 2).

Furthermore, as described on page 21, line 13 to page 22, line 7, the apparatus may comprise "a tri-leaflet" prosthetic valve (12b, Fig. 12 illustrated below) having an inlet and an outlet, which may be made of a biological material (page 21, line 23) and/or a biocompatible material (page 21, line 26), both of which constituting a pliant material. According to page 21, lines 14 to 15, the apparatus of Fig. 12 is, besides having such a "tri-leaflet" configuration, constructed as the apparatus of Figs. 2 to 8. According to page 8, lines 6 to 8, the prosthetic valve is secured "*by sutures or other suitable means*" within the support member (40, Fig. 4). Accordingly, WBH10 also discloses feature **1.2**. Feature 1.2 is also directly and unambiguously derivable from the priority document of WBH10 (see page 13, line 16 to page 14, line 2, page 10, lines 13 to 21, Fig. 7).

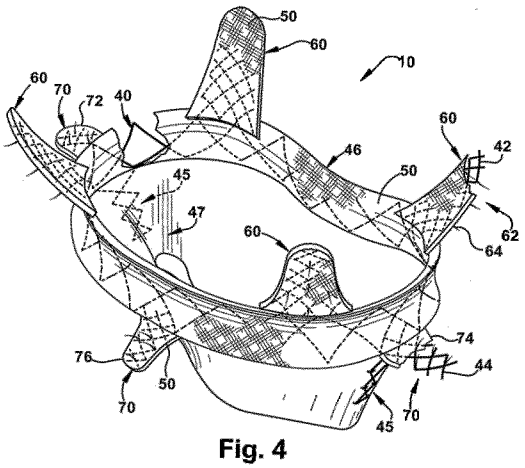


Fig. 4

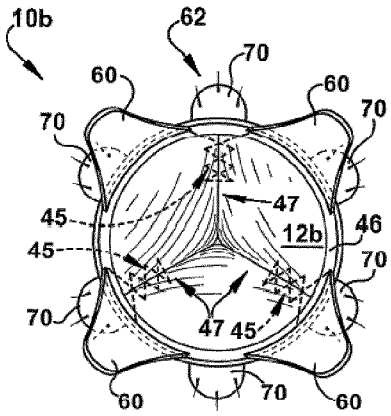


Fig. 12

Finally, we note that the device of WBH10 may include a layer of biocompatible material (50, Fig. 4), which can cover the outside surface of the support member (40, Fig. 4) (see page 6, lines 10 to 12) and which may be attached around the entire circumference of the support member (40, Fig. 4) (see page 6, lines 12 to 13). The layer (50, Fig. 4) may be "*a synthetic such as Dacron, Gore-Tex, woven velour, polyurethane, polytetrafluorethylene (PTFE), or heparin-coated fabric. Alternatively, the layer 50 may be a biological material such as bovine or equine pericardium, peritoneal tissue, an allograft, a homograft, patient graft, or a cell-seeded tissue*" (see page 6, lines 5 to 9). Accordingly, the layer (50, Fig. 4) is suitable to fill gaps between the prosthetic valve in the body channel and comprises a plurality of fibers (e.g. when being made from woven velour), therefore constituting a compressible material according to features **1.3** and **1.4**. Features 1.3 and 1.4 are also directly and unambiguously derivable from the priority document (see page 8, line 13 to page 9, line 2).

In view of the above, the subject-matter of Claim 1 of the opposed patent is not novel over WBH10.

5.3 Lack of novelty over US 2005/0137698 A1 (WBH11)

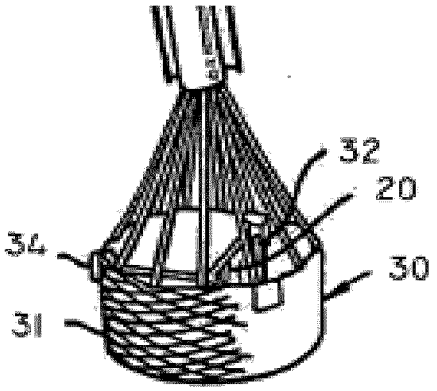
WBH11 is a US patent application published on June 23, 2005 and, thus, prior to the filing date of the opposed patent. Since the opposed patent does not validly claim the priority (see 5.1.1 and 5.1.2), WBH11 constitutes prior art according to Art. 54(2) EPC.

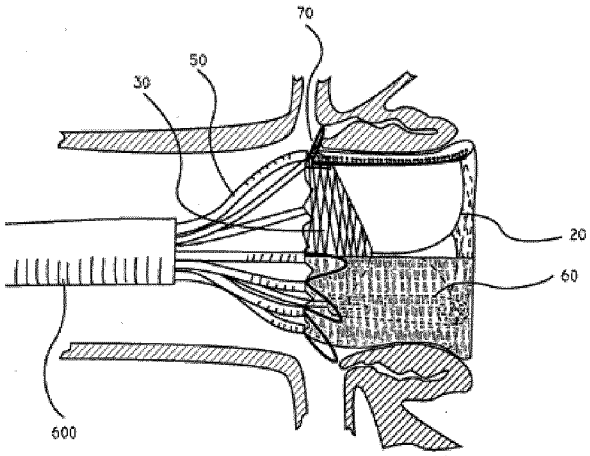
WBH11 relates to a prosthetic valve for percutaneous implantation in a body channel (see paragraph [0002]), which includes an expandable anchor and a replacement valve (see paragraph [0013]). The anchor (30, Fig. 1B illustrated below) may be self-collapsing and/or self-expanding and may be made out of a shape memory material, such as Nitinol as described in paragraph [0036]. The replacement valve (20, Fig. 1B illustrated below) can be composed of "a metal, a synthetic material and/or may be derived from animal tissue" as described in the last three lines of paragraph [0035]. Furthermore, as shown in Fig. 1B and as described in paragraph [0035], the replacement valve (20, Fig. 1B) comprises

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three commissure attachments secured at three posts of the anchor. The matter of fact that the replacement valve comprises three commissure attachments implies to that it also comprises three leaflets as a commissure attachment is provided at the interface of two leaflets. Accordingly, WBH11 discloses features **1, 1.1** and **1.2**.

Furthermore, as described in paragraph [0071] of WBH11, anchor (30, Fig. 8C illustrated below) may be "*externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric*."





As described in paragraph [0073] of WBH11, seal (60, Fig. 8C) can be bunched up and create pleats, which "*pleats can then fill pockets thereby improving the paravalvular seal*". Accordingly, we note that seal (60, Fig. 8C) of WBH11 constitutes a compressible material adapted to fill gaps between the prosthetic valve and the body channel. Therefore, feature **1.3** is disclosed in WBH11. Finally, we note that a seal composed of a fabric comprises a plurality of fibers, some of which also always extending outward from the outer surface. Accordingly, WBH11 also discloses feature **1.4**.

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In view of the above, the subject-matter of Claim 1 also lacks novelty over WBH11.

5.4 Lack of novelty over WO 2004/082527 A2 (WBH12)

WBH12 is an International patent application published on September 30, 2004 and constitutes prior art according to Art. 54(2) EPC since the opposed patent does not validly claim its priority.

WBH12 discloses a prosthetic heart valve that can be implanted in a minimally invasive manner (see paragraph [0014]) comprising a support frame (50, Fig. 5 illustrated below), which may be "*elastic*", e.g. manufactured from a Nitinol alloy (see paragraph [0066]). The valve comprising three flexible leaflets is attached within the support frame (see paragraph [0057]). Accordingly, WBH13 discloses features **1, 1.1** and **1.2**.

Fig. 3A

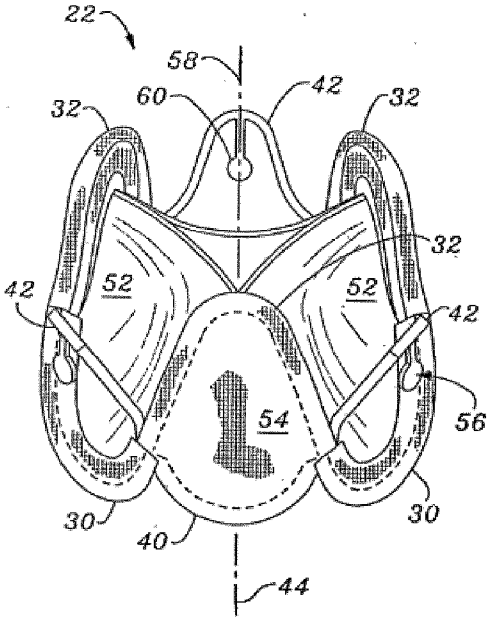
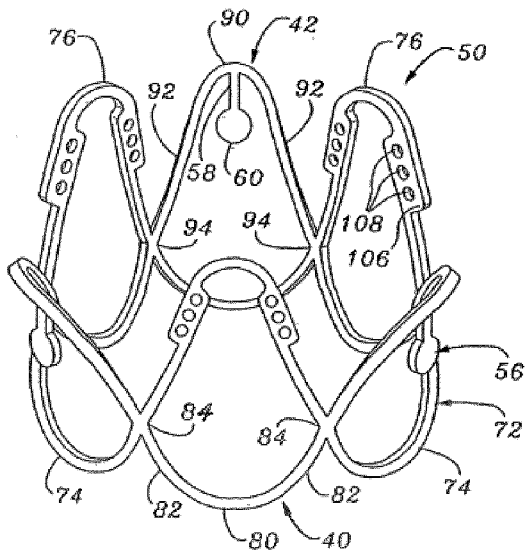


Fig. 5



In addition, the prosthetic heart valve comprises an exterior layer of a fabric, e.g. polyethylene terephthalate providing "*a matrix into which surrounding tissue can grow to help anchor the valve in place*" (see paragraph [0056]). The same

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paragraph states that the exterior layer of fabric covers the entire support frame. As the fabric made from polyethylene terephthalate exhibits a matrix-like structure, it must comprise fibers, some of which extending outward from the outer surface. Thus, WBH13 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH12.

5.5 Lack of novelty over WO 01/54625 A1 (WBH13)

WBH13 is an International patent application published on August 02, 2001 and, thus, constitutes prior art according to Art. 54(2) EPC.

WBH13 discloses a prosthetic valve for percutaneous implantation in a body channel (see Claims 1, 26 and 34) having a self-expanding stent (see Claim 2) (20, Fig. 15 illustrated below) and a valve, which may exhibit three leaflets (column 5, lines 9 to 12). Accordingly, WBH13 discloses features **1, 1.1** and **1.2**.

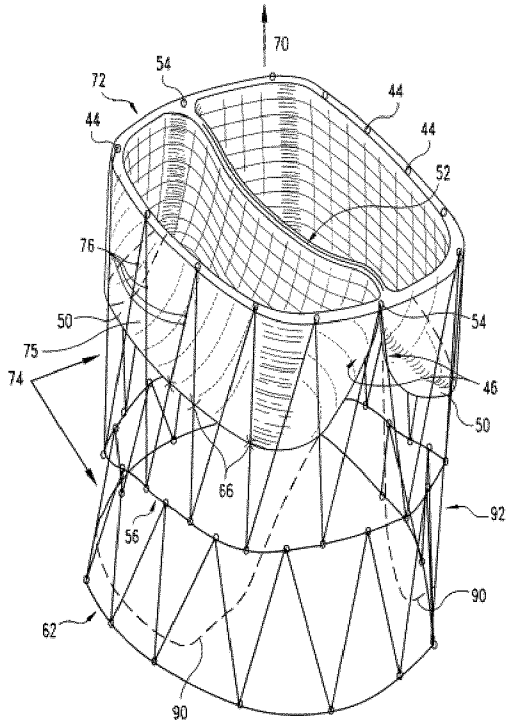


Fig. 15

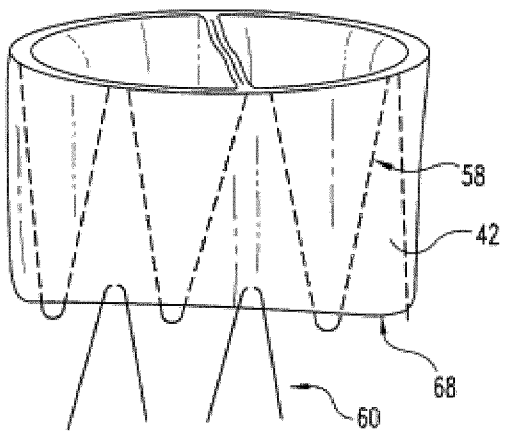


Fig. 13A

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Furthermore, as described in the last paragraph on page 7, excess material of the valve material "*can be kept outside the stent, which will later become a potential fold-over 42*". As described in the third paragraph on page 15, "*the external surface of the frame can be covered with a sheath that is not necessarily the same material as the valve 41. For example, while the valve can be a naturally occurring material, the outer sheath can be synthetic material such as described herein. The sheath, therefore, can be the fold-over of the valve material, another type of naturally occurring material, or a synthetic material. Accordingly, the sheath may partially or totally cover the frame*". The second paragraph of page 8 provides examples of the type of material from which the sheath may be manufactured and explicitly names PET, PP, PTFE or any polymer or derivative thereof as well as Gore-Tex, Dacron or other any synthetic material. As described in lines 6 to 11 of page 17, the fold-over or sheath may include "*barbs, hooks, adhesives, notches, a textured surface, or any other treated surface that facilitates relative affixation of the device in its location*". Accordingly, WBH13 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH13.

5.6 Lack of novelty over WO 01/76510 (WBH14)

WBH14 is an International patent application published on October 18, 2001 and, thus, constitutes prior art according to Art. 54(2) EPC.

WBH14 discloses a prosthetic valve for percutaneous implantation in a body channel (see title and Claims 35 to 39) comprising a substantially cylindrical stent structure for radial expansion (flexible tubular member 42 and support stent 24, Fig. 1, page 7, lines 26 to 28). Furthermore, as derivable from Fig. 2 of WBH14 illustrated below, the prosthetic valve comprises a valvular structure being formed of a pliant material and forming three valve leaflets (82, Fig. 2 illustrated below, page 11, lines 4 to 6).

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In addition, we note that the heart valve may comprise a fabric section (34, Fig. 2 illustrated below), which may be "*a woven polyester, such as polyethylene terephthalate. Alternatively, the fabric section 34 may be formed of polytetrafluorethylene (PTFE), or other suitable biocompatible sheet material*" (see page 8, line 30 to page 9, line 1). As described on page 8, lines 21 to 23, the fabric section may be formed as a tube extending entirely around the stent structure. As described on page 12, lines 8 to 9, the fabric section (34, Fig. 2 illustrated below) is compressible to be compressed against the host annulus. Accordingly, WBH14 also discloses feature **1.3**. We also note that feature **1.4** is disclosed by WBH14 since the fabric section may be formed from a woven polyester, therefore exhibiting fibers, which inevitably extend outward from the outer surface.

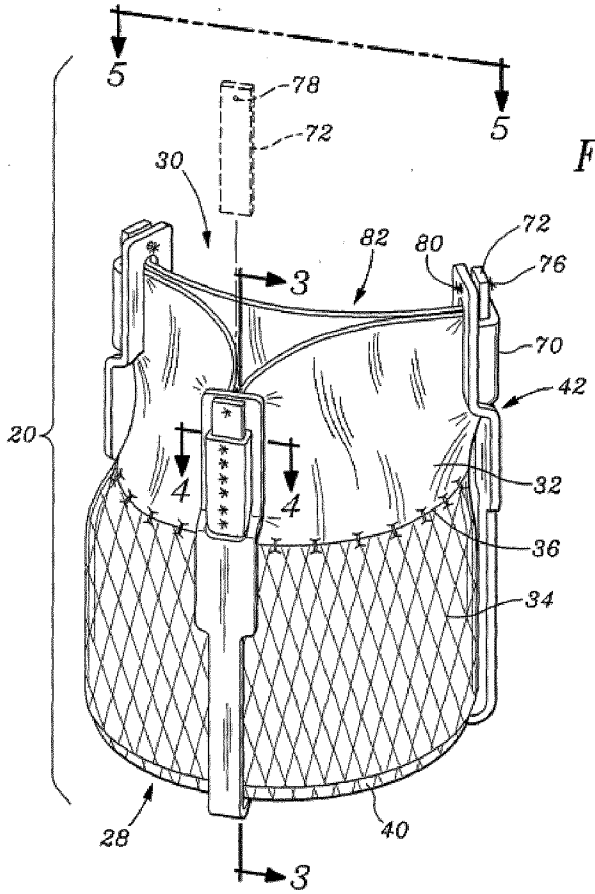


Fig. 2

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH14.

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5.7 Lack of novelty over US 2004/0210304 A1 (WBH15)

WBH15 is a US patent application published on October 21, 2004 and constitutes prior art according to Art. 54(2) EPC since the opposed patent does not validly claim its priority.

WBH15 discloses a device for replacing a heart valve by a percutaneous route (see paragraph [0106]) which comprises a support structure (101, Fig. 14 illustrated below) containing a valve (102, Fig. 14 illustrated below) (see paragraph [0115]). As described in paragraph [0116], the support structure can be made from a material with shape memory characteristics, such as Nitinol. The valve (102, Fig. 14) is provided inside of the support structure and may be connected to the support structure by sutures or other appropriate means of attachment (see paragraph [0116]). Thus, WBH14 discloses features **1, 1.1** and **1.2.**

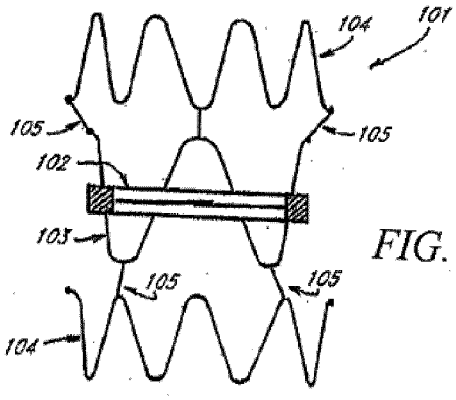
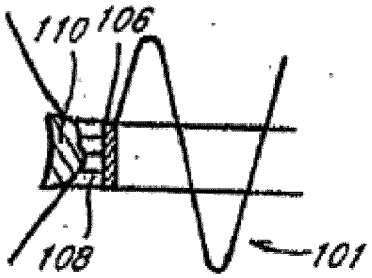


FIG. 14

FIG. 29



As described in paragraph [0115], the support structure (101, Fig. 14) comprises a shell (108, Fig. 29 illustrated above) made from a compressible material. As described in paragraph [0121] under reference to Fig. 29 illustrated above, the compressible material (108, Fig. 29) "*can absorb the surface irregularities possibly existing at or near ring 110, which results from calcifications*". Paragraph [0026] of WBH15 discloses that the sealing means "*can consist of a peripheral shell made from a compressible material such as polyester or tissue … This sealing means can also include a material that can be applied between the existing cardiac ring and the axial valve support portion, this material being*

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capable of solidifying after a predetermined delay following this application.". Thus, WBH15 also discloses features **1.3** and **1.4.**

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH15.

5.8 Lack of novelty over US 5,855,601 (WBH16)

WBH16 was published on January 5, 1999 and, thus, constitutes prior art according to Art. 54(2) EPC. WBH16 relates to a heart valve prosthesis, which may be implanted percutaneously comprising a stent member and a valve means (see column 2, lines 55 to 60). According to column 3, lines 52 to 55, "*the stent member is self-expanding and has a first cylindrical shape in its compressed or collapsed configuration and a second, larger cylindrical shape in its expanded configuration*". According to column 3, lines 55 to 57 and column 4, lines 1 to 3, the valve means is flexible and may contain three leaflets (stent member 32, valve member 35 with leaflets 36 and cuff portion 37, Fig. 4 illustrated below).

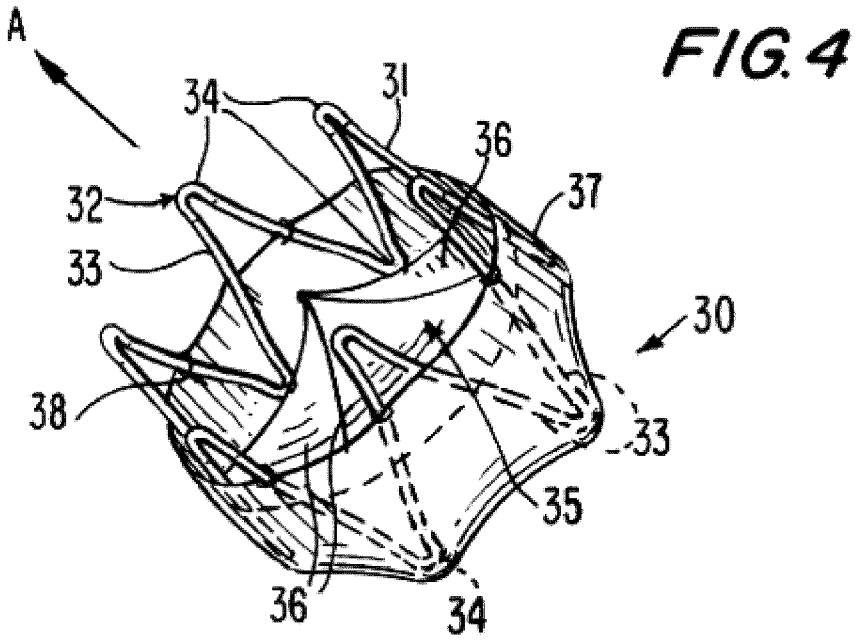


FIG. 4

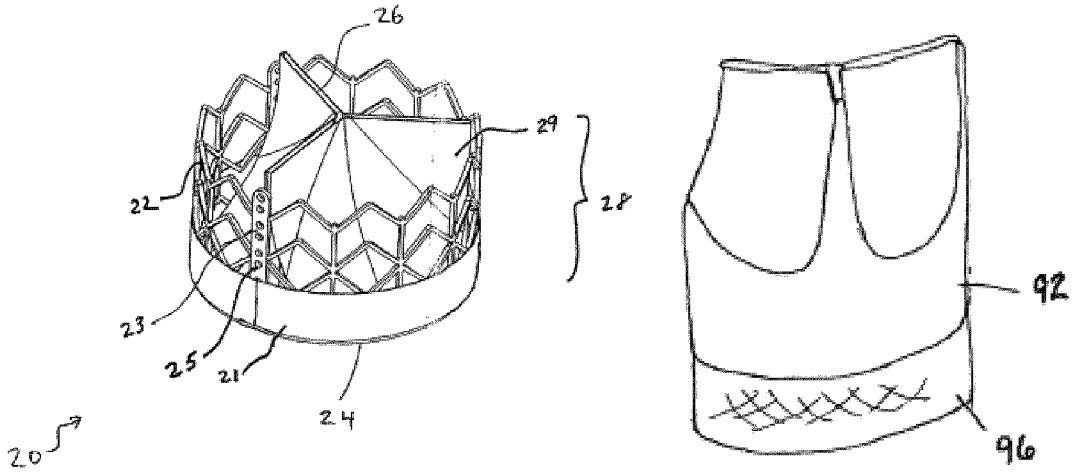
Furthermore, as described in column 4, lines 4 to 6, the valve means further comprises a cuff portion, which may extend wholly around the outer perimeter of the stent member. According to Claim 1 of WBH16, the cuff portion is configured "*to position the valve snugly and sealingly at a valve side*". As described in column 6, lines 19 to 31, the "*valve member is flexible, compressible, host-compatible, and non-thrombogenic*", wherein biocompatible materials "*such as polytetrafluorethylene, polyester and the like may be used*". Accordingly, the cuff portion, which constitutes part of the valve member, is compressible and adapted to fill gaps between the prosthetic valve and the body channel and comprises fibers extending outward. Therefore, WBH16 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH16.

5.9 Lack of novelty over US 2003/0153974 A1 (WBH9)

WBH9 is a US patent application published on August 14, 2003 and, thus, constitutes prior art according to Art. 54(2) EPC. WBH9 is cited in paragraph [0009] of the opposed patent. As explicitly stated in paragraph [0009] of the opposed patent, WBH9 discloses a prosthetic device suitable for implantation in body ducts, the device comprising a support stent "*of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radially forces from within by means of a deployment device to a deployed state in the target location*". The support stent comprises a "*valve assembly comprising a flexible conduit having an inlet and an outlet, made of pliant material attached to the support stent*". Accordingly, WBH9 discloses features **1, 1.1** and **1.2.**

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In paragraph [0010] of the opposed patent, it is stated that WBH9 does not address leaks that can occur around the implanted valve. This is not correct. According to paragraph [0112] of WBH9, the valve assembly may exhibit "*a rolled sleeve, which enhances the sealing of the device at the valve inlet*". This rolled sleeve is indicated with reference sign 24 in Fig. 1 and reference sign 96 in Fig. 8A, both figures being illustrated side-by-side above. As described in paragraph [0118] of WBH9, the sleeve may be made from PET, therefore constituting a compressible material in line with feature **1.4**. Furthermore, we note that the PET sleeve comprises fibers, some of which extending outward from the outer surface. Thus, WBH9 also discloses feature **1.5**.

In view of the above, the subject-matter of Claim 1 of the opposed patent is also not novel over WBH9.

5.10 Lack of inventive step starting from WBH9/WBH12-WBH16 in combination with WO 03/053287 A1 (WBH17) or US 2002/0052649 A1 (WBH18)

Should the Opposition Division, for any reason, be of the opinion that one of documents WBH9 and WBH12-WBH16 does not disclose feature 1.4, i.e. that the compressible material includes a plurality of fibers extending outward from the outer surface, we note that the subject-matter of Claim 1 of the opposed patent lacks an inventive step over WBH9 or either one of documents WBH12-WBH16 in combination with either WBH17 or WBH18.

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The technical effect of feature 1.4 is derivable from paragraphs [0011], [0025] and [0064] of the opposed patent and is directed to the mitigation of paravalvular leakage.

Starting from either one of WBH9 and WBH12-WBH16, the objective technical problem is thus the mitigation of paravalvular leakage.

WBH17 was published on July 3, 2003 and WBH18 on May 2, 2002. Therefore, both documents constitute prior art according to Art. 54(2) EPC. When being confronted with the above technical problem, the skilled person learns from both documents that providing fibers extending outward from the outer surface of the stent structure mitigates paravalvular leakage.

For WBH17, we refer to column 1, lines 18-20 already stating that it "*is known that tufts of fibrous material may be placed on grafts to enhance blood clotting*". Furthermore, we refer to Fig. 4 of WBH17 illustrated below showing a stent graft comprising a "*band of fibrous material 25 provided by brushing or similar means to raise fibres 26 from the material of the graft 1*" (see column 6, lines 7-8). As described in lines 23.26 of column 5, this provides the technical effect that leakage around the device is prohibited.

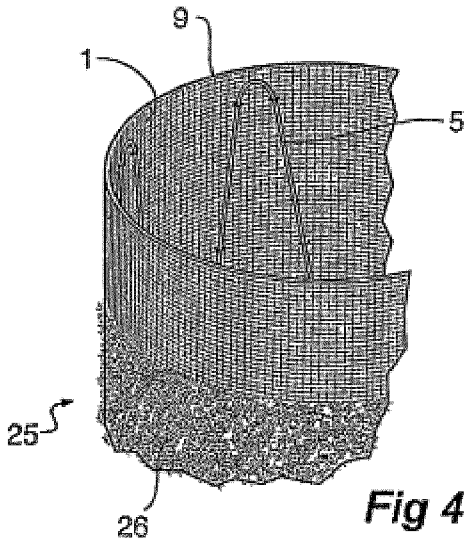


Fig 4

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For WBH18, we refer to Fig. 4a illustrated below showing a stent graft comprising a tissue engaging region 22 with a "*textured surface 23 having increased surface area. The increased surface area preferably comprises loops 28 which extend outward from the substrate 18*" (see paragraph [0032]). According to the last two lines of paragraph [0032] of WBH18, this enhances sealing.

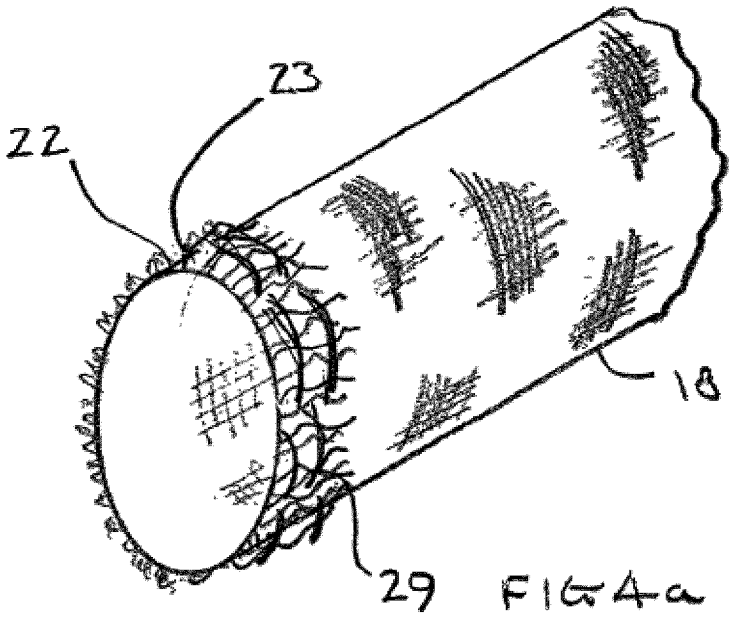


FIG 4a

When being confronted with the above stated objective technical problem of mitigating paravalvular leakage, the skilled person would thus provide fibers according to feature 1.4 to the valve prostheses of WBH9/WBH12-WBH16, therefore arriving at the subject-matter of Claim 1 of the opposed patent without inventive activity.

Therefore, the subject-matter of Claim 1 of the opposed patent also lacks an inventive step over WBH9 or either one of documents WBH12-WBH16 in combination with WBH17 or WBH18.

5.11 Lack of patentability of dependent claims

Also the dependent claims lack novelty and/or inventive step as outlined in the following:

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- dependent Claim 2: not novel over WBH10 (see Fig. 4), WBH11 Fig. (see Fig. 8C), WBH12 (see Fig. 3a), WBH13 (see Fig. 13A), WBH14 (see Fig. 2), WBH16 (see Fig. 4), WBH9 (see 1).
- dependent Claim 3: not novel over WBH10-WBH16 and WBH9. We note that the burden of proof that the prior art does not exhibit parameter lies with Proprietor. No benefit of doubt can be accorded if the Proprietor does not provide respective evidence support (see T 1764/06).
- dependent Claim 4: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above).
- dependent Claims 5 and 6: not novel over at least WBH10 (see page 15, last paragraph), WBH13 (see page 19, line 27) and anticipated by WBH1 (see column 5, line 60).
- dependent Claim 7: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above) – all of the fibers must be curved since they collectively form a tube-shaped covering.
- dependent Claim 8: not novel over at least WBH15 (see paragraph [0026] – "sealing means ... in the form of an inflatable insert").
- dependent Claim 9: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above) – all of the coverings are suitable to be adjusted in shape to cavities existing between the valve and the wall of the body vessel.

Consequently, the request for revocation of the patent in its entirety is justified at least due to the facts and arguments presented above.

-electronically signed-

Thorsten Haslinde
European Patent Attorney
WBH Wachenhausen Patentanwälte PartG mbB
Association 786

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Enclosures

WBH1 US 5,258,023 A

WBH2 FR 2 337 543 A1

WBH3 WO 00/64380 A1

WBH4 FR 2 815 844 A1

WBH5 EP 2 537 487 A1

WBH6 US 5,554,184 A

WBH7 US 6,454,799 B1

WBH8 US 6,638,257 B2

WBH9 US 2003/0153974 A

WBH10 WO 2006/089236 A1

WBH11 US 2005/0137698 A1

WBH12 WO 2004/082527 A2

WBH13 WO 01/54625 A1

WBH14 WO 01/76510

WBH15 US 2004/0210304 A1

WBH16 US 5,855,601

WBH17: WO 03/053287 A1

WBH18: US 2002/0052649 A1

Annex 2: Feature analysis Claim 1

Annex 3: Assignment

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Annex 2
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

WBH Wachenhausen
Patentanwälte

Feature analysis of independent Claim 1 of EP 2 982 337 B1

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

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European Patent Office
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European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

WBH Wachenhausen Patentanwälte PartG mbB
Müllerstraße 40
80469 München
ALLEMAGNE

Formalities officer
Heim, Patrick

Date
10.06.2021

Reference		Application No./Patent No.
272.0046OP	OPPO02	15180327.7 - 1122 / 2982337
Applicant/Proprietor		
Edwards Lifesciences PVT, Inc.		

Communication of further notices of opposition pursuant to Rule 79(2) EPC

You are hereby informed pursuant to Rule 79(2) EPC of further notices of opposition. The documents specified as patent documents and as non-patent literature in the notice of opposition are available for inspection via the European Patent Register at **www.epo.org/register**. Should you wish to receive any citations in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (see OJ EPO 2020, A106).

If oral proceedings are to take place, parties are advised to check the electronic file via the European Patent Register in advance of the hearing to ensure they are in possession of all relevant documents.

A copy of the communication pursuant to Rule 79(1) EPC sent to the proprietor of the patent is also enclosed for your information.

The observations of the patent proprietor on the notice of opposition will be communicated to the opponents without delay. A time limit for reply will be fixed if the Opposition Division considers this expedient.

If no reply to a communication is received within the time limit set, the proceedings will be continued. Your attention is drawn to Article 114(2) EPC.

For the Opposition Division

Europäisches Patentamt • European Patent Office • Office européen des brevets •

Enclosures: copy of the communication pursuant to Rule 79(1) EPC (Form 2317A)
O1 Abbott Cardiovascular Systems, Inc. + annex

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GERMANY

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Formalities officer
Heim, Patrick

Dolleymores
9 Rickmansworth Road
Watford, Hertfordshire WD18 0JU
ROYAUME UNI

Date
10.06.2021

Reference	Application No./Patent No.
P/14624EPWD1:RK	15180327.7 - 1122 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of notices of opposition (R. 79(1) EPC)

Notices of opposition have been filed within the opposition period by:

01.
Abbott Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054
ETATS-UNIS D'AMERIQUE
02.
Neovasc Tiara Inc.
13562 Maycrest Way, Suite 5138
Richmond, BC V6V 2J7
CANADA

The notices of opposition indicated above have already been communicated to you.

You are requested to file your observations within a period of **four months** from notification of this communication.

You may also file amendments, where appropriate, to the description, claims and drawings within the period specified. One set of these documents is to be filed.

If you introduced documents which have not yet been mentioned during the proceedings, your attention is drawn to Rule 83 EPC.

Enclosures:

For the Opposition Division

Europäisches Patentamt
European Patent Office
Office européen des brevets

Notice of opposition to a European patent

I. Patent opposed

Patent No.	EP2982337
Application No.	EP15180327.7
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	26 August 2020
Title of the invention	Paravalvular leak detection, sealing, and prevention

II. Proprietor of the patent

first named in the patent specification	Edwards Lifesciences PVT, Inc.
Opponent's or representative's reference	255.0051G1

III. Opponent

Name	Abbott Cardiovascular Systems, Inc.
Address:	3200 Lakeside Drive Santa Clara CA California 95054 United States of America
State of residence or of principal place of business	United States of America
Multiple opponents (see additional sheet)	☐

IV. Authorisation

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Telephone/Fax	+49 (89) 262097170	+49 (89) 550568610
E-mail:	abbott@lkglobal.com	
Additional representative(s) on additional sheet/see authorisation	☐	

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Authorisation(s)

is/are enclosed ☐

has/have been registered under No. ☐

V. Opposition is filed against

the patent as a whole ☒

claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

- it is not new (Art. 52(1); Art. 54 EPC) ☒
- it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒
- patentability is excluded on other grounds, namely articles ☐

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on an attached document ☒

VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.

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IX. Evidence presented

A1	Other evidence	Annex A1 original file name: Annex A1.pdf attached as: Other-evidence-1.pdf
D1	Patent document	US5,258,023 (A) , 02.11.1993 original file name: D1_US000005258023A.pdf attached as: Published-Evidence-1.pdf
D10	Patent document	WO 03/053287 (A1) , 03.07.2003 original file name: D10_WO002003053287A1.pdf attached as: Published-Evidence-13.pdf
D11	Patent document	US6,729,356 (B1) , 04.05.2004 original file name: D11_US000006729356B1.pdf attached as: Published-Evidence-14.pdf
D12	Patent document	US2004/0082989 (A1) , 29.04.2004 original file name: D12_US020040082989A1.pdf attached as: Published-Evidence-15.pdf
D13	Non-patent literature - article	Moazami, Nader et al., "Transluminal Aortic Valve Placement " Deterioration of bioprosthetic heart valves, 1996 original file name: D13_Moazami_Transluminal.pdf attached as: Published-Evidence-17.pdf
D14	Patent document	WO 03/039613 (A1) , 15.03.2003 original file name: D14_WO002003039613A1.pdf attached as: Published-Evidence-16.pdf
D2	Patent document	FR2337543 (A) , 05.08.1977 original file name: D2_FR000002337543A1.pdf attached as: Published-Evidence-2.pdf
D2a	Patent document	US4,106,129 (A) , 15.08.1978 original file name: D2a_US000004106129A.pdf attached as: Published-Evidence-3.pdf
D3	Patent document	WO 00/64380 (A1) , 02.11.2000 original file name: D3_WO002000064380A1.pdf attached as: Published-Evidence-4.pdf
D4	Patent document	FR2815844 (A1) , 03.05.2002 original file name: D4_FR000002815844A1.pdf attached as: Published-Evidence-5.pdf
D5	Patent document	EP2537487 (A1) , 26.12.2012 original file name: D5_EP000002537487A1.pdf attached as: Published-Evidence-6.pdf
D5a	Patent document	US2005/0137688 (A) , 23.06.2005 original file name: D5a_US020050137688A1.pdf attached as: Published-Evidence-7.pdf
D5b	Patent document	US2005/0137698 (A) , 23.06.2005

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		original file name: D5b_US020050137698A1.pdf attached as: Published-Evidence-8.pdf
D6	Patent document	WO 01/56512 (A1) , 09.08.2001 original file name: D6_WO002001056512A1.pdf attached as: Published-Evidence-9.pdf
D7	Patent document	US6,454,799 (B1) , 24.09.2002 original file name: D7_US000006454799B1.pdf attached as: Published-Evidence-10.pdf
D8	Patent document	US2003/0153974 (A1) , 14.08.2003 original file name: D8_US020030153974A1.pdf attached as: Published-Evidence-11.pdf
D9	Patent document	DE26 13 575 (A1) , 04.08.1977 original file name: D9_DE000002613575A1.pdf attached as: Published-Evidence-12.pdf
E1a	Patent document	US10/883,575 (A) , 30.06.2005 original file name: E1a_US10883575.pdf attached as: Published-Evidence-18.pdf
E1b	Patent document	WO 2006/005015 (A2) , 12.01.2006 original file name: E1b_WO002006005015A2.pdf attached as: Published-Evidence-19.pdf
E1c	Patent document	EP2 982 337 (A1) , 10.02.2016 original file name: E1c_EP000002982337A1.pdf attached as: Published-Evidence-20.pdf
E1d	Patent document	EP2 982 337 (B1) , 26.08.2020 original file name: E1d_EP000002982337B1.pdf attached as: Published-Evidence-21.pdf

X. Payment

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Fees	Factor applied	Fee schedule	Amount to be paid
010 Opposition fee	1	815.00	815.00
Total:		EUR	815.00

	A Forms	Details:	System file name:
A-1	Form for notice of opposition		ep-oppo.pdf

	B Attached document files	Original file name:	System file name:
B-1	1. Facts and arguments	20210525_NtcOfOppo.pdf	OPPO.pdf

	C Attached evidence files	Original file name:	System file name:
C-1	1. Patent document	D1_US000005258023A.pdf	Published-Evidence-1.pdf
C-2	2. Patent document	D2_FR000002337543A1.pdf	Published-Evidence-2.pdf
C-3	3. Patent document	D2a_US000004106129A.pdf	Published-Evidence-3.pdf
C-4	4. Patent document	D3_WO002000064380A1.pdf	Published-Evidence-4.pdf
C-5	5. Patent document	D4_FR000002815844A1.pdf	Published-Evidence-5.pdf
C-6	6. Patent document	D5_EP000002537487A1.pdf	Published-Evidence-6.pdf
C-7	7. Patent document	D5a_US020050137688A1.pdf	Published-Evidence-7.pdf

C-8	8. Patent document	D5b_US020050137698A1.pdf	Published-Evidence-8.pdf
C-9	9. Patent document	D6_WO002001056512A1.pdf	Published-Evidence-9.pdf
C-10	10. Patent document	D7_US000006454799B1.pdf	Published-Evidence-10.pdf
C-11	11. Patent document	D8_US020030153974A1.pdf	Published-Evidence-11.pdf
C-12	12. Patent document	D9_DE000002613575A1.pdf	Published-Evidence-12.pdf
C-13	13. Patent document	D10_WO002003053287A1.pdf	Published-Evidence-13.pdf
C-14	14. Patent document	D11_US000006729356B1.pdf	Published-Evidence-14.pdf
C-15	15. Patent document	D12_US020040082989A1.pdf	Published-Evidence-15.pdf
C-16	16. Patent document	D14_WO002003039613A1.pdf	Published-Evidence-16.pdf
C-17	17. Patent document	E1a_US10883575.pdf	Published-Evidence-18.pdf
C-18	18. Patent document	E1b_WO002006005015A2.pdf	Published-Evidence-19.pdf
C-19	19. Patent document	E1c_EP000002982337A1.pdf	Published-Evidence-20.pdf
C-20	20. Patent document	E1d_EP000002982337B1.pdf	Published-Evidence-21.pdf
C-21	1. Non-patent literature - article	D13_Moazami_Transluminal.pdf	Published-Evidence-17.pdf
C-22	1. Other evidence	Annex A1.pdf	Other-evidence-1.pdf

Signature of opponent or representative

Place	**Munich**
Date:	**25 May 2021**
Signed by:	**Korbinian Kopf 47644**
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European Patent Office

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Munich, 25.05.2021

Opposition to:	EP 2 982 337 B1
Application No.:	15180327.7
Proprietor:	Edwards Lifesciences PVT, Inc. Irvine, CA 92614 (US)
Title:	Paravalvular leak detection, sealing, and prevention
Opponent:	Abbott Cardiovascular Systems, Inc.
Our Ref.:	255.0051G1

According to Art. 99(1) EPC, we herewith give

NOTICE OF OPPOSITION

to the above indicated patent in the name and on behalf of

Abbott Cardiovascular Systems, Inc.

3200 Lakeside Drive, Santa Clara

California 95054, US

The notice of opposition is filed against the following European Patent:

European Patent No.	EP 2 982 337 B1
Title:	Paravalvular leak detection, sealing, and prevention
Date of filing:	30.06.2005

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I. REQUESTS

1. It is requested to revoke the opposed patent in its entirety for the following reasons:

a) its subject matter is not patentable (Article 100(a) EPC and Articles 52 to 57 EPC);

b) it does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) and Article 83 EPC); and

c) it extends beyond the content of the application as filed (Article 100(c) EPC and Articles 76(1) and 123 (2) EPC).

2. As an auxiliary request, oral proceedings before the Opposition Division are requested.

3. The opposition fee in the amount of 815.00 EURO is to be debited from account number 28003046.

4. Prior art references referred to in this notice of opposition are listed below and filed herewith. The opponent reserves the right to refer to prior art documents referenced in the opposed patent, the search reports or elsewhere in the EPO file history of this patent, or related family members of this patent, and in the references mentioned in foreign equivalent and family member patents and patent applications.

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II. FILED DOCUMENTS

1. The following documents relate to the opposed patent:

E1a: US 10/883,575 (priority document)
E1b: WO 2006/005015 A2 (original application, i.e., parent application)
E1c: EP 2 982 337 A1 (application as filed)
E1d: EP 2 982 337 B1 (opposed patent)

2. The following prior art documents (together with their respective publication dates or patent dates) are discussed in the "Facts and Evidence" in the present opposition and are enclosed:

D1: US 5,258,023 A (02.11.1993))
D2: FR 2 337 543 (05.08.1977)
D2a: US 4,106,129 (15.08.1978)
D3: WO 00/64380 A1 (02.11.2000)
D4: FR 2 815 844 A1 (03.05.2002)
D5: EP 2 537 487 A1 (26.12.2012)
D5a US 2005/0137688 (23.06.2005)
D5b US 2005/0137698 (23.06.2005)
D6: WO 01/56512 A1 (09.08.2001)
D7: US 6,454,799 B1 (24.09.2002)
D8: US 2003/0153974 A1 (14.08.2003)
D9: DE 26 13 575 A1 (04.08.1977)
D10: WO 03/053287 A1 (03.07.2003)
D11: US 6,729,356 B1 (04.05.2004)
D12: US 2004/0082989 A1 (29.04.2004)
D13: Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)
D14 : WO 03/039613 A1 (15.03.2003)

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As will be shown in the following, the priority claim of the opposed patent is not valid. The effective date of the opposed patent is therefore the international filing date of the original application E1b, i.e., 30 June 2005. Documents D1, D2, D3, D4 and D5 were cited during the examination proceedings leading to the opposed patent, with D5 cited as prior art under Art. 54(3) EPC. However, documents D5a and D5b include as patent family members the disclosure of D5 and were published before the effective filing date of the opposed patent.

Besides D5, all the above cited prior art documents were published before the effective date of the opposed patent and constitute prior art under Art. 54(2) EPC.

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III. FACTS AND EVIDENCE

1. Feature Analysis of independent claim 1 (also filed as Annex A1)

Independent claim 1 of the opposed patent as granted has been partitioned into the following features:

F1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

F2 a substantially cylindrical stent structure (252) configured for radial expansion,

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,

F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F5 the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Basically, a stented valve with a layer of material on the outside of the stent is claimed. The material is compressible and includes fibers. Interestingly, these fibers extend from the outer surface of the stent structure outwardly.

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According to paragraph [0064] of the description of the patent, it is intended to encourage coagulation of blood by means of the fibers to fill gaps between the stented valve and surrounding tissue. In consequence, it must be assumed that the fibers extend from the inner side of the layer of material, i.e. from the outer surface of the stent structure into the layer, through the layer and further outwardly. However, there is contradicting disclosure in the patent.

In the following, it will be shown that the claim language is not supported by the description, that neither the original claims nor the original description may form basis for the claims of the opposed patent. The claimed subject-matter cannot be put into practice, and in as far as it can be understood, the subject-matter is known or at least not inventive.

2. Inadmissible extension, violation of Art. 100(c) EPC

2.1 Potential basis in the originally filed application

With the characterizing feature of "a layer of compressible material", only the embodiment of figure 22 may provide basis for the claimed subject-matter. The embodiment of figure 22 is the only embodiment which is disclosed as having a layer of compressible material.

It will be shown in the following that neither the claims nor the description as originally filed disclose the features of the patent as granted, and in particular not the specific combination of these features. The subject-matter of the granted claims is not directly and unambiguously disclosed in the application E1b as originally filed.

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2.1.1 Claims as originally filed

The originally filed application E1b includes claims 27 to 29 directed to a prosthetic valve comprising, inter alia, a layer of compressible material. These claims read as follows, wherein the reproduced original claims show amendments which would have been necessary to achieve granted claim 1.

> 27. A prosthetic valve for implantation in a body channel, comprising:
> a substantially cylindrical stent structure configured for radial expansion,
> a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,
> a layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.
>
> 28. The prosthetic valve of claim 27.
>
> 29. The prosthetic valve of claim 28, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

As can be easily recognized, several features are missing in the subject-matter of claim 1 of the opposed patent so that the subject-matter surely extends beyond the content of the claims as originally filed.

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2.1.2 Description as originally filed

Alternatively, there is the embodiment of figure 22 described in the application E1b as originally filed.

In the section of the BRIEF DESCRIPTION OF THE FIGURES in E1b, figure 22 is described as following:

[0085] Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

In the section of the DETAILED DESCRIPTION OF THE INVENTION in E1b, figure 22 is described as follows, wherein the sentences of the related paragraphs [00144] and [00145] are divided and numbered:

> [00144.1] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks.
> [00144.2] The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254.
> [00144.3] The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter.
> [00144.4] The valvular structure 254 forms three leaflets and is illustrated in the open configuration.
>
> [00145.1] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.

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[00145.2] The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve.

[00145.3] In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm.

[00145.4] In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.

[00145.5] In various embodiments, the fibers may be straight, curved or hook-shaped.

[00145.6] The compressible material expands after deployment at a treatment site.

[00145.7] As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.

[00145.8] Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.

[00145.9] In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.

[00145.10] In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps.

[00145.11] Any suitable tissue growth factor may be used.

[00145.12] In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

Based on the description, the subject-matter of claim 1 of the patent cannot be directly and unambiguously achieved. Features are arbitrarily selected

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from sentences, with other features being omitted, and not all features are present in the description at all.

2.2 Inadmissible extension of features **F1**, **F2** and **F3**

Features **F1** to **F3** define a typical stent-valve.

Description paragraph [00144] of E1b mentions a stented valve with an expandable stent structure supporting a valve structure which forms three leaflets. The wording of features **F1**, **F2** and **F3** cannot be found in the description. For example, it is not described that the stent structure is substantially cylindrical and that the valve structure has an inlet and an outlet. Further, it is not described that the valve structure is formed of a pliant material.

Rather, features **F1**, **F2** and **F3** may be taken from claim 27 as indicated above. However, claim 27 defines the valve structure as providing a flexible conduit which has an inlet and an outlet. Feature **F3** of claim 1 of the patent does not include the underlined feature. It is noted that the description does not describe the valve structure in such detail. There is no hint that the flexible conduit may intentionally be omitted.

Consequently, feature **F3** extends beyond the content of the application E1b as originally filed.

2.3 Inadmissible extension of features **F4** and **F5**

Features **F4** and **F5** define a location of compressible material relative to the stent structure as well as a functionality thereof.

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However, original claim 27 of E1b does not include that the compressible material forms a sleeve which extends entirely around the stent structure. The feature combination of feature **F4** may rather be found in sentences [00145.1] and [00145.2] of the description, with the difference that it is disclosed in E1b that the material extends entirely around the stent structure and not a sleeve as in claim feature **F4**.

Further, it is noted that the "sleeve" is present as a distinct structural component in claim 1 of the patent since the claim defines that the compressible material forms a sleeve. However, the original application does not disclose at all a sleeve as a structural component as such. Paragraph sentence [00145.2] reads: *"The **material** may extend partially around the stent structure or may extend entirely around the stent structure, such as **in the form of** a sleeve"*. This sentence merely describes the geometrical appearance of the material, i.e., that it may have the form of a sleeve (*e.g.*, that it extends entirely around the stent structure), but this sentence does not provide any basis for the presence of a sleeve (as a structural component) as such. In view of the specific language in the original disclosure, the presence of a sleeve in claim 1 as a distinct structural component extends the subject-matter beyond the content of the application as originally filed.

Furthermore, when compared with the wording of claim 27 of E1b, it is missing in feature **F5** of claim 1 of the patent that the compressible material is adapted to expand after deployment to fill gaps between the prosthetic valve and the body channel.

The original disclosure in claim 27 of E1b is in line with the description. Sentence [00145.6] of the description also states that "the compressible material expands after deployment at a treatment site." It is noted that this sentence does not include any wording allowing the expansion to be optional. To the contrary, the next sentence [00145.7] emphasizes that, "as the

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compressible material expands, it fills the gaps between the stented valve and the surrounding tissue." That is, the expansion is disclosed as causing the filling of gaps.

The omission of a feature which is inextricably linked to features already in the claim constitutes an inadmissible extension of the claimed subject-matter.

2.4 Inadmissible extension of feature **F6**

Feature **F6** requires a plurality of fibers extending outwardly.

The wording of feature **F6** may only be found in claim 29 of E1b which depends on claim 28 which in turn depends on claim 27. However, claim 1 of the patent is missing the features "the compressible material is formed of polyethylene terephthalate (PET)" and "the prosthetic valve further comprises a tissue growth factor disposed along the compressible material," at least when trying to find basis for claim 1 of the patent in the originally filed claims in E1b.

When alternatively trying to find support for claim 1 of the patent in paragraph [00145] of the description, three aspects stand in the way.

In sentence [00145.4], it is defined that "the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material." According to that sentence, the fibers are part of a cloth or fabric. This is in contrast to the teaching of the original claims which require the fibers to extend from the stent structure.
Further, claim 1 of the patent allows any other material as compressible material like a foam. According to claim 1, there must be fibers extending from the outer surface. In fact, claim 1 requires that the fibers extend from the outer surface of the stent structure, due to the definite article so that "the

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outer surface" refers back to "an outer surface of the stent structure" (in feature F4) along which outer surface a layer of compressible material is disposed.

Moreover, that sentence [00145.4] starts with the language "in certain configurations". In consequence, the fibers are not only isolated from the cloth or fabric but are also arbitrarily selected from features disclosed in a sequence of optional features provided in the sentences of paragraph [00145]. There is no hint in the original disclosure of E1b that, for example, PET as compressible material, i.e., sentence [00145.3] and/or claim 28, may be omitted while the fibers are included.

Summarizing, paragraph [00145] does nowhere disclose fibers that extend **outward from the outer surface** as claimed, such that this paragraph cannot provide a basis for feature **F6**. Original claim 29 is the only basis for this feature, however, in this case at least the above-mentioned features of original claims 28 and 29 are missing.

2.5 No disclosure of feature combination of claim 1

As already discussed above, the feature combination of claim 1 of the patent cannot be based on original claims 27 to 29. The original claims 27 to 29 include four features in addition to those of claim 1 of the patent.

When construing the feature combination of claim 1 of the patent based on the description, the following must be recognized.
Sentence [00145.1] is written as mandatory and is part of feature F4.
Sentence [00145.2] is written as optional but selected as part of feature F4.
Sentence [00145.3] identifies a preferred embodiment but is not present in claim 1.

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Sentence [00145.4] is written as relevant only in certain configuration, wherein a part of that sentence found its way into claim 1.
Sentence [00145.5] is written as optional and is not selected.
Sentence [00145.6] is written as mandatory but is not in claim 1.
Sentence [00145.7] is again written as mandatory but only part of it is in claim 1.
Further optional features are mentioned in sentences [00145.8] to [00145.12] all being not part of claim 1 of the patent.

An arbitrary selection from both mandatory and optional features, without any pointer that the resulting combination was originally intended, does not fulfil the requirements of direct and unambiguous disclosure. Several decisions of the Boards of Appeal made clear that the content of an application must not be considered to be a reservoir from which features could be combined in order to artificially create a particular embodiment. It is established case law that in the absence of any pointer to that particular combination, this combined selection of features does **not**, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (see e.g., **T 686/99**, **T 1853/13** or **T 1252/13**).

The subject-matter of claim 1 of the patent extends beyond the content of the application E1b as originally filed and, thus, violates Art. 76(1) EPC.

2.6 Dependent claims

Since claim 1 of the opposed patent E1d already violates Art. 76(1) EPC, any combination of claim 1 with a dependent claim also leads to an inadmissible extension in violation of Art. 76(1) EPC for the resulting subject-matter. Already for this reason, dependent claims 2 to 9 violate Art. 76(1) EPC.

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As shown in the following, at least some features of the dependent claims have no basis in the original application E1b.

Claim 2:

According to claim 2, the sleeve surrounds an inflow end of the stent structure.

That feature is nowhere disclosed in the application as originally filed. In connection with the embodiment of figure 22, reproduced below, an arrangement of the sleeve is neither mentioned in any of the related claims 27 to 29 of E1b nor discussed in the related description paragraphs [00144] and [00145]. In figure 22, only the front half of the valve is visible. Figure 22 cannot serve as basis for a sleeve much less a sleeve that surrounds an inflow end of the stent structure.

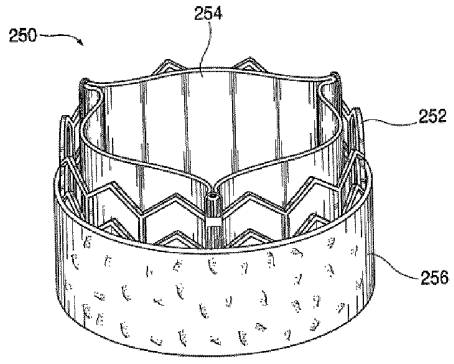


FIG. 22

Claim 2 violates Art. 76(1) EPC.

Claim 3:

According to claim 3, the compressible material has a thickness ranging from 1 to 5mm.

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That feature is only disclosed in sentence [00145.3] of the description. However, that sentence further defines that the compressible material is formed of polyethylene terephthalate (PET). That is, it is only disclosed that a compressible material formed of PET may have a thickness ranging from about 1 to 5 mm.

Claim 3 violates Art. 76(1) EPC.

Claim 4:

According to claim 4, the compressible material comprises a cloth or fabric.

That feature may be taken from sentence [00145.4] of the description, but not in isolation. According to sentence [00145.4], a material which resembles a cloth or fabric is disclosed as having small fibers extending from the surface of the material. In other words, claim 4 confirms that claim 1 is inadmissibly extended, i.e., that it is intended to cover other materials by claim 1.

Claim 4 violates Art. 76(1) EPC.

Claim 5:

According to claim 5, the prosthetic valve further comprises a tissue growth factor disposed along the compressible material.

That feature may be found in claim 29 of E1b. Like claim 4, claim 5 thus proves that claim 1 extends the content of the application E1b as originally filed. Claim 5 introduces the feature omitted in claim 1 as discussed above, thus, illustrates that it is intended to broaden the scope of claim 1.

Claim 5 violates Art. 76(1) EPC.

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Claim 6:

According to claim 6, the growth factor according to claim 5 is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

That language seems to be taken from sentence [00145.12] which however describes a method. Indeed, claim 6 still includes language of a method claim. Without any indication, it is principally not possible to include a method feature that was only disclosed in context with a method into a device claim.

Claim 6 violates Art. 76(1) EPC.

Claim 7:

According to claim 7, the fibers are straight, curved or hook-shaped.

That feature can be found in sentence [00145.5], as aspect of various embodiments. With claim 7 depending from any one of claims 1 to 6, various combinations of features are possible. However, there is no pointer in the description that it was intended at the date of filing of the original application E1b, to combine a specific selection of features while omitting others.

Claim 7 violates Art. 76(1) EPC.

Claim 8:

According to claim 8, the compressible material is configured to expand into the gaps.

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Again, that dependent claim shows that it is intended to broaden the scope of claim 1 by omitting a feature, here the feature of claim 8. As discussed above, the filling of gaps is only disclosed in connection with the expansion of the compressible material (cf. sentence [00145.7]).

Claim 8 violates Art. 76(1) EPC.

Claim 9:

According to claim 9, the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

The original disclosure is completely silent with respect to any behaviour of a sleeve-like compressible material upon stent opening. The features of claim 9 are not disclosed in the application E1b as originally filed.

Consequently, all dependent claims, both when considered alone and in combination with other claims, violate at least Art. 76(1) EPC.

3. Insufficient disclosure, violation of Art. 100(b) and Art. 83 EPC

The opposed European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

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Claim 1 of the patent defines an outer surface of the stent structure in feature F4 as well as fibers extending outward from said outer surface (of the stent) in feature F6. Claim 1 defines only one outer surface, i.e., the outer surface of the stent. It is noted that the second mentioning of the outer surface in feature F6 of claim 1 must be the outer surface of the stent that is first mentioned in feature F4 of claim 1 since the definite article is used (cf. last line in claim 1).

As discussed above, it is only disclosed in paragraph [0064] of the description of the patent that the compressible material is a cloth or fabric from which fibers extend. There is no teaching in the patent as to how fibers can extend outwardly from an outer surface of a stent. This would mean that the fibers must start on the stent and then extend outwardly therefrom. The entire disclosure does not give any hint or indication how fibers should be arranged on the stent such that these fibers might be considered as extending outwardly from the outer surface of the stent. It is noted that the term "outward" is only found in the originally filed claim 29. No description in the specification explains how the fibers of the compressible material extend "outward" particularly outward from the outer surface of the stent.

Even when accepting that the fibers are part of the compressible material, it is not disclosed as to how those fibers might be arranged in the compressible material so as to extend outward from the outer surface of the stent structure.

According to the teaching of the patent, it seems intended to encourage coagulation of blood at the fibers outside of the compressible material. To achieve this, the fibers would have to extend from the stent structure through the compressible material outwardly. There is no disclosure in the patent as to how fibers might be integrated into the compressible material so as to extend through the material and outwardly of it to encourage coagulation of blood. In particular, there is no disclosure in the patent as to how fibers might extend through a compressible material which expands after deployment.

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The skilled person is completely left in the dark when trying to figure out how fibers can extend outward from a stent surface as required in feature F6 of claim 1 of the patent.

The opposed patent therefore does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Consequently, the requirements of Article 83 EPC are not fulfilled.

4. Invalid Priority

The priority of the opposed patent is not valid.

As discussed above, the disclosure of the embodiment of figure 22 of the parent application might be a basis for the claimed subject-matter, if at all.

That embodiment, however, is not included in the priority application. In fact, the priority application does not disclose the specific features combination of claim 1 of the opposed patent, in particular not a stent structure covered by a sleeve formed by a compressible material from which fibers extend outwardly.

In consequence, the effective filing date of the opposed patent therefore is the international filing date of the original application E1b, i.e., 30 June 2005.

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5. Lack of patentability, Art. 100(a) EPC

In the following, the subject-matter of claim 1 of the patent is discussed in view of prior art, although it is expected that further features must be added to claim 1 due to the above discussed deficiencies of claim 1 in light of the disclosure as originally filed and as present in the patent.

In particular, claim 1 of the patent requires a layer of material on the outside of the stented valve, the material being compressible and includes fibers extending outwardly. The patent is, however, silent as to how such fibers are arranged in the compressible material so as to extend from the outer surface of the stent. The patent is also silent as to how the intended effect of filling gaps is achieved without expansion of the compressible material.

For the assessment of patentability, it is assumed that a skilled person which is, for the sake of argument, assumed to be able to understand what is intended to be covered by the claims and which is able to put the claimed subject-matter into practice, would comparably understand the teaching of prior art documents even without explicit teaching of the one or the other mentioned aspects.

The subject matter of claim 1 is not new and does not establish an inventive step and, therefore, violates the requirements of Art. 100(a) EPC in combination with Art. 52 to 57 EPC. In detail:

5.1 Lack of novelty in view of D6 (WO 01/56512 A1)

The subject-matter of claim 1 of the opposed patent lacks novelty in view of D6.

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D6 discloses on page 14, lines 30 to 32 that "the instrument 70A shown in Fig. 5 is intended for use when implanting the valve 10A by a transluminal procedure through a vessel."

Consequently, D6 discloses a prosthetic valve for percutaneous implantation in a body channel, as in feature **F1** of claim 1 of the opposed patent.

In the description of figure 2, D6 discloses on page 8, lines 7 to 10 that, "as illustrated in Fig. 2, the artificial valve 10M comprises a flexibly resilient external frame, generally designated by 20, and a flexible valve element, generally designated by 22", and in lines 18 to 21 that, "Although four frame elements 30 are shown in Figs. 2 and 3, the valve 10M may have fewer or more elements without departing from the scope of the present invention."

That is, D6 discloses features **F2** and **F3** of claim 1 of the opposed patent, i.e., a substantially cylindrical stent structure configured for radial expansion, and a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure. The formation of three valve leaflets is at least implicitly disclosed in D6.

Further, D6 discloses a band 40 which corresponds to the layer of compressible material forming a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure. According to page 9, lines 23 to 25 of D6, the band extends around the frame 20 between each of the frame elements 30. That is, D6 discloses feature **F4**.

Finally, D6 discloses on page 11, lines 6 to 11 that "it is also envisioned that an exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron® velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth to enhance stability of the device after its implantation."

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First of all, it is noted that "velour" is a fabric characterized by fibers extending from a surface thereof. Also a "felt" can be understood as a basis from which fibers extend outwardly. Further, it is noted that a velour or a felt material can be compressed. Finally, it is noted that gaps will be filled after implantation as soon as even tissue ingrowth occur.

Although not literally, D6 discloses feature **F5** and **F6** of claim 1 of the opposed patent, namely a compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, the compressible material including a plurality of fibers extending outward from the outer surface.

D6 discloses all features of claim 1 of the opposed patent.

The subject matter of claim 1 of the opposed patent is not new in view of D6 and violates Art. 100(a) in combination with Art. 54 EPC.

5.2 Lack of novelty in view of D14 (WO 03/039613 A1)

The subject-matter of claim 1 of the patent lacks novelty in view of D14.

D14 relates to synthetic vascular prosthesis (title of D14) and to a novel method for the treatment of a cardiovascular disorder, inter alia applying an endovascular prosthesis in an intra-cardio-vascular setting, such as a heart valve (page 16, lines 5-8 of D14). The prosthesis can be placed into the vascular system by a catheter-delivery based minimal invasive endovascular technique (page 15, line 8-11 of D14).

Thus, features **F1**, **F2** and **F3** are disclosed, i.e. a prosthetic valve with an expandable stent structure and a valvular structure. It is noted that three-leaflet valve are typically used in the art of replacement heart valve so that

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D14 at least implicitly discloses a valve structure with all aspects as in feature **F3**.

According to page 7, lines 10-25, a graft material with filaments is disclosed, also known as "velours" material, with both inner and outer surfaces are provided with these filaments, as well as with open pores extending from the inner wall to the outer wall of the graft and forming a spongy material.

Thus, a hollow tubular structure formed of compressible material with outwardly extending fibers is disclosed which will, due to the spongy material and the filaments, fill gaps between the valve and the body channel after deployment. Also features **F4**, **F5** and **F6** are disclosed in D14.

When considering the disclosure of D14 strictly literally, one may conclude that e.g. the three leaflets are not mentioned as required in feature **F3**. However, the provision of a three-leaflet valve is notoriously known so that the subject-matter of claim 1 must at least be considered as lacking an inventive step in view of the teaching of D14 together with common knowledge.

5.3 Lack of inventive step in view of D3 in combination with either D9 or D1

Documents D3 have been cited during the examination procedure. The disclosure of D3 has been considered by the examiner in the annex to the summons to attend oral proceedings of 14 January 2019 as follows, (with references to D3 in parentheses):

> "A prosthetic valve (figure 1, feature 100) for percutaneous implantation in a
> body channel, comprising:

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a substantially cylindrical stent structure (feature 110) configured for radial
expansion (page 6, lines 3 - 15);
a valvular structure (feature 120) having an inlet and an outlet, the valvular
structure being formed of a pliant material attached to the stent structure and
forming three valve leaflets (figures 1 and 2; page 5, lines 34 - 36);
characterised by a layer of compressible material, which forms a sleeve
disposed along an outer surface of the stent structure and extending entire
around the stent structure, the compressible material being adapted after
deployment to fill gaps between the prosthetic valve and the body channel
(page 6, line 34 - page 7, line 10) wherein the compressible material is polyurethane or polyethylene terephthalate (page 7, line 8)."

In fact, page 7, lines 6 to 10 of D3 discloses that "Gasket 150 may preferably be formed from a soft, deformable biocompatible material, e.g., polyurethane, silicone, Dacron or other suitable material that readily conforms to existing tissue, yet provides a fluid-tight seal around valve 110."

The feature of a plurality of fibers extending from an outer surface of the compressible material, was considered as being not disclosed by D3.

Feature **F6** of claim 1 of the opposed patent may thus be considered as distinguishing feature over D3.

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A technical effect of fibers extending from an outer surface of a material can be seen in a promotion of ingrowth of tissue on the surface.

The objective technical problem, when starting from the teaching of D3, may be to provide a graft material which facilitates formation of tissue on surfaces thereof without impeding the flow of blood therethrough.

When looking for a solution, a person skilled in the art would consider the teaching of document D9 which discloses "Synthetische Gefäßtransplantate" (title of D9). According to claim 1 of D9, a "Synthetisches Gefäßtransplantat in Form einer Doppelvelour-Kettenwirkware aus einem Material, an dem Zellgewebe haften kann" is disclosed. In English, a warp-knit, double velour, synthetic vascular graft" is disclosed in D9. A method of preparing such graft is also disclosed.

In D3, Dacron is already suggested as suitable material for the sleeve on the outside of the stent structure. Dacron is disclosed in claim 24 of D9 as material of the velour material of the graft, solving the above-mentioned problem.

In consequence, a skilled person would have no problems to achieve the claimed subject-matter. The skilled person would have to apply the method of preparing a graft as in D9 when providing the sleeve made of Dacron material as known in D3.

Alternatively, the skilled person knows from D1 that a Dacron velour would be a suitable material for covering a stent structure of a stented heart valve. It is noted that D1 was already cited by the examiner and was considered in the extended European search opinion as including all features of claim 1 as filed. Thus, the skilled person would have no problem to combine the teachings of two documents disclosing almost the same valve prosthesis.

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The subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from D3.

Comparably, the subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from each of D5a, D5b, D7 and D8.

D5 has been considered during examination as disclosing all features of claim 1 (prior to the introduction of feature F6). D5a is a family member of D5 and discloses the embodiments of figures 13, 15A – 16C and 27 – 34 to which the examiner referred to, wherein D5a is published before the effective filing date of the opposed patent. D5b discloses a similar embodiment in figures 8A - 10B, including a stented valve with a sleeve made from compressible material.

D7 also discloses a stent-valve with a covering of the frame. According to column 6, lines 31-33, the fabric section 34, i.e., the covering, is desirably a woven polyester, such as polyethylene terephthalate, i.e., PET like Dacron. Finally, D8 discloses an implantable prosthetic valve with a cuff portion. According to [0104] of D8, to prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to prevent rolled-up sleeve-like portion at the inlet.

D5a, D5b, D7 and D8 may be considered as missing feature F6. Following the problem-solution-approach presented above, a skilled person would achieve the subject-matter of claim 1 of the opposed patent when starting from any one of D5a, D5b, D7 and D8 and combining this document with one of D1 and D9.

5.4 Lack of inventive step in view of D1 in combination with any one of D4, D5a, D5b D7, D8

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As mentioned above, D1 was considered in the extended European search report as disclosing the following claim features (references to D1 in parentheses):

A prosthetic valve for implantation in a body channel (column 7, lines 22 - 24), comprising: a substantially cylindrical stent structure configured
for radial expansion (figures, feature 30, 130, 230); a valvular structure having
an inlet and an outlet, the valvular structure being formed of a pliant material
located within the stent structure and forming three valve leaflets (feature 20);
a layer of compressible material disposed along an outer surface of the stent
structure, the compressible material being adapted after deployment to fill
gaps between the prosthetic valve and the body channel (feature 15; column
8, line 61 - column 9,line14column10,line 37 - column 11, line 3).

During examination, the following marked features have been amended in claim 1:

F1 A prosthetic valve (250) for <u>percutaneous</u> implantation in a body channel, comprising:

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material ~~located within~~ <u>attached to</u> the stent structure and forming three valve leaflets,

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F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Document D1 discloses the amendment of feature **F3**, namely that the valvular structure is not just located within but is attached to the stent structure, cf. column 4, lines 12 and 13 of D1. D1 further discloses in column 3, lines 49 to 53, a brim cover comprising a cylinder of material surrounding, folded over, and securely sutured to the two-layered brim to provide a tissue adhering cover above and below the brim, i.e., a sleeve as in amended feature **F4**. With the Dacron velour disclosed in D1, feature **F6** is at least implicitly disclosed. Features **F2** and **F5** remained unamended during examination.

The subject-matter of claim 1 of the opposed patent seems to merely distinguish from the disclosure of document D1 in that the prosthetic valve is suitable for percutaneous implantation, as required by feature **F1**.

However, D1 already discloses in column 8, lines 47 to 49, that the frame may be capable of annular deformity and slight perimetric expansion. Consequently, the subject-matter of claim 1 of the opposed patent actually differs from the disclosure of D1 by a different amount of expansion of the stent structure.

The technical effect of that other amount of expansion can be seen in a suitability of percutaneous implantation.

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When starting from the teaching of D1, a skilled person may thus be confronted with the problem to provide a prosthesis which can be implanted by means of a catheter.

From any one of documents D4 (Title: Support Tubulaire de Mise en Place, par voie Percutanee, d'une valve cardiaque de remplacement), D5 (Abstract: A method for percutaneously replacing a heart valve of a patient.), D7 (Title: Minimally-Invasive Heart Valve and Method of Use), and D8 (Abstract: A valve prosthesis device is disclosed suitable for implantation in body ducts), a skilled person knows how to design a stent structure so as to allow for percutaneous implantation by means of a catheter.

The subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from D1.

5.5 Lack of inventive step in view of D10 in combination with D13

Document D10 is directed to a stent graft with improved graft adhesion. On page 1, lines 13 and 14, it is noted that "a surgical stent graft may be placed into a lumen in the body by endoluminal techniques". In other words, D10 discloses a prosthesis for percutaneous implantation in a body channel with a substantially cylindrical stent structure configured for radial expansion.

Claim 1 of D10 discloses "a stent graft comprising a tubular graft having a distal end, a proximal end, and an outer surface; at least one expandable stent disposed on said tubular graft; and a band of fibrous material on said outer surface and adjacent at least one of said distal end and said proximal end of said tubular graft, said band of fibrous material extending circumferentially around said graft."

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Therefore, D10 discloses features **F1**, **F2** and **F4**.

According to the last paragraph on page 3 of D10, "It is desirable that the band be continuous around the proximal end of the graft so that with fibrous ingrowth of the cells of the wall of the lumen into the band of fibrous material on the graft, union of the wall and graft is obtained which provides sealing for blood flow which could occur between the graft and the wall as well as prevention of movement of the graft longitudinally within the lumen. In so doing there is improved incorporation of the graft into the wall of the lumen."

Providing a sealing for blood flow corresponds to the effect of filling gaps as in feature **F5**.

Feature **F6** is in fact in more detail disclosed in claims 4 to 8 of D10, reading:

"4. The stent graft as in Claim 1 wherein said band of fibrous material includes
velour material.
5. The stent graft as in Claim 4 wherein said velour material includes a loop pile
velour material.
6. The stent graft as in Claim 4 wherein said velour material includes a cut pile
velour material.
7. The stent graft as in Claim 1 wherein said band of fibrous material includes
fibres woven or knitted into material of said graft.
8. The stent graft as in Claim 1 wherein said graft includes a graft material and
wherein said band of fibrous material comprises brushed raised fibres of said graft material."

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In consequence, a three-leaflet valve as in feature **F3** may be seen as distinguishing feature over D10.

When starting from D10, a skilled person may thus be confronted with the objective technical problem to provide a valve functionality for blood flowing through the stented graft.

It is common knowledge, as evidence by the scientific article D13 (cf. paragraph bridging columns 1 and 2 on page 1 of D13), that "intravascular stents have gradually obtained acceptance for peripheral and coronary vascular occlusive disease. Combinations of stents with grafts have allowed for intraluminal bypass of aneurysms and long segment atherosclerotic lesions. Transfemoral percutaneous aortic valve replacement is an extended application of this new technology…". In other words, transfemoral percutaneous aortic valve replacement has been developed based on stented grafts.

The authors of D13 developed a novel sutureless bovine pericardial bioprosthetic aortic valve mounted on a collapsible stent suitable for implantation by means of a catheter (cf. second paragraph of right column on page 1 of D13.

That is, D13 discloses the solution for the above identified problem, namely to provide a stented graft with a valve.

The subject-matter of claim 1 of the opposed patent is thus not inventive when starting from D10.

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Alternatively, a skilled person would be hinted to provide a three-leaflet valve attached to a collapsible and expandable stent from each of, for example, documents D3, D4, D5, D7, and D8.

Comparably, the subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from each of D11 and D12.

Like D10, D11 discloses a stented graft. In particular with reference to figures 20 to 24, D11 discloses in detail how to form a sleeve with fibers protruding therefrom. For example, the following is described in D11, starting in column 9, line 16:

> "When the graft is deployed in a diseased vessel (not shown), the tufted yarn 932 operates to fill spaces between the vascular wall and the tubular member 934, thereby substantially forming a seal..... The tufted-yarn sealing member 932, may simply be attached to an outer wall of the graft 931 by stitching the yarn onto the wall of the tubular member 934. The tufts of yarn may be made from the fabric making up the tubular member 934 itself. The fabric 940 (See FIG. 22) from which the graft is manufactured may be woven so that weft threads (running horizontally) are omitted from certain zones 942 thereof. The lengths of warp threads (running vertically) which are not connected to each other by weft threads are pulled radially outward to form a loop 944 (See FIG. 23). The loops of warp thread 944 are cut at the apex of each loop 944, leaving single linear strands of yarn 946 (See FIG. 24) circumferentially protruding from the tubular member 934.

D12 discloses a stented graft with material folded over on itself such that a

> "distal 5 cm of a cuff includes a region in which the threads and fibers of the DACRON® polyester fabric have been at least partially separated from one another to create a frayed region that extends outward from the graft and facilitates sealing by encouraging

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thrombus formation and tissue ingrowth. Graft material, such as DACRON® polyester fiber, is particularly well-suited to form thrombus." (cf. [0009] of D12).

When starting from either D11 or D12, a skilled person would achieve the claimed subject-matter following the above discussed problem-solution-approach, i.e., simply adding a three-leaflet valve to the stented graft already including a sleeve of compressible material having fibers extending therefrom.

5.6 Dependent claims

The features of the dependent claims are not new, at least constitute straightforward modifications and do not establish an inventive step.

Claim 2:

According to claim 2, the sleeve surrounds an inflow end of the stent structure.

This feature is known, for example, from figures 21, 22 of D1, figure 10 of D2, figure 1 of D3, figure 1 of D8, figure 1 of D10, figure 1 of D11, figure 2 of D12, paragraph bridging pages 5 and 6 of D14.

Claim 3:

According to claim 3, the compressible material has a thickness ranging from 1 to 5mm.

Regarding the feature of claim 3, it is noted that the opposed patent does not provide any indication as to what kind of compressible material is measured in which state (compressed or expanded).

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For example, D2 discloses a resilient foam or sponge rubber 29 in figure 9 and 29' in figure 10. As these sealing elements in D2 are provided to fill gaps like the compressible material, a skilled person will, due to anatomical circumstances at an implantation site, consider the same range of thickness for the compressible material.

Alternatively, when considering a velour material as the compressible material, the skilled person would provide the velour band of D6 with an appropriate thickness, measured from the outermost tips of the outwardly extending fibers in an expanded state. Comparably, the skilled person knows outwardly extending fibers from D10 and would consider an appropriate length. Also the tufted yarns in D11 extend a few millimeters away from the base material.

Claim 4:

According to claim 4, the compressible material comprises a cloth or fabric.

Velour is typically formed as woven or knitted fabric. Thus, that feature is known from D1, D6, D9, D10, D11, D12 and D14 as shown above.

Claim 5:

According to claim 5, the prosthetic valve further comprises a tissue growth factor disposed along the compressible material.

For example, such a tissue growth factor is disclosed as active substance on page 9, lines 11-14 of D14.

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Claim 6:

According to claim 6, the growth factor according to claim 5 is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

It is known from, e.g., paragraph [0040] of D12 that, besides tissue-engaging structures (like fibers), an external sealing zone may be impregnated with a bioactive or pharmacological agent that enhances sealing properties, such as thrombin powder or another agent for stimulating thrombus formation about the external sealing zone 21. Other possible materials or agents, include, but are not limited to, growth factors or biomaterials for stimulating tissue ingrowth, materials that swell in the presence of blood, or other substances that help form a physical barrier to fluids. Also D14 discloses an impregnation of the material by a growth factor on page 12, line 26.

Claim 7:

According to claim 7, the fibers are straight, curved or hook-shaped.

That feature is self-evident. Fibers must be curved in a woven fabric. Outwardly extending fibers will be straight or curved. There is no other possibility.

Claim 8:

According to claim 8, the compressible material is configured to expand into the gaps.

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Assuming a foam as compressible material (as disclosed for example in D2), it is an intrinsic feature of such a material to expand as soon as a compression force is taken away. That is, a foam would surely expand into a gap. The same applies for the spongy material according to D14.

Claim 9:

According to claim 9, the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

This it, what a foam or sponge would do, see e.g. page 8, lines 1-13 of D14.

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IV. SUMMARY

The subject-matter of the claims is extended beyond the content of the application as originally filed, at least due to an omission of several features. Without any definition regarding specific features of the claims, a skilled person is not able to put the claimed subject-matter into practice, at least not based on the teaching of the patent. Assuming that the skilled person would nevertheless be able to do so, said skilled person would recognize that the subject-matter is known or at least not inventive.

Accordingly, the opposed patent is to be revoked in its entirety.

/electronically signed/
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Enclosures
Annex A1 - feature analysis
E1a – E1d;
D1 – D14.

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Annex A1

Feature Analysis of independent claim 1

Independent claim 1 of the opposed patent as granted has been partitioned into the following features:

F1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

F2 a substantially cylindrical stent structure (252) configured for radial expansion,

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,

F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F5 the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Basically, a stented valve with a layer of material on the outside of the stent is claimed. The material is compressible and includes fibers. Interestingly, these fibers extend from the outer surface of the stent structure outwardly.

According to paragraph [0064] of the description of the patent, it is intended to encourage coagulation of blood by means of the fibers to fill gaps between the stented valve and surrounding tissue. In consequence, it must be assumed that the fibers extend from the inner side of the layer of material, i.e. from the outer surface of the stent structure into the layer,

through the layer and further outwardly. However, there is contradicting disclosure in the patent.

In the following, it will be shown that the claim language is not supported by the description, that neither the original claims nor the original description may form basis for the claims of the opposed patent. The claimed subject-matter cannot be put into practice, and in as far as it can be understood, the subject-matter is known or at least not inventive.

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European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

LKGLOBAL
Lorenz & Kopf PartG mbB Patentanwälte
Brienner Straße 11
80333 München
ALLEMAGNE

Date
09.06.21

Reference	Application No./Patent No.
255.0051G1	15180327.7 - 1126 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Refund of fees

The following fee has been paid in respect of application No. 15180327.7:

Fee	Reference	Voucher No.	Date	Currency	Amount
Opposition fee	010	60359281	25.05.21	EUR	815,00
The fee was paid by LKLGOBAL |.					
Opposition fee	010	22771188	25.05.21	EUR	815,00
The fee was paid by Kopf & Partner mbB Patentanwälte.					
Opposition fee	010	22773527	26.05.21	EUR	815,00
The fee was paid by WBH Wachenhausen Patentanwälte Part.					

Amount refundable:	Reference	Currency	Amount	Voucher No.
	010	EUR	815,00	10172062

Refund order

1. Reason for refund: Fee paid twice

2. In accordance with the information on file, the refund:

(x) will be credited to EPO deposit account number 28003046

The authorising officer
Heim

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Office européen des brevets

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Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Formalities officer
Mazzariol, Francesca

Dolleymores
9 Rickmansworth Road
Watford, Hertfordshire WD18 0JU
ROYAUME UNI

Date
07.06.2021

Reference	Application No./Patent No.
P/14624EPWD1:RK	15180327.7 - 1122 / 2982337

Applicant/Proprietor
Edwards Lifesciences PVT, Inc.

BRIEF COMMUNICATION

Subject:
- ☐ Your letter of
- ☐ Our telephone conversation of
- ☐ Communication of
- ☒ O1/Abbott Cardiovascular Systems Inc.

Enclosure(s):
- ☐ Letter from the proprietor of the patent of
- ☐ Letter from the opponent of
- ☒ Copy (copies) Annex A1 to O1's letter of 25.05.2021

Communication:

☐ The documents specified as patent documents and as non-patent literature in this letter are available for inspection via the European Patent Register at **www.epo.org/register.** Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2020, A106).

☐

For the Opposition Division

Europäisches Patentamt • European Patent Office • Office européen des brevets

☐ **Registered letter**

Annex A1

Feature Analysis of independent claim 1

Independent claim 1 of the opposed patent as granted has been partitioned into the following features:

F1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

F2 a substantially cylindrical stent structure (252) configured for radial expansion,

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,

F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F5 the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Basically, a stented valve with a layer of material on the outside of the stent is claimed. The material is compressible and includes fibers. Interestingly, these fibers extend from the outer surface of the stent structure outwardly.

According to paragraph [0064] of the description of the patent, it is intended to encourage coagulation of blood by means of the fibers to fill gaps between the stented valve and surrounding tissue. In consequence, it must be assumed that the fibers extend from the inner side of the layer of material, i.e. from the outer surface of the stent structure into the layer,

through the layer and further outwardly. However, there is contradicting disclosure in the patent.

In the following, it will be shown that the claim language is not supported by the description, that neither the original claims nor the original description may form basis for the claims of the opposed patent. The claimed subject-matter cannot be put into practice, and in as far as it can be understood, the subject-matter is known or at least not inventive.

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Questions about this communication ?
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Formalities officer
Mazzariol, Francesca

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9 Rickmansworth Road
Watford, Hertfordshire WD18 0JU
ROYAUME UNI

Date
07.06.2021

Reference	Application No./Patent No.
P/14624EPWD1:RK	15180327.7 - 1122 / 2982337

Applicant/Proprietor
Edwards Lifesciences PVT, Inc.

BRIEF COMMUNICATION

Subject:
- ☐ Your letter of
- ☐ Our telephone conversation of
- ☐ Communication of
- ☒ O2/Neovasc Tiara Inc.

Enclosure(s):
- ☐ Letter from the proprietor of the patent of
- ☐ Letter from the opponent of
- ☒ Copy (copies) Annex 2 to O2's letter of 26.05.2021

Communication:

☐ The documents specified as patent documents and as non-patent literature in this letter are available for inspection via the European Patent Register at **www.epo.org/register.** Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2020, A106).

☐

For the Opposition Division

Europäisches Patentamt • European Patent Office • Office européen des brevets

☐ **Registered letter**

Annex 2
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

WBH Wachenhausen
Patentanwälte

Feature analysis of independent Claim 1 of EP 2 982 337 B1

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

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European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY

Questions about this communication ?
Contact Customer Services at www.epo.org/contact

Formalities officer
Mazzariol, Francesca

Dolleymores
9 Rickmansworth Road
Watford, Hertfordshire WD18 0JU
ROYAUME UNI

Date
31.05.2021

Reference	Application No./Patent No.
P/14624EPWD1:RK	15180327.7 - 1122 / 2982337
Applicant/Proprietor	
Edwards Lifesciences PVT, Inc.	

Communication of a notice of opposition

You are hereby informed of a notice of opposition to the European patent specified above (see attached copy in the enclosure). The documents specified as patent documents and as non-patent literature in the notice of opposition are available for inspection via the European Patent Register at **www.epo.org/register**. Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (see OJ EPO 2020, A106).

If oral proceedings are to take place, parties are advised to check the electronic file via European Patent Register in advance of the hearing to ensure they are in possession of all relevant documents.

An invitation to file observations and to file amendments, where appropriate, to the description, claims and drawings (R. 79(1) EPC) will be issued separately.

The period within which such observations may be filed will not be fixed until the following conditions are met:

(a) the opposition period has expired;

(b) the notice of opposition has been examined for certain formal requirements (R. 77 EPC).

For the Opposition Division

Europäisches Patentamt • European Patent Office • Office européen des brevets

Enclosure: Notice of opposition

O1: Abbott Cardiovascular Systems, Inc.
O2: Neovasc Tiara Inc.

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 336
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Europäisches Patentamt
European Patent Office
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Notice of opposition to a European patent

I. Patent opposed

Patent No.	EP2982337
Application No.	EP15180327.7
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	26 August 2020
Title of the invention	Paravalvular leak detection, sealing, and prevention

II. Proprietor of the patent

first named in the patent specification	Edwards Lifesciences PVT, Inc.
Opponent's or representative's reference	255.0051G1

III. Opponent

Name	Abbott Cardiovascular Systems, Inc.
Address:	3200 Lakeside Drive Santa Clara CA California 95054 United States of America
State of residence or of principal place of business	United States of America
Multiple opponents (see additional sheet)	☐

IV. Authorisation

1. Representative

	LKGLOBAL | Lorenz & Kopf PartG mbB Patentanwälte	
Association No.:	708	
Address of place of business	Brienner Str. 11 80333 München Germany	
Telephone/Fax	+49 (89) 262097170	+49 (89) 550568610
E-mail:	abbott@lkglobal.com	
Additional representative(s) on additional sheet/see authorisation	☐	

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 337
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Authorisation(s)

is/are enclosed ☐

has/have been registered under No. ☐

V. Opposition is filed against

the patent as a whole ☒

claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

- it is not new (Art. 52(1); Art. 54 EPC) ☒
- it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒
- patentability is excluded on other grounds, namely articles ☐

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on an attached document ☒

VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

IX. Evidence presented

A1	Other evidence	Annex A1 original file name: Annex A1.pdf attached as: Other-evidence-1.pdf
D1	Patent document	US5,258,023 (A) , 02.11.1993 original file name: D1_US000005258023A.pdf attached as: Published-Evidence-1.pdf
D10	Patent document	WO 03/053287 (A1) , 03.07.2003 original file name: D10_WO002003053287A1.pdf attached as: Published-Evidence-13.pdf
D11	Patent document	US6,729,356 (B1) , 04.05.2004 original file name: D11_US000006729356B1.pdf attached as: Published-Evidence-14.pdf
D12	Patent document	US2004/0082989 (A1) , 29.04.2004 original file name: D12_US020040082989A1.pdf attached as: Published-Evidence-15.pdf
D13	Non-patent literature - article	Moazami, Nader et al., "Transluminal Aortic Valve Placement " Deterioration of bioprosthetic heart valves, 1996 original file name: D13_Moazami_Transluminal.pdf attached as: Published-Evidence-17.pdf
D14	Patent document	WO 03/039613 (A1) , 15.03.2003 original file name: D14_WO002003039613A1.pdf attached as: Published-Evidence-16.pdf
D2	Patent document	FR2337543 (A) , 05.08.1977 original file name: D2_FR000002337543A1.pdf attached as: Published-Evidence-2.pdf
D2a	Patent document	US4,106,129 (A) , 15.08.1978 original file name: D2a_US000004106129A.pdf attached as: Published-Evidence-3.pdf
D3	Patent document	WO 00/64380 (A1) , 02.11.2000 original file name: D3_WO002000064380A1.pdf attached as: Published-Evidence-4.pdf
D4	Patent document	FR2815844 (A1) , 03.05.2002 original file name: D4_FR000002815844A1.pdf attached as: Published-Evidence-5.pdf
D5	Patent document	EP2537487 (A1) , 26.12.2012 original file name: D5_EP000002537487A1.pdf attached as: Published-Evidence-6.pdf
D5a	Patent document	US2005/0137688 (A) , 23.06.2005 original file name: D5a_US020050137688A1.pdf attached as: Published-Evidence-7.pdf
D5b	Patent document	US2005/0137698 (A) , 23.06.2005

		original file name: D5b_US020050137698A1.pdf attached as: Published-Evidence-8.pdf
D6	Patent document	WO 01/56512 (A1) , 09.08.2001 original file name: D6_WO002001056512A1.pdf attached as: Published-Evidence-9.pdf
D7	Patent document	US6,454,799 (B1) , 24.09.2002 original file name: D7_US000006454799B1.pdf attached as: Published-Evidence-10.pdf
D8	Patent document	US2003/0153974 (A1) , 14.08.2003 original file name: D8_US020030153974A1.pdf attached as: Published-Evidence-11.pdf
D9	Patent document	DE26 13 575 (A1) , 04.08.1977 original file name: D9_DE000002613575A1.pdf attached as: Published-Evidence-12.pdf
E1a	Patent document	US10/883,575 (A) , 30.06.2005 original file name: E1a_US10883575.pdf attached as: Published-Evidence-18.pdf
E1b	Patent document	WO 2006/005015 (A2) , 12.01.2006 original file name: E1b_WO002006005015A2.pdf attached as: Published-Evidence-19.pdf
E1c	Patent document	EP2 982 337 (A1) , 10.02.2016 original file name: E1c_EP000002982337A1.pdf attached as: Published-Evidence-20.pdf
E1d	Patent document	EP2 982 337 (B1) , 26.08.2020 original file name: E1d_EP000002982337B1.pdf attached as: Published-Evidence-21.pdf

X. Payment

Method of payment	Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated in the fees section below.

Currency:	EUR
Deposit account number:	28003046
Account holder:	LKGLOBAL | Lorenz & Kopf PartG mbB Patentanwälte

Refunds

Any refunds should be made to EPO deposit account:	28003046
Account holder:	LKGLOBAL | Lorenz & Kopf PartG mbB Patentanwälte

Fees	Factor applied	Fee schedule	Amount to be paid
010 Opposition fee	1	815.00	815.00
Total:		EUR	815.00

	A Forms	Details:	System file name:
A-1	Form for notice of opposition		ep-oppo.pdf

	B Attached document files	Original file name:	System file name:
B-1	1. Facts and arguments	20210525_NtcOfOppo.pdf	OPPO.pdf

	C Attached evidence files	Original file name:	System file name:
C-1	1. Patent document	D1_US000005258023A.pdf	Published-Evidence-1.pdf
C-2	2. Patent document	D2_FR000002337543A1.pdf	Published-Evidence-2.pdf
C-3	3. Patent document	D2a_US000004106129A.pdf	Published-Evidence-3.pdf
C-4	4. Patent document	D3_WO002000064380A1.pdf	Published-Evidence-4.pdf
C-5	5. Patent document	D4_FR000002815844A1.pdf	Published-Evidence-5.pdf
C-6	6. Patent document	D5_EP000002537487A1.pdf	Published-Evidence-6.pdf
C-7	7. Patent document	D5a_US020050137688A1.pdf	Published-Evidence-7.pdf

C-8	8. Patent document	D5b_US020050137698A1.pdf	Published-Evidence-8.pdf
C-9	9. Patent document	D6_WO002001056512A1.pdf	Published-Evidence-9.pdf
C-10	10. Patent document	D7_US000006454799B1.pdf	Published-Evidence-10.pdf
C-11	11. Patent document	D8_US020030153974A1.pdf	Published-Evidence-11.pdf
C-12	12. Patent document	D9_DE000002613575A1.pdf	Published-Evidence-12.pdf
C-13	13. Patent document	D10_WO002003053287A1.pdf	Published-Evidence-13.pdf
C-14	14. Patent document	D11_US000006729356B1.pdf	Published-Evidence-14.pdf
C-15	15. Patent document	D12_US020040082989A1.pdf	Published-Evidence-15.pdf
C-16	16. Patent document	D14_WO002003039613A1.pdf	Published-Evidence-16.pdf
C-17	17. Patent document	E1a_US10883575.pdf	Published-Evidence-18.pdf
C-18	18. Patent document	E1b_WO002006005015A2.pdf	Published-Evidence-19.pdf
C-19	19. Patent document	E1c_EP000002982337A1.pdf	Published-Evidence-20.pdf
C-20	20. Patent document	E1d_EP000002982337B1.pdf	Published-Evidence-21.pdf
C-21	1. Non-patent literature - article	D13_Moazami_Transluminal.pdf	Published-Evidence-17.pdf
C-22	1. Other evidence	Annex A1.pdf	Other-evidence-1.pdf

Signature of opponent or representative

Place	**Munich**
Date:	**25 May 2021**
Signed by:	**Korbinian Kopf 47644**
Association:	**LKGLOBAL | Lorenz & Kopf PartG mbB Patentanwälte**
Representative name:	**Korbinian Kopf**
Capacity:	**(Representative)**

LKGLOBAL

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Munich Germany
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Joel C. Watkins US-(AZ, CO), PA
Dr. Daniel Westenberger DE, EP

DE Patentanwalt, Germany *
EP European Patent Attorney
PA Registered before the USPTO **
UK UK Patent Attorney
US US Attorney at Law **

* located in Germany and acting for:
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Patentanwälte
Partnerschaftsregister des
Amtsgerichts München: PR 1528
Offices: Munich, Hamburg.

** located in USA and acting for:
Lorenz & Kopf, LLP
registered in Arizona, no. 4004092
Offices: Phoenix, Detroit, San Diego.

*** located in UK and acting for:
LKGLOBAL UK Ltd.

European Patent Office

80298 Munich

Munich, 25.05.2021

Opposition to:	EP 2 982 337 B1
Application No.:	15180327.7
Proprietor:	Edwards Lifesciences PVT, Inc. Irvine, CA 92614 (US)
Title:	Paravalvular leak detection, sealing, and prevention
Opponent:	Abbott Cardiovascular Systems, Inc.
Our Ref.:	255.0051G1

According to Art. 99(1) EPC, we herewith give

NOTICE OF OPPOSITION

to the above indicated patent in the name and on behalf of

Abbott Cardiovascular Systems, Inc.

3200 Lakeside Drive, Santa Clara

California 95054, US

The notice of opposition is filed against the following European Patent:

European Patent No.	EP 2 982 337 B1
Title:	Paravalvular leak detection, sealing, and prevention
Date of filing:	30.06.2005

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 343
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

I. REQUESTS

1. It is requested to revoke the opposed patent in its entirety for the following reasons:

a) its subject matter is not patentable (Article 100(a) EPC and Articles 52 to 57 EPC);

b) it does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) and Article 83 EPC); and

c) it extends beyond the content of the application as filed (Article 100(c) EPC and Articles 76(1) and 123 (2) EPC).

2. As an auxiliary request, oral proceedings before the Opposition Division are requested.

3. The opposition fee in the amount of 815.00 EURO is to be debited from account number 28003046.

4. Prior art references referred to in this notice of opposition are listed below and filed herewith. The opponent reserves the right to refer to prior art documents referenced in the opposed patent, the search reports or elsewhere in the EPO file history of this patent, or related family members of this patent, and in the references mentioned in foreign equivalent and family member patents and patent applications.

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 344
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

II. FILED DOCUMENTS

1. The following documents relate to the opposed patent:

E1a: US 10/883,575 (priority document)
E1b: WO 2006/005015 A2 (original application, i.e., parent application)
E1c: EP 2 982 337 A1 (application as filed)
E1d: EP 2 982 337 B1 (opposed patent)

2. The following prior art documents (together with their respective publication dates or patent dates) are discussed in the "Facts and Evidence" in the present opposition and are enclosed:

D1: US 5,258,023 A (02.11.1993))
D2: FR 2 337 543 (05.08.1977)
D2a: US 4,106,129 (15.08.1978)
D3: WO 00/64380 A1 (02.11.2000)
D4: FR 2 815 844 A1 (03.05.2002)
D5: EP 2 537 487 A1 (26.12.2012)
D5a US 2005/0137688 (23.06.2005)
D5b US 2005/0137698 (23.06.2005)
D6: WO 01/56512 A1 (09.08.2001)
D7: US 6,454,799 B1 (24.09.2002)
D8: US 2003/0153974 A1 (14.08.2003)
D9: DE 26 13 575 A1 (04.08.1977)
D10: WO 03/053287 A1 (03.07.2003)
D11: US 6,729,356 B1 (04.05.2004)
D12: US 2004/0082989 A1 (29.04.2004)
D13: Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)
D14 : WO 03/039613 A1 (15.03.2003)

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

As will be shown in the following, the priority claim of the opposed patent is not valid. The effective date of the opposed patent is therefore the international filing date of the original application E1b, i.e., 30 June 2005. Documents D1, D2, D3, D4 and D5 were cited during the examination proceedings leading to the opposed patent, with D5 cited as prior art under Art. 54(3) EPC. However, documents D5a and D5b include as patent family members the disclosure of D5 and were published before the effective filing date of the opposed patent.

Besides D5, all the above cited prior art documents were published before the effective date of the opposed patent and constitute prior art under Art. 54(2) EPC.

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 346
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

III. FACTS AND EVIDENCE

1. Feature Analysis of independent claim 1 (also filed as Annex A1)

Independent claim 1 of the opposed patent as granted has been partitioned into the following features:

F1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

F2 a substantially cylindrical stent structure (252) configured for radial expansion,

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,

F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F5 the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Basically, a stented valve with a layer of material on the outside of the stent is claimed. The material is compressible and includes fibers. Interestingly, these fibers extend from the outer surface of the stent structure outwardly.

Aortic Innovations, LLC, Exhibit 2040
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According to paragraph [0064] of the description of the patent, it is intended to encourage coagulation of blood by means of the fibers to fill gaps between the stented valve and surrounding tissue. In consequence, it must be assumed that the fibers extend from the inner side of the layer of material, i.e. from the outer surface of the stent structure into the layer, through the layer and further outwardly. However, there is contradicting disclosure in the patent.

In the following, it will be shown that the claim language is not supported by the description, that neither the original claims nor the original description may form basis for the claims of the opposed patent. The claimed subject-matter cannot be put into practice, and in as far as it can be understood, the subject-matter is known or at least not inventive.

2. Inadmissible extension, violation of Art. 100(c) EPC

2.1 Potential basis in the originally filed application

With the characterizing feature of "a layer of compressible material", only the embodiment of figure 22 may provide basis for the claimed subject-matter. The embodiment of figure 22 is the only embodiment which is disclosed as having a layer of compressible material.

It will be shown in the following that neither the claims nor the description as originally filed disclose the features of the patent as granted, and in particular not the specific combination of these features. The subject-matter of the granted claims is not directly and unambiguously disclosed in the application E1b as originally filed.

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2.1.1 Claims as originally filed

The originally filed application E1b includes claims 27 to 29 directed to a prosthetic valve comprising, inter alia, a layer of compressible material. These claims read as follows, wherein the reproduced original claims show amendments which would have been necessary to achieve granted claim 1.

> 27. A prosthetic valve for implantation in a body channel, comprising:
> a substantially cylindrical stent structure configured for radial expansion,
> a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,
> a layer of compressible material which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.
>
> 28. The prosthetic valve of claim 27.
>
> 29. The prosthetic valve of claim 28, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

As can be easily recognized, several features are missing in the subject-matter of claim 1 of the opposed patent so that the subject-matter surely extends beyond the content of the claims as originally filed.

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2.1.2 Description as originally filed

Alternatively, there is the embodiment of figure 22 described in the application E1b as originally filed.

In the section of the BRIEF DESCRIPTION OF THE FIGURES in E1b, figure 22 is described as following:

[0085] Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

In the section of the DETAILED DESCRIPTION OF THE INVENTION in E1b, figure 22 is described as follows, wherein the sentences of the related paragraphs [00144] and [00145] are divided and numbered:

> [00144.1] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks.
> [00144.2] The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254.
> [00144.3] The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter.
> [00144.4] The valvular structure 254 forms three leaflets and is illustrated in the open configuration.
>
> [00145.1] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.

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[00145.2] The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve.

[00145.3] In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm.

[00145.4] In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.

[00145.5] In various embodiments, the fibers may be straight, curved or hook-shaped.

[00145.6] The compressible material expands after deployment at a treatment site.

[00145.7] As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.

[00145.8] Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.

[00145.9] In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.

[00145.10] In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps.

[00145.11] Any suitable tissue growth factor may be used.

[00145.12] In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

Based on the description, the subject-matter of claim 1 of the patent cannot be directly and unambiguously achieved. Features are arbitrarily selected

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from sentences, with other features being omitted, and not all features are present in the description at all.

2.2 Inadmissible extension of features **F1**, **F2** and **F3**

Features **F1** to **F3** define a typical stent-valve.

Description paragraph [00144] of E1b mentions a stented valve with an expandable stent structure supporting a valve structure which forms three leaflets. The wording of features **F1**, **F2** and **F3** cannot be found in the description. For example, it is not described that the stent structure is substantially cylindrical and that the valve structure has an inlet and an outlet. Further, it is not described that the valve structure is formed of a pliant material.

Rather, features **F1**, **F2** and **F3** may be taken from claim 27 as indicated above. However, claim 27 defines the valve structure as providing a flexible conduit which has an inlet and an outlet. Feature **F3** of claim 1 of the patent does not include the underlined feature. It is noted that the description does not describe the valve structure in such detail. There is no hint that the flexible conduit may intentionally be omitted.

Consequently, feature **F3** extends beyond the content of the application E1b as originally filed.

2.3 Inadmissible extension of features **F4** and **F5**

Features **F4** and **F5** define a location of compressible material relative to the stent structure as well as a functionality thereof.

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However, original claim 27 of E1b does not include that the compressible material forms a sleeve which extends entirely around the stent structure. The feature combination of feature **F4** may rather be found in sentences [00145.1] and [00145.2] of the description, with the difference that it is disclosed in E1b that the material extends entirely around the stent structure and not a sleeve as in claim feature **F4**.

Further, it is noted that the "sleeve" is present as a distinct structural component in claim 1 of the patent since the claim defines that the compressible material forms a sleeve. However, the original application does not disclose at all a sleeve as a structural component as such. Paragraph sentence [00145.2] reads: *"The **material** may extend partially around the stent structure or may extend entirely around the stent structure, such as **in the form of** a sleeve"*. This sentence merely describes the geometrical appearance of the material, i.e., that it may have the form of a sleeve (*e.g.*, that it extends entirely around the stent structure), but this sentence does not provide any basis for the presence of a sleeve (as a structural component) as such. In view of the specific language in the original disclosure, the presence of a sleeve in claim 1 as a distinct structural component extends the subject-matter beyond the content of the application as originally filed.

Furthermore, when compared with the wording of claim 27 of E1b, it is missing in feature **F5** of claim 1 of the patent that the compressible material is adapted to expand after deployment to fill gaps between the prosthetic valve and the body channel.

The original disclosure in claim 27 of E1b is in line with the description. Sentence [00145.6] of the description also states that "the compressible material expands after deployment at a treatment site." It is noted that this sentence does not include any wording allowing the expansion to be optional. To the contrary, the next sentence [00145.7] emphasizes that, "as the

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compressible material expands, it fills the gaps between the stented valve and the surrounding tissue." That is, the expansion is disclosed as causing the filling of gaps.

The omission of a feature which is inextricably linked to features already in the claim constitutes an inadmissible extension of the claimed subject-matter.

2.4 Inadmissible extension of feature **F6**

Feature **F6** requires a plurality of fibers extending outwardly.

The wording of feature **F6** may only be found in claim 29 of E1b which depends on claim 28 which in turn depends on claim 27. However, claim 1 of the patent is missing the features "the compressible material is formed of polyethylene terephthalate (PET)" and "the prosthetic valve further comprises a tissue growth factor disposed along the compressible material," at least when trying to find basis for claim 1 of the patent in the originally filed claims in E1b.

When alternatively trying to find support for claim 1 of the patent in paragraph [00145] of the description, three aspects stand in the way.

In sentence [00145.4], it is defined that "the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material." According to that sentence, the fibers are part of a cloth or fabric. This is in contrast to the teaching of the original claims which require the fibers to extend from the stent structure.
Further, claim 1 of the patent allows any other material as compressible material like a foam. According to claim 1, there must be fibers extending from the outer surface. In fact, claim 1 requires that the fibers extend from the outer surface of the stent structure, due to the definite article so that "the

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outer surface" refers back to "an outer surface of the stent structure" (in feature F4) along which outer surface a layer of compressible material is disposed.

Moreover, that sentence [00145.4] starts with the language "in certain configurations". In consequence, the fibers are not only isolated from the cloth or fabric but are also arbitrarily selected from features disclosed in a sequence of optional features provided in the sentences of paragraph [00145]. There is no hint in the original disclosure of E1b that, for example, PET as compressible material, i.e., sentence [00145.3] and/or claim 28, may be omitted while the fibers are included.

Summarizing, paragraph [00145] does nowhere disclose fibers that extend **outward from the outer surface** as claimed, such that this paragraph cannot provide a basis for feature **F6**. Original claim 29 is the only basis for this feature, however, in this case at least the above-mentioned features of original claims 28 and 29 are missing.

2.5 No disclosure of feature combination of claim 1

As already discussed above, the feature combination of claim 1 of the patent cannot be based on original claims 27 to 29. The original claims 27 to 29 include four features in addition to those of claim 1 of the patent.

When construing the feature combination of claim 1 of the patent based on the description, the following must be recognized.
Sentence [00145.1] is written as mandatory and is part of feature F4.
Sentence [00145.2] is written as optional but selected as part of feature F4.
Sentence [00145.3] identifies a preferred embodiment but is not present in claim 1.

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Sentence [00145.4] is written as relevant only in certain configuration, wherein a part of that sentence found its way into claim 1.
Sentence [00145.5] is written as optional and is not selected.
Sentence [00145.6] is written as mandatory but is not in claim 1.
Sentence [00145.7] is again written as mandatory but only part of it is in claim 1.
Further optional features are mentioned in sentences [00145.8] to [00145.12] all being not part of claim 1 of the patent.

An arbitrary selection from both mandatory and optional features, without any pointer that the resulting combination was originally intended, does not fulfil the requirements of direct and unambiguous disclosure. Several decisions of the Boards of Appeal made clear that the content of an application must not be considered to be a reservoir from which features could be combined in order to artificially create a particular embodiment. It is established case law that in the absence of any pointer to that particular combination, this combined selection of features does **not**, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (see e.g., **T 686/99**, **T 1853/13** or **T 1252/13**).

The subject-matter of claim 1 of the patent extends beyond the content of the application E1b as originally filed and, thus, violates Art. 76(1) EPC.

2.6 Dependent claims

Since claim 1 of the opposed patent E1d already violates Art. 76(1) EPC, any combination of claim 1 with a dependent claim also leads to an inadmissible extension in violation of Art. 76(1) EPC for the resulting subject-matter. Already for this reason, dependent claims 2 to 9 violate Art. 76(1) EPC.

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As shown in the following, at least some features of the dependent claims have no basis in the original application E1b.

Claim 2:

According to claim 2, the sleeve surrounds an inflow end of the stent structure.

That feature is nowhere disclosed in the application as originally filed. In connection with the embodiment of figure 22, reproduced below, an arrangement of the sleeve is neither mentioned in any of the related claims 27 to 29 of E1b nor discussed in the related description paragraphs [00144] and [00145]. In figure 22, only the front half of the valve is visible. Figure 22 cannot serve as basis for a sleeve much less a sleeve that surrounds an inflow end of the stent structure.

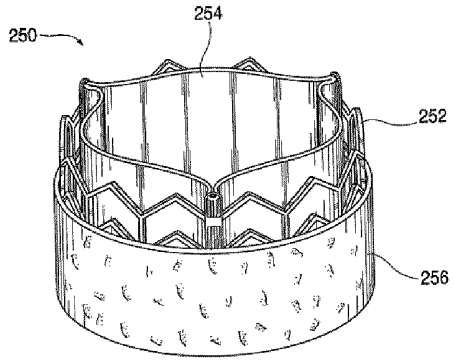


FIG. 22

Claim 2 violates Art. 76(1) EPC.

Claim 3:

According to claim 3, the compressible material has a thickness ranging from 1 to 5mm.

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That feature is only disclosed in sentence [00145.3] of the description. However, that sentence further defines that the compressible material is formed of polyethylene terephthalate (PET). That is, it is only disclosed that a compressible material formed of PET may have a thickness ranging from about 1 to 5 mm.

Claim 3 violates Art. 76(1) EPC.

Claim 4:

According to claim 4, the compressible material comprises a cloth or fabric.

That feature may be taken from sentence [00145.4] of the description, but not in isolation. According to sentence [00145.4], a material which resembles a cloth or fabric is disclosed as having small fibers extending from the surface of the material. In other words, claim 4 confirms that claim 1 is inadmissibly extended, i.e., that it is intended to cover other materials by claim 1.

Claim 4 violates Art. 76(1) EPC.

Claim 5:

According to claim 5, the prosthetic valve further comprises a tissue growth factor disposed along the compressible material.

That feature may be found in claim 29 of E1b. Like claim 4, claim 5 thus proves that claim 1 extends the content of the application E1b as originally filed. Claim 5 introduces the feature omitted in claim 1 as discussed above, thus, illustrates that it is intended to broaden the scope of claim 1.

Claim 5 violates Art. 76(1) EPC.

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Claim 6:

According to claim 6, the growth factor according to claim 5 is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

That language seems to be taken from sentence [00145.12] which however describes a method. Indeed, claim 6 still includes language of a method claim. Without any indication, it is principally not possible to include a method feature that was only disclosed in context with a method into a device claim.

Claim 6 violates Art. 76(1) EPC.

Claim 7:

According to claim 7, the fibers are straight, curved or hook-shaped.

That feature can be found in sentence [00145.5], as aspect of various embodiments. With claim 7 depending from any one of claims 1 to 6, various combinations of features are possible. However, there is no pointer in the description that it was intended at the date of filing of the original application E1b, to combine a specific selection of features while omitting others.

Claim 7 violates Art. 76(1) EPC.

Claim 8:

According to claim 8, the compressible material is configured to expand into the gaps.

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Again, that dependent claim shows that it is intended to broaden the scope of claim 1 by omitting a feature, here the feature of claim 8. As discussed above, the filling of gaps is only disclosed in connection with the expansion of the compressible material (cf. sentence [00145.7]).

Claim 8 violates Art. 76(1) EPC.

Claim 9:

According to claim 9, the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

The original disclosure is completely silent with respect to any behaviour of a sleeve-like compressible material upon stent opening. The features of claim 9 are not disclosed in the application E1b as originally filed.

Consequently, all dependent claims, both when considered alone and in combination with other claims, violate at least Art. 76(1) EPC.

3. Insufficient disclosure, violation of Art. 100(b) and Art. 83 EPC

The opposed European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

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Claim 1 of the patent defines an outer surface of the stent structure in feature F4 as well as fibers extending outward from said outer surface (of the stent) in feature F6. Claim 1 defines only one outer surface, i.e., the outer surface of the stent. It is noted that the second mentioning of the outer surface in feature F6 of claim 1 must be the outer surface of the stent that is first mentioned in feature F4 of claim 1 since the definite article is used (cf. last line in claim 1).

As discussed above, it is only disclosed in paragraph [0064] of the description of the patent that the compressible material is a cloth or fabric from which fibers extend. There is no teaching in the patent as to how fibers can extend outwardly from an outer surface of a stent. This would mean that the fibers must start on the stent and then extend outwardly therefrom. The entire disclosure does not give any hint or indication how fibers should be arranged on the stent such that these fibers might be considered as extending outwardly from the outer surface of the stent. It is noted that the term "outward" is only found in the originally filed claim 29. No description in the specification explains how the fibers of the compressible material extend "outward" particularly outward from the outer surface of the stent.

Even when accepting that the fibers are part of the compressible material, it is not disclosed as to how those fibers might be arranged in the compressible material so as to extend outward from the outer surface of the stent structure.

According to the teaching of the patent, it seems intended to encourage coagulation of blood at the fibers outside of the compressible material. To achieve this, the fibers would have to extend from the stent structure through the compressible material outwardly. There is no disclosure in the patent as to how fibers might be integrated into the compressible material so as to extend through the material and outwardly of it to encourage coagulation of blood. In particular, there is no disclosure in the patent as to how fibers might extend through a compressible material which expands after deployment.

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The skilled person is completely left in the dark when trying to figure out how fibers can extend outward from a stent surface as required in feature F6 of claim 1 of the patent.

The opposed patent therefore does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Consequently, the requirements of Article 83 EPC are not fulfilled.

4. Invalid Priority

The priority of the opposed patent is not valid.

As discussed above, the disclosure of the embodiment of figure 22 of the parent application might be a basis for the claimed subject-matter, if at all.

That embodiment, however, is not included in the priority application. In fact, the priority application does not disclose the specific features combination of claim 1 of the opposed patent, in particular not a stent structure covered by a sleeve formed by a compressible material from which fibers extend outwardly.

In consequence, the effective filing date of the opposed patent therefore is the international filing date of the original application E1b, i.e., 30 June 2005.

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5. Lack of patentability, Art. 100(a) EPC

In the following, the subject-matter of claim 1 of the patent is discussed in view of prior art, although it is expected that further features must be added to claim 1 due to the above discussed deficiencies of claim 1 in light of the disclosure as originally filed and as present in the patent.

In particular, claim 1 of the patent requires a layer of material on the outside of the stented valve, the material being compressible and includes fibers extending outwardly. The patent is, however, silent as to how such fibers are arranged in the compressible material so as to extend from the outer surface of the stent. The patent is also silent as to how the intended effect of filling gaps is achieved without expansion of the compressible material.

For the assessment of patentability, it is assumed that a skilled person which is, for the sake of argument, assumed to be able to understand what is intended to be covered by the claims and which is able to put the claimed subject-matter into practice, would comparably understand the teaching of prior art documents even without explicit teaching of the one or the other mentioned aspects.

The subject matter of claim 1 is not new and does not establish an inventive step and, therefore, violates the requirements of Art. 100(a) EPC in combination with Art. 52 to 57 EPC. In detail:

5.1 Lack of novelty in view of D6 (WO 01/56512 A1)

The subject-matter of claim 1 of the opposed patent lacks novelty in view of D6.

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D6 discloses on page 14, lines 30 to 32 that "the instrument 70A shown in Fig. 5 is intended for use when implanting the valve 10A by a transluminal procedure through a vessel."

Consequently, D6 discloses a prosthetic valve for percutaneous implantation in a body channel, as in feature **F1** of claim 1 of the opposed patent.

In the description of figure 2, D6 discloses on page 8, lines 7 to 10 that, "as illustrated in Fig. 2, the artificial valve 10M comprises a flexibly resilient external frame, generally designated by 20, and a flexible valve element, generally designated by 22", and in lines 18 to 21 that, "Although four frame elements 30 are shown in Figs. 2 and 3, the valve 10M may have fewer or more elements without departing from the scope of the present invention."

That is, D6 discloses features **F2** and **F3** of claim 1 of the opposed patent, i.e., a substantially cylindrical stent structure configured for radial expansion, and a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure. The formation of three valve leaflets is at least implicitly disclosed in D6.

Further, D6 discloses a band 40 which corresponds to the layer of compressible material forming a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure. According to page 9, lines 23 to 25 of D6, the band extends around the frame 20 between each of the frame elements 30. That is, D6 discloses feature **F4**.

Finally, D6 discloses on page 11, lines 6 to 11 that "it is also envisioned that an exterior surface of the band 40 may include a continuous or interrupted sheath of Dacron® velour material, porous PTFE felt or the like to provide sites for vascular connective tissue ingrowth to enhance stability of the device after its implantation."

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First of all, it is noted that "velour" is a fabric characterized by fibers extending from a surface thereof. Also a "felt" can be understood as a basis from which fibers extend outwardly. Further, it is noted that a velour or a felt material can be compressed. Finally, it is noted that gaps will be filled after implantation as soon as even tissue ingrowth occur.

Although not literally, D6 discloses feature **F5** and **F6** of claim 1 of the opposed patent, namely a compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, the compressible material including a plurality of fibers extending outward from the outer surface.

D6 discloses all features of claim 1 of the opposed patent.

The subject matter of claim 1 of the opposed patent is not new in view of D6 and violates Art. 100(a) in combination with Art. 54 EPC.

5.2 Lack of novelty in view of D14 (WO 03/039613 A1)

The subject-matter of claim 1 of the patent lacks novelty in view of D14.

D14 relates to synthetic vascular prosthesis (title of D14) and to a novel method for the treatment of a cardiovascular disorder, inter alia applying an endovascular prosthesis in an intra-cardio-vascular setting, such as a heart valve (page 16, lines 5-8 of D14). The prosthesis can be placed into the vascular system by a catheter-delivery based minimal invasive endovascular technique (page 15, line 8-11 of D14).

Thus, features **F1**, **F2** and **F3** are disclosed, i.e. a prosthetic valve with an expandable stent structure and a valvular structure. It is noted that three-leaflet valve are typically used in the art of replacement heart valve so that

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D14 at least implicitly discloses a valve structure with all aspects as in feature **F3**.

According to page 7, lines 10-25, a graft material with filaments is disclosed, also known as "velours" material, with both inner and outer surfaces are provided with these filaments, as well as with open pores extending from the inner wall to the outer wall of the graft and forming a spongy material.

Thus, a hollow tubular structure formed of compressible material with outwardly extending fibers is disclosed which will, due to the spongy material and the filaments, fill gaps between the valve and the body channel after deployment. Also features **F4**, **F5** and **F6** are disclosed in D14.

When considering the disclosure of D14 strictly literally, one may conclude that e.g. the three leaflets are not mentioned as required in feature **F3**. However, the provision of a three-leaflet valve is notoriously known so that the subject-matter of claim 1 must at least be considered as lacking an inventive step in view of the teaching of D14 together with common knowledge.

5.3 Lack of inventive step in view of D3 in combination with either D9 or D1

Documents D3 have been cited during the examination procedure. The disclosure of D3 has been considered by the examiner in the annex to the summons to attend oral proceedings of 14 January 2019 as follows, (with references to D3 in parentheses):

> "A prosthetic valve (figure 1, feature 100) for percutaneous implantation in a
> body channel, comprising:

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a substantially cylindrical stent structure (feature 110) configured for radial
expansion (page 6, lines 3 - 15);
a valvular structure (feature 120) having an inlet and an outlet, the valvular
structure being formed of a pliant material attached to the stent structure and
forming three valve leaflets (figures 1 and 2; page 5, lines 34 - 36);
characterised by a layer of compressible material, which forms a sleeve
disposed along an outer surface of the stent structure and extending entire
around the stent structure, the compressible material being adapted after
deployment to fill gaps between the prosthetic valve and the body channel
(page 6, line 34 - page 7, line 10) wherein the compressible material is polyurethane or polyethylene terephthalate (page 7, line 8)."

In fact, page 7, lines 6 to 10 of D3 discloses that "Gasket 150 may preferably be formed from a soft, deformable biocompatible material, e.g., polyurethane, silicone, Dacron or other suitable material that readily conforms to existing tissue, yet provides a fluid-tight seal around valve 110."

The feature of a plurality of fibers extending from an outer surface of the compressible material, was considered as being not disclosed by D3.

Feature **F6** of claim 1 of the opposed patent may thus be considered as distinguishing feature over D3.

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A technical effect of fibers extending from an outer surface of a material can be seen in a promotion of ingrowth of tissue on the surface.

The objective technical problem, when starting from the teaching of D3, may be to provide a graft material which facilitates formation of tissue on surfaces thereof without impeding the flow of blood therethrough.

When looking for a solution, a person skilled in the art would consider the teaching of document D9 which discloses "Synthetische Gefäßtransplantate" (title of D9). According to claim 1 of D9, a "Synthetisches Gefäßtransplantat in Form einer Doppelvelour-Kettenwirkware aus einem Material, an dem Zellgewebe haften kann" is disclosed. In English, a warp-knit, double velour, synthetic vascular graft" is disclosed in D9. A method of preparing such graft is also disclosed.

In D3, Dacron is already suggested as suitable material for the sleeve on the outside of the stent structure. Dacron is disclosed in claim 24 of D9 as material of the velour material of the graft, solving the above-mentioned problem.

In consequence, a skilled person would have no problems to achieve the claimed subject-matter. The skilled person would have to apply the method of preparing a graft as in D9 when providing the sleeve made of Dacron material as known in D3.

Alternatively, the skilled person knows from D1 that a Dacron velour would be a suitable material for covering a stent structure of a stented heart valve. It is noted that D1 was already cited by the examiner and was considered in the extended European search opinion as including all features of claim 1 as filed. Thus, the skilled person would have no problem to combine the teachings of two documents disclosing almost the same valve prosthesis.

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The subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from D3.

Comparably, the subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from each of D5a, D5b, D7 and D8.

D5 has been considered during examination as disclosing all features of claim 1 (prior to the introduction of feature F6). D5a is a family member of D5 and discloses the embodiments of figures 13, 15A – 16C and 27 – 34 to which the examiner referred to, wherein D5a is published before the effective filing date of the opposed patent. D5b discloses a similar embodiment in figures 8A - 10B, including a stented valve with a sleeve made from compressible material.

D7 also discloses a stent-valve with a covering of the frame. According to column 6, lines 31-33, the fabric section 34, i.e., the covering, is desirably a woven polyester, such as polyethylene terephthalate, i.e., PET like Dacron. Finally, D8 discloses an implantable prosthetic valve with a cuff portion. According to [0104] of D8, to prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to prevent rolled-up sleeve-like portion at the inlet.

D5a, D5b, D7 and D8 may be considered as missing feature F6. Following the problem-solution-approach presented above, a skilled person would achieve the subject-matter of claim 1 of the opposed patent when starting from any one of D5a, D5b, D7 and D8 and combining this document with one of D1 and D9.

5.4 Lack of inventive step in view of D1 in combination with any one of D4, D5a, D5b D7, D8

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As mentioned above, D1 was considered in the extended European search report as disclosing the following claim features (references to D1 in parentheses):

A prosthetic valve for implantation in a body channel (column 7, lines 22 - 24), comprising: a substantially cylindrical stent structure configured
for radial expansion (figures, feature 30, 130, 230); a valvular structure having
an inlet and an outlet, the valvular structure being formed of a pliant material
located within the stent structure and forming three valve leaflets (feature 20);
a layer of compressible material disposed along an outer surface of the stent
structure, the compressible material being adapted after deployment to fill
gaps between the prosthetic valve and the body channel (feature 15; column
8, line 61 - column 9,line14column10,line 37 - column 11, line 3).

During examination, the following marked features have been amended in claim 1:

F1 A prosthetic valve (250) for <u>percutaneous</u> implantation in a body channel, comprising:

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material ~~located within~~ <u>attached to</u> the stent structure and forming three valve leaflets,

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F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Document D1 discloses the amendment of feature **F3**, namely that the valvular structure is not just located within but is attached to the stent structure, cf. column 4, lines 12 and 13 of D1. D1 further discloses in column 3, lines 49 to 53, a brim cover comprising a cylinder of material surrounding, folded over, and securely sutured to the two-layered brim to provide a tissue adhering cover above and below the brim, i.e., a sleeve as in amended feature **F4**. With the Dacron velour disclosed in D1, feature **F6** is at least implicitly disclosed. Features **F2** and **F5** remained unamended during examination.

The subject-matter of claim 1 of the opposed patent seems to merely distinguish from the disclosure of document D1 in that the prosthetic valve is suitable for percutaneous implantation, as required by feature **F1**.

However, D1 already discloses in column 8, lines 47 to 49, that the frame may be capable of annular deformity and slight perimetric expansion. Consequently, the subject-matter of claim 1 of the opposed patent actually differs from the disclosure of D1 by a different amount of expansion of the stent structure.

The technical effect of that other amount of expansion can be seen in a suitability of percutaneous implantation.

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When starting from the teaching of D1, a skilled person may thus be confronted with the problem to provide a prosthesis which can be implanted by means of a catheter.

From any one of documents D4 (Title: Support Tubulaire de Mise en Place, par voie Percutanee, d'une valve cardiaque de remplacement), D5 (Abstract: A method for percutaneously replacing a heart valve of a patient.), D7 (Title: Minimally-Invasive Heart Valve and Method of Use), and D8 (Abstract: A valve prosthesis device is disclosed suitable for implantation in body ducts), a skilled person knows how to design a stent structure so as to allow for percutaneous implantation by means of a catheter.

The subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from D1.

5.5 Lack of inventive step in view of D10 in combination with D13

Document D10 is directed to a stent graft with improved graft adhesion. On page 1, lines 13 and 14, it is noted that "a surgical stent graft may be placed into a lumen in the body by endoluminal techniques". In other words, D10 discloses a prosthesis for percutaneous implantation in a body channel with a substantially cylindrical stent structure configured for radial expansion.

Claim 1 of D10 discloses "a stent graft comprising a tubular graft having a distal end, a proximal end, and an outer surface; at least one expandable stent disposed on said tubular graft; and a band of fibrous material on said outer surface and adjacent at least one of said distal end and said proximal end of said tubular graft, said band of fibrous material extending circumferentially around said graft."

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Therefore, D10 discloses features **F1**, **F2** and **F4**.

According to the last paragraph on page 3 of D10, "It is desirable that the band be continuous around the proximal end of the graft so that with fibrous ingrowth of the cells of the wall of the lumen into the band of fibrous material on the graft, union of the wall and graft is obtained which provides sealing for blood flow which could occur between the graft and the wall as well as prevention of movement of the graft longitudinally within the lumen. In so doing there is improved incorporation of the graft into the wall of the lumen."

Providing a sealing for blood flow corresponds to the effect of filling gaps as in feature **F5**.

Feature **F6** is in fact in more detail disclosed in claims 4 to 8 of D10, reading:

"4. The stent graft as in Claim 1 wherein said band of fibrous material includes
velour material.
5. The stent graft as in Claim 4 wherein said velour material includes a loop pile
velour material.
6. The stent graft as in Claim 4 wherein said velour material includes a cut pile
velour material.
7. The stent graft as in Claim 1 wherein said band of fibrous material includes
fibres woven or knitted into material of said graft.
8. The stent graft as in Claim 1 wherein said graft includes a graft material and
wherein said band of fibrous material comprises brushed raised fibres of said graft material."

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In consequence, a three-leaflet valve as in feature **F3** may be seen as distinguishing feature over D10.

When starting from D10, a skilled person may thus be confronted with the objective technical problem to provide a valve functionality for blood flowing through the stented graft.

It is common knowledge, as evidence by the scientific article D13 (cf. paragraph bridging columns 1 and 2 on page 1 of D13), that "intravascular stents have gradually obtained acceptance for peripheral and coronary vascular occlusive disease. Combinations of stents with grafts have allowed for intraluminal bypass of aneurysms and long segment atherosclerotic lesions. Transfemoral percutaneous aortic valve replacement is an extended application of this new technology…". In other words, transfemoral percutaneous aortic valve replacement has been developed based on stented grafts.

The authors of D13 developed a novel sutureless bovine pericardial bioprosthetic aortic valve mounted on a collapsible stent suitable for implantation by means of a catheter (cf. second paragraph of right column on page 1 of D13.

That is, D13 discloses the solution for the above identified problem, namely to provide a stented graft with a valve.

The subject-matter of claim 1 of the opposed patent is thus not inventive when starting from D10.

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Alternatively, a skilled person would be hinted to provide a three-leaflet valve attached to a collapsible and expandable stent from each of, for example, documents D3, D4, D5, D7, and D8.

Comparably, the subject-matter of claim 1 of the opposed patent does not involve an inventive step when starting from each of D11 and D12.

Like D10, D11 discloses a stented graft. In particular with reference to figures 20 to 24, D11 discloses in detail how to form a sleeve with fibers protruding therefrom. For example, the following is described in D11, starting in column 9, line 16:

> "When the graft is deployed in a diseased vessel (not shown), the tufted yarn 932 operates to fill spaces between the vascular wall and the tubular member 934, thereby substantially forming a seal..... The tufted-yarn sealing member 932, may simply be attached to an outer wall of the graft 931 by stitching the yarn onto the wall of the tubular member 934. The tufts of yarn may be made from the fabric making up the tubular member 934 itself. The fabric 940 (See FIG. 22) from which the graft is manufactured may be woven so that weft threads (running horizontally) are omitted from certain zones 942 thereof. The lengths of warp threads (running vertically) which are not connected to each other by weft threads are pulled radially outward to form a loop 944 (See FIG. 23). The loops of warp thread 944 are cut at the apex of each loop 944, leaving single linear strands of yarn 946 (See FIG. 24) circumferentially protruding from the tubular member 934.

D12 discloses a stented graft with material folded over on itself such that a

> "distal 5 cm of a cuff includes a region in which the threads and fibers of the DACRON® polyester fabric have been at least partially separated from one another to create a frayed region that extends outward from the graft and facilitates sealing by encouraging

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thrombus formation and tissue ingrowth. Graft material, such as DACRON® polyester fiber, is particularly well-suited to form thrombus." (cf. [0009] of D12).

When starting from either D11 or D12, a skilled person would achieve the claimed subject-matter following the above discussed problem-solution-approach, i.e., simply adding a three-leaflet valve to the stented graft already including a sleeve of compressible material having fibers extending therefrom.

5.6 Dependent claims

The features of the dependent claims are not new, at least constitute straightforward modifications and do not establish an inventive step.

Claim 2:

According to claim 2, the sleeve surrounds an inflow end of the stent structure.

This feature is known, for example, from figures 21, 22 of D1, figure 10 of D2, figure 1 of D3, figure 1 of D8, figure 1 of D10, figure 1 of D11, figure 2 of D12, paragraph bridging pages 5 and 6 of D14.

Claim 3:

According to claim 3, the compressible material has a thickness ranging from 1 to 5mm.

Regarding the feature of claim 3, it is noted that the opposed patent does not provide any indication as to what kind of compressible material is measured in which state (compressed or expanded).

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For example, D2 discloses a resilient foam or sponge rubber 29 in figure 9 and 29' in figure 10. As these sealing elements in D2 are provided to fill gaps like the compressible material, a skilled person will, due to anatomical circumstances at an implantation site, consider the same range of thickness for the compressible material.

Alternatively, when considering a velour material as the compressible material, the skilled person would provide the velour band of D6 with an appropriate thickness, measured from the outermost tips of the outwardly extending fibers in an expanded state. Comparably, the skilled person knows outwardly extending fibers from D10 and would consider an appropriate length. Also the tufted yarns in D11 extend a few millimeters away from the base material.

Claim 4:

According to claim 4, the compressible material comprises a cloth or fabric.

Velour is typically formed as woven or knitted fabric. Thus, that feature is known from D1, D6, D9, D10, D11, D12 and D14 as shown above.

Claim 5:

According to claim 5, the prosthetic valve further comprises a tissue growth factor disposed along the compressible material.

For example, such a tissue growth factor is disclosed as active substance on page 9, lines 11-14 of D14.

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Claim 6:

According to claim 6, the growth factor according to claim 5 is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

It is known from, e.g., paragraph [0040] of D12 that, besides tissue-engaging structures (like fibers), an external sealing zone may be impregnated with a bioactive or pharmacological agent that enhances sealing properties, such as thrombin powder or another agent for stimulating thrombus formation about the external sealing zone 21. Other possible materials or agents, include, but are not limited to, growth factors or biomaterials for stimulating tissue ingrowth, materials that swell in the presence of blood, or other substances that help form a physical barrier to fluids. Also D14 discloses an impregnation of the material by a growth factor on page 12, line 26.

Claim 7:

According to claim 7, the fibers are straight, curved or hook-shaped.

That feature is self-evident. Fibers must be curved in a woven fabric. Outwardly extending fibers will be straight or curved. There is no other possibility.

Claim 8:

According to claim 8, the compressible material is configured to expand into the gaps.

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Assuming a foam as compressible material (as disclosed for example in D2), it is an intrinsic feature of such a material to expand as soon as a compression force is taken away. That is, a foam would surely expand into a gap. The same applies for the spongy material according to D14.

Claim 9:

According to claim 9, the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

This it, what a foam or sponge would do, see e.g. page 8, lines 1-13 of D14.

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IV. SUMMARY

The subject-matter of the claims is extended beyond the content of the application as originally filed, at least due to an omission of several features. Without any definition regarding specific features of the claims, a skilled person is not able to put the claimed subject-matter into practice, at least not based on the teaching of the patent. Assuming that the skilled person would nevertheless be able to do so, said skilled person would recognize that the subject-matter is known or at least not inventive.

Accordingly, the opposed patent is to be revoked in its entirety.

/electronically signed/
Knut M. Schwarz
Philipp Sünder
Ralph Fernolend
Korbinian Kopf

European Patent Attorneys
Association No. 708

Enclosures
Annex A1 - feature analysis
E1a – E1d;
D1 – D14.

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Europäisches Patentamt
European Patent Office
Office européen des brevets

Notice of opposition to a European patent

I. Patent opposed

Patent No.	EP2982337
Application No.	EP15180327.7
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	26 August 2020
Title of the invention	PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

II. Proprietor of the patent

first named in the patent specification	Edwards Lifesciences PVT, Inc.
Opponent's or representative's reference	272.0046OP

III. Opponent

Name	Neovasc Tiara Inc.
Address:	13562 Maycrest Way Suite 5138 Richmond British Columbia V6V 2J7 Canada
State of residence or of principal place of business	Canada
Multiple opponents (see additional sheet)	☐

IV. Authorisation

1. Representative

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Additional representative(s) on additional sheet/see authorisation ☐

Authorisation(s)

is/are enclosed ☐

has/have been registered under No. ☐

V. Opposition is filed against

the patent as a whole ☒

claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

- it is not new (Art. 52(1); Art. 54 EPC) ☒
- it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒
- patentability is excluded on other grounds, namely articles ☐

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on an attached document ☒

VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.

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IX. Evidence presented

WBH1	Patent document	US5,258,023 (A) , 02.11.1993 original file name: WBH1_US5258023A.pdf attached as: Published-Evidence-1.pdf
WBH10	Patent document	WO2006/089236 (A1) , 24.08.2006 original file name: WBH10_WO2006089236A1.pdf attached as: Published-Evidence-10.pdf
WBH11	Patent document	US2005/0137698 (A1) , 23.06.2005 original file name: WBH11_US20050137698A1.pdf attached as: Published-Evidence-11.pdf
WBH12	Patent document	WO2004/082527 (A2) , 30.09.2004 original file name: WBH12_WO2004082527A2.pdf attached as: Published-Evidence-12.pdf
WBH13	Patent document	WO01/54625 (A1) , 02.08.2001 original file name: WBH13_WO01054625A1.pdf attached as: Published-Evidence-13.pdf
WBH14	Patent document	WO01/76510 (A2) , 18.10.2001 original file name: WBH14_WO01076510A2.pdf attached as: Published-Evidence-14.pdf
WBH15	Patent document	US2004/0210304 (A1) , 21.10.2004 original file name: WBH15_US20040210304A1.pdf attached as: Published-Evidence-15.pdf
WBH16	Patent document	US5,855,601 (A) , 05.01.1999 original file name: WBH16_US5855601A.pdf attached as: Published-Evidence-16.pdf
WBH17	Patent document	WO 03/053287 (A1) , 03.07.2003 original file name: WBH17_WO03053287A1.pdf attached as: Published-Evidence-17.pdf
WBH18	Patent document	US2002/0052649 (A1) , 02.05.2002 original file name: WBH18_US20020052649A1.pdf attached as: Published-Evidence-18.pdf
WBH2	Patent document	FR2337543 (A) , 05.08.1977 original file name: WBH2_FR2337543A1.pdf attached as: Published-Evidence-2.pdf
WBH3	Patent document	WO00/64380 (A1) , 02.11.2000 original file name: WBH3_WO0064380A1.pdf attached as: Published-Evidence-3.pdf
WBH4	Patent document	FR2815844 (A1) , 03.05.2002 original file name: WBH4_FR2815844A1.pdf attached as: Published-Evidence-4.pdf
WBH5	Patent document	EP2537487 (A1) , 26.12.2012 original file name: WBH5_EP2537487A1.pdf

		attached as: Published-Evidence-5.pdf
WBH6	Patent document	US5,554,184 (A) , 10.09.1996 original file name: WBH6_US5554184A.pdf attached as: Published-Evidence-6.pdf
WBH7	Patent document	US6,454,799 (B1) , 24.09.2002 original file name: WBH7_US6454799B1.pdf attached as: Published-Evidence-7.pdf
WBH8	Patent document	US6,638,257 (B2) , 28.10.2003 original file name: WBH8_US6638257B2.pdf attached as: Published-Evidence-8.pdf
WBH9	Patent document	US2003/0153974 (A1) , 14.08.2003 original file name: WBH9_US20030153974A1.pdf attached as: Published-Evidence-9.pdf

X. Payment

Method of payment: Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated in the fees section below.

Currency: EUR

Deposit account number: 28003089

Account holder: WBH Wachenhausen Patentanwälte PartG mbB

Refunds

Any refunds should be made to EPO deposit account: 28003089

Account holder: WBH Wachenhausen Patentanwälte PartG mbB

Fees	Factor applied	Fee schedule	Amount to be paid
010 Opposition fee	1	815.00	815.00
Total:		EUR	815.00

	A Forms	Details:	System file name:
A-1	Form for notice of opposition		ep-oppo.pdf

	B Attached document files	Original file name:	System file name:
B-1	1. Facts and arguments	20210525_Annex 1_Facts and Arguments_272.0046OP.pdf	OPPO.pdf
B-2	1. Any annexes (other than citation) to an opposition letter - Annex 3_Assignment	Annex 3_Assignment.pdf	OTHER-2.pdf
B-3	2. Any annexes (other than citation) to an opposition letter - Annex 2_Feature Analysis	20210525_Annex 2_Feature Analysis_272.0046OP.pdf	OTHER-1.pdf

	C Attached evidence files	Original file name:	System file name:
C-1	1. Patent document	WBH3_WO0064380A1.pdf	Published-Evidence-3.pdf
C-2	2. Patent document	WBH4_FR2815844A1.pdf	Published-Evidence-4.pdf
C-3	3. Patent document	WBH5_EP2537487A1.pdf	Published-Evidence-5.pdf

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C-4	4. Patent document	WBH6_US5554184A.pdf	Published-Evidence-6.pdf
C-5	5. Patent document	WBH7_US6454799B1.pdf	Published-Evidence-7.pdf
C-6	6. Patent document	WBH8_US6638257B2.pdf	Published-Evidence-8.pdf
C-7	7. Patent document	WBH9_US20030153974A1.pdf	Published-Evidence-9.pdf
C-8	8. Patent document	WBH10_WO2006089236A1.pdf	Published-Evidence-10.pdf
C-9	9. Patent document	WBH11_US20050137698A1.pdf	Published-Evidence-11.pdf
C-10	10. Patent document	WBH12_WO2004082527A2.pdf	Published-Evidence-12.pdf
C-11	11. Patent document	WBH13_WO01054625A1.pdf	Published-Evidence-13.pdf
C-12	12. Patent document	WBH14_WO01076510A2.pdf	Published-Evidence-14.pdf
C-13	13. Patent document	WBH15_US20040210304A1.pdf	Published-Evidence-15.pdf
C-14	14. Patent document	WBH16_US5855601A.pdf	Published-Evidence-16.pdf
C-15	15. Patent document	WBH17_WO03053287A1.pdf	Published-Evidence-17.pdf
C-16	16. Patent document	WBH18_US20020052649A1.pdf	Published-Evidence-18.pdf
C-17	17. Patent document	WBH1_US5258023A.pdf	Published-Evidence-1.pdf
C-18	18. Patent document	WBH2_FR2337543A1.pdf	Published-Evidence-2.pdf

Signature of opponent or representative

Place	**Munich**
Date:	**26 May 2021**
Signed by:	**Thorsten Haslinde 53075**
Association:	**WBH Wachenhausen Patentanwälte PartG mbB**
Representative name:	**Thorsten Haslinde**
Capacity:	**(Representative)**

WBH Wachenhausen
Patentanwälte

FACTS & ARGUMENTS

On behalf of the Neovasc Tiara Inc., 13562 Maycrest Way #5138 of Richmond, BC V6V 2J7, Canada, it is requested to revoke European Patent EP 2 982 337 B1 (in the following referred to as "opposed patent") in its entirety on the grounds of Art. 100(a) EPC, Art. 100(b) EPC and Art. 100(c) EPC. The opposed patent was granted to Edwards Lifesciences PVT, Inc., One Edwards Way, Irvine, CA 92614 (US) and is entitled "Paravalvular leak Detection, sealing, and prevention".

As an auxiliary measure, if the Patent in its entirety is not revoked on the basis of the written proceedings, oral proceedings are requested.

The opposition grounds will be substantiated in the following. The below arguments are made without prejudice to the right to adapt and supplement them in the course of the Opposition Proceedings.

1 Introduction

The opposed patent relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses (see paragraph [0001]).

The opposed patent is a first generation divisional application from the parent application with the application number EP 05769359.0 of 30 June 2005 and claims the priority of the US patent application filed on June 30, 2004 with application number US 10/883,575.

During prosecution, 5 prior art documents were cited:

WBH1	US 5,258,023 A
WBH2	FR 2 337 543 A1
WBH3	WO 00/64380 A1
WBH4	FR 2 815 844 A1
WBH5	EP 2 537 487 A1

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The Applicant further cited the following documents in the opposed patent:

WBH6	US 5,554,184 A
WBH7	US 6,454,799 B1
WBH8	US 6,638,257 B2
WBH9	US 2003/0153974 A

In addition to the prior art documents already known from the prosecution phase, it is referred to the following documents:

WBH10	WO 2006/089236 A1
WBH11	US 2005/0137698 A1
WBH12	WO 2004/082527 A2
WBH13	WO 01/54625 A1
WBH14	WO 01/76510 A2
WBH15	US 2004/0210304 A1
WBH16	US 5,855,601 A
WBH17	WO 03/053287 A1
WBH18	US 2002/0052649 A1

2 Construction of Claim 1

The opposed patent comprises one independent device Claim 1 followed by dependent Claims 2 to 9.

Independent device Claim 1 can be structured as follows:

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

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1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

For ease of reference, the feature analysis is submitted along with this opposition brief as

Annex 2.

3 Added matter (Art. 100(c) EPC)

Applicant filed the present divisional application with a new set of claims and with the claims of the parent application as filed included as clauses at the end of the description. Applicant did not provide any kind of basis where the subject-matter of the new claims is disclosed in the parent application as filed. It appears as if Claim 1 of the opposed patent is based on Claim 27 of the parent application as filed. However, as derivable from the below marked-up version, in which Claim 1 of the opposed patent is compared to Claim 27 of the parent application as filed, Applicant has significantly amended and shifted the claims' subject-matter during prosecution of this divisional application.

Marked-up claim 1

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) ~~providing a flexible conduit~~ having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

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1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted ~~for expansion~~ after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Among other amendments, Applicant has

a) deleted that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel

b) added that the compressible material includes a plurality of fibers extending outward from the outer surface

c) deleted that the valvular structure provides a flexible conduit

d) added that the layer of compressible material forms a sleeve.

As outlined below, at least each of the amendments a)-d) add matter to the application as filed, contravening either Art. 76 EPC, Art. 123(2) EPC or both.

3.1 Amendment a): deletion of adaptation of compressible material for expansion after deployment

In Claim 27 of the parent application as filed, it is claimed that the compressible material is "*adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel*". Likewise, paragraph [0055] of the description of the parent application as filed states that the compressible material "*is configured to expand into the gaps*". The same applies to paragraph [00145] of the description of the parent application *mutatis mutandis*, stating in lines 22 to 23 that the "*compressible material expands after deployment at a treatment side. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.*"

The parent application as filed only provides support for a prosthetic valve, which comprises a compressible material adapted for expansion after

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deployment (of the cylindrical stent structure) to fill gaps between the prosthetic valve and the body channel. In other words, the parent application as filed only provides support for embodiments in which the compressible material expands to fill gaps between the prosthetic valve and the native anatomy, said expansion occurring after deployment of the prosthetic valve from the delivery device. This implies that the parent application as filed does not provide any kind of basis for a prosthetic valve with an expandable stent structure and a compressible material, the compressible material being pressed into gaps between the valve prosthesis and the native anatomy via the stent structure during deployment of the stent structure, for example.

Thus, by conducting amendment a), Applicant has deleted a feature from independent Claim 27 of the parent application, which is outlined as being essential in the parent application as filed. This constitutes a breach of Art. 123(2) EPC (see *Case Law of the Boards of Appeal, 9th edition, II-E-1.4.3*).

Furthermore, we stress that the underlying idea of Art. 123(2) EPC is that an Applicant should not be allowed to improve his/her position by adding subject-matter not disclosed in the application as filed, which would give him/her an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application (see G1/93, *Case Law of the Boards of Appeal, 9th edition, II-E-1.1*). The public may not be confronted with an extent of protection, which could not have been established by a skilled person having studied the whole content of the technical disclosure of the originally filed patent application (see e.g. T157/90 and T187/91).

As outlined in detail above, the parent application as originally filed does not provide support for a prosthetic valve having a stent, a valvular structure and a generic compressible material adapted to fill gaps between the prosthesis and the native tissue but only for such a valve prosthesis having a compressible material adapted to expand after deployment to fill said gaps between the prosthetic valve and the body channel. The latter has already been claimed in Claim 27 of the parent application as filed and the entire disclosure of the parent application does not teach any alternative. Applicant thus extended the scope

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of protection to an extent not justified by the overall disclosure damaging the legal security of third parties.

The subject-matter of Claim 1 of the opposed patent therefore contravenes the requirements of Art. 76 EPC.

3.2 Amendment b): addition that the compressible material includes a plurality of fibers extending outward from the outer surface

During prosecution, Applicant specified that the compressible material includes a plurality of fibers extending outward from the outer surface. This feature finds basis in Claim 29 of the parent application as filed but only in combination with the feature that the prosthetic valve further comprises "*a tissue growth factor disposed along the compressible material*". According to paragraph [00145] of the description of the parent application as filed, the tissue growth factor is applied to "*the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps*". This additional sealing functionality is provided by the combination of the fibers and the tissue growth factor, which are therefore functionally interlinked.

Separating the fibers from the tissue growth factor constitutes an unallowable intermediate generalization, contravening the requirements of Art. 76 EPC.

3.3 Amendments c) and d): deletion that the valvular structure provides a flexible conduit and addition that the compressible material forms a sleeve

Amendments c) and d) constitute unallowable intermediate generalizations.

Firstly, we note that the parent application as filed only provides support for a valvular structure providing a flexible conduit having an inlet and an outlet but not for a valvular structure with an inlet and an outlet having an arbitrary shape. We refer to Fig. 22 of the parent application as filed showing an elongated valvular structure in the form of a conduit. No other type of configuration of the valvular structure is disclosed in the parent application as filed.

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By deleting the feature that the valvular structure provides a flexible conduit, Applicant extended the scope of protection to an extent not justified by the overall disclosure. Amendment b) therefore contravenes the requirements of Art. 76 EPC.

Secondly, we note that the addition of the feature that the compressible material forms a sleeve constitutes an unallowable intermediate generalization. Specifically, a sleeve is only mentioned in paragraph [00145] of the parent application as filed. However, this paragraph states that the compressible material "*may extend entirely around the stent structure, such as in the form of a sleeve*". In contrast, Claim 1 of the opposed patent requires the layer of compressible material to form a sleeve.

The *Merriam Webster* dictionary defines a "*sleeve*" as "*a tubular part … designed to fit over another part*". The purpose of the sleeve is to protect the other part, i.e. the part over which it is fitted. Accordingly, a compressible material forming a sleeve of a stent structure is required to engage with the stent structure to provide covering and protection functionalities. In contrast, a compressible material in the form of a sleeve may be provided spaced apart from the stent structure, for example.

It is not directly and unambiguously derivable from the parent application that the compressible material actually forms a sleeve – that it exhibits a configuration and is adapted to the remaining parts of the prosthesis so as to provide covering and protection functionalities. In contrast, the parent application as filed merely provides support for a compressible material extending around the stent structure in the form of a sleeve but not of a compressible material which actually forms a sleeve.

Claim 1 of the opposed patent therefore contravenes the requirements of Art. 76 EPC. For the sake of completeness, we note that amending Claim 1 by specifying that the compressible material is extending around the stent in the form of a sleeve to overcome the Art. 76 EPC objection, Proprietor would broaden the scope of protection contravening the stipulations of Art. 123(3) EPC.

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3.4 Lack of basis of other parts of the disclosure

Furthermore, the subject-matter of dependent Claims 2, 3, 4 and 9 is not directly and unambiguously derivable from the parent application as filed. In detail:

- Claim 2: It is not directly and unambiguously derivable from the parent application that the sleeve may surround an inflow end of the stent structure. In fact, the term "inflow" is not used at any point in the parent application as filed. Likewise, it is not directly and unambiguously derivable from Fig. 22 of the parent application as filed that the sleeve surrounds the inflow end since the inflow of the stent structure is not visible in Fig. 22.

- Claim 3: The feature that the compressible material exhibits a thickness ranging from 1 to 5 mm is only mentioned in paragraph [00145] of the parent application. However, it is only disclosed in combination with the compressible material being formed of polyethylene terephthalate (PET). There is no teaching in the entire parent application of a compressible material having a thickness ranging from about 1 to 5 mm that is formed from any other type of material. Claim 3 of the opposed patent therefore constitutes an unallowable intermediate generalization.

- Claim 4 of the opposed patent specifies that the compressible material comprises a cloth or fabric. This feature is also only mentioned in paragraph [00145] of the parent application as filed. However, said paragraph only discloses that the compressible material resembles a cloth or fabric having small fibers extending from the surface of the material. Claim 4 of the opposed patent thus constitutes an unallowable intermediate generalization since it only requires the compressible material to comprise a cloth of fabric while the parent application as filed requires the compressible material to resemble a cloth of fabric having small fibers.

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- Claim 8 of the opposed patent specifies the compressible material to be configured to expand into gaps. However, said claim does not specify at what point in time the compressible material is configured to expand into gaps during the delivery process of the prosthetic valve. As outlined in detail under section 3.1 above, the parent application as filed merely provides basis for a compressible material being adapted for expansion after deployment to fill gaps. As the specification of the point in time for the expansion of the compressible material is lacking in Claim 8 of the opposed patent, it constitutes an unallowable intermediate generalization which contravenes Art. 76 EPC.

- Claim 9 specifies the compressible material to be configured to adjust to the shape of the cavity existing between the valve and the wall of the body vessel upon stent opening. It appears as if the subject-matter of Claim 9 is ought to be directed to an embodiment in which the compressible material is passively introduced into gaps between the prosthetic valve in the body channel via the radially expanding stent structure. We have outlined in detail under section 3.1 above that such an embodiment does not find any kind of basis in the parent application as filed. Claim 9 of the opposed patent therefore contravenes the requirements of Art. 76 EPC.

Finally, we note that the parent application was filed with a provisional set of drawings while the opposed patent was filed with a substituted set of formal drawings. The provisional drawings originally filed with the parent application and the substituted formal drawings originally filed with this divisional application deviate in multiple aspects, thereby adding subject-matter against the stipulations of Art. 76 EPC.

Specifically, as derivable from a comparison of Fig. 22 of the provisional drawings of the parent application and Fig. 22 of the substituted formal drawings of this divisional application illustrated side-by-side below, the compressible material (256, Fig. 22) of the substituted formal drawing exhibits a plurality of components, which appear to be the claimed fibes. Said components are not depicted in Fig. 22 of the provisional drawings. Instead, the compressible

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material of Fig. 22 of the provisional drawings exhibits a continuous and uniform planar outer surface. Accordingly, Fig. 22 of the opposed patent as originally filed provides the skilled person with additional information not derivable from Fig. 22 of the parent application as filed. Similar objections apply to Fig. 2B, Fig. 3, Figs. 5C and D, Figs. 8C and D, Fig. 10E, Figs. 11C and D, Figs. 13A and B, Fig. 15A, Fig. 16A, Fig. 17B, Fig. 19D, Fig. 20A as well as Figs. 20E and 20G.

Also because of these reasons, the subject-matter of the opposed patent contravenes the requirements of Art. 76 EPC.

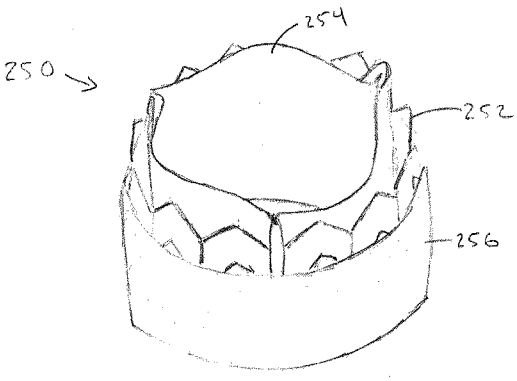


Fig 22 as filed of parent

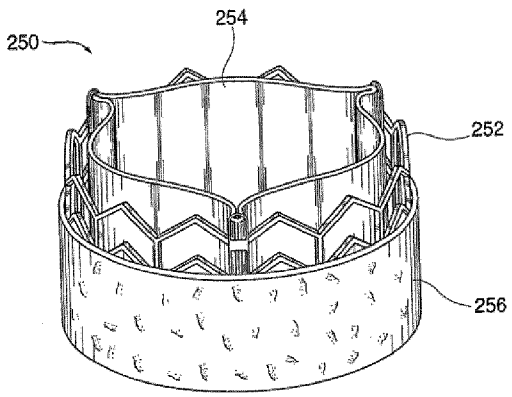


Fig. 22 as filed of divisional

4 Insufficiency (Art. 100(b) EPC)

Claim 1 of the opposed patent requires the compressible material to be adapted after deployment to fill gaps between the prosthetic valve and the body channel (feature 1.3). According to paragraph [0064] of the opposed patent, "*the compressible material creates a mechanical seal that prevents paravalvular leakage*". The skilled person therefore takes from feature 1.3 that the compressible material is compressed against the tissue of the native anatomy. At the same time, feature 1.4 of Claim 1 of the opposed patent requires the compressible material to comprise fibers extending outward from the outer surface.

The skilled person is provided with contradictory teaching. The compressible material and therefore also the fibers are supposed to be compressed against

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the native anatomy, implying that the fibers are bent to not extend outward from the outer surface. However, in contradiction with this teaching of feature 1.3, feature 1.4 requires the fibers to extend outward the outer surface.

Neither the disclosure of the opposed patent nor the common general knowledge provides the skilled person with any kind of teaching on how this contradictory teaching can be resolved and the invention can be put into practice over the whole area claimed without undue burden and without requiring inventive activity.

Due to the above, the opposed patent does not fulfil the requirements of Art. 83 EPC.

5 Lack of patentability (Art. 100(a) EPC)

The opposed patent lacks novelty over several prior art documents not considered during prosecution – inter alia since the priority of the opposed patent is not validly claimed. In addition, also some of the prior art documents cited during prosecution are prejudicial to novelty of the opposed patent. Besides, the opposed patent lacks an inventive step.

5.1 Priority not validly claimed

The opposed patent does not validly claim the priority due to formal reasons and due to the subject-matter of the claims of the opposed patent not being directly and unambiguously derivable from the priority application.

5.1.1 Priority claim invalid due to formal reasons

Pursuant to Art. 87(1) EPC, a right of priority originates in the Applicant of a first application. However, pursuant to the same provision, the right of priority may also be invoked by the "successor in title" of the person who has filed the first application. It is generally accepted that the right of priority is transferable. However, according to well established case law of the Boards of Appeal, the transfer must have occurred before the filing date of the subsequent application

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(see e.g. T 1201/14). The Boards of Appeal confirmed in T 577/11 that a succession in title that occurred after the filing date of the subsequent application was not sufficient to comply with the requirements of Art. 87(1) EPC.

The priority application of the opposed patent, US 10/883,575 filed on June 30, 2004, was filed with the Inventors as Applicant. The latter already becomes evident from the matter of fact that all US patent applications prior to the American Invents Act (AIA) in 2011 had to be filed with the Inventors as Applicant. The filing date of the opposed patent is of course the filing date of the PCT application with the publication number WO 2006/005015 from which the opposed patent's parent derives. WO 2006/005015 was filed on June 30, 2005 in the name of Edwards Lifesciences PVT, Inc. In view of the above outlined requirements, for the priority to be validly claimed, the right to priority must have been validly transferred to the Applicant of the opposed patent, i.e. Edwards Lifesciences PVT, Inc., prior to the filing date of the opposed patent.

This is not the case. As derivable from the attached assignment, which we enclose as

Annex 3,

the right to priority was only transferred from the Inventors to the predecessor in title, the proprietor of the opposed patent, in April/May 2007 and, thus, after filing of the opposed patent.

In view of the above, the opposed patent does not validly claim the priority since the Applicant/Proprietor of the opposed patent was not entitled to the priority right at the time of filing of the opposed patent.

5.1.2 Subject matter of Claim 1 not disclosed in priority application

Furthermore, we note that the subject-matter of Claim 1 of the opposed patent is not directly and unambiguously derivable from the priority document (US 10/883,575). We note that Art. 87(1) EPC stipulates that the subject-matter of a claim is only entitled to priority in respect of "the same invention" as was

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disclosed in the previous application. The Enlarged Board of Appeal has decided in the landmark decisions G 3/93 and G 2/98 that for assessing the "same invention" requirement, the "Gold standard" disclosure test must be applied. The latter implies that priority of a claim is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the priority application as a whole. This has been confirmed by the decisions of the Enlarged Board of Appeal G 1/03, G 2/03, G 2/10 and G 1/16.

The subject-matter of Claim 1 of the opposed patent relates to a prosthetic valve with a cylindrical stent structure, a valvular structure with three leaflets and a layer of compressible material having a plurality of fibers adapted to fill gaps between the prosthetic valve and a body channel. The compressible material is disposed on an outer surface of the stent structure and extends entirely around the stent structure. Only the embodiment of Fig. 22 of the opposed patent, which is described in paragraphs [0063] to [0064], relates to such a prosthetic valve having a stent, a valvular structure with three leaflets and a layer of compressible material extending around the outer surface of the stent structure. However, the configuration illustrated in Fig. 22 and described in the above listed passages of the description is missing in the priority document. In fact, if any, the priority document only shows configurations according to Figs. 1 to 19 of the opposed patent. A compressible material being provided on the outer surface of the stent, in particular a compressible material comprising a plurality of fibers, is not disclosed in the priority document whatsoever. Likewise, the priority document does not disclose a valvular structure having three leaflets.

In view of the above, for the subject-matter of the claims of the opposed patent, the priority is not validly claimed since it is not directly and unambiguously derivable from the priority document.

5.2 Lack of novelty over WO 2006/089236 A1 (WBH10)

WBH10 was filed on February 18, 2006 and validly claims a priority of February 18, 2005. Since the opposed patent does not validly claim the priority (see 5.1.1 and 5.1.2 above) and WBH10 validly entered the EP regional phase,

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WBH10 constitutes prior art according to Art. 54(3) EPC in line with Rule 165 EPC.

WBH10 relates to an apparatus (10, Fig. 4) having an expandable support member (40, Fig. 4) – a stent – and a prosthetic valve (page 5, lines 23 to 25). According to page 22, lines 8 to 11, the apparatus may be delivered "with a percutaneous approach". Furthermore, according to page 5, lines 25 to 28, the support member "*has a known stent configuration that allows it to be collapsed and expanded*" and may be made from "*shape memory materials such as Nitinol*". Accordingly, WBH10 discloses features **1** and **1.1**. Features 1 and 1.1 are also directly and unambiguously derivable from the priority document of WBH10 (see page 8, lines 1 to 6, page 14, lines 4 to 8 and Fig. 2).

Furthermore, as described on page 21, line 13 to page 22, line 7, the apparatus may comprise "a tri-leaflet" prosthetic valve (12b, Fig. 12 illustrated below) having an inlet and an outlet, which may be made of a biological material (page 21, line 23) and/or a biocompatible material (page 21, line 26), both of which constituting a pliant material. According to page 21, lines 14 to 15, the apparatus of Fig. 12 is, besides having such a "tri-leaflet" configuration, constructed as the apparatus of Figs. 2 to 8. According to page 8, lines 6 to 8, the prosthetic valve is secured "*by sutures or other suitable means*" within the support member (40, Fig. 4). Accordingly, WBH10 also discloses feature **1.2**. Feature 1.2 is also directly and unambiguously derivable from the priority document of WBH10 (see page 13, line 16 to page 14, line 2, page 10, lines 13 to 21, Fig. 7).

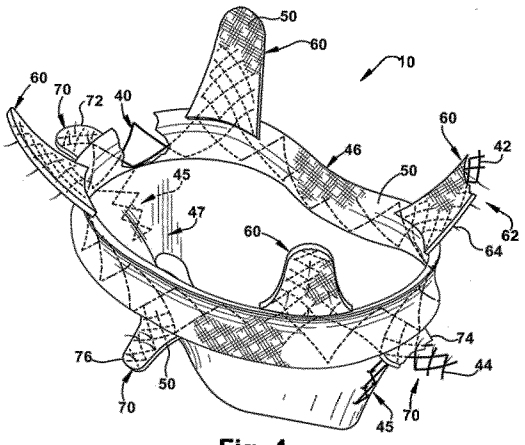


Fig. 4

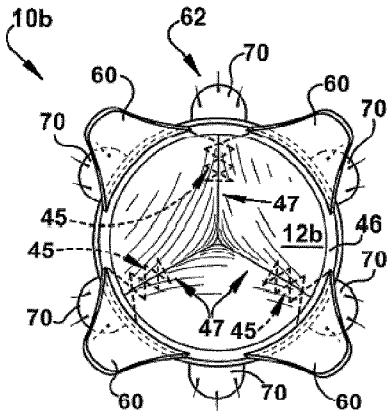


Fig. 12

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Finally, we note that the device of WBH10 may include a layer of biocompatible material (50, Fig. 4), which can cover the outside surface of the support member (40, Fig. 4) (see page 6, lines 10 to 12) and which may be attached around the entire circumference of the support member (40, Fig. 4) (see page 6, lines 12 to 13). The layer (50, Fig. 4) may be "*a synthetic such as Dacron, Gore-Tex, woven velour, polyurethane, polytetrafluorethylene (PTFE), or heparin-coated fabric. Alternatively, the layer 50 may be a biological material such as bovine or equine pericardium, peritoneal tissue, an allograft, a homograft, patient graft, or a cell-seeded tissue*" (see page 6, lines 5 to 9). Accordingly, the layer (50, Fig. 4) is suitable to fill gaps between the prosthetic valve in the body channel and comprises a plurality of fibers (e.g. when being made from woven velour), therefore constituting a compressible material according to features **1.3** and **1.4**. Features 1.3 and 1.4 are also directly and unambiguously derivable from the priority document (see page 8, line 13 to page 9, line 2).

In view of the above, the subject-matter of Claim 1 of the opposed patent is not novel over WBH10.

5.3 Lack of novelty over US 2005/0137698 A1 (WBH11)

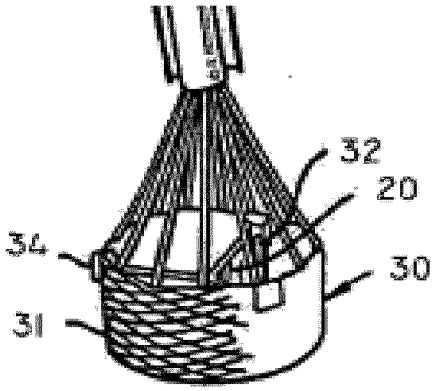
WBH11 is a US patent application published on June 23, 2005 and, thus, prior to the filing date of the opposed patent. Since the opposed patent does not validly claim the priority (see 5.1.1 and 5.1.2), WBH11 constitutes prior art according to Art. 54(2) EPC.

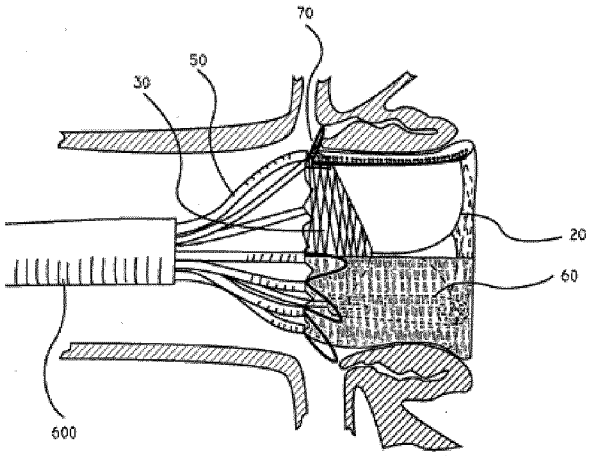
WBH11 relates to a prosthetic valve for percutaneous implantation in a body channel (see paragraph [0002]), which includes an expandable anchor and a replacement valve (see paragraph [0013]). The anchor (30, Fig. 1B illustrated below) may be self-collapsing and/or self-expanding and may be made out of a shape memory material, such as Nitinol as described in paragraph [0036]. The replacement valve (20, Fig. 1B illustrated below) can be composed of "a metal, a synthetic material and/or may be derived from animal tissue" as described in the last three lines of paragraph [0035]. Furthermore, as shown in Fig. 1B and as described in paragraph [0035], the replacement valve (20, Fig. 1B) comprises

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three commissure attachments secured at three posts of the anchor. The matter of fact that the replacement valve comprises three commissure attachments implies to that it also comprises three leaflets as a commissure attachment is provided at the interface of two leaflets. Accordingly, WBH11 discloses features **1, 1.1** and **1.2**.

Furthermore, as described in paragraph [0071] of WBH11, anchor (30, Fig. 8C illustrated below) may be "*externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric*."





As described in paragraph [0073] of WBH11, seal (60, Fig. 8C) can be bunched up and create pleats, which "*pleats can then fill pockets thereby improving the paravalvular seal*". Accordingly, we note that seal (60, Fig. 8C) of WBH11 constitutes a compressible material adapted to fill gaps between the prosthetic valve and the body channel. Therefore, feature **1.3** is disclosed in WBH11. Finally, we note that a seal composed of a fabric comprises a plurality of fibers, some of which also always extending outward from the outer surface. Accordingly, WBH11 also discloses feature **1.4**.

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In view of the above, the subject-matter of Claim 1 also lacks novelty over WBH11.

5.4 Lack of novelty over WO 2004/082527 A2 (WBH12)

WBH12 is an International patent application published on September 30, 2004 and constitutes prior art according to Art. 54(2) EPC since the opposed patent does not validly claim its priority.

WBH12 discloses a prosthetic heart valve that can be implanted in a minimally invasive manner (see paragraph [0014]) comprising a support frame (50, Fig. 5 illustrated below), which may be "*elastic*", e.g. manufactured from a Nitinol alloy (see paragraph [0066]). The valve comprising three flexible leaflets is attached within the support frame (see paragraph [0057]). Accordingly, WBH13 discloses features **1, 1.1** and **1.2**.

Fig. 3A

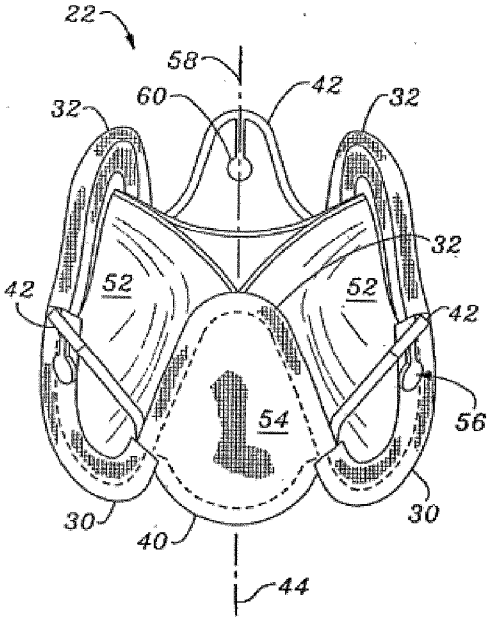
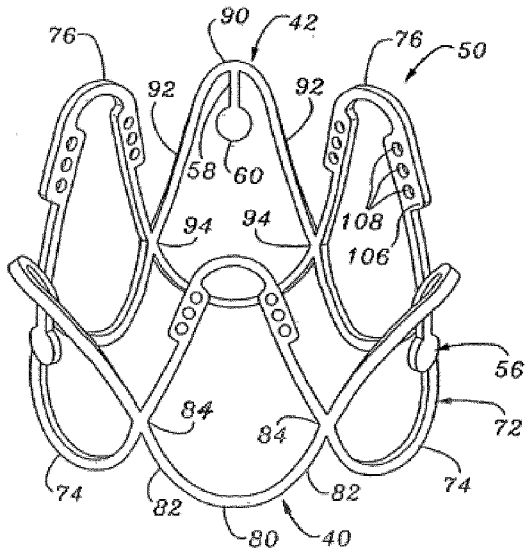


Fig. 5



In addition, the prosthetic heart valve comprises an exterior layer of a fabric, e.g. polyethylene terephthalate providing "*a matrix into which surrounding tissue can grow to help anchor the valve in place*" (see paragraph [0056]). The same

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paragraph states that the exterior layer of fabric covers the entire support frame. As the fabric made from polyethylene terephthalate exhibits a matrix-like structure, it must comprise fibers, some of which extending outward from the outer surface. Thus, WBH13 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH12.

5.5 Lack of novelty over WO 01/54625 A1 (WBH13)

WBH13 is an International patent application published on August 02, 2001 and, thus, constitutes prior art according to Art. 54(2) EPC.

WBH13 discloses a prosthetic valve for percutaneous implantation in a body channel (see Claims 1, 26 and 34) having a self-expanding stent (see Claim 2) (20, Fig. 15 illustrated below) and a valve, which may exhibit three leaflets (column 5, lines 9 to 12). Accordingly, WBH13 discloses features **1, 1.1** and **1.2**.

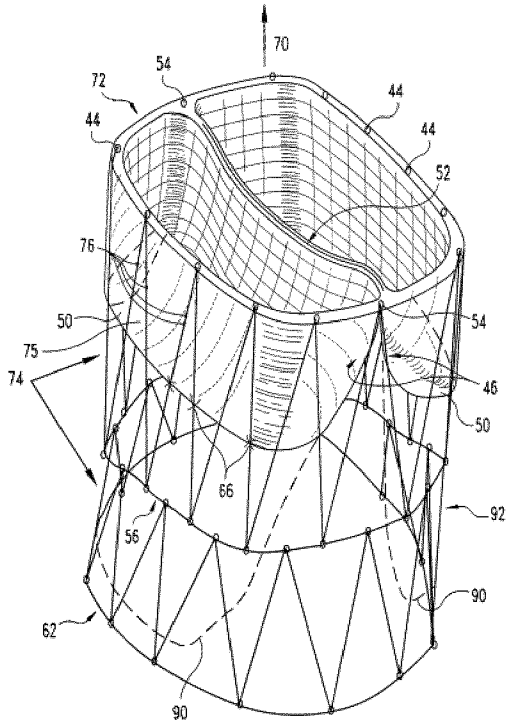


Fig. 15

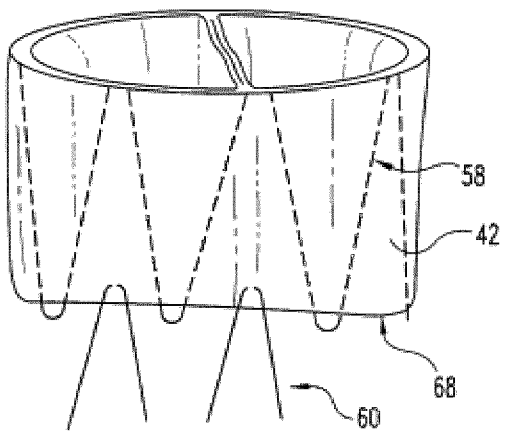


Fig. 13A

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Furthermore, as described in the last paragraph on page 7, excess material of the valve material "*can be kept outside the stent, which will later become a potential fold-over 42*". As described in the third paragraph on page 15, "*the external surface of the frame can be covered with a sheath that is not necessarily the same material as the valve 41. For example, while the valve can be a naturally occurring material, the outer sheath can be synthetic material such as described herein. The sheath, therefore, can be the fold-over of the valve material, another type of naturally occurring material, or a synthetic material. Accordingly, the sheath may partially or totally cover the frame*". The second paragraph of page 8 provides examples of the type of material from which the sheath may be manufactured and explicitly names PET, PP, PTFE or any polymer or derivative thereof as well as Gore-Tex, Dacron or other any synthetic material. As described in lines 6 to 11 of page 17, the fold-over or sheath may include "*barbs, hooks, adhesives, notches, a textured surface, or any other treated surface that facilitates relative affixation of the device in its location*". Accordingly, WBH13 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH13.

5.6 Lack of novelty over WO 01/76510 (WBH14)

WBH14 is an International patent application published on October 18, 2001 and, thus, constitutes prior art according to Art. 54(2) EPC.

WBH14 discloses a prosthetic valve for percutaneous implantation in a body channel (see title and Claims 35 to 39) comprising a substantially cylindrical stent structure for radial expansion (flexible tubular member 42 and support stent 24, Fig. 1, page 7, lines 26 to 28). Furthermore, as derivable from Fig. 2 of WBH14 illustrated below, the prosthetic valve comprises a valvular structure being formed of a pliant material and forming three valve leaflets (82, Fig. 2 illustrated below, page 11, lines 4 to 6).

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In addition, we note that the heart valve may comprise a fabric section (34, Fig. 2 illustrated below), which may be "*a woven polyester, such as polyethylene terephthalate. Alternatively, the fabric section 34 may be formed of polytetrafluorethylene (PTFE), or other suitable biocompatible sheet material*" (see page 8, line 30 to page 9, line 1). As described on page 8, lines 21 to 23, the fabric section may be formed as a tube extending entirely around the stent structure. As described on page 12, lines 8 to 9, the fabric section (34, Fig. 2 illustrated below) is compressible to be compressed against the host annulus. Accordingly, WBH14 also discloses feature **1.3**. We also note that feature **1.4** is disclosed by WBH14 since the fabric section may be formed from a woven polyester, therefore exhibiting fibers, which inevitably extend outward from the outer surface.

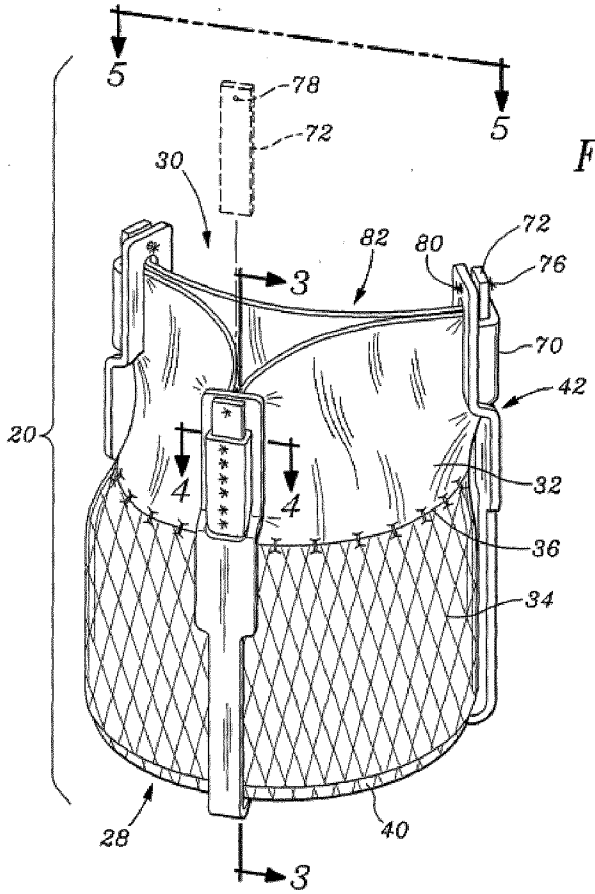


Fig. 2

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH14.

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5.7 Lack of novelty over US 2004/0210304 A1 (WBH15)

WBH15 is a US patent application published on October 21, 2004 and constitutes prior art according to Art. 54(2) EPC since the opposed patent does not validly claim its priority.

WBH15 discloses a device for replacing a heart valve by a percutaneous route (see paragraph [0106]) which comprises a support structure (101, Fig. 14 illustrated below) containing a valve (102, Fig. 14 illustrated below) (see paragraph [0115]). As described in paragraph [0116], the support structure can be made from a material with shape memory characteristics, such as Nitinol. The valve (102, Fig. 14) is provided inside of the support structure and may be connected to the support structure by sutures or other appropriate means of attachment (see paragraph [0116]). Thus, WBH14 discloses features **1, 1.1** and **1.2.**

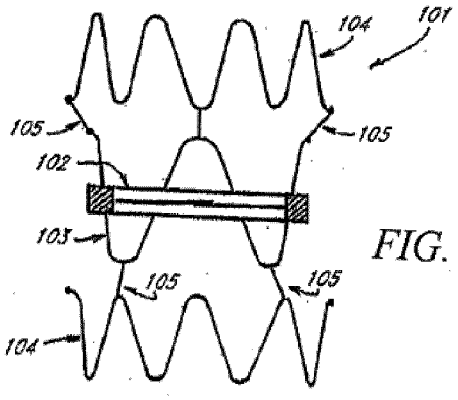
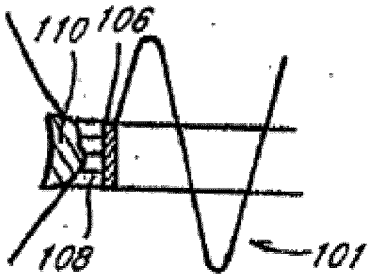


FIG. 14

FIG. 29



As described in paragraph [0115], the support structure (101, Fig. 14) comprises a shell (108, Fig. 29 illustrated above) made from a compressible material. As described in paragraph [0121] under reference to Fig. 29 illustrated above, the compressible material (108, Fig. 29) "*can absorb the surface irregularities possibly existing at or near ring 110, which results from calcifications*". Paragraph [0026] of WBH15 discloses that the sealing means "*can consist of a peripheral shell made from a compressible material such as polyester or tissue … This sealing means can also include a material that can be applied between the existing cardiac ring and the axial valve support portion, this material being*

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capable of solidifying after a predetermined delay following this application.". Thus, WBH15 also discloses features **1.3** and **1.4.**

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH15.

5.8 Lack of novelty over US 5,855,601 (WBH16)

WBH16 was published on January 5, 1999 and, thus, constitutes prior art according to Art. 54(2) EPC. WBH16 relates to a heart valve prosthesis, which may be implanted percutaneously comprising a stent member and a valve means (see column 2, lines 55 to 60). According to column 3, lines 52 to 55, "*the stent member is self-expanding and has a first cylindrical shape in its compressed or collapsed configuration and a second, larger cylindrical shape in its expanded configuration*". According to column 3, lines 55 to 57 and column 4, lines 1 to 3, the valve means is flexible and may contain three leaflets (stent member 32, valve member 35 with leaflets 36 and cuff portion 37, Fig. 4 illustrated below).

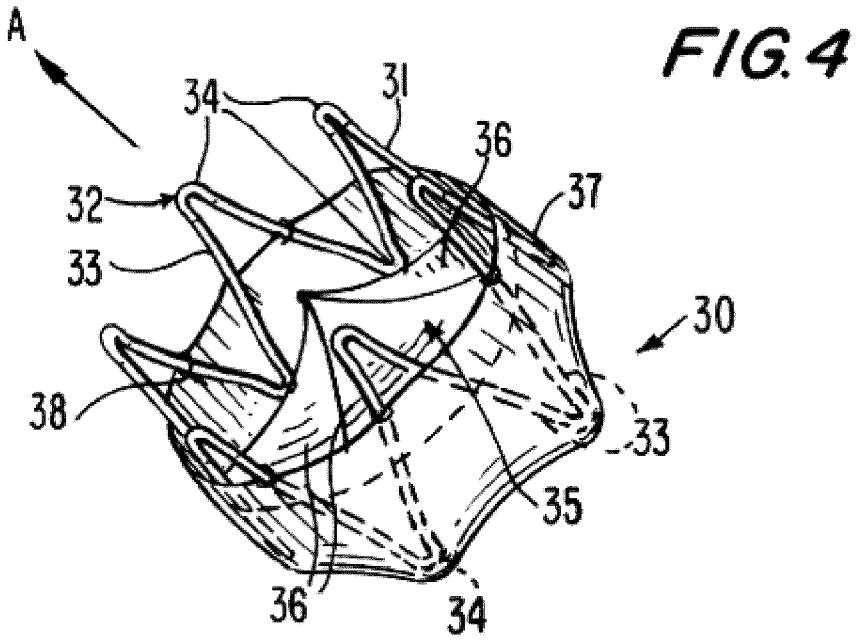


FIG. 4

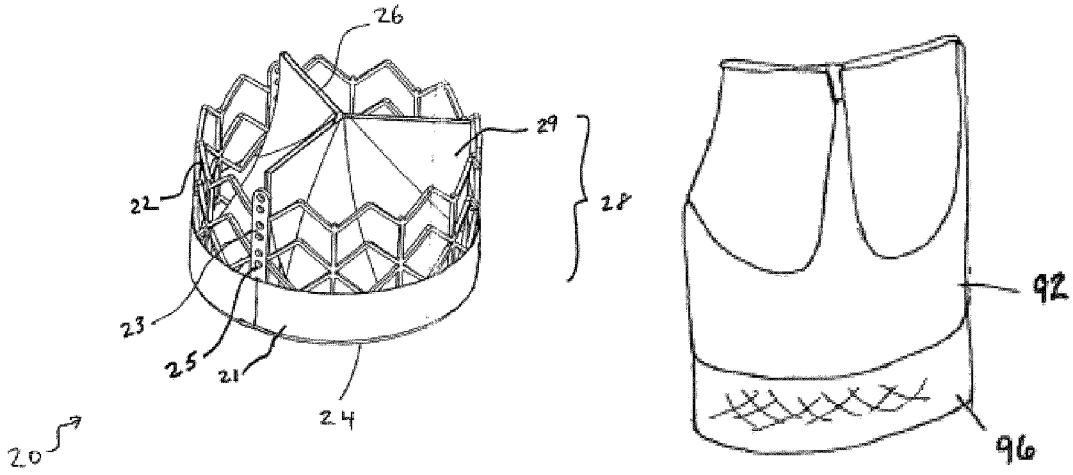
Furthermore, as described in column 4, lines 4 to 6, the valve means further comprises a cuff portion, which may extend wholly around the outer perimeter of the stent member. According to Claim 1 of WBH16, the cuff portion is configured "*to position the valve snugly and sealingly at a valve side*". As described in column 6, lines 19 to 31, the "*valve member is flexible, compressible, host-compatible, and non-thrombogenic*", wherein biocompatible materials "*such as polytetrafluorethylene, polyester and the like may be used*". Accordingly, the cuff portion, which constitutes part of the valve member, is compressible and adapted to fill gaps between the prosthetic valve and the body channel and comprises fibers extending outward. Therefore, WBH16 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH16.

5.9 Lack of novelty over US 2003/0153974 A1 (WBH9)

WBH9 is a US patent application published on August 14, 2003 and, thus, constitutes prior art according to Art. 54(2) EPC. WBH9 is cited in paragraph [0009] of the opposed patent. As explicitly stated in paragraph [0009] of the opposed patent, WBH9 discloses a prosthetic device suitable for implantation in body ducts, the device comprising a support stent "*of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radially forces from within by means of a deployment device to a deployed state in the target location*". The support stent comprises a "*valve assembly comprising a flexible conduit having an inlet and an outlet, made of pliant material attached to the support stent*". Accordingly, WBH9 discloses features **1, 1.1** and **1.2.**

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In paragraph [0010] of the opposed patent, it is stated that WBH9 does not address leaks that can occur around the implanted valve. This is not correct. According to paragraph [0112] of WBH9, the valve assembly may exhibit "*a rolled sleeve, which enhances the sealing of the device at the valve inlet*". This rolled sleeve is indicated with reference sign 24 in Fig. 1 and reference sign 96 in Fig. 8A, both figures being illustrated side-by-side above. As described in paragraph [0118] of WBH9, the sleeve may be made from PET, therefore constituting a compressible material in line with feature **1.4**. Furthermore, we note that the PET sleeve comprises fibers, some of which extending outward from the outer surface. Thus, WBH9 also discloses feature **1.5**.

In view of the above, the subject-matter of Claim 1 of the opposed patent is also not novel over WBH9.

5.10 Lack of inventive step starting from WBH9/WBH12-WBH16 in combination with WO 03/053287 A1 (WBH17) or US 2002/0052649 A1 (WBH18)

Should the Opposition Division, for any reason, be of the opinion that one of documents WBH9 and WBH12-WBH16 does not disclose feature 1.4, i.e. that the compressible material includes a plurality of fibers extending outward from the outer surface, we note that the subject-matter of Claim 1 of the opposed patent lacks an inventive step over WBH9 or either one of documents WBH12-WBH16 in combination with either WBH17 or WBH18.

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The technical effect of feature 1.4 is derivable from paragraphs [0011], [0025] and [0064] of the opposed patent and is directed to the mitigation of paravalvular leakage.

Starting from either one of WBH9 and WBH12-WBH16, the objective technical problem is thus the mitigation of paravalvular leakage.

WBH17 was published on July 3, 2003 and WBH18 on May 2, 2002. Therefore, both documents constitute prior art according to Art. 54(2) EPC. When being confronted with the above technical problem, the skilled person learns from both documents that providing fibers extending outward from the outer surface of the stent structure mitigates paravalvular leakage.

For WBH17, we refer to column 1, lines 18-20 already stating that it "*is known that tufts of fibrous material may be placed on grafts to enhance blood clotting*". Furthermore, we refer to Fig. 4 of WBH17 illustrated below showing a stent graft comprising a "*band of fibrous material 25 provided by brushing or similar means to raise fibres 26 from the material of the graft 1*" (see column 6, lines 7-8). As described in lines 23.26 of column 5, this provides the technical effect that leakage around the device is prohibited.

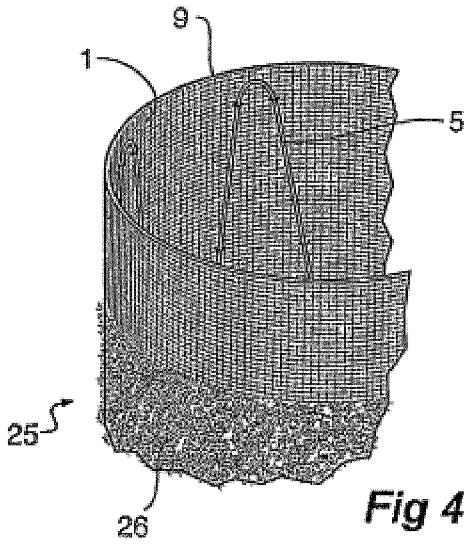


Fig 4

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For WBH18, we refer to Fig. 4a illustrated below showing a stent graft comprising a tissue engaging region 22 with a "*textured surface 23 having increased surface area. The increased surface area preferably comprises loops 28 which extend outward from the substrate 18*" (see paragraph [0032]). According to the last two lines of paragraph [0032] of WBH18, this enhances sealing.

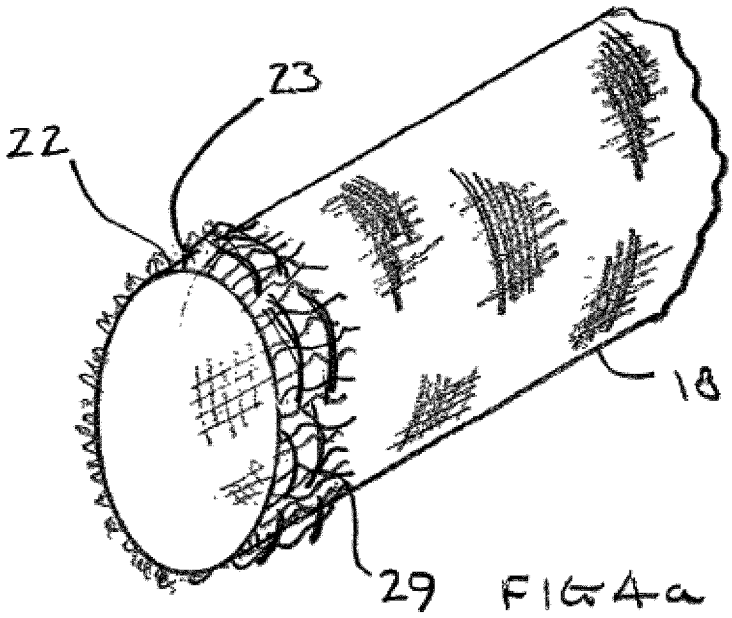


FIG 4a

When being confronted with the above stated objective technical problem of mitigating paravalvular leakage, the skilled person would thus provide fibers according to feature 1.4 to the valve prostheses of WBH9/WBH12-WBH16, therefore arriving at the subject-matter of Claim 1 of the opposed patent without inventive activity.

Therefore, the subject-matter of Claim 1 of the opposed patent also lacks an inventive step over WBH9 or either one of documents WBH12-WBH16 in combination with WBH17 or WBH18.

5.11 Lack of patentability of dependent claims

Also the dependent claims lack novelty and/or inventive step as outlined in the following:

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- dependent Claim 2: not novel over WBH10 (see Fig. 4), WBH11 Fig. (see Fig. 8C), WBH12 (see Fig. 3a), WBH13 (see Fig. 13A), WBH14 (see Fig. 2), WBH16 (see Fig. 4), WBH9 (see 1).
- dependent Claim 3: not novel over WBH10-WBH16 and WBH9. We note that the burden of proof that the prior art does not exhibit parameter lies with Proprietor. No benefit of doubt can be accorded if the Proprietor does not provide respective evidence support (see T 1764/06).
- dependent Claim 4: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above).
- dependent Claims 5 and 6: not novel over at least WBH10 (see page 15, last paragraph), WBH13 (see page 19, line 27) and anticipated by WBH1 (see column 5, line 60).
- dependent Claim 7: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above) – all of the fibers must be curved since they collectively form a tube-shaped covering.
- dependent Claim 8: not novel over at least WBH15 (see paragraph [0026] – "sealing means ... in the form of an inflatable insert").
- dependent Claim 9: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above) – all of the coverings are suitable to be adjusted in shape to cavities existing between the valve and the wall of the body vessel.

Consequently, the request for revocation of the patent in its entirety is justified at least due to the facts and arguments presented above.

-electronically signed-

Thorsten Haslinde
European Patent Attorney
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Association 786

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Enclosures

WBH1 US 5,258,023 A

WBH2 FR 2 337 543 A1

WBH3 WO 00/64380 A1

WBH4 FR 2 815 844 A1

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WBH6 US 5,554,184 A

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WBH11 US 2005/0137698 A1

WBH12 WO 2004/082527 A2

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WBH14 WO 01/76510

WBH15 US 2004/0210304 A1

WBH16 US 5,855,601

WBH17: WO 03/053287 A1

WBH18: US 2002/0052649 A1

Annex 2: Feature analysis Claim 1

Annex 3: Assignment

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Acknowledgement of receipt

We hereby acknowledge receipt of the Notice of Opposition:

Submission number	9831876
Application number	EP15180327.7
Patent number	EP2982337
Date of receipt	26 May 2021
Your reference	272.0046OP
Opponent	Neovasc Tiara Inc.
Title	PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

Documents submitted

package-data.xml	ep-opposition-data.xml
ep-oppo.pdf (6 p.)	OTHER-2.pdf\Annex 3_Assignment.pdf (5 p.)
OTHER-1.pdf\20210525_Annex 2_Feature Analysis_272.0046OP.pdf (1 p.)	OPPO.pdf\20210525_Annex 1_Facts and Arguments_272.0046OP.pdf (28 p.)
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/European Patent Office/

Annex 2
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

WBH Wachenhausen
Patentanwälte

Feature analysis of independent Claim 1 of EP 2 982 337 B1

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

US005258023A

United States Patent [19]

Reger

[11] Patent Number: 5,258,023

[45] Date of Patent: Nov. 2, 1993

[54] **PROSTHETIC HEART VALVE**

[75] Inventor: **Vincent A. Reger**, Portland, Oreg.

[73] Assignee: **Reger Medical Development, Inc.**, Portland, Oreg.

[21] Appl. No.: **834,416**

[22] Filed: **Feb. 12, 1992**

[51] **Int. Cl.**[5] **A61F 2/24**

[52] **U.S. Cl.** **623/2**

[58] **Field of Search** 623/2, 11, 66, 900

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(List continued on next page.)

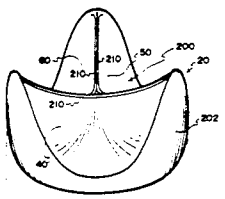
Primary Examiner—Paul Prebilic

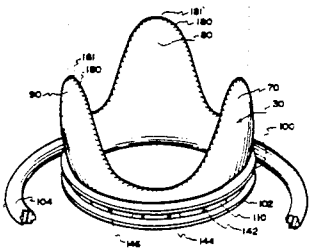
Attorney, Agent, or Firm—Lynn G. Foster

[57] **ABSTRACT**

A novel long lasting prosthetic heart valve compatible with implantation in a human natural heart valve annulus. The prosthetic heart valve comprises a trileaflet heart valve apparatus which in form, dimension, and function resembles a human trileaflet heart valve, but which is formed of synthetic resinous material. A seamless supporting frame capable of annular deformation and limited perimetric expansion during each heartbeat is totally enveloped in an essentially biologically inert cylindrical cover to form a cusp supporting stent for the valve leaflet apparatus. The free top and bottom edges of the cylindrical cover are disposed on the exterior of the stent and everted outward to provide at least one sewing ring. Valve embodiments comprise aortic and mitral implantable valves. For the aortic implant, the outwardly everting free sewing ring forming edges are separated by circumferentially disposed compressible and expandable material which provides a pliable, compliant interface between the valve and the natural valve annulus at the implanting site. Valve sewing ring covers can be selectively impregnated with antibiotic medicants to substantially eliminate early post implant infection. Use of non-thrombogenic biochemically inert materials in a valve apparatus which mimics operation of a natural heart valve essentially eliminates the need for long term administration of anticoagulants.

32 Claims, 5 Drawing Sheets





WBH1
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

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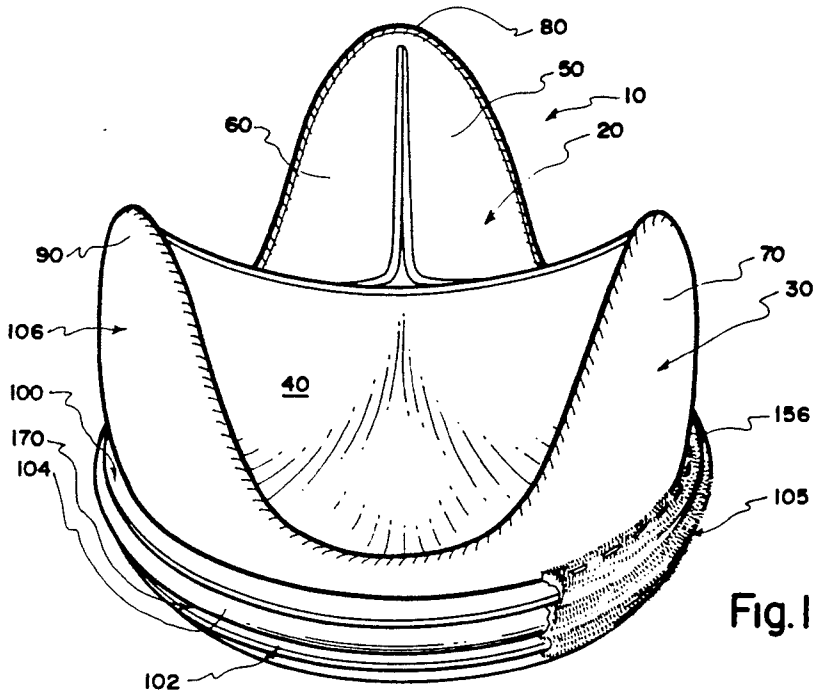


Fig. 1

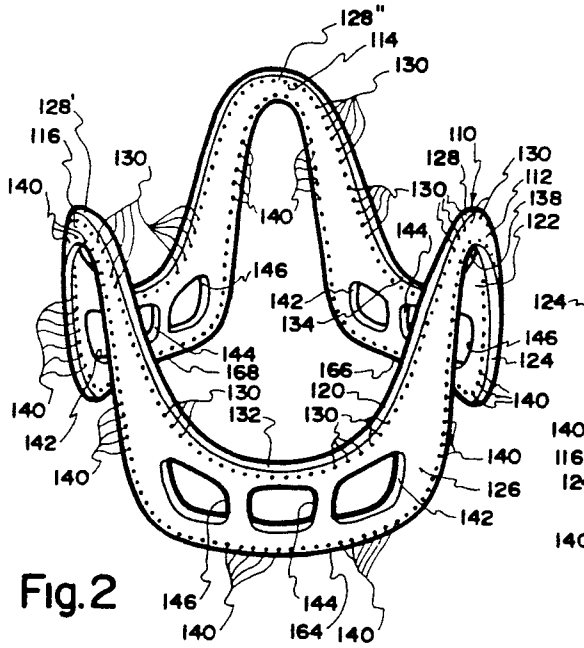


Fig. 2

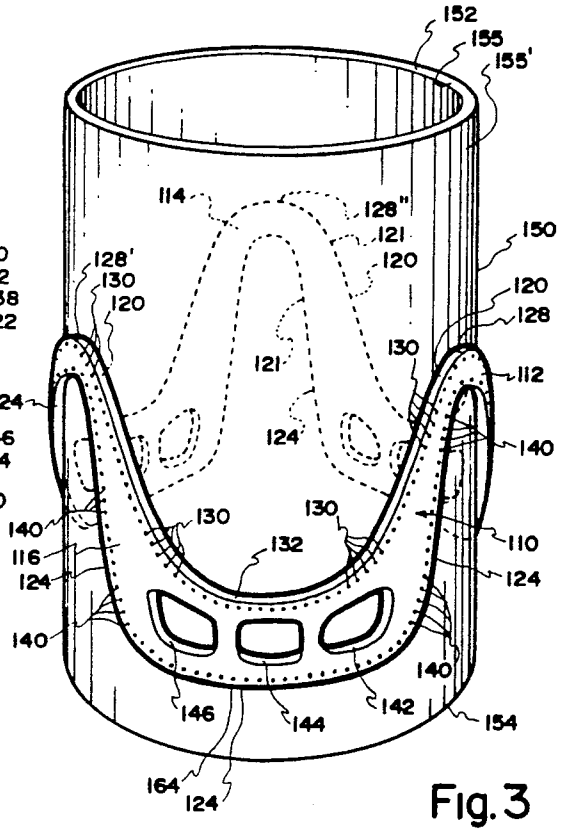
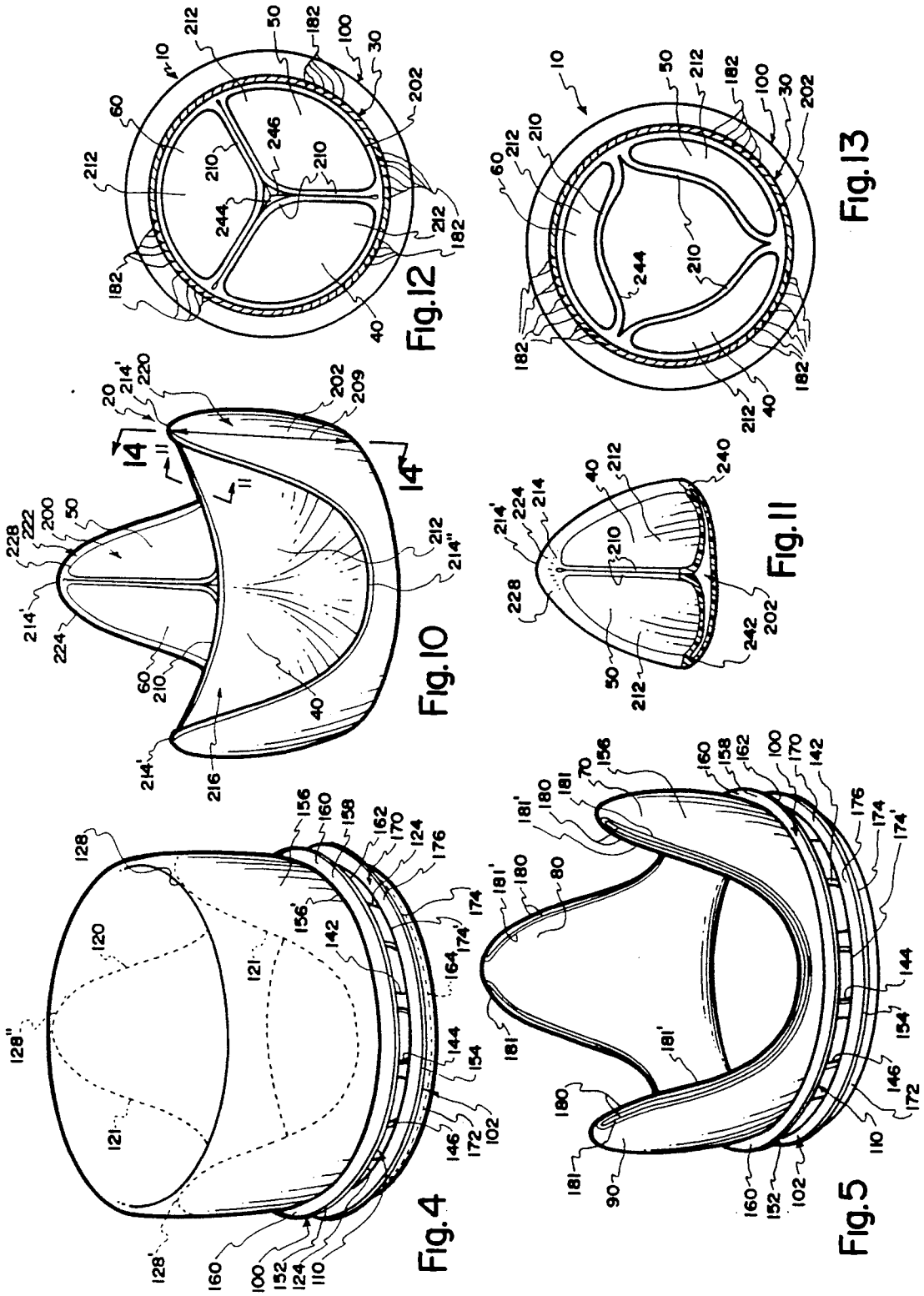


Fig. 3


Fig.12
Fig.13
Fig.10
Fig.11
Fig.4
Fig.5

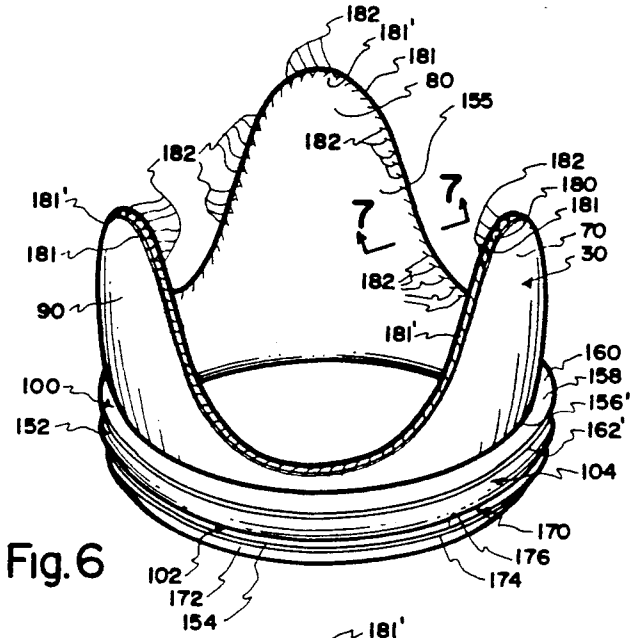


Fig. 6

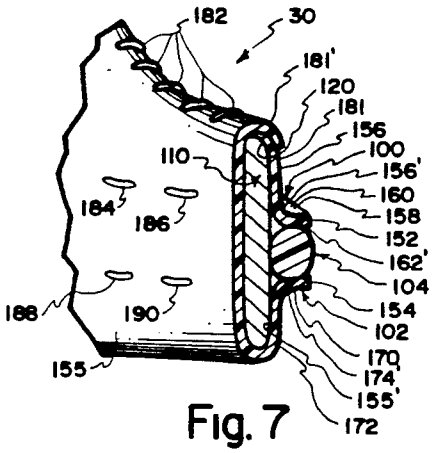


Fig. 7

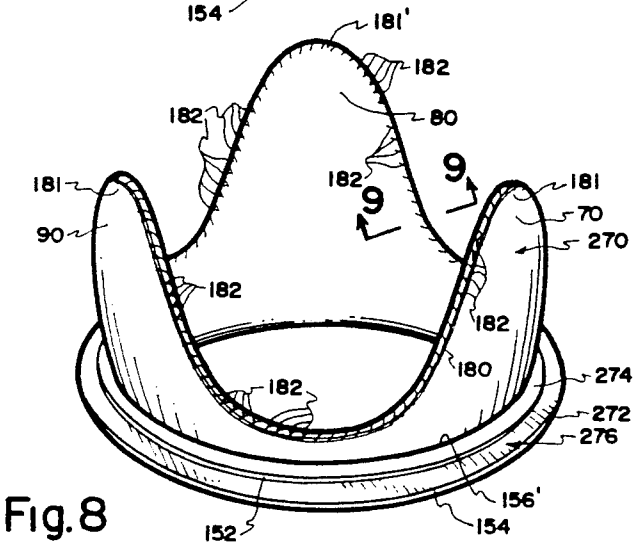


Fig. 8

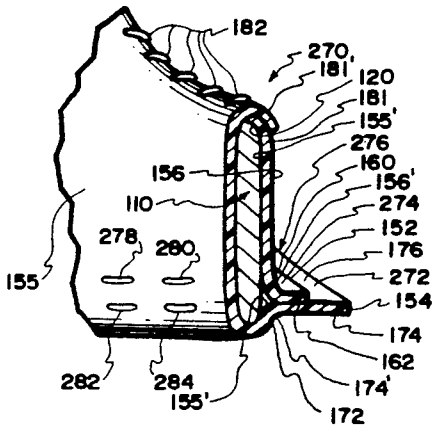


Fig. 9

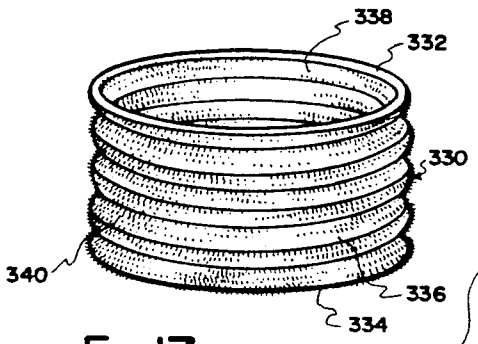


Fig. 17

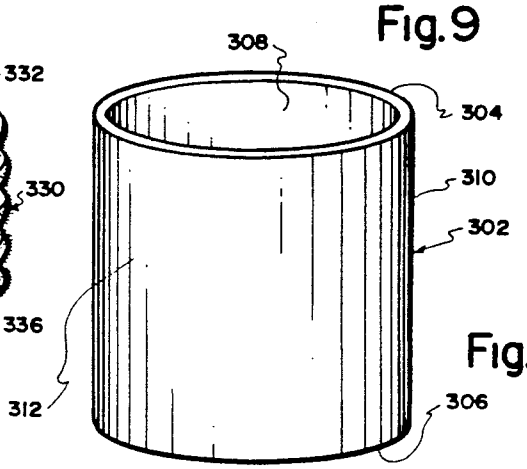
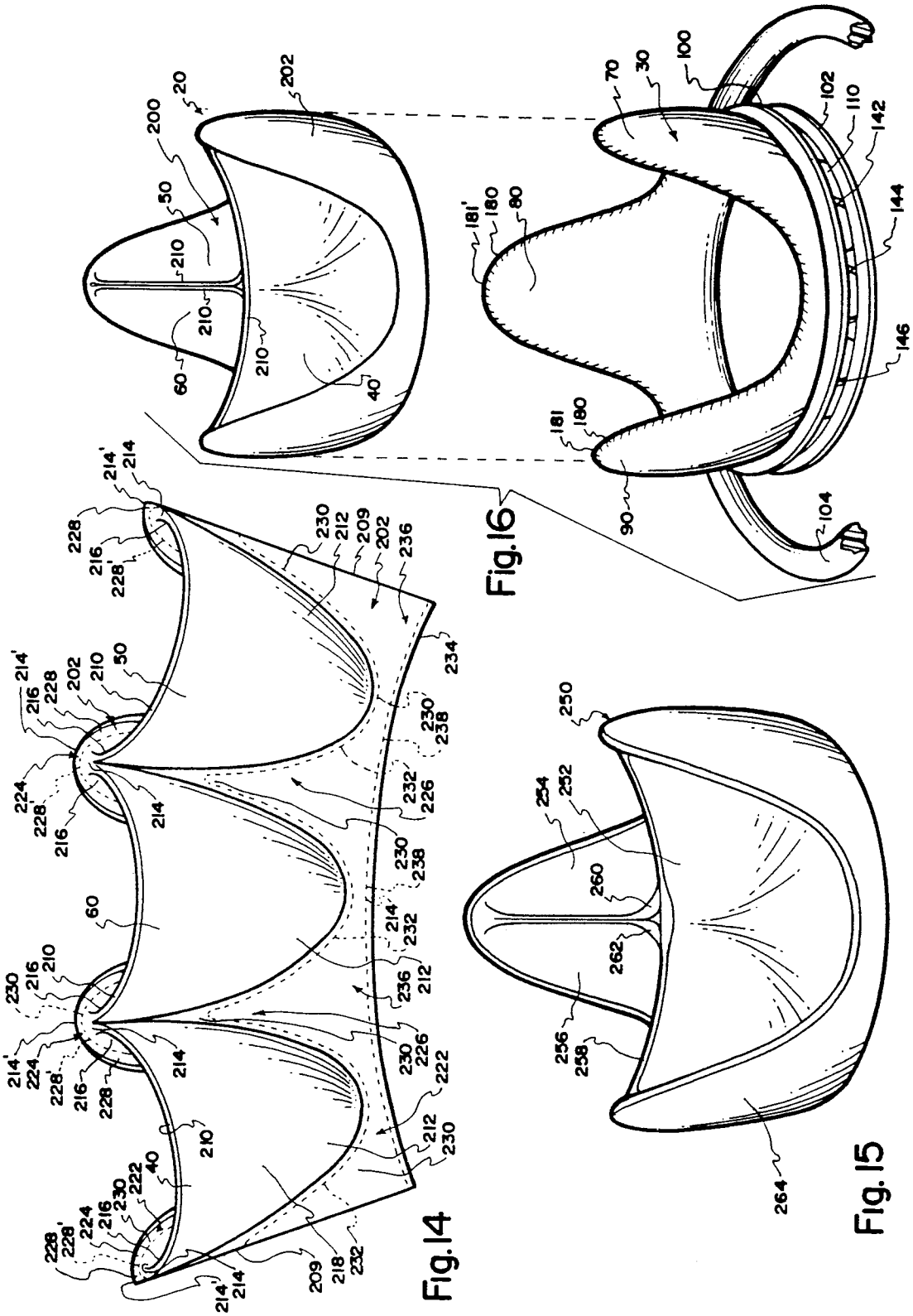


Fig. 20


Fig.14
Fig.15
Fig.16

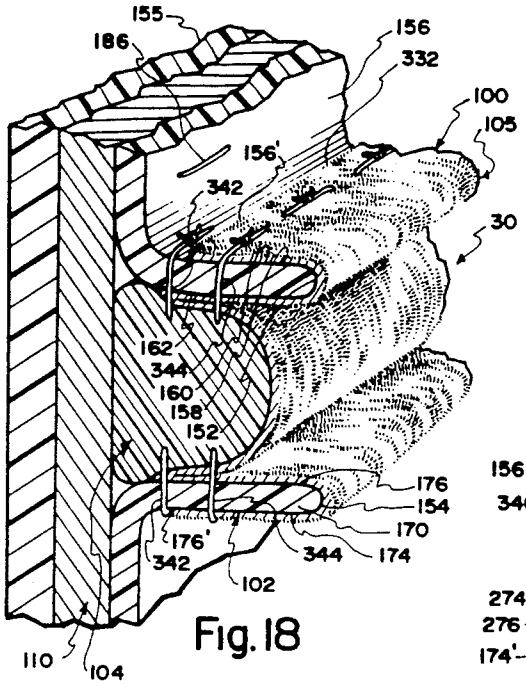


Fig. 18

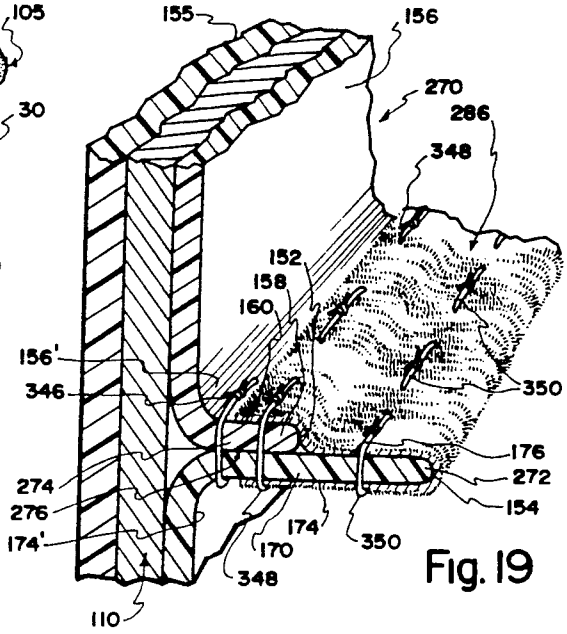


Fig. 19

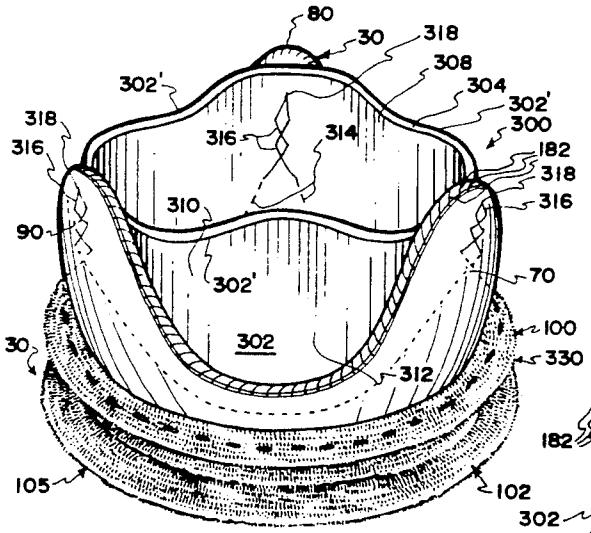


Fig. 21

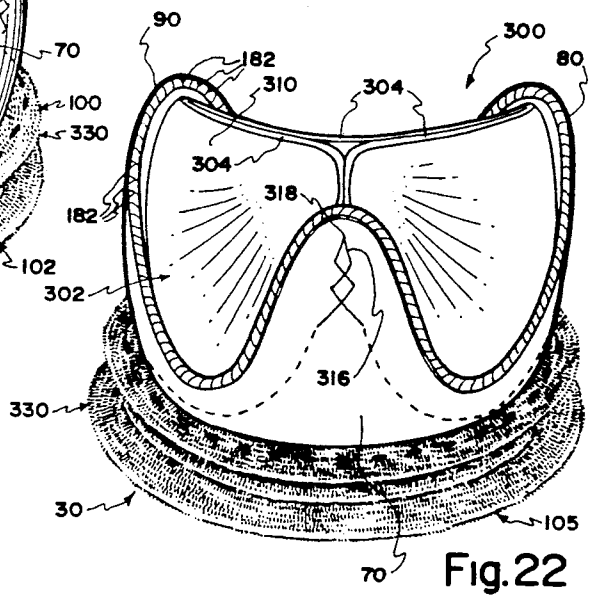


Fig. 22

PROSTHETIC HEART VALVE

FIELD OF INVENTION

This invention relates to implantable heart valves and in particular to long-lasting implantable prosthetic heart valves comprising valve leaflets made from synthetic materials.

BACKGROUND AND DESCRIPTION OF RELATED ART

Two types of replacement heart valve prostheses are generally known in the art. A first replacement type comprises totally mechanical heart valves which effect unidirectional blood flow through the use of a device using a mechanical closure. The more common mechanical heart valves comprise pressure responsive, pressure directed movement of a ball in a cage or tilting or caged discs.

Examples of pressure responsive, pressure directed ball movement devices are found in U.S. Pat. Nos. 3,263,239, 3,365,728, 3,466,671, 3,509,582, 3,534,410, and 3,723,996. Earliest valve designs were strictly concerned with providing a one-way valve which could be used as a replacement for natural mitral and aortic valves. The earliest known artificial caged ball prothesis was first successfully used for treatment of cardiac valve disease in 1953. With improvements in valves and medical procedures, caged valve prosthesis rapidly became commonplace in the early 1960's.

A source of historical and background information in Mechanical Valve Prostheses is found in The Fourth Edition of Thoracic and Cardiovascular Surgery, published in 1983 by Appleton-Century-Crofts, a publishing division of Prentice-Hall, inc. The earliest caged ball valves comprised stainless steel outflow orifice and rib cages and silicone rubber poppets. Such valves experienced a high incidence of thromboembolism associated with the outflow orifices and rib cages. The silicone rubber poppets after a period of use often became grossly deformed with resulting incompetence.

To slow the degeneration of the silicone rubber poppets, cloth and plastic coverings were provided for the metal parts. Such coverings resulted in effects of wear and tissue growth in the coverings. The tissue growth, especially in the coverings over struts of the cages led to a thickening of the struts which slowed or stopped ball movement Fibrous growth across the orifice of the valve led to severe valvular stenosis.

The use of hollow metal spheres and metal tracks in later models of the caged ball rib valves have overcome some of the original problems, and improvements continue to be made to make caged rib ball valve safer and more efficacious.

However, problems inherent with the geometry of the caged ball valve also leads to physiological problems with the use of the valve as a heart valve replacement prosthesis. The caged rib ball valve comprises three orifices through which blood must flow. The primary orifice is the orifice through which blood passes from the effluent chamber being valved. From the primary orifice the blood passes through a secondary orifice defined by the cage and ball, the size of which is determined by the height of the cage and diameter of the ball. The third orifice is the hollow cylindrical path between the ball and cage and the surrounding influent chamber into which the blood flows from the effluent chamber.

The three orifice pattern in a caged ball valve requires sometimes difficult tradeoffs to be made in design. For example, when the ball is large, the third orifice is relatively smaller leading to third orifice stenosis. When the ball is small, the primary orifice is small and relatively stenotic. Further, if travel of the ball in the cage is restricted, as may be required by physiological free space in either the ascending aorta or left ventricle of a patient, the second orifice size must be reduced with resulting relative stenosis thereat. For these reasons, even in a caged ball valve without physiological or structural complications, use is restricted by the inherent three orifice geometry.

Disc valves have been made in the form of caged disc valves and tilting disc valves. Disc valves are generally preferred over caged ball valves because of the inherent low profile configuration of the disk valve. One of the major problems with disc valves and in particular with caged disc valves, is thrombogenicity. Other problems comprise obstructive characteristics inherent to the basic geometry of caged disc valves and degeneration of the disc occluder and strut fracture. Also hemolysis with disc prostheses is especially common.

An example of a tilting disc valve is found in U.S. Pat. No. 4,892,540. Tilting disc valve prostheses have proved to be more satisfactory than the caged disc valves The tilting disc valve prostheses generally have less hemolysis, lower cross valve gradients, and little wear of carbon pyrolyte discs. However, the tilting disc prostheses have a tendency to clot, and a strict anticoagulant regimen is required. Also movement of the disc in close relation with the sewing ring generally increases chances of interference by contact with adjacent mural endocardium or aortic intima and requires extra care be taken to prevent interference with movement of the disc.

A second replacement type of heart valve prothesis is the "tissue-type" valve which structurally resembles and functions similarly to at least one of the human heart valves. Such valves are most often harvested from pigs or cows and are mounted on a prosthetic stent with an affiliated sewing ring for attachment to the annulus of the valve being replaced. Problems related to the requirement for anticoagulants are usually short term with "tissue-type" valves and failure of such valves is seldom abrupt.

However, such valves are generally slowly rejected from the patient as a foreign body. The rejection is manifested as motion limiting calcification of the leaflets of the "tissue-type" valve and slowly ensuing functional failure. Such failure commonly necessitates replacement within fifteen years of original implantation. Examples of devices which apply to human and other animal "tissue-type" valvular prostheses are found in U.S. Pat. Nos. 3,656,185 and 4,106,129. Two examples of currently manufactured and marketed "tissue-type" valves are the MITROFLOW TM Heart Valve by Mitroflow International, Inc., 11220 Voyager Way, Unit 1, Richmond, B.C., Canada V6X 351 and Bovine Pericardial Valve by Sorin Biomedical, S.P.A., 13040 Saluggia (VC), Italy.

BRIEF SUMMARY AND OBJECTS OF THE INVENTION

In brief summary, this novel invention alleviates all of the known problems related to the substantial and long

term requirement for administrating anticoagulants, "tissue-type" rejection, stenotic operation especially with a low profile valve prostheses, thrombogenesis, and post placement infection. The invention is a long-lasting implantable prosthetic heart valve which contains no tissue component.

The valve leaflet apparatus is produced as a unicast or extruded prosthetic valve leaflet apparatus and is devoid of tilting or traveling metal or plastic components. The invention comprises a stent which provides an implanting support for the valve leaflet apparatus. The stent has a novel sewing ring which provides a hard surface component to which anchoring sutures are tied and an optionally used soft component against which the anchoring valve receiving orifice of the heart is free to compliantly expand and contract as the heart beats.

The stent comprises a frame which is fully covered by a biochemically inert or physiologically compatible shroud. The frame is generally a light weight, hollow cylinder, machined or trimmed to provide a suturing support ring, extended cusp stanchions, and interference free blood flow to the coronary arteries. The frame is joint free and is slightly deformable to conform to contractile changes of the heart.

The shroud comprises two or three parts, depending upon use of the valve. A first part of the shroud comprises a hollow cylindrical seamless material which has substantially the same diameter as the frame. The seamless material is inserted into the cylinder of the frame and folded outward and downward at the top and outward and upward at the bottom such that the top and bottom parts meet at a site at the more medial part of the suturing support ring. If the shroud is made of two parts, each top and bottom part is folded outward at the site to form a contiguous two-layered brim. The brim provides the hard surface component forming a sewing ring for suturing the stent for the anchoring sutures. If the shroud comprises three parts, the top and bottom parts are folded outward to form two separated sewing rings.

Above the sewing ring or rings, the shroud is trimmed and sewn or otherwise fused together such as by heat bonding to conform to the shape of the frame and provide an encompassing cover therefor. When the sewing rings are separated, a soft, compliant material is interposed to provide a cushion between the stent and the natural orifice in which the valve resides between the two sewing rings.

Another part of each shroud is a brim cover. In the case of the two part shroud, the brim cover comprises a cylinder of material surrounding, folded over, and securely sutured to the two-layered brim to provide a tissue adhering cover above and below the brim. For the three part shroud, the brim area also comprises a cylinder of material. However, in this latter case, more central portions of the brim cover are folded and inserted between the interfaces between each brim and the soft compliant material, thereby providing a continuous tissue adhering cover which covers each brim, the soft compliant material and interface there between. Each brim cover is selectively complexed and impregnated with antibiotics to reduce the likelihood of infections, anticoagulant and endothelial cells or endothelial growth factors to selectively control incorporation of surrounding tissue of the natural orifice interface.

The valve leaflet apparatus comprises a multiple leaf valve which resembles in form and function a natural heart valve. The valve is a resilient synthetic resinous material part having an outside diameter which is substantially the same size as the stent. The valve leaflet apparatus may be formed by molding or extruding. The valve comprises a plurality of cusps which form medially disposed leaves which coapt upon closure to reduce leaflet wear and tear. When the synthetic resinous material from which the valve is molded is porous and chemically compatible, it is selectively complexed and impregnated with antibiotic medications to decrease the risk of post placement valve infection and anticoagulants to totally eliminate the need for initial exogenous anticoagulation o the part of the patient. The valves are sutured or otherwise permanently attached to the stent.

Accordingly, it is a primary object to provide a prosthetic heart valve having a mean-time-to-failure which is substantially longer than the expected life span of the patient.

It is another primary object to provide such a durable prosthetic heart valve which is simple in construction and low in manufacturing cost.

It is a significant object to provide a prosthetic heart valve configured entirely of biochemically-inert and biocompatible materials.

It is another significant object to provide a heart valve which is devoid of adhesives or bonding resins which might be released into the bloodstream of a receiving patient over a period of time.

It is another significant object to provide a prosthetic heart valve comprising an artificial leaflet valve mechanism which is similar to a natural valve in shape and function and which is assembled into a stent which provides mounting support for the valve in a native orifice from which a natural valve has been excised.

It is another significant object to provide the prosthetic heart valve with a sewing ring comprising a superior and an inferior hard surface against which knots in anchoring sutures are securely affixed.

It is a key object to provide at least one embodiment of a prosthetic heart valve configured to replace a natural mitral valve.

It is another key object to provide at least one embodiment of a prosthetic heart valve conformably configured to replace a natural aortic valve.

It is another key object to provide the prosthetic hear valve with a soft portion interposed between superior and inferior hard valve anchoring surfaces which perimetrically expands between the two hard surfaces and a juxtaposed natural and somewhat irregular native valve annulus to form a conformable seal.

It is still another key object to provide the soft portion comprising material which comprises a cover, the surface of which is permissive only to limited tissue ingrowth such that the soft portion is separable from the native valve annulus should removal of the valve become necessary.

It is fundamental object to provide a stent which comprises a frame, a frame shroud or cover comprising a two part sewing ring which encompasses at least a large measure of the frame, and optional additional cover parts which cover otherwise uncovered parts of the frame in the area where the sewing ring is attached to the native valve orifice.

It is significant object to provide a stent which permits the prosthetic valve to deform slightly with heart motion thereby permitting leaflets of the valve mechanism to coapt with a sliding motion to reduce wear at the free margins of the leaflets.

It is another significant object to provide a stent frame which is capable of annular deformity and slight perimetric expansion such that the stent frame diametrally varies expansively and contractually with the natural valve orifice within which the stent frame is disposed.

It is another significant object to provide a stent which permits the prosthetic valve to expand and contract with the natural valve orifice in which the prosthetic valve resides to reduce tugging forces upon the sutures and thereby reduce the likelihood of eventual valve dehiscence.

It is a basic object to provide a stent frame comprised of metal or synthetic resinous material which describes a continuous, seamless circular plane.

It is an essential object to provide a stent frame which comprises a plurality of circumferentially-spaced, axially projecting cusp supports.

It is consequential object to provide a stent frame comprising a plurality of windows which reduce the weight of the stent frame.

It is another object to provide a stent frame comprising a series of holes therein which allow margins of a valve leaflet apparatus to be securely affixed to the stent frame.

It is vital object to provide a double walled shroud of biocompatible material which covers at least a large measure of the stent frame.

It is another vital object to provide the double walled envelope which comprises pockets which receive and cover the cusp supports of the stent frame.

It is another significant object to provide a stent frame enveloping cover which comprises superior and inferior members of a sewing ring by which the prosthetic heart valve is sewingly affixed about the native orifice.

It is another fundamental object to provide the double walled stent frame enveloping cover comprising a continuous connection to each sewing ring.

It is another important object to provide at least one sewing ring comprising a firm, knot supporting inferior and superior surface for sewingly affixing the prosthetic heart valve to the native valve orifice.

It is another key object to provide a cover for the sewing rings and a soft, deformable, space filling material intermediate portion interposed between two sewing rings, the space filling material perimetrically expanding to fill and seal against a native valve annulus when the sewing ring are drawn tightly into place around the annulus.

It is another key object to provide a soft, deformable intermediate portion which comprises material which results in variable incorporation of surrounding tissue, thereby providing optimal balance between ease of removal and prevention of infection.

It is a notable object to provide a cover for the stent frame at least a part of which is impregnated with at least one active biochemical from a group comprising antibiotics, anticoagulant medications, endothelial cells or endothelial cell growth factors.

It is a main object to provide a heart valve leaflet apparatus which resembles in form and function a human trileaflet heart valve.

It is another main object to provide a valve mechanism which comprises no centrally disposed members during the time the valve is open.

It is another main object to provide a valve leaflet apparatus comprising members which move toward the inner surface of the stent when the valve is coursed with maximum flow thereby providing a valve having a flow cross section substantially as large as the stent.

It is another notable object to provide a valve mechanism which comprises a trileaflet configuration of substantially the same dimensions as a natural aortic valve thereby providing a prosthetic valve of relatively low silhouette compared to a caged ball valve.

It is another fundamental object to provide a valve mechanism which comprises a functionally continuous surface over all aspects of the valve.

It is a principal object to provide a valve mechanism which is non-thrombogenic.

It is another notable object to provide at least one valve leaflet apparatus which is impregnated with anticoagulant medication to eliminate the need for initial exogenous anticoagulation on the part of the patient.

These and other objects and features of the present invention will be apparent from the detailed description taken with reference to accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective of an implantable prosthetic aortic heart valve comprising a heart valve leaflet apparatus suitably joined to a supporting stent and brim-formed double sewing rings seen partially covered by a brim cover, a portion of the brim covering portion of the apparatus being removed to reveal other details of the sewing rings.

FIG. **2** is a perspective of the frame of the stent.

FIG. **3** is a perspective of the frame and a length of foldable cylindrical covering material disposed therein as a first step in a stent assembly process.

FIG. **4** is a perspective of steps following the step of FIG. **3** in the stent assembly process wherein the covering material is folded outward and over the frame at both the top and bottom and then folded outward to form double brim sewing rings of the implantable prosthetic aortic heart valve.

FIG. **5** is a perspective of a partially completed aortic heart valve stent with the covering trimmed along dashed lines seen in FIG. **4** to encompass rising cusp supports of the frame.

FIG. **6** is a perspective of a covered aortic heart valve stent wherein the trimmed cover is sewn together.

FIG. **7** is a section along lines **7—7** of FIG. **6**.

FIG. **8** is a perspective of a covered stent for a mitral heart valve prosthesis.

FIG. **9** is a section along lines **9—9** of FIG. **8**.

FIG. **10** is a perspective of a heart valve leaflet apparatus.

FIG. **11** is a section along lines **11—11** of FIG. **10**.

FIG. **12** is a top elevation of a closed trileaflet valve.

FIG. **13** is a top elevation of an open trileaflet valve.

FIG. **14** is a perspective of the heart valve leaflet apparatus incised along line **14—14** in FIG. **10** and opened for clarity of presentation.

FIG. **15** is a perspective of a prosthetic heart valve leaflet apparatus wherein the leaflets are leaflet models cast from a mold of a natural heart valve.

FIG. **16** is an exploded perspective of the heart valve prosthesis seen in FIG. **1**.

FIG. **17** is a perspective of a cylinder of material used to cover a brim portion of the stent.

FIG. **18** is an exterior perspective of a medial section of the aortic valve prosthesis stent of FIG. **7** showing the cylinder of material seen in FIG. **17** disposed about

and securely affixed to the brim portion of the aortic valve stent.

FIG. **19** is an exterior perspective of a medial section of the mitral heart valve prosthesis stent of FIG. **9** showing the cylinder of material seen in FIG. **17** disposed about and securely affixed to the brim of the mitral valve stent.

FIG. **20** is a perspective of a cylinder of material from which a trileaflet valve is made.

FIG. **21** is a perspective of the cylinder of material of FIG. **20** sewn into a stent to form an aortic valve prosthesis, said valve being seen in a nearly fully open configuration.

FIG. **22** is a perspective of the aortic valve seen in FIG. **21** rotated about a vertical axis and closed.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Reference is now made to the embodiments illustrated in FIGS. **1–22** wherein like numerals are used to designate like parts throughout.

A first illustrated embodiment of the invention, seen in FIG. **1**, is a prosthetic aortic heart valve **10**. Aortic heart valve **10** comprises a heart valve leaflet apparatus **20** and a heart valve leaflet apparatus supporting stent **30**. Heart valve leaflet apparatus **20** is disposed medially to stent **30** and therein comprises three cusps **40**, **50**, and **60** which are similar in form and function to cusps of a natural heart valve. Stent **30** comprises three upright, cusp supports **70**, **80**, and **90**, each of which provides a vertical stay for the cusps **40**, **50**, and **60**.

Further, in this embodiment, aortic valve **10** comprises two radially projecting sewing rings **100** and **102**. Interposed between sewing rings **100** and **102** is a soft, deformable intermediate natural valve orifice interfacing portion **104**, the purpose and character of which is provided in detail hereafter.

Seen in part, covering sewing rings **100** and **102** and interfacing portion **104**, is a brim cover **105**. Brim cover **105** is described in detail hereafter.

While sewing rings may be differently constructed within the scope of the invention, in this first illustrated embodiment, sewing rings **100** and **102** are contiguous segments of a stent cover **106** which, in large measure, covers and protects a supporting frame **110**, seen in FIG. **2**, from biologic activity. The reasons for so making and the method for fabricating sewing rings **100** and **102** is covered fully below.

Frame **110** is generally of a continuous hollow cylindrical form and is substantially rectangular in cross section. Although frame **110** is completely covered and sealed from biological fluid in each implanted aortic valve **10**, the material selected for frame **110** is non-corrosive, fatigue resistant, and substantially biologically inert. As such, frame **110** may be made from stainless steel or a carbon based material such as pyrolytic carbon on a graphite substrate. However, frame **110** may be made from materials having comparable weight, biocompatibility, flexibility, and strength characteristics similar to the materials of preference within the scope of this invention.

To provide support for stent **30** and the three superior circumferential edges of cusps **40**, **50**, and **60** of valve leaflet apparatus **20**, frame **110** comprises three inverted "U" shaped stanchions **112**, **114**, and **116**. In this first illustrated embodiment, each of the stanchions **112**, **114**, and **116** are identical. For this reason, only stanchion **112** will be described in detail with the understanding the description of stanchion **112** applies equally to stanchions **114** and **116**.

Inverted "U" shaped stanchion **112** comprises a superior edge **120**, an inner surface **122**, an inferior edge **124**, and an outer surface **126**, as best seen in FIG. **2**. At the highest point, inverted "U" shaped stanchion **112** comprises an apex **128** superiorly disposed on edge **120**. Similarly, stanchion **114** comprises an apex **128"** and stanchion **116** comprises a stanchion **128'**. Disposed below apex **128** and inferior to superior edge **120**, frame **110** comprises a plurality of holes, generally numbered **130**, disposed between surfaces **122** and **124**. Holes **130** are provided for the purpose of sewing corresponding margins of the heart valve leaflet apparatus **20** to stent **30**. For this reason, superior edge **120** is arcuately formed to follow a path which provides a margin superior to holes. Thus, edge **120** arcuately follows a distally descending path from apex **128** to a most inferiorly disposed medial point **132** where stanchion **112** extends to circumferentially smoothly connect to stanchion **116**. Edge **120** similarly descends distally from apex **128** on the other side of stanchion **112** to an inferiorly disposed medial point **134** extending circumferentially to connect smoothly to stanchion **114**.

Inferior edge **124** comprises an apex **138** disposed immediately below apex **128** and offset from apex **128** to provide inferiorly disposed support for attaching marginally disposed portions o heart valve leaflet apparatus **20** associated with cusps **40** and **50**, as is described in detail hereafter. As seen in FIG. **2**, proximally disposed in a margin of frame **110** above inferior edge **124**, are a plurality of holes, generally numbered **140**, disposed between surfaces **122** and **126**. Holes **140** comprise a second set of holes inferior to holes **130** through which heart valve leaflet apparatus **20** is also sewingly or otherwise attached to stent **30**. While attachment of the heart valve leaflet apparatus **20** to stent **30** is described to be accomplished by sewing, one who is skilled in the art would understand that other methods of attachment, such as by a plastic connector or by fusing parts together through the holes, generally numbered **130** and **140**, are within the scope of the invention.

As seen in FIG. **2**, superior edge **120** and inferior edge **124** combine to describe the inverted "U" shape of stanchion **112**. Flexibility of the material used to make frame **110** in combination with the inferior opening of the inverted "U" of stanchion **112** provides a frame capable of annular deformity and slight perimetric expansion. Such deformity and expansion permits the frame to compliantly respond to expansion and contraction of the native valve orifice of the beating heart in which aortic valve **10** is implanted to reduce beat by beat stress on aortic valve **10** anchoring sutures and thereby reduce the likelihood of eventual valve dehiscence. Also, to reduce the likelihood of valve dehiscence, the mass of frame **110** is reduced by excising material which is essentially unnecessary for strength, but which adds to the weight of frame **110** and therefore of stent **30**. Therefor, windows **142**, **144**, and **146** are formed as best seen in FIG. **2**.

Reference is now made to FIGS. **3–5** wherein the steps used to cover at least a large measure of frame **110** are seen. As seen in FIG. **3**, the covering is a cylindrical seamless section **150** of material which is essentially biologically inert. A material such as GORTEX TM , a polytetrafluoroethylene (PTFE) composite, is preferable, however materials such as continuous knit comprising a commercially available, medical grade DA-

CRON TM velour for example, knitted velour polyethylene glycol terephthalate or other materials having biochemically inert and compatible characteristics similar to those of PTFE derivatives may be used. All GORTEX TM materials referenced hereafter are products of and available from W.L. Gore and Associates, Inc., Medical Products Division, P.0. Box 900, Flagstaff, Ariz. 86002. Section **150** is of substantially the same exterior diametrical size as the interior diameter of frame **110** and comprises a length which exceeds twice the height of stanchions **112**, **114**, and **116** for reasons which are described in detail hereafter. Section **150** comprises a top edge **152**, a bottom edge **154**, an inside surface **155**, and an outside surface **155'**.

As a first step in covering frame **110**, section **150** is inserted into frame **110** as seen in FIG. **3** to cover inner surface **122**. That portion of frame **110** which is hidden from view by the insertion of section **150** is shown by dashed lines **121**.

As seen in FIG. **4**, the top edge **152** of section **150** is folded radially outward and downward until the originally outside disposed surface **155'** of section **150** rests upon apex **128** of stanchion **112** and resides similarly upon apex **128'** of stanchion **116** and upon apex **128''** of stanchion **114** whereby the originally inside disposed surface **155** forms an outside sidewall **156**. So downwardly extended, section **150** comprises sufficient length such that edge **152** is everted radially outward to form a brim **158**.

Thus brim **158** is a continuous, seamless extension of sidewall **156**, along a connecting line **156'**. The originally inside disposed surface **155** of section **150** therefore becomes a superior surface **160** and the originally outside disposed surface **155'** of section **150** becomes an inferior surface **162** of brim **158**. Brim **158** extends radially outward a sufficient distance from the vertical portion of sidewall **156** to provide a superiorly disposed sewing ring **100**. Sewing ring **100** comprises a width which is adequate for aortic valve **10** implanting purposes as is well known in the art.

Similarly bottom edge **154** is turned outward and upward until originally outside disposed surface **155'** is in firm contact with an inferior segment **164** of inferior edge **124** of frame **110** between stanchions **112** and **116** (see also FIGS. **2** and **3**). Inferior segment **164** is seen as a hidden dashed line in FIG. **4**. Thereat, originally outside disposed surface **155'** is likewise in firm contact with each inferior segment **166** and **168** (see FIG. **2**) which resides between stanchions **112** and **114** and stanchions **114** and **116**, respectively. So disposed, inferior edge **154** is everted outward to form a second brim **170**. Thereby originally inside disposed surface **155** forms an exterior inferior sidewall **172** which forms a contiguous, seamless connecting line with an inferior side **174** of brim **170**. Similarly, originally outside disposed surface **155'** forms a contiguous, seamless connection **174'** with a superior side **176** of brim **170**. In aortic heart valve **10**, the width of brim **170** is similar to the width of brim **158** thereby providing a second sewing ring **102** of substantially the same dimensions as sewing ring **100** but separated therefrom as seen in FIG. **4**.

Following the pattern of the superior edge **120** seen as dashed lines **121** in FIG. **4**, material is trimmed away along trim line **180** along a pattern superior to edge **120** to reveal parted edges **181** and **181'** as seen in FIG. **5**. Sufficient material is retained superior to edge **120** to close and completely cover superior edge **120** of frame **110** by tightly sewing parted edges **181** and **181'** together along trim line **180**, as seen in FIG. **6**.

Sewing to join parted edges **181** and **181'** together is currently preferred; however, the parted edges **181** and **181'** may be tightly bonded together by other methods such as heat fusing. The method of bonding depends upon the frame covering material selected. In any event, the edges are tightly bound together and completely cover frame **110** along edge **120**, as seen in FIG. **6**. So covered, stent **30** comprises the three cusp supports **70**, **80** and **90** respectively supported by covered stanchions **112**, **114**, and **116**.

Reference is now made to FIGS. **6**, **7** and **16–19**, wherein additional details of construction of stent **30** are seen. Stent **30** is particularly configured for use as an aortic valve. As a natural aortic valve orifice, in which aortic valve **10** is implanted, comprises tissue which changes the lateral dimensions of the natural valve orifice during each cycle of a beating heart, it is important to compensate for those changes to reduce effects which might increase the likelihood of valve dehiscence due to structural failure of the sewing ring, sutures, or natural tissue surrounding the valve.

For these reasons, stent **30** comprises the flexible frame **110**, as earlier described, which responsively reacts to expansion and contraction of the natural valve orifice. Also, an intermediate, orifice size compensating and interfacing portion **104** is disposed between sewing ring **100** and **102** and to provide a soft elastically compressible space filling component which perimetrically expands and compresses to effect a good annular seal between frame **110** and the natural orifice by valve **30**. As seen in FIG. **6**, the orifice interfacing portion **104** is externally and peripherally disposed about frame **11** between superiorly disposed sewing ring **100** and inferiorly disposed sewing ring **102**.

Natural valve interfacing portion **104** is preferably formed to be a contiguous ring of material which is compressible, but which comprises memory which responsively expands to fill space previously vacated and unfilled by the remainder of stent **30** when compressive pressures are relieved. Such material may be non-expanded GORTEX TM . However, interfacing portion **104** may be a linear segment of deformable material sewn or otherwise secured end-to-end to form a continuous ring.

When the interfacing and sewing ring materials are biochemically inert such that tissue does not adhesively attach thereto, brim cover **105** is used to provide the interface between the natural excised valve orifice and implanted prosthetic heart valve. Referring again to FIG. **1**, a portion of brim cover **105** is seen on the right viewing side of aortic heart valve **10**. As seen therein, brim cover **105** covers each sewing ring **100** and **102** and the orifice interfacing portion **104** disposed therebetween.

Brim cover **105** is preferably made from a material which is permissive to tissue in-growth so that a degree of adhesion improves adhesion of the grafted valve within the native excised valve orifice. Such material is preferably velour a commercially available, medical grade DACRON TM , but other relatively biologically compatible, biologically inert and physiologically stable materials may be used within the scope of the invention. A detailed description of the process for making and attaching brim **105** is provided hereafter. One important factor in the selection of materials for brim cover **105** is the choice of materials which may be complexed with

appropriate biochemicals from a group comprising antibiotics, anticoagulant medications, endothelial cells or endothelial cell growth factors.

Incorporation of complexed antibiotics about the site of the excision significantly reduces the risk of post placement infection thereat, potentially reducing the amount of otherwise administered antibiotics and relieving the valve **10** recipient o a post placement antibiotics regimen. Incorporating complexed anticoagulants when possible, in prosthetic leaflet apparatus **20**, reduces or eliminates the need for an initial exogenous anticoagulation regimen on the part of the valve recipient. Such a regimen is currently common place for prosthetic heart valve recipients.

A cross section of stent **30** made along line 7—7 in FIG. **6** is seen in FIG. 7. The cross section of stent **30** comprises frame **110** totally enclosed by material of section **150** and interfacing portion **104**. As seen therein, material remaining after being parted along trim line **180** is folded to form a seam along superior edge **120** of frame **110** and tightly bound thereat with a plurality of sutures **182** to close parted edge **181'** over parted edge **181**.

Additional sutures, represented by sutures **184** and **186** in FIG. 7, tightly bind sewing ring **100** through windows and inferiorly disposed openings in frame **110** to outside sidewall **156** along seamless connection line **156'**. Similarly, sewing ring **102** is tightly bound through the windows and inferiorly disposed openings in frame **110** to exterior inferior sidewall **172** along seamless connection line **174'** by sutures, represented by sutures **188** and **190** in FIG. 7. All such sutures used in valve **10** and similarly constructed valves preferably constitute GORTEX TM 3-0 suture material. However, other strong, long-lasting suture material which is essentially biochemically inert and of other preferable sizes can be used within the scope of the invention.

The ring comprising interfacing portion **104** is snugly inserted between sewing rings **100** and **102** and firmly affixed thereat by additional sutures or by a ring-tight fit against frame **110** between sewing rings **100** and **102**. Thus covered, frame **110** is enclosed and substantially free from interfacing liquids and tissue which surround an operative valve **10**.

In this first illustrated embodiment, heart valve leaflet apparatus **20** comprises a prosthetic trileaflet valve apparatus **200** which is operatively similar to a natural aortic heart valve. See FIG. **10**. Heart valve leaflet apparatus **20** comprises a support collar **202** and thereto integrally connected leaflet cusps **40**, **50**, and **60** of prosthetic trileaflet valve apparatus **200**. In FIG. **14**, heart valve leaflet apparatus **20** is excised along line **209**, seen in FIG. **10**, and opened to provide a view of the inside of cusps **40**, **50**, and **60** and collar **202**. FIG. **11** comprises a section along lines **11—11** of FIG. **10** and shows the unitary construction of heart valve leaflet apparatus **20** and attachment between collar **202** and cusps **40** and **50** of prosthetic apparatus **200**.

In a natural aortic heart valve, the cusps are individually identifiable as an anterior cusp, a left posterior cusp, and a right posterior cusp. Identifying features of the anterior cusp and left posterior cusp are depressions for connecting coronary arteries. In prosthetic apparatus **200**, each leaflet cusp **40**, **50**, and **60** is substantially like the others. For this reason, only one cusp **40** will be described in detail with the understanding that a like description applies for cusps **50** and **60** as well.

Cusp **40** comprises a thickened superior edge which forms a commissure or lip **210** and a thin substantially uniform leaf membrane **212**. In this embodiment, Cusp **40** is preferably molded as a unitary part of heart valve leaflet apparatus **20** and thereby comprises a thickened connecting intersection **214** disposed along the interface between collar **202** and commissure **210** and leaf membrane **212**, as best seen in FIG. **11**. The thickening of commissure **210** and connecting intersection **214** is necessary to provide reliable structure where flexing and wear is the greatest in heart valve leaflet apparatus **20**. As seen in FIG. **10**, cusp **40** comprises an exterior facing side **216**. An interior facing side **218** of cusp **40** is best seen in FIG. **14**.

Collar **202** is a stent interconnecting structure which supports cusps **40**, **50**, and **60**, substitutes for natural supporting structure in the native orifice and, thereby, provides an interface to stent **30**. As such collar **202** rises to an apex **214'** above connecting intersection **214** where collar **202** interconnects to each commissure **210**. To provide effluent access for blood flow to the coronary arteries during diastole, collar **202** is dramatically decreased in vertical height between each apex **214'** to a medially disposed low point **214''**.

The connecting features of collar **202** are seen from an exterior perspective in FIG. **10** and from an interior perspective in FIG. **14**. Collar **202** comprises an exterior side **220** and an interior side **222**. The interface with each cusp **40**, **50** and **60** is entirely disposed on interior side **222** of collar **202**. Generally, inner side **222** is divided into a section **224** superior to the interface with each cusp **40**, **50**, and **60** and a section **226** inferior to the interface with each cusp **40**, **50**, and **60**.

For the purpose of affixing each cusp **40**, **50**, and **60** solidly to stent **30** and, in particular, to frame **110**, collar **202** comprises a superior binding margin **228** and an inferior binding margin **230**. Superior binding margin **228** is disposed within superior section **224** and comprises an area adequate to suture collar **202** to stent **30** thereat. A dashed line **228'** traces a portion of the suture trail within superior binding margin **228** in FIG. **14**.

Similarly, inferior binding margin **230** is disposed within inferior section **226** and comprises an area adequate to suture collar **202** to stent **30** thereat also. Another dashed line **232** traces the suture trail inferiorly disposed to cusps **40**, **50**, and **60** in FIG. **14**. As seen therein, collar **202** comprises a bottom edge **234** and a binding margin **236** immediately superior to bottom edge **234**. A third suturing trail, seen as dashed line **238**, is disposed within binding margin **236** for the purpose of providing a region for binding the bottom of collar **202** to stent **30** to eliminate any cavities of low or no liquid flow between collar **202** and stent **30**.

While it is within the scope of the invention to provide prosthetic trileaflet valve apparatus having cusps which are manufactured separately and later affixed to a collar, it is preferred in this embodiment that heart valve leaflet apparatus **20** be cast as a unit or unicast. Methods for casting such a valve are well known in the art. One material which may be used is silicone. An advantage derived from the use of silicone is the opportunity for complexing with other materials, such as antibiotics to decrease the risk of post placement valve infection and anticoagulant medication to eliminate the need for initial exogenous anticoagulation on the part of the patient.

Referring to the section along lines **11—11** of FIG. **10** as seen in FIG. **11**, continuity between cusp **40** and

collar **202** is seen at juncture **240** and similar continuity between cusp **50** and collar **202** is seen at juncture **242**. Each cusp **40** and **50** is seen to comprise a separate commissure **210** and a pliant leaf membrane **212** there below. The separation of each juncture **240** and **242** is seen to occur medial to superior binding margin **228** such that binding sutures do not impair movement of any leaf membrane **212**.

Leaflet apparatus **20**, comprising prosthetic trileaflet valve apparatus **200** and collar **202**, is inserted to snugly fit into stent **30**. So disposed, collar **202** is firmly affixed to stent **30** by suturing along dashed lines **228'**, **232**, and **238**. Suturing along dashed lines **228'** and **232** comprises passing suturing materials through holes **130** and **140** circumferentially disposed in frame **110**, as earlier described. Suturing along dashed line **238** may alternatively attach collar **202** to sites inferior to edge **164** of frame **110** in inside surface **155** or directly through frame **110** through a series of holes therein which are not shown.

Thereby, heart valve leaflet apparatus **20** is firmly affixed to stent **30** to complete prosthetic aortic valve **10** providing an aortic replacement valve which comprises a soft portion **104** with a tissue compatible brim cover **105** for interfacing with an irregular native annulus from which the natural valve has been excised and hard surfaced sewing rings **100** and **102**, also covered by brim cover **105**, externally disposed upon the stent **30**. As the sutures which anchor valve **10** in the native orifice pass through sewing rings **100** and **102** and are firmly, tightly affixed thereto, the deformable intermediate interfacing portion **104** and brim cover **105** perimetrically compress and expand to fill and seal against the irregular native valve annulus.

Reference is now made to FIGS. **12** and **13** wherein valve **10** is seen closed and opened, respectively. As seen in FIG. **12**, each commissure **210** is aligned with the other two juxtaposed commissures **210** to substantially close valve **10**. However, as each commissure **210** is not perfectly flexible and pliant, a triangular orifice **244** is formed which, if not otherwise closed, provides a regurgitant pathway through orifice **244** and a resulting valvular insufficiency. However, the flexibility of frame **110** and therefore stent **30** and the pliability of each leaf membrane **212** permits membranes **212** to coapt and close valve **10** at contacting surfaces inferior to commissures **210**. exemplarily seen as contact lines **246** within triangular orifice **244**.

When valve **10** is open, triangular orifice **244** is enlarged, providing a medially free passageway through which blood courses. Each commissure **210** and associated leaf membrane **212** is forced radially outward to provide an orifice operatively similar to a natural aortic valve orifice opening.

A second illustrated embodiment of an aortic valve leaflet apparatus **250** is seen in FIG. **15**. Aortic valve leaflet apparatus **250** is similar to heart valve leaflet apparatus **20** seen in FIG. **10**, comprising three leaflets membranes **252**, **254**, and **256**, each membrane **252**, **254**, and **256** comprising a superiorly disposed commissure **258**, **260**, and **262**, respectively. However, in this case, the leaflet membranes **252**, **254**, and **256** are not alike. Similarly, each commissure **258**, **260**, and **262** is different from the other two commissures.

Such is the case because aortic valve leaflet apparatus **250** is produced from a mold of a natural valve. As such, the more medial portions of the each commissure **258**, **260**, and **262** comprises a thicker, non-uniform appearance associated with naturally grown valves. Material from which aortic valve leaflet apparatus **250** is made is the same as that specified for heart valve leaflet apparatus **20**. The characteristics of a surrounding, mounting collar **264** are the same as that described for collar **202**, including all cusp-collar interfaces and suturing lines.

Another illustrated embodiment for a stent **270** is seen in FIG. **8** and **9**. Except for the steps of outward eversion of each brim, stent **270** is made as stent **30** is made. As is the case for stent **30**, a section **150** of cylindrical material is used to cover frame **110**. However, in this case, section **150** is disposed to entirely cover frame **110** and produce a stent preferably for a prosthetic valve used as a valve replacement in a native orifice having the geometry of an orifice similar to that from which a natural mitral valve has been excised To provide a stent **270** with sewing rings which correspond to the funnel-like contour of an excised mitral valve orifice, the structure and steps in manufacture of the sewing ring forming brims are markedly different than similar steps in forming brims for stent **30**.

Reference is again made to FIGS. **3–5** wherein the steps used to cover at least a large measure of frame **110** are seen. As seen in FIG. **3**, the covering is cylindrical seamless section **150** of the same essentially biologically inert material used to make stent **30**. The frame **110** covering process to the step of everting each edge **152** and **154** outwardly to form a brim is the same as the covering steps for stent **30**.

Therefore, as the first step in covering frame **110** to make stent **270**, section **150** is inserted into frame **110** as seen in FIG. **3** to cover inner surface **122**. As seen in FIG. **4**, the top edge **152** of section **150** is folded radially outward and downward until the outside surface **155'** of section **150** rests upon apex **128** of stanchion **112** and resides similarly upon apex **128'** of stanchion **116** and upon apex **128"** of stanchion **114** whereby inside surface **155** forms an outside sidewall **156**.

Similarly bottom edge **154** is turned outward and upward until outside surface **155'** is in firm contact with an inferior segment **164** of inferior edge **124** of frame **110** between stanchions **112** and **116** and is likewise in firm contact with each inferior segment **166** and **168** which resides between stanchions **112** and **114** and stanchions **114** and **116**, respectively. So disposed, inferior edge **154** is everted outward to form an inferiorly disposed wide brim **272**. See FIG. **8**. Thereby inner surface **155** forms an exterior inferior sidewall **172**, see FIG. **9**, which forms a contiguous, seamless connecting line **174'** with an inferior side **174** of brim **272**. Similarly, originally outside surface **155'** forms a contiguous, seamless connection with a superior side **176** of brim **272**.

The downwardly extended portion of section **150** comprises sufficient length such that edge **152** is everted radially outward to form a narrow brim **274** in direct contact with brim **272**. The originally inside disposed surface **155** of section **150** therefore becomes a superior surface **160** and the originally outside surface **155'** of section **150** becomes an inferior surface **162** of narrow brim **274**. Thus brim **274** is a continuous, seamless extension of sidewall **156**, along connecting line **156'**.

Note that, in the case of stent **270**, the eversion of edge **152** occurs at a site inferior to the eversion of brim **158** of stent **30**. Brim **274** extends radially outward a sufficient distance from the vertical portion of sidewall **156** to provide a connecting surface with brim **272** to form a single sewing ring **276**. As seen in FIG. **8**, sewing ring **276** comprises a width which is adequate for ex-

cised mitral valve orifice implanting purposes as is well known in the art.

The steps of trimming material along trim line **180** and joining parted edges **181** and **181'** together are the same as for stent **30**.

FIG. **9** shows a cross section of stent **270** made along line **9—9** in FIG. **8**. The cross section of stent **270** comprises frame **110** totally enclosed by material of section **150**. As seen therein, material remaining after being parted along trim line **180** is folded to form a seam along superior edge **120** and tightly bound thereat with a plurality of sutures **182** to close parted edge **181'** over parted edge **181**.

Additional sutures, represented by sutures **278** and **280** in FIG. **9**, tightly bind brim **274** through windows and inferiorly disposed openings of frame **110** to inner surface **155** along seamless connection line **156'**. Similarly, sewing ring **276** is tightly bound through the windows and inferiorly disposed openings in frame **110** to inner surface **155** along seamless connection line **174'** by sutures, represented by sutures **282** and **284** in FIG. **9**. All such sutures used in stent **270** are preferably GORTEX TM 3-0 suture material. However, other strong, long-lasting suture material which is essentially biochemically inert can be used within the scope of the invention. A brim cover **286**, as seen in FIG. **19**, for covering stent **270** sewing ring **276** is described in detail hereafter.

Thus covered, frame **110** is substantially free from interfacing liquids and tissue which surround an operative prosthetic mitral valve replacement.

A third illustrated embodiment of a heart valve **300** is seen in FIGS. **21** and **22**. Valve cusps are formed from a single piece of material, such as a hollow cylinder of material **302** seen in FIG. **20**. Cylinder **302** may be formed by a cylindrical extrusion or by suturing vertical edges together. Material cylinder **302** comprises a substantially planar superior edge **304** and an oppositely disposed inferior edge **306**. Further material cylinder **302** comprises an inner surface **308** and an outer surface **310** disposed between edges **304** and **306** forming cylindrical wall **312**. Cylindrical wall **312** is of uniform thickness and is preferably thin and pliable, yet strong and enduring under pressure and flexure.

One material from which heart valve leaflet apparatus **20** may be made is a synthetic, stretchable polytetrafluoroethylene (PTFE) material known as GORTEX SURGICAL MEMBRANE TM. GORTEX SURGICAL MEMBRANE TM is essentially biochemically inert, hydrophobic and non-thrombogenic. It has been used in pleural, peritoneal and pericardial reconstruction where absolute prevention of tissue adhesion to it is desired.

The outside diameter of cylinder **302** is essentially the same as the internal diameter of stent **30**. To form valve **300**, cylinder **302** is displaced into stent **30**, as seen in FIG. **21**. Cusp **302'** forming, attaching sutures **314** are sewn through cylinder **302** and stent **30** to securely tie cylinder **302** to each cusp **302'** support **70**, **80**, and **90** as seen in FIG. **21**. The more superior sutures **316** are cross stitched at apical connections **318** of each cusp **302'** support **70**, **80**, and **90** attachment site and then securely stitched in place along each cusp **302'** periphery in a descending and ascending pattern similar to that seen in FIG. **14**. The manner of suturing seen in FIG. **21** is used in valves where cusps are formed from tissue such as flattened pericardium derived from living organs and is well known in the art. Also, cylinder **302** may be doubly attached at a second suture line (not shown) similar to suturing line **238** seen in FIG. **14** to provide a guard against eventual dehiscence due to systolic blood flow. The free leaflet surfaces forming each cusp **302'** between cusp supports **70**, **80**, and **90** are preferably made concave so that the leaflet surfaces of each cusp **302'** tend to reside in the closed position. The leaflet surfaces of each cusp **302'** can be made concave by heat treatment or other material forming methods generally known in the art.

As earlier specified, sutures are preferably GORTEX TM 3-0 suture material; however, other suture material comprising acceptable biochemical inertness and lasting characteristics may be used. As cylinder **302** is attached to stent **30** and as see in FIG. **21**, valve **300** is completely centrally, patently open as in systole. In FIG. **22**, valve **300** is rotated and closed such that corresponding sections of superior edge **304** closes upon itself to provide a closed orientation. To reduce pressure loss across valve **300**, thin walled GORTEX SURGICAL MEMBRANE TM having a wall thickness of 0.10 mm may be used. While valve **300** is seen to be an aortic valve configuration in FIGS. **21** and **22**, the material of cylinder **302** is similarly configured and equally as effectively incorporated into a mitral valve stent **270**.

As earlier indicated, each stent **30** and **270** comprises a brim cover **105** and **286**, respectively. There are two important reasons for providing a brim cover. First, controlled and limited tissue in-growth at the site of each stent **30** and **270** emplacement allows a balance to be struck between valve adherence to and valve removability from the annulus into which it is implanted. Second, it is desirable to implant the material of cylinder **330** with antibiotics to decrease the risk of post placement valve infection.

As described earlier, all other parts of each stent **30** and **270** comprise exterior surfaces which are biochemically inert, each brim cover **105** and **286** provides the only surface area whereat adhesion is permitted to occur due to such tissue ingrowth. Such tissue ingrowth improves adhesion of the grafted valve within the native excised valve orifice. Providing the limited surface area of the brim cover for tissue in-growth also selectively permits a relatively easy excision should valve replacement be necessary.

Each brim cover **105** and **286** is formed from a hollow cylinder **330** of pliant, biocompatible material cut to a length which covers brims of sewing rings **100** and **102** and **276**, respectively. A section of such cylinder material is seen in FIG. **17**. Cylinder **330** is preferably made of velour a commercially available, medical grade DACRON TM, similar to straight knitted a commercially available, medical grade DACRON TM velour available Bard Implants Division, C. R. Inc., Concord Road, P.O. Box M, Billerica, Mass. 01821. Velour a commercially available, medical grade DACRON TM is compatible with earlier mentioned antibiotic implantation and tissue in-growth.

As seen in FIG. **17**, cylinder **330** comprises a free top edge **332**, a free bottom edge **334**, an exterior surface **336**, and an interior surface **338**. Disposed between exterior surface **336** and interior surface **338** and between top edge **332** and bottom edge **334** is a plaint, foldable material wall **340**. As seen by the section shown in FIG. **18**, pliant, foldable wall **340** comprises an inside diameter which distends to the same outside diameter as sewing rings **100** and **102** or alternatively with sewing ring **276** without losing structural integrity.

Preparatory to adding brim cover **105** to stent **30**, brims **158** and **170** are securely attached to deformable intermediate interfacing portion **104**. As seen in FIG. **18**, sutures, generally numbered **342**, securely anchor portion **104** between brims **158** and **170**. Cylinder **330** is then disposed about sewing rings **100** and **102** such that top edge **332** is foldably disposed in proximity to seamless connection line **156'**, earlier described. Similarly, free bottom edge **334** is disposed in the proximity of seamless connection line **174'**.

Between top edge **332** and bottom edge **334**, wall **340** is folded upon itself, in two places, and interposed between interfacing portion **104** and each of the sewing rings **100** and **102** such that interior surface **338** contacts, in seriatum, brim **158** superior surface **160**, edge **152**, inferior surface **162**, the associated exterior surface of interfacing portion **104**, and brim **170** superior surface **176**, edge **154**, and inferior surface **174**. So disposed, sutures, generally numbered **344**, tightly secure wall **336** to sewing ring **100** and interfacing portion **104** at the top and to sewing ring **102** and interfacing portion **104** at the bottom as seen in FIG. **18**.

In similar fashion, sewing ring **276** is covered by another cylinder **330** as seen in FIG. **19**. Preparatory to adding brim cover **286** to stent **270**, brims **272** and **274** are securely attached to each other. As seen in FIG. **19**, sutures, generally numbered **346**, affix brim **272** to brim **274**. Cylinder **330** is then disposed about sewing ring **276** such that top edge **332** is foldably disposed in proximity to seamless connection line **156'**. Similarly, free bottom edge **334** is disposed in the proximity of seamless connection line **174'**.

Sutures, generally numbered **348**, are affixed to tightly secure wall **336** more medially to brims **158** and **170**. Other sutures, generally numbered **350**, are disposed radially outwardly from edge **152** to affix wall **336** to brim **170** alone. So disposed wall **336** provides a smooth transition between the otherwise discontinuous connection between edge **152** and superior surface **176** as seen in FIG. **19**.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by Letters Patent is:

1. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between and seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

2. The long lasting prosthetic heart valve according to claim **1** further comprising means for adjoining unitable parts of the long lasting prosthetic heart valve by stitching or other connecting means void of resins which release into the blood stream of a patient over a period of time.

3. The long lasting prosthetic heart valve according to claim **1** wherein the leaflet valve means comprise a trileaflet valve.

4. The long lasting prosthetic heart valve according to claim **1** wherein the cusp means comprise exposed side means having free margins which coapt, in combination with associated commissures, to close the valve thereby reducing wear on the cusps at contacting areas of the free margins.

5. The long lasting prosthetic heart valve according to claim **1** wherein the essentially biochemically inert material means of the leaflet valve means is combined with at least one biologically active impregnating substance from a group of biologically active substances consisting of antibiotics, anticoagulant medicants, endothelial cells and endothelial cell growth factors.

6. The long lasting prosthetic heart valve according to claim 1 wherein the leaflet valve means comprise valve means molded in the form of a human aortic valve.

7. The long lasting prosthetic heart valve according to claim 1 wherein the leaflet valve means comprise a unicast valve means.

8. The long lasting prosthetic heart valve according to claim 1 wherein the essentially biochemically inert material means comprise silicone.

9. The long lasting prosthetic heart valve according to claim 1 wherein the leaflet means comprise surface means which are functionally continuous and non-thrombogenic.

10. The long lasting prosthetic heart valve according to claim 1 wherein the cusp means and stent attachment means, in combination, comprise means for joining together in a smooth, seamless interface.

11. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame means comprise windows primarily disposed in the base means, said windows providing a reduction of weight of the frame and a plurality of orifices through which each sewing ring is affixed to the interior an exterior interfacing wall means.

12. The long lasting prosthetic heart valve according to claim 1 wherein said cylindrical frame means comprise interior and exterior surface means which in combination comprise a plurality of holes disposed therebetween for firmly anchoring the leaflet valve means to the stent.

13. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises stainless steel.

14. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises flexible resilient synthetic resinous material.

15. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises graphite.

16. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises pyrolytic carbon.

17. The long lasting prosthetic heart valve according to claim 1 wherein the enveloping cover means comprise tailored pocket means which conformably cover the substantially symmetrical extending members.

18. The long lasting prosthetic heart valve according to claim 17 wherein the tailored pocket means comprise mean for tightly sealing edges thereof.

19. The long lasting prosthetic heart valve according to claim 18 wherein said sealing means comprise means for suturing.

20. The long lasting prosthetic heart valve according to claim 18 wherein said sealing means comprise means for heat sealing the edges thereof.

21. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice said essentially biochemically inert material means comprising a porous material comprising at least one medically advantageous biochemical selected from a group of biochemicals consisting of antibiotics, anticoagulant medications, and endothelial cell growth factors

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between the seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending member which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

22. The long lasting prosthetic heart valve according to claim 1 wherein said essentially biochemically inert material means of said covering means comprise PTFE.

23. The long lasting prosthetic heart valve according to claim 1 wherein said essentially biochemically inert material means comprise polyethylene glycol terephtalate.

24. The long lasting prosthetic heart valve according to claim 1 wherein said essentially biochemically inert material means comprise firm surface support means whereby sutures are firmly and securely affixed to the at least one sewing ring.

25. The long lasting prosthetic heart valve according to claim 1 wherein the sewing ring means comprise two separated sewing rings.

26. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised form a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice, the leaflet valve means comprising surface means which are functionally continuous and non-thrombogenic;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between and seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the based of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall mans interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve, the covering means comprising a perimetrically variable compliant ring of soft material means disposed between the two separated sewing rings adapted to be an annulus left by excision of a natural valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

27. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction form bases of said cusps, and stent attachment means comprising cusp supporting means which extend int eh first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for enveloping covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between the seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve, the covering means comprising perimetrically variable compliant ring of soft material means comprising non-expanded polytetrafluoroethylene disposed between the two separated sewing rings adapted to be placed in an annulus left by excision of a natural valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring

thereby comprising only contiguous and continuous connection with the exterior wall means.

28. The long lasting prosthetic heart valve according to claim **1** wherein said covering means comprise means for covering the at least one sewing ring and for interfacing with tissue within the annulus from which a natural valve has been excised.

29. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between the seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve, said covering means comprising means for covering the at least one sewing ring and for interfacing with tissue within the annulus from which a natural valve has been excised, the at least one sewing ring covering and interfacing means comprising at least one impregnated biochemical selected form a group consisting of antibiotics and anticoagulant medicants;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

30. The long lasting prosthetic heart valve according to claim **28** wherein at least one sewing ring covering and interfacing means comprise means for variably incorporating surrounding tissue, said ring of soft material means comprising means having variable porosity and providing a predetermined balance between ease of removal of the ring of soft material means and prevention of infection.

31. The long lasting prosthetic heart valve according to claim **30** wherein variable incorporating means ring of soft material means comprise at least one impregnated biochemical selected form a group comprising antibiotics, anticoagulant medicants, and endothelial cell growth factors.

32. The long lasting prosthetic heart valve according to claim **1** wherein the sewing ring means comprise a single sewing ring wherein each of the outwardly everted ends are joined to form the single sewing ring.

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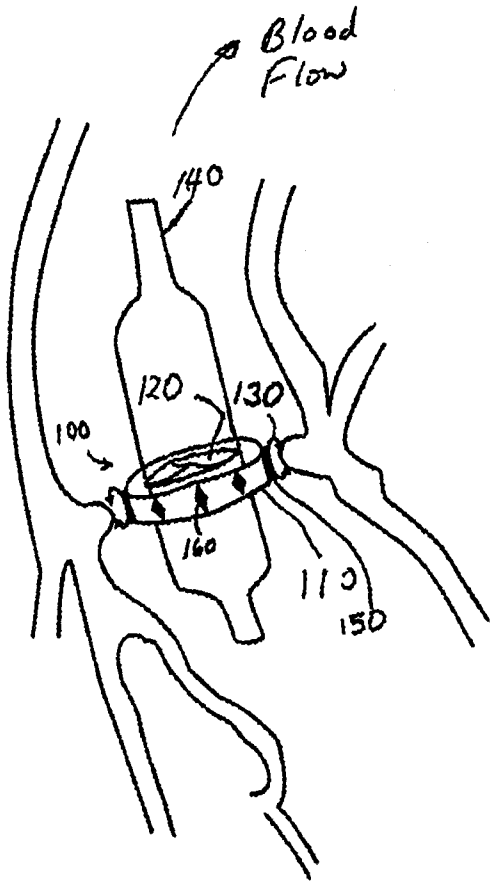
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(57) Abstract

Heart valve attachment apparatus and methods that significantly reduce attachment times are provided. The apparatus and methods utilize a connector band to form an interface between a unidirectional valve and a tissue annulus. The connector band is secured to the tissue annulus by retention fingers.



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ARTIFICIAL HEART VALVE ATTACHMENT APPARATUS

Background of the Invention

This invention relates to apparatus and methods for attaching replacement heart valves.

The replacement of a defective heart valve requires an open heart procedure in which the old, defective, valve is removed and replaced with an artificial valve. Generally, this procedure requires the heart to be placed on a cardiopulmonary bypass (CPB) to allow the heart to be stopped and the new valve to be carefully sewn in place.

This method of valve attachment, commonly known as suturing, is an effective method of attaching the new heart valve to the heart. However, it requires significant time and skill to complete. Therefore, extended CPB time is required. The extended CPB time associated with suturing, in conjunction with the complex nature of the procedure itself, may increase the likelihood of complications, including stroke, heart block and long patient recovery times.

Therefore, it would be desirable to provide heart valve attachment apparatus and methods that significantly reduce attachment times.

Brief Description of the Drawings

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout:

FIG. 1 is an elevational view of a preferred embodiment of a heart valve according to the invention.

FIG. 2 is an elevational view of the heart valve of FIG. 1 in a deployed position.

FIG. 3 is an elevational view of another embodiment of a heart valve according to the invention.

FIG. 4 is an elevational view of the heart valve of FIG. 3 in a deployed position.

FIG. 5 is an elevational view of a connector band according to the invention.

FIG. 6 is an elevational view of the heart valve of FIGS. 3 and 4 in a deployed position.

FIG. 7 is an elevational view of another embodiment of a heart valve according to the invention.

FIG. 8 is an elevational view of the heart valve of FIG. 7 in a deployed position.

FIG. 9 is an elevational view of another embodiment of a heart valve according to the invention.

FIG. 10 is an elevational view of the heart valve of FIG. 9 in a deployed position.

FIG. 11 is an elevational view of another connector band according to the invention.

FIG. 12 is an elevational view of another connector band according to the invention.

FIG. 13 is a top view of the connector band in FIG. 12.

FIG. 14 is an elevational view of another embodiment of a heart valve according to the invention.

Summary of the Invention

It is an object of the invention to provide heart valve attachment apparatus and methods that significantly reduce attachment times.

A valve apparatus for deploying in, and securing to, a tissue annulus, includes: a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction, a connector band located circumferentially around, and attached to, the valve portion and a plurality of fingers located circumferentially around, and attached to, the band. The fingers are adapted to secure the valve to the tissue annulus.

In an alternative embodiment, a connector band can be deployed separate from the valve portion. After the band is deployed, a valve can be attached to the band by screws, pop rivets or other suitable attachment device or method.

In another alternative embodiment, fingers can be implemented on the valve portion itself, thereby obviating the need for a connector band.

Detailed Description of the Invention

This invention relates to heart valves which are modified so that the valve can be attached to the heart without the need for suturing. Significant technology has been developed related to replacing sutures in bypass grafting -- i.e., attaching a tissue conduit to another with a mechanical connector rather than sewing the conduits to each other to form the anastamosis. Examples of such technology are found in commonly assigned United States Patent No. 5,976,178 and co-pending commonly assigned patent applications 08/839,199, 08/946,742, 09/016,721, 09/187,335, 09/187,361 and 09/186,774, all of which are incorporated by reference herein in their entireties.

These references, at least in part, disclose inventions related to methods and apparatus for attaching synthetic or biological tissue grafts without the need for sutures. Portions of the references deal specifically with methods and apparatus for attaching synthetic or biological tissue grafts to a connector, which is then secured to a blood vessel -- e.g., the aorta -- by using hooked or barbed fingers. In certain embodiments, the fingers are formed from an elastic material -- e.g., nitinol wire. In these embodiments, the fingers may be stretched or otherwise manipulated to pierce the tissue graft and retain the tissue graft with the hooked or barbed ends of the fingers. The elasticity of the fingers then causes the fingers to snap back such that the tissue graft is secured to the connector. The connector is then connected to a blood vessel to complete an anastamosis.

Alternatively, the fingers may be formed from relatively non-elastic stainless steel. In these embodiments, the fingers are deformed to properly engage the tissue graft and then mechanically crimped to seal the connector to the tissue graft.

The present invention provides methods and apparatus for using retention fingers, such as the fingers described above, to attach heart valves to hearts.

FIG. 1 shows an artificial heart valve 100 having a balloon expandable connector band 110 with a one-way valve portion 120 integrated within connector band 110. Valve 100 is positioned for deployment in the left ventricle outflow valve of a heart (this location illustrates only one possible exemplary embodiment of the invention, and is not intended to limit the invention to use only in the left ventricle outflow valve.) Connector band 110 preferably includes a series of retention fingers 130 with barbed ends --

i.e., the ends of the fingers have small projections that secure the fingers to their surface of engagement -- or, alternatively, hooked ends -- i.e., the ends of the fingers are bent --, or a combination of the two, spaced substantially circumferentially around band 110. Each finger preferably is attached adjacent to one end of the length of band 110 and has a corresponding finger that opposes it and is attached to the other end of the length of band 110. Thus, when the length of band 110 is reduced, the ends of each set of corresponding fingers 130 converge and engage the surrounding tissue.

The invention operates as follows: first, valve 100 is positioned for securing to the tissue annulus that surrounded the old valve. Then, balloon 140 is preferably positioned through the orifice of valve 100. Balloon 140 is then expanded. The positioning and expansion of balloon 140 can be accomplished by methods that are known to those in the art and explained in more detail in the references which are incorporated by reference above -- e.g., U.S. Patent No. 5,976,178.

Expansion of balloon 140 increases the circumference of band 110 to conform to, and substantially fill, the tissue annulus. As connector band 110 expands circumferentially, it shortens in length -- i.e., the dimension of band 110 that is substantially parallel to the blood flow. The shortening in length causes the barbed heads on each corresponding pair of retention fingers 130 to converge and engage the surrounding tissue annulus, thereby securing valve 100 to the tissue annulus. When the heads of fingers 130 engage the tissue annulus, they preferably remain there permanently. Valve 120, which may preferably be formed from porcine tissue, or other suitable natural or synthetic tissue, can be pushed out

of the way during expansion and then naturally returns following expansion.

FIG. 2 shows valve 100 after it has been deployed. Band 110 may be formed from expandable metal -- i.e., metal that has been perforated and cut in such a way that it can be expanded in one or more directions by deforming the metal in the vicinity of the cuts and perforations. This type of structure is frequently found in stents used to prevent collapses of tubular body structures; and band 110 could be a converted stent, possibly with some modifications. Alternatively, band 110 may be constructed from an expandable open mesh framework (see mesh 360 in FIG. 3 and 4) -- e.g., a braid of nitinol, stainless steel, tungsten wires or polymer strands -- which may be covered with a rubber-like web -- e.g., of silicone --.

It should be noted that, following expansion of band 110, the diameter of band 110 has increased, while the length of band 110 has decreased. As the length of band 110 is decreased, the barbed heads of axially opposite fingers 130 converge, engage the tissue annulus, and secure valve 100 to the tissue annulus. The broadening and shortening of the black diamonds 160 shown in FIGS. 1 and 2 indicate the circumferential expansion and the lengthwise contraction of the metal. Following deployment, fingers 130 grab the tissue annulus and exert a force joining band 110 to the tissue annulus. The force exerted by the fingers on the tissue annulus forms a substantially leak-proof compression seal between band 110 and the tissue annulus. Thus, the tissue preferably forms a lip which abuts the valve portion 120 of valve 110.

The outer walls of band 110 may include a gasket-like material. In an alternative embodiment, a separate gasket 150 (shown in FIG. 1) may be attached

around band 110. To further enhance the seal between band 110 and valve portion 120 the gasket-like material, or gasket 150, preferably conforms to the existing tissue annulus and seals the new valve to the tissue annulus to protect against leakage around, or through, band 110. Gasket 150 may preferably be formed from a soft, deformable biocompatible material -- e.g., polyurethane, silicone, dacron or other suitable material -- that readily conforms to existing tissue, yet provides a fluid-tight seal around valve 110.

FIG. 3 shows another embodiment of an artificial heart valve 300 according to the principles of the invention. Valve 300 includes fingers 330 that are substantially perpendicular to the length of band 310.

FIG. 4 shows valve 300 after it has been deployed. Fingers 330 are shown secured to the tissue annulus by the barbed heads of fingers 330 and a compression seal is preferably formed between band 310 and the tissue annulus.

FIG. 5 shows one embodiment of an band 510 suitable for deployment to attach to the tissue annulus as shown in FIGS. 3 and 4. At this stage, fingers 530 are parallel to the length of band 510. However, fingers 530 may be redirected radially outward, perpendicular to the length of band 510 by some suitable means. After redirection, fingers 530 may preferably appear similar to fingers 330 shown in FIGS. 3 and 4. Thereafter, band 510 can be further expanded such that fingers 530 engage, and are secured to, the tissue annulus.

One advantage of the embodiment shown in FIG. 5 is that the band can be positioned using suture threads or other suitable devices which can be attached to rings 550. Rings 550 may be linked to the infrastructure of fingers 530.

Band 510 should preferably be expandable. Fingers 530 can be oriented outward before expansion -- e.g., during production of band 510. Then, band 530 is positioned within the tissue annulus. Thereafter, fingers 530 are secured to the tissue annulus upon expansion of band 510.

In an alternative embodiment of the invention, a connector band can also be deployed separate from a valve. In this embodiment, a band, such as band 510, may first be expanded and secured to the tissue annulus at the required implant site. Then, the valve can be incorporated into the band. To facilitate the connection of the band to the valve, the band may contain a number of holes or recesses adapted to receive screws from an implanted valve, or seats for rivets or clips which are used to secure the valve to the previously deployed band. Alternatively, rivets which require no-preformed seats, but are popped through a flat portion of the band may also be used to secure the valve to the band. Examples of recesses 350, 450 are shown in FIGS. 3 and 4. The recesses may preferably be located on the interior side of the band.

FIG. 6 shows an exemplary valve 600 deployed in a left ventricle outflow valve of a complete heart. Valve 600 has fingers 630 similar to the valve shown in FIGS. 3 and 4. Balloon 640 is shown as exiting from a guide catheter 660, as is known in the art. One way to guide balloon 640 is by markers 650 which are implemented on balloon 640, as is known in the art. Markers 650 allow the balloon to be positioned using x-rays or fluoroscopically. Once a desired position for balloon 640 is achieved, balloon 640 is expanded, and valve 600 is secured to the tissue annulus. In one embodiment, the old valve may not require removal, but

may just be compressed out of the way by expanding the new valve.

FIG. 7 shows an embodiment of a non-expanding valve 700 according to the principles of the invention. Valve 700 preferably includes fingers 730 that are oriented in a direction that is substantially parallel to the length of band 710 and are oriented in the direction of the blood flow. The exact orientation of the fingers can be configured before insertion. In this embodiment, once valve 700 is positioned within the tissue annulus, the surrounding tissue can be pulled up and over each retention finger. The tissue can be manipulated using a tweezers or other suitable tool.

The fingers described throughout this application are preferably formed from an elastic material -- e.g., nitinol. The elasticity of the material allows the fingers to be expanded without undesirable deformation. The fingers may be heat-set to be flat against the length of band 710, or to be slightly projecting out from band 710. During deployment through expansion of fingers 730, each flat individual finger 730 may be temporarily erected simultaneous to the tissue from the tissue annulus being pulled up and over the erected fingers. Thereafter, fingers 730 are released. When released, fingers 730 snap back to their original position, compressing and securing the tissue annulus to valve 700.

In an alternative embodiment of valve 700, retention fingers 730 may preferably be formed from relatively non-elastic, preferably annealed, stainless steel. Each finger is erected before deployment. Then, once the tissue annulus is pulled up and over each finger 730 such that the tissue annulus is pierced by each finger 730, the finger is crimped down against

the valve body to secure the tissue annulus to valve 700.

FIG. 8 shows valve 700 after it has been deployed within the tissue annulus. In FIG. 8, fingers 730 secure valve 700 to the tissue annulus.

FIGS. 9 and 10 show a valve 900 with fingers 930 oriented in a direction that is parallel to the length of band 710 but, unlike valve 700, is substantially opposite to the blood flow. One advantage of this embodiment is that fingers 930 are oriented in the direction of insertion which, in the case of the left ventricle outflow valve, is opposite the blood flow. Thus, the orientation of fingers 930 allows the surgeon to more readily advance the valve into the tissue annulus and to engage and secure the valve to the annulus. Another advantage of valve 900 is that the deployment of valve 900 does not require a tool to pull the flesh of the tissue annulus over the finger heads. Rather, valve 900 can be directly engaged to the tissue annulus by applying pressure to valve 900 opposite the direction of the blood flow.

FIG. 11 shows an embodiment of a preferably non-expandable connector band 1110 for use in the valves shown in FIGURES 7-10. When band 1110 is inserted into the tissue annulus. Fingers 1130 and arches 1140 are caused to project outwards from band 1110. Fingers 1130 may be caused to project outwards when they are formed in the production process. When the band is expandable, it may be positioned within the tissue annulus, and, thereafter, the fingers are secured to the tissue annulus upon expansion of the band.

FIG. 12 shows yet another embodiment of a valve 1210 according to the present invention. In valve 1210, fingers 1230 are oriented in a

circumferential direction around the circumference of valve 1210.

Valve 1210 operates as follows: first, valve 1210 is positioned in the tissue annulus. This can be done by rotating valve 1210 into position (in the exemplary valve shown in FIG. 12, this requires a clockwise rotation around central longitudinal axis 1270) so fingers 1230 do not engage the tissue annulus. Then, valve 1210 is rotated in a counterclockwise direction around central longitudinal axis 1270. This rotation causes fingers 1230 to pierce the tissue annulus. Thereafter, fingers 1230 return to their original position (or, in the case of stainless steel fingers, the fingers are mechanically crimped to return to their original position) and the valve 1210 is secured to the tissue annulus. Rotation of valve 1210 can be accomplished using a tool which may be designed to rotate valve 1210 or with another suitable technique.

FIG. 13 shows an end view of valve 1210. In this view, fingers 1230 are shown in a substantially fully expanded state.

FIG. 14 shows another alternative embodiment of the invention wherein the fingers 1430 are preferably placed on the heart valve 1410 directly, without the interface of the connector band. In this embodiment, the fingers are distributed circumferentially around the heart valve, and the heart valve is inserted directly into the tissue annulus. Fingers 1430 may preferably be attached to heart valve 1410 in any of the possible configurations described herein.

In addition, though fingers 1430 are shown as hooked and barbed, they may be either hooked or barbed. As mentioned above, this feature of hooked and/or

barbed fingers may preferably be used in each embodiment of the invention.

Each of the artificial heart valve attachment apparatus described herein preferably allows a replacement valve according to the invention to be implanted surgically or percutaneously.

The diameter of an exemplary expandable valve and/or connector band, like the valves and bands described herein in accordance with the present invention, is preferably between 3 and 5 millimeters before expansion. After expansion, the diameter of the valve and/or band is preferably between 15 and 20 millimeters. The length of the valve and/or band is preferably between .75 and 2 inches before expansion, and, after expansion, is preferably between .5 and 1.5 inches.

Materials that are suitable for use in a connector band according to the invention and as described herein, preferably include stainless steel or tantalum. These materials are relatively easily yieldable under balloon pressure when constructed as described above with either a bio-compatible mesh or with perforations, and are substantially radiopaque. The preferably substantially uni-directional valve element itself is flexible, preferably porcine, tissue (the valve element may allow for a minimal backflow of fluid upon the change in direction of fluid flow). The valve in the embodiment described above in which the connector band is deployed separate from the valve, is preferably a rigid valve formed from a suitable bio-compatible material -- e.g., stainless steel -- which may provide improved connectability with the connector band.

In addition, for the embodiments of the invention described herein, the number of fingers required may preferably be between 10 and 40 barbed or

hooked fingers around the circumference of the valve, and most preferably 24 fingers. As mentioned above, the fingers may be formed from a variety of substances, including, but not limited to, nitinol or stainless steel.

Thus, an artificial heart valve attachment apparatus and methods that significantly reduce attachment times is provided. Persons skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration rather than of limitation, and the present invention is limited only by the claims which follow.

WHAT IS CLAIMED IS:

1. A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction;

a connector band located circumferentially around, and attached to, said valve portion; and

a plurality of fingers located circumferentially around, and attached to, said band, said fingers being adapted to secure said valve to said tissue annulus.

2. The valve of claim 1, wherein said fingers are adapted to secure said valve to said tissue annulus upon expansion of said band.

3. The valve of claim 1, wherein said fingers can be expanded from a first position adjacent to said band, engaged to said tissue annulus, and returned to said first position following said engagement, thereby securing said band to said tissue annulus.

4. The valve of claim 1, wherein said fingers are formed from an elastic material.

5. The valve of claim 1, wherein said band comprises a gasket located around an outer circumference of said band, said gasket for sealing between said band and said tissue annulus.

6. The valve of claim 1, wherein said fingers are hooked.

7. The valve of claim 1, wherein said fingers are barbed.

8. The valve of claim 1, wherein said fingers are barbed and hooked.

9. The valve of claim 1, wherein said fingers are substantially parallel to a central longitudinal axis of said band.

10. The valve of claim 1, wherein said fingers are substantially perpendicular to a central longitudinal axis of said band.

11. The valve of claim 1, wherein said band is expandable.

12. A method for attaching a uni-directional valve to a tissue annulus, said valve having a connector band attached circumferentially around said valve, said band having fingers attached circumferentially around said band, said method comprising:

positioning said uni-directional valve within said annulus; and

engaging said fingers to said annulus such that said fingers secure said valve to said annulus and such that said valve controls the flow of fluid through said annulus.

13. The method of claim 12 the engaging further comprising engaging such that said valve permits substantially only uni-directional flow through said annulus.

14. The method of claim 12 wherein said positioning comprises expanding said valve such that said valve substantially fills said annulus and wherein said expanding occurs before said engaging.

15. The method of claim 12 wherein said positioning comprises expanding said valve such that said valve substantially fills said annulus and wherein said expanding occurs before said engaging.

16. The method of claim 12 wherein said engaging is caused by expanding said valve such that said valve substantially fills said annulus.

17. The method of claim 12 wherein said engaging further comprises expanding said fingers for engaging said fingers to said annulus.

18. The method of claim 12 wherein said engaging further comprises expanding said fingers and rotating said valve to engage said fingers to said annulus.

19. The method of claim 12 wherein said engaging said fingers to said annulus comprises repeatedly pulling a single portion of said annulus onto at least a single one of said fingers.

20. A connector band for providing an interface between a uni-directional valve and a tissue annulus, said band comprising:

a wall for location circumferentially around, and attachment to, said valve, said wall having a plurality of recesses for receiving said valve; and

a plurality of fingers located circumferentially around, and attached to, said wall,

said fingers being adapted to secure said band to said tissue annulus.

21. The valve of claim 20, wherein said band is expandable.

22. The band of claim 20, wherein said fingers are adapted to secure said band to said tissue annulus upon expansion of said band.

23. The valve of claim 20, wherein said fingers can be expanded from a first position adjacent to said band, engaged to said tissue annulus, and returned to said first position following said engagement, thereby securing said band to said tissue annulus.

24. The valve of claim 20, wherein said fingers are formed from an elastic material.

25. The valve of claim 20, wherein said band comprises a gasket located around an outer circumference of said band, said gasket for sealing between said band and said tissue annulus.

26. The valve of claim 20, wherein said fingers are hooked.

27. The valve of claim 20, wherein said fingers are barbed.

28. The valve of claim 20, wherein said fingers are hooked and barbed.

29. The valve of claim 20, wherein said fingers are substantially parallel to a central longitudinal axis of said band.

30. The valve of claim 20, wherein said fingers are substantially perpendicular to a central longitudinal axis of said band.

31. The valve of claim 20, wherein said recesses are adapted to receive rivets, said rivets being to attach said valve to said band.

32. The valve of claim 20, wherein said recesses are adapted to receive screws, said screws being to attach said valve to said band.

33. The valve of claim 20, wherein said recesses are for receiving clips, said clips being for attaching said valve to said band.

34. A method for attaching a uni-directional valve to a tissue annulus using a connector band attached circumferentially around said valve, said band having fingers attached circumferentially around said band, said method comprising:

positioning said band within said annulus;

engaging said fingers to said annulus such that said fingers secure said band to said annulus; and

attaching said valve to said band such that said valve controls the flow of fluid through said annulus.

35. The method of claim 34 the engaging further comprising engaging such that said valve

permits substantially only uni-directional flow through said annulus.

36. The method of claim 34 wherein positioning comprises expanding said band such that said band substantially fills said annulus before said engaging.

37. The method of claim 34 wherein positioning comprises expanding said band such that said band substantially fills said annulus simultaneous to said engaging.

38. The method of claim 34 wherein said engaging is caused by expanding said band.

39. The method of claim 34 wherein said engaging further comprises expanding said fingers for engaging said fingers to said annulus.

40. The method of claim 34 wherein said engaging further comprises expanding said fingers and rotating said valve to engage said fingers to said annulus.

41. The method of claim 34 wherein said engaging said fingers to said annulus comprises pulling a portion of said annulus onto one of said fingers.

42. The method of claim 34 said attaching further comprising riveting said valve to said band.

43. The method of claim 34 said attaching further comprising clipping said valve to said band.

44. The method of claim 34 said attaching further comprising screwing said valve to said band.

45. A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction; and

a plurality of fingers located circumferentially around, and attached to, said valve, said fingers being adapted to secure said valve to said tissue annulus.

46. The valve of claim 45, wherein said fingers are adapted to secure said valve to said tissue annulus upon deployment of said valve.

47. The valve of claim 45, wherein said fingers can be expanded from a first position adjacent to said valve, engaged to said tissue annulus, and returned to said first position following said engagement, thereby securing said valve to said tissue annulus.

48. The valve of claim 45, wherein said fingers are formed from an elastic material.

49. The valve of claim 45, wherein said valve comprises a gasket located around an outer circumference of said valve, said gasket for sealing between said valve and said tissue annulus.

50. The valve of claim 45, wherein said fingers are hooked.

51. The valve of claim 45, wherein said fingers are barbed.

52. The valve of claim 45, wherein said fingers are barbed and hooked.

53. The valve of claim 45, wherein said fingers are substantially parallel to a central longitudinal axis of said valve.

54. The valve of claim 45, wherein said fingers are substantially perpendicular to a central longitudinal axis of said valve.

55. A method for attaching a uni-directional valve to a tissue annulus, said valve having fingers attached circumferentially around said valve, said method comprising:

positioning said uni-directional valve within said annulus such that said valve substantially fills said annulus; and

engaging said fingers to said annulus such that said fingers secure said valve to said annulus and such that said valve controls the flow of fluid through said annulus.

56. The method of claim 55 the engaging further comprising engaging such that said valve permits substantially only uni-directional flow through said annulus.

57. The method of claim 55 wherein said engaging further comprises expanding said fingers for engaging said fingers to said annulus.

58. The method of claim 55 wherein said engaging further comprises expanding said fingers and rotating said valve to engage said fingers to said annulus.

59. The method of claim 52 wherein said engaging said fingers to said annulus comprises repeatedly pulling a single portion of said annulus onto at least a single one of said fingers.

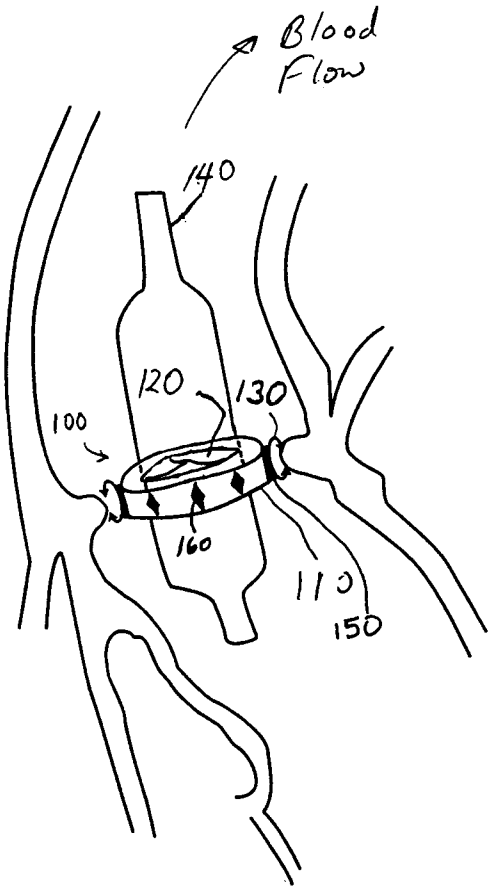


FIG. 1

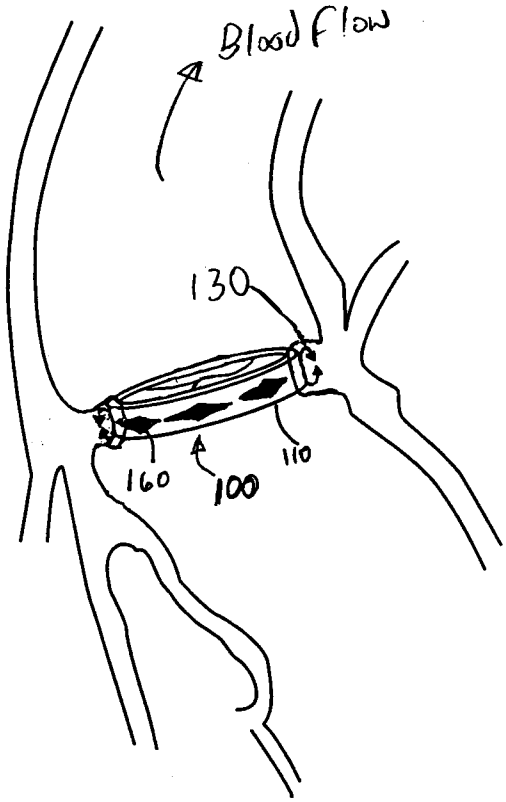


FIG. 2

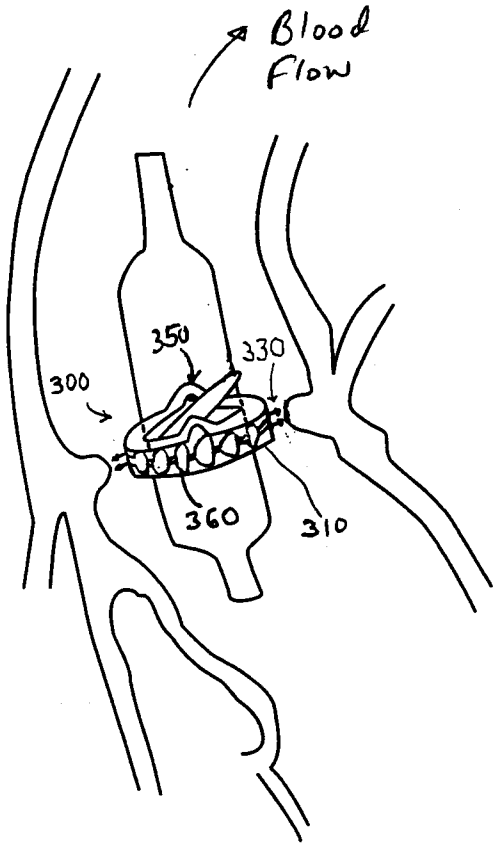


FIG. 3

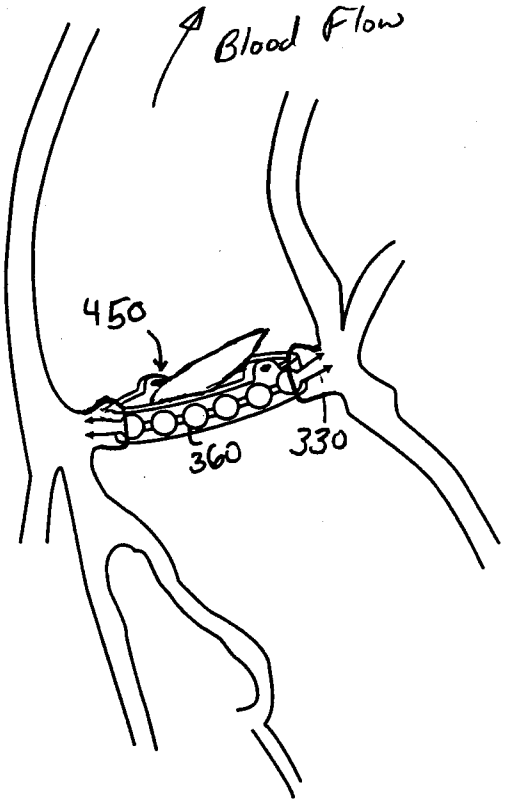


Fig. 4

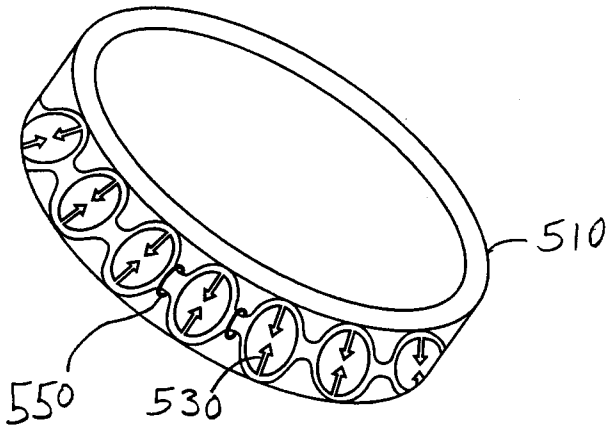


FIG. 5

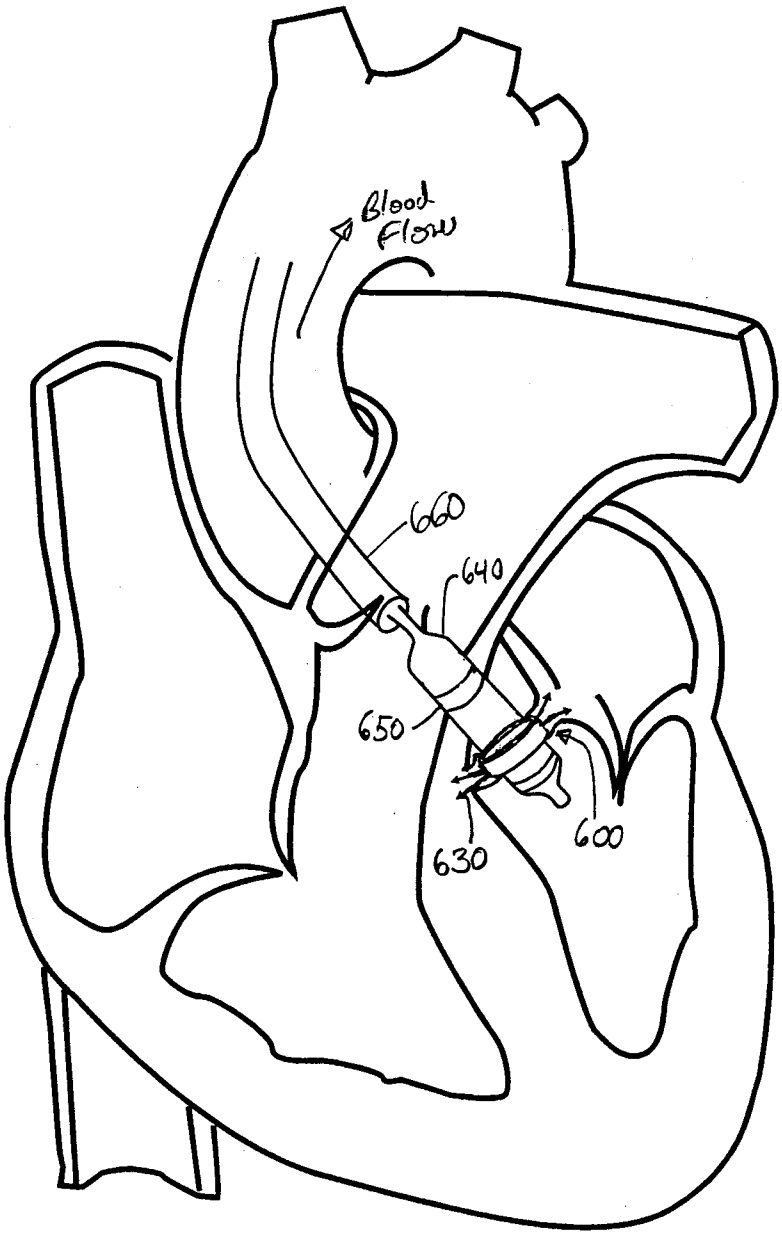


FIG. 6

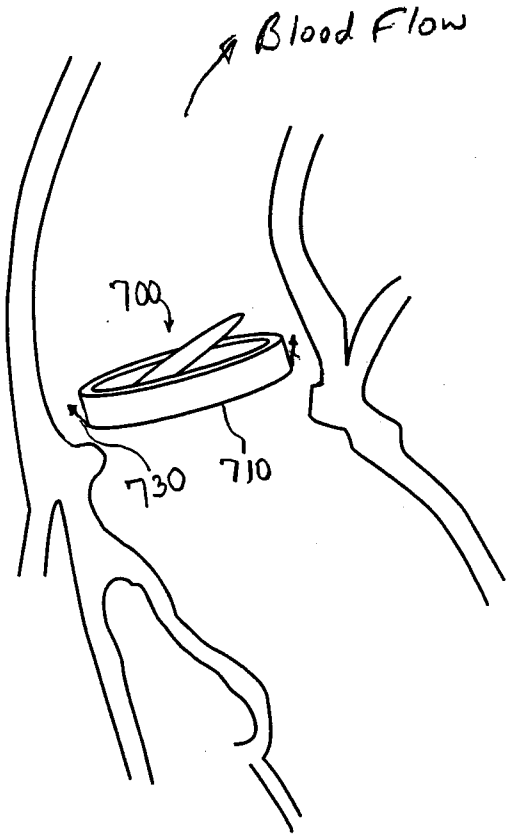


FIG. 7

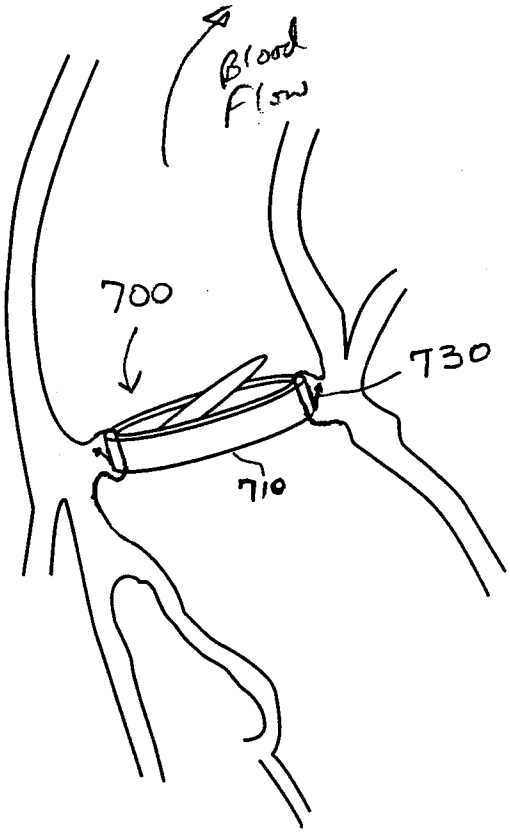


FIG. 8

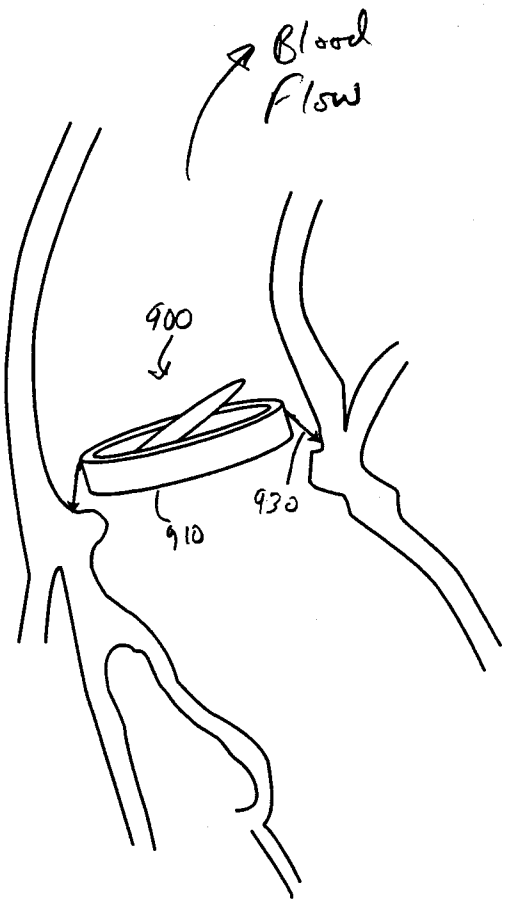


FIG. 9

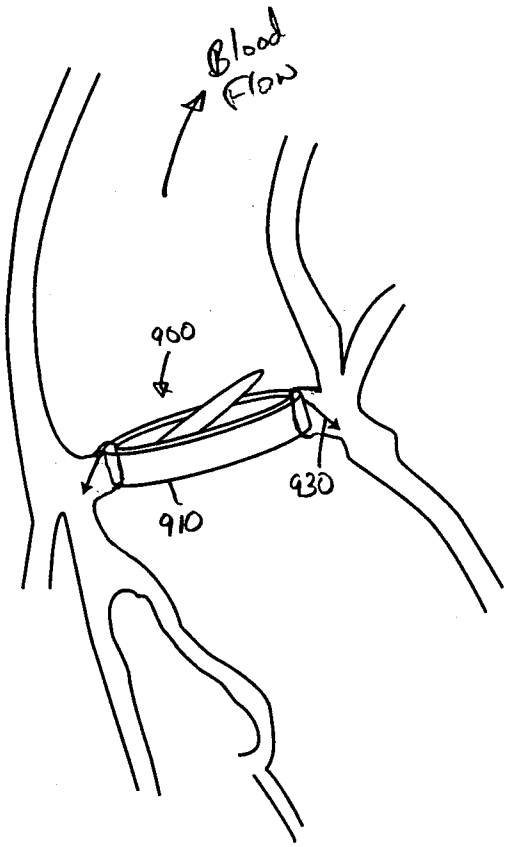


FIG. 10

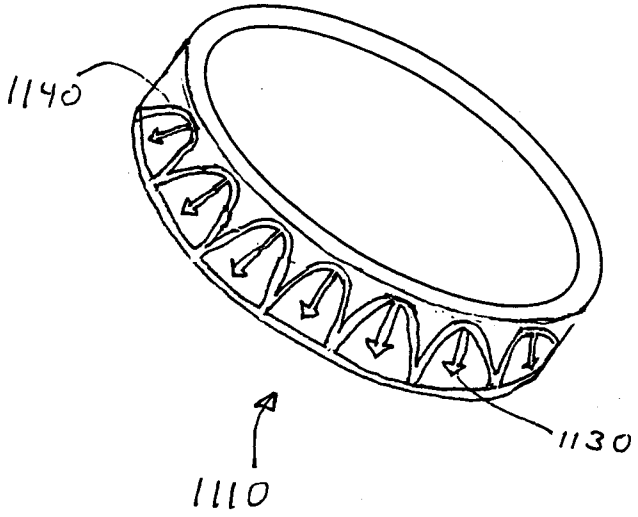


FIG. 11

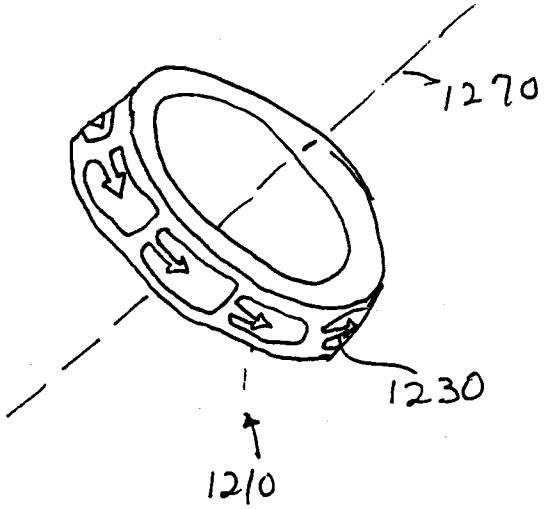


FIG. 12

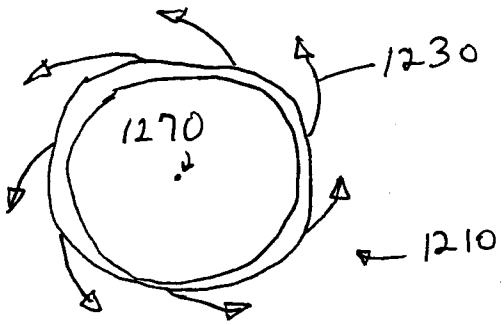


FIG. 13

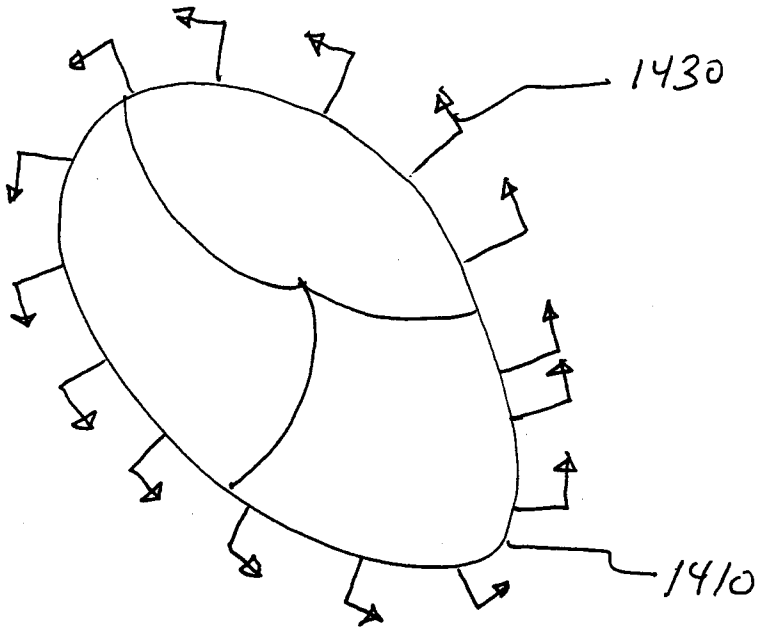


FIG. 14

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/10081

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 686 740 A (D.P. SHILEY) 29 August 1972 (1972-08-29)	1-3,6, 10,11, 20-23, 25,26, 29, 45-47, 49,50,54
Y	column 18, line 1 -column 21, line 17; figures 23-30	4,7,8, 24,27, 28, 31-33, 48,51,52

Y	WO 99 04724 A (E.P. STRECKER) 4 February 1999 (1999-02-04) abstract; claim 10; figures	4,24, 31-33,48

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 June 2000	06/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Wolf, C

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Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 476
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

INTERNATIONAL SEARCH REPORT

Interr nal Application No
PCT/US 00/10081

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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P,X	WO 99 56665 A (AXYA MEDICAL,INC.) 11 November 1999 (1999-11-11) abstract; figures 1-6	1,9,20, 29,45, 46,53
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A	WO 99 18887 A (VASCULAR SCIENCE INC.) 22 April 1999 (1999-04-22) cited in the application abstract; figures 21,23 page 6, line 25 -page 7, line 7	4,7,8, 24,27, 28,48, 51,52
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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 477
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 00/10081

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US006454799B1

(12) **United States Patent**
Schreck

(10) **Patent No.: US 6,454,799 B1**
(45) **Date of Patent: Sep. 24, 2002**

(54) **MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE**

(75) Inventor: **Stefan Schreck**, Vista, CA (US)

(73) Assignee: **Edwards Lifesciences Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/549,413**

(22) Filed: **Apr. 6, 2000**

(51) **Int. Cl.**[7] **A61F 2/24**
(52) **U.S. Cl.** **623/2.18**; 623/2.1; 623/2.14; 623/2.17; 623/2.28; 623/2.33
(58) **Field of Search** 623/2.1, 2.14, 623/2.17, 2.18, 2.38, 2.33, 2.23, 2.28

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Primary Examiner—Corrine McDermott
Assistant Examiner—Cheryl L. Miller
(74) *Attorney, Agent, or Firm*—Debra D. Condino; John Christopher James; Guy L. Cumberbatch

(57) **ABSTRACT**

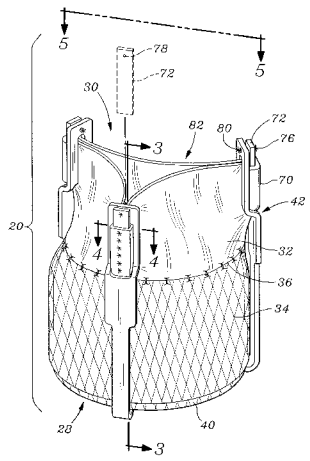
Expandable heart valves for minimally invasive valve replacement surgeries are disclosed. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably, the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably, the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

20 Claims, 10 Drawing Sheets

WBH7
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP



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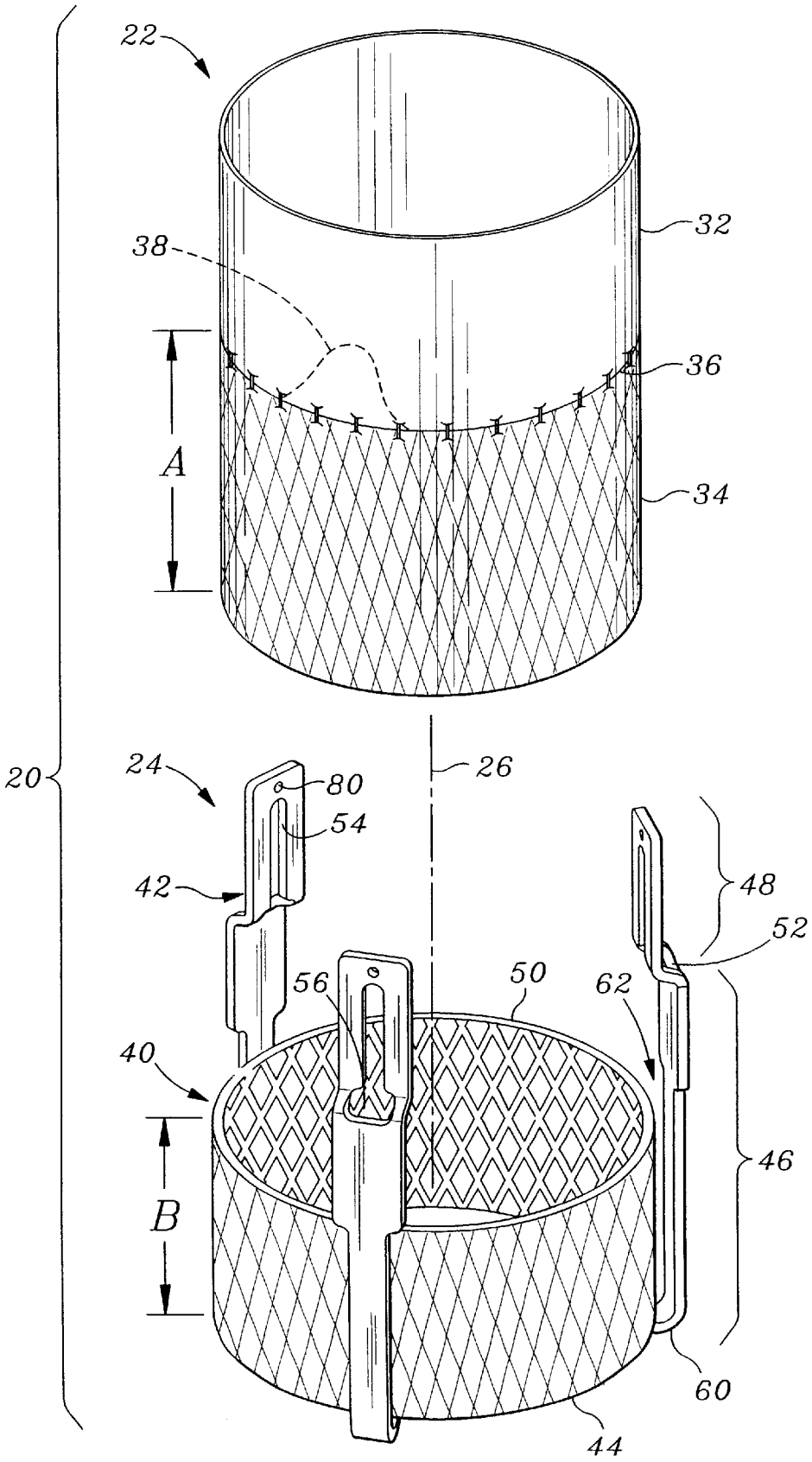
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Fig. 1



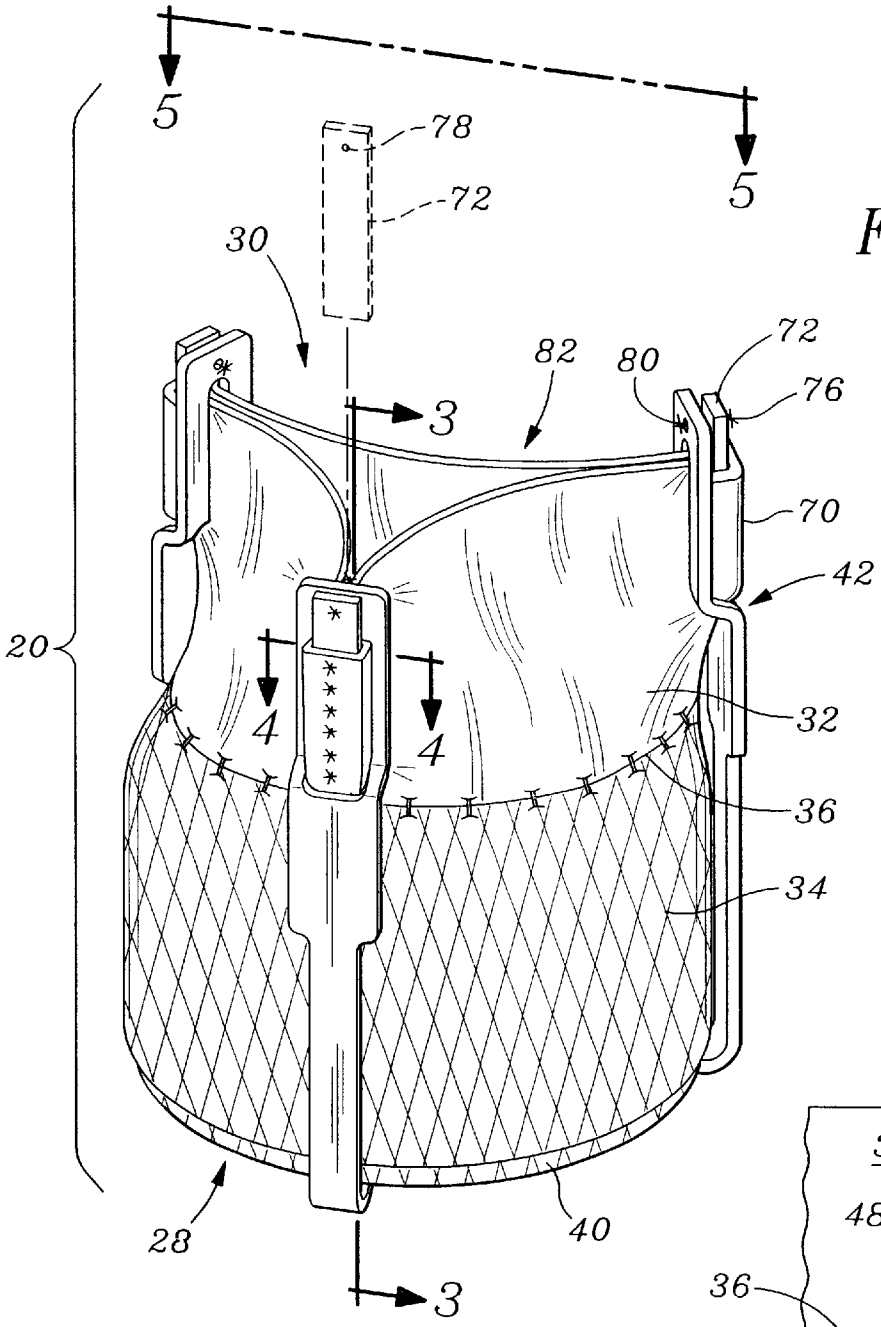

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Fig. 2

Fig. 3

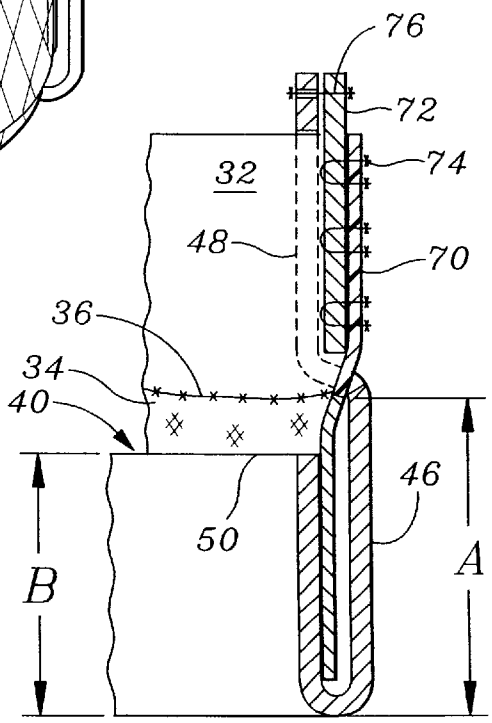

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Fig. 4

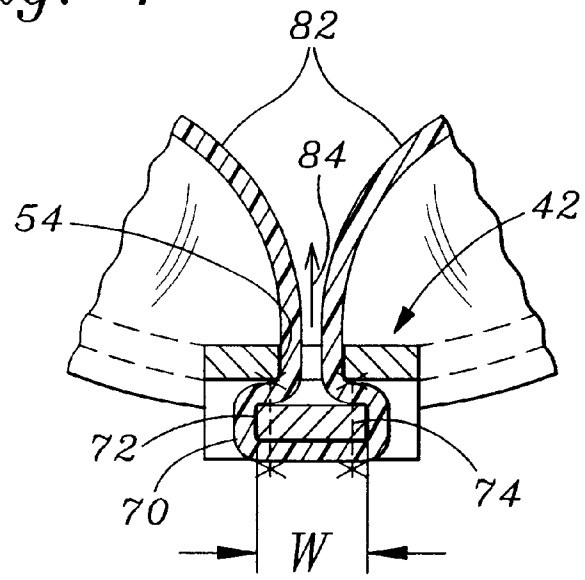


Fig. 5

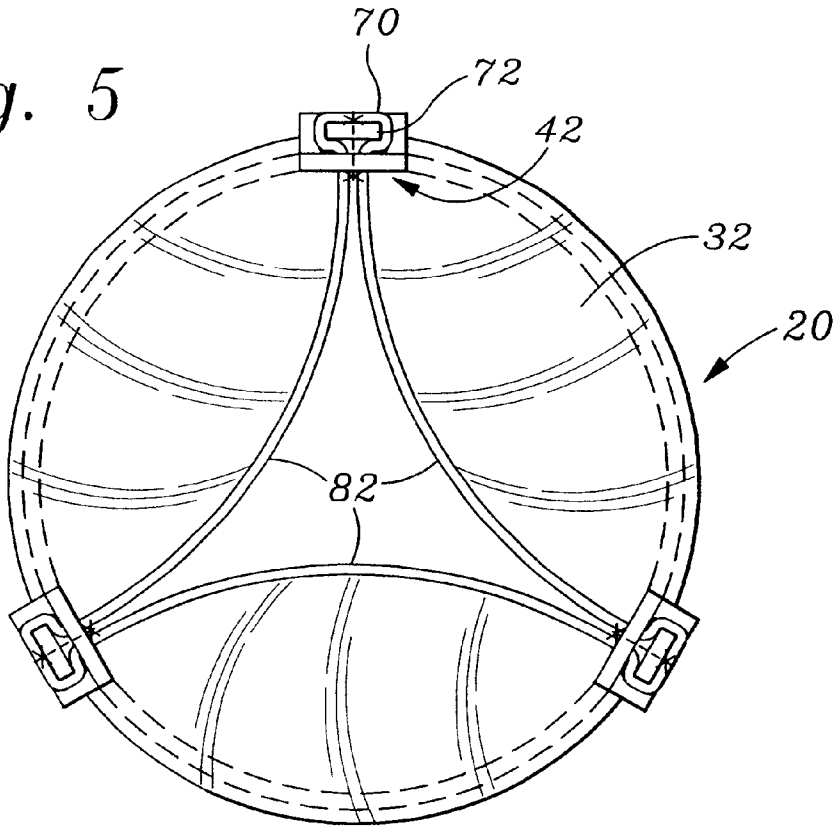


Fig. 6

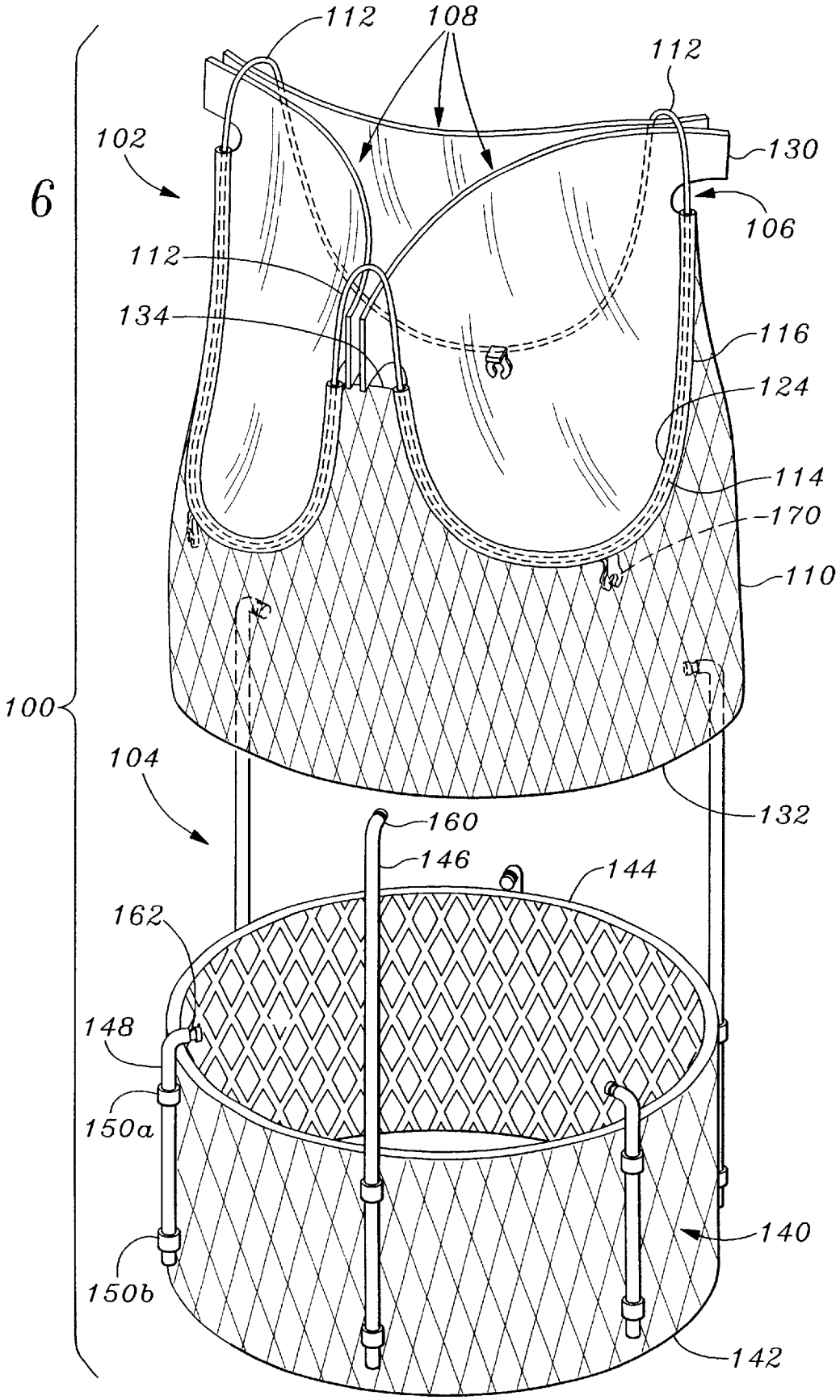

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Fig. 9

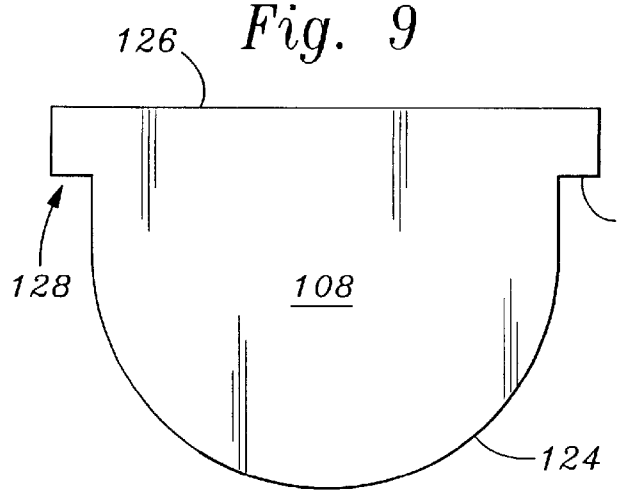
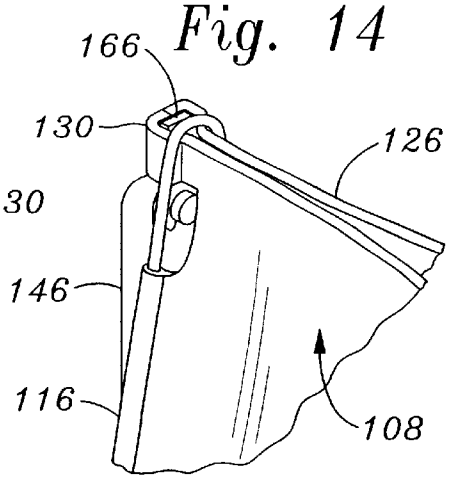


Fig. 14



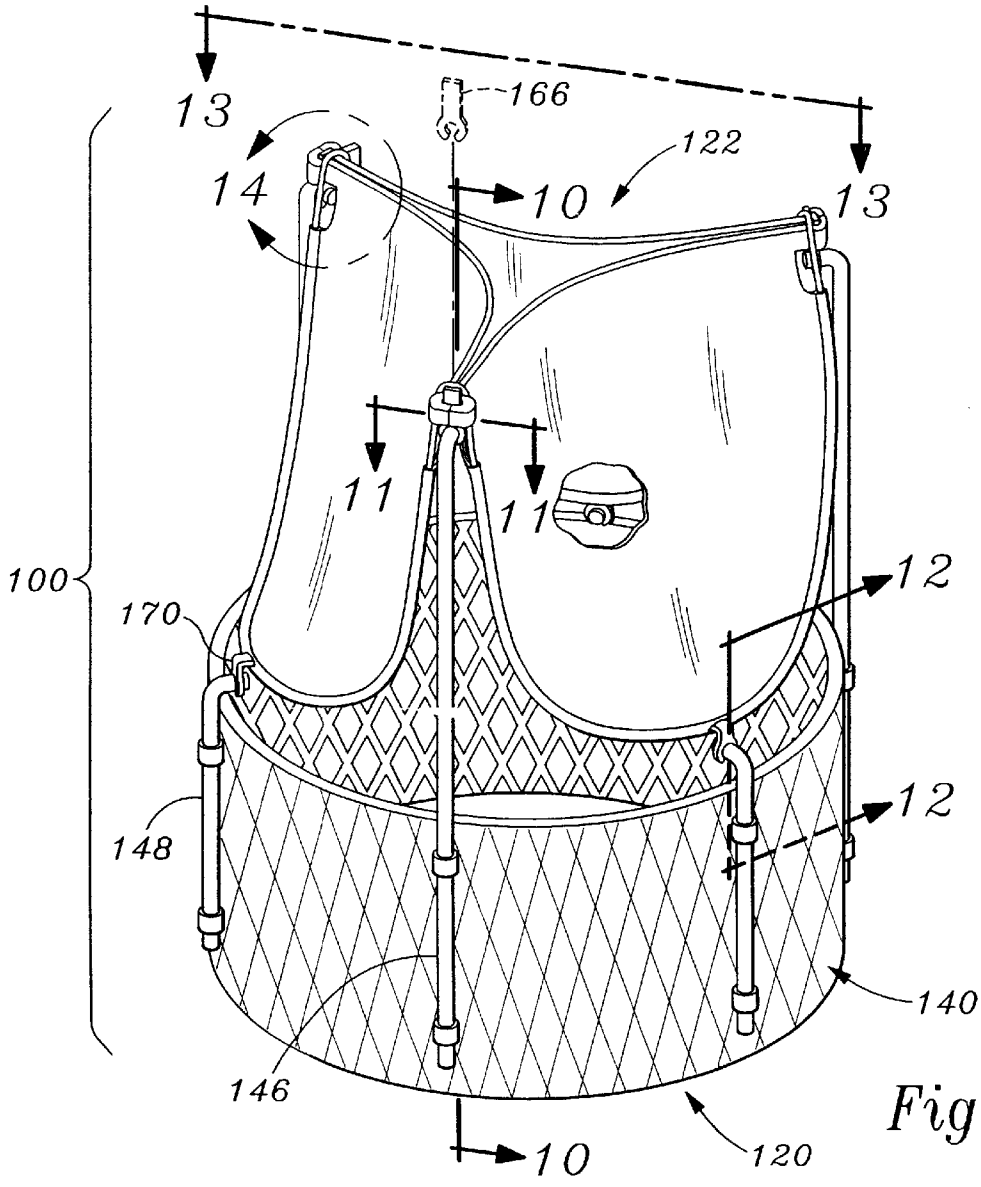


Fig. 7

Fig. 12

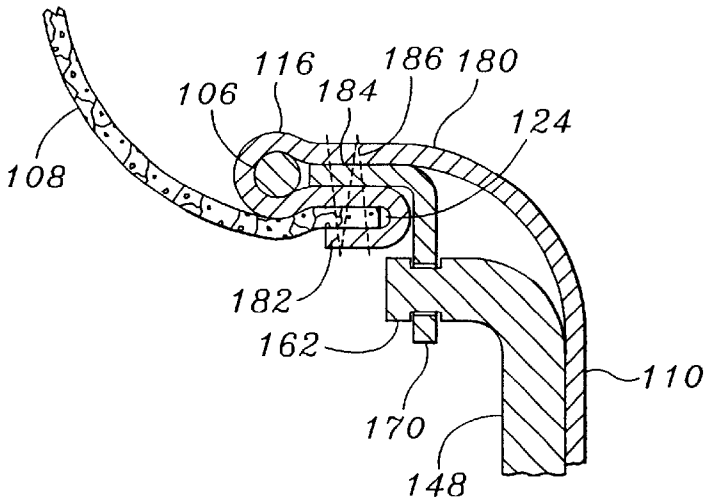


Fig. 8

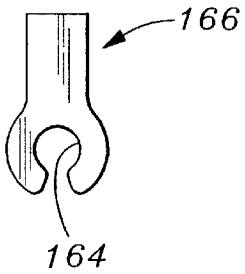


Fig. 10

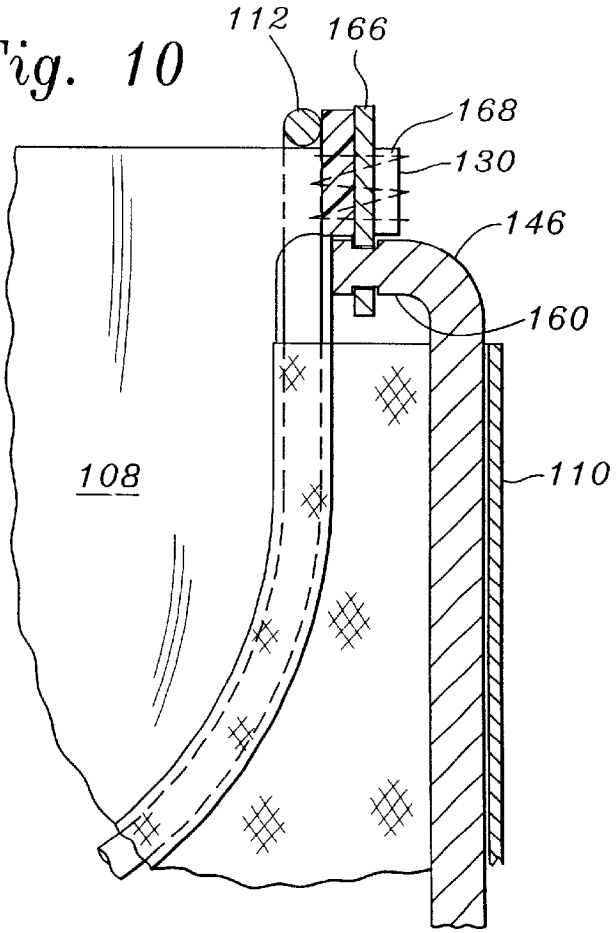


Fig. 11

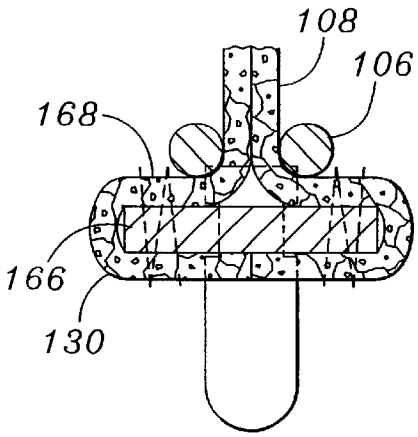


Fig. 15

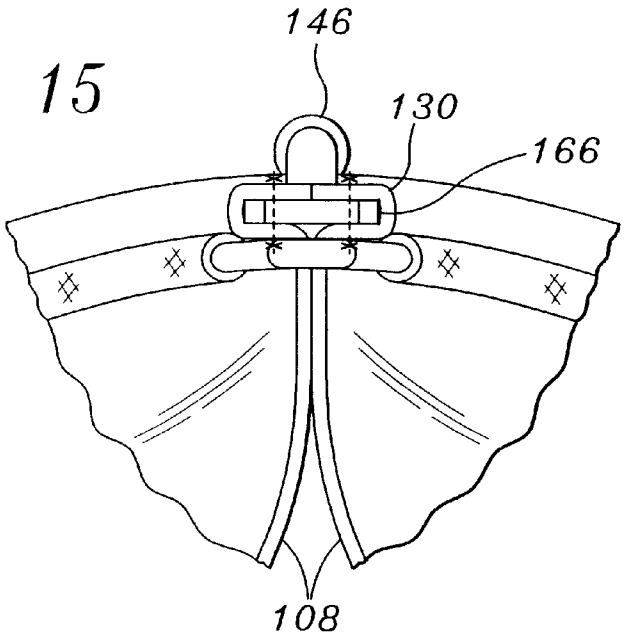
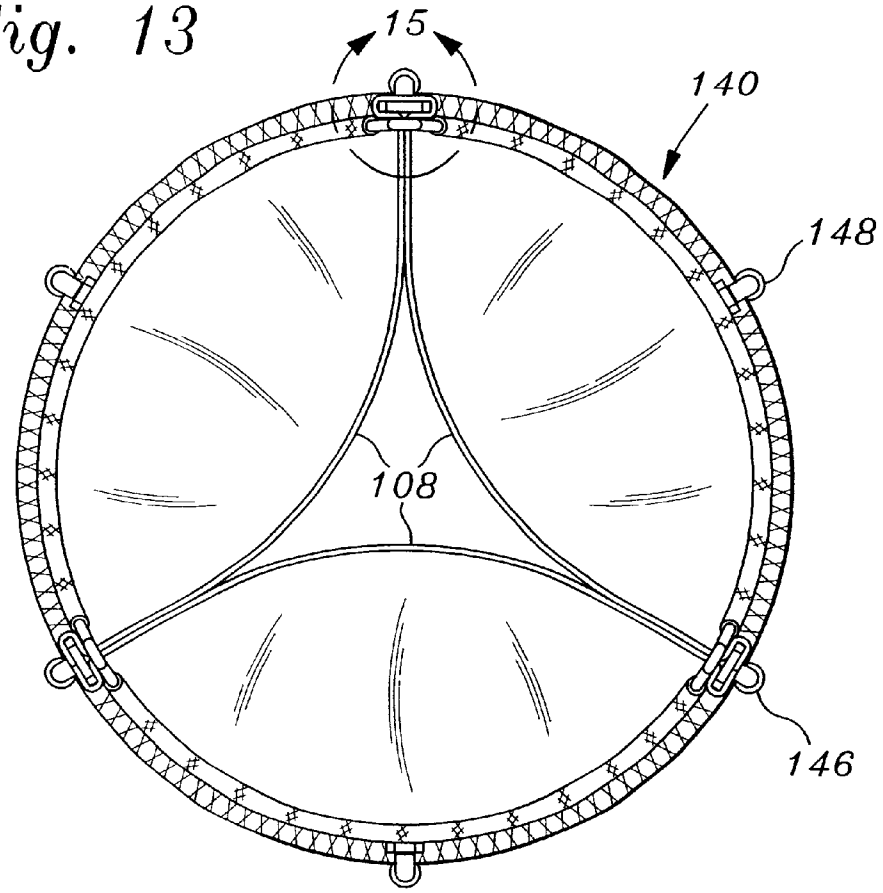


Fig. 13



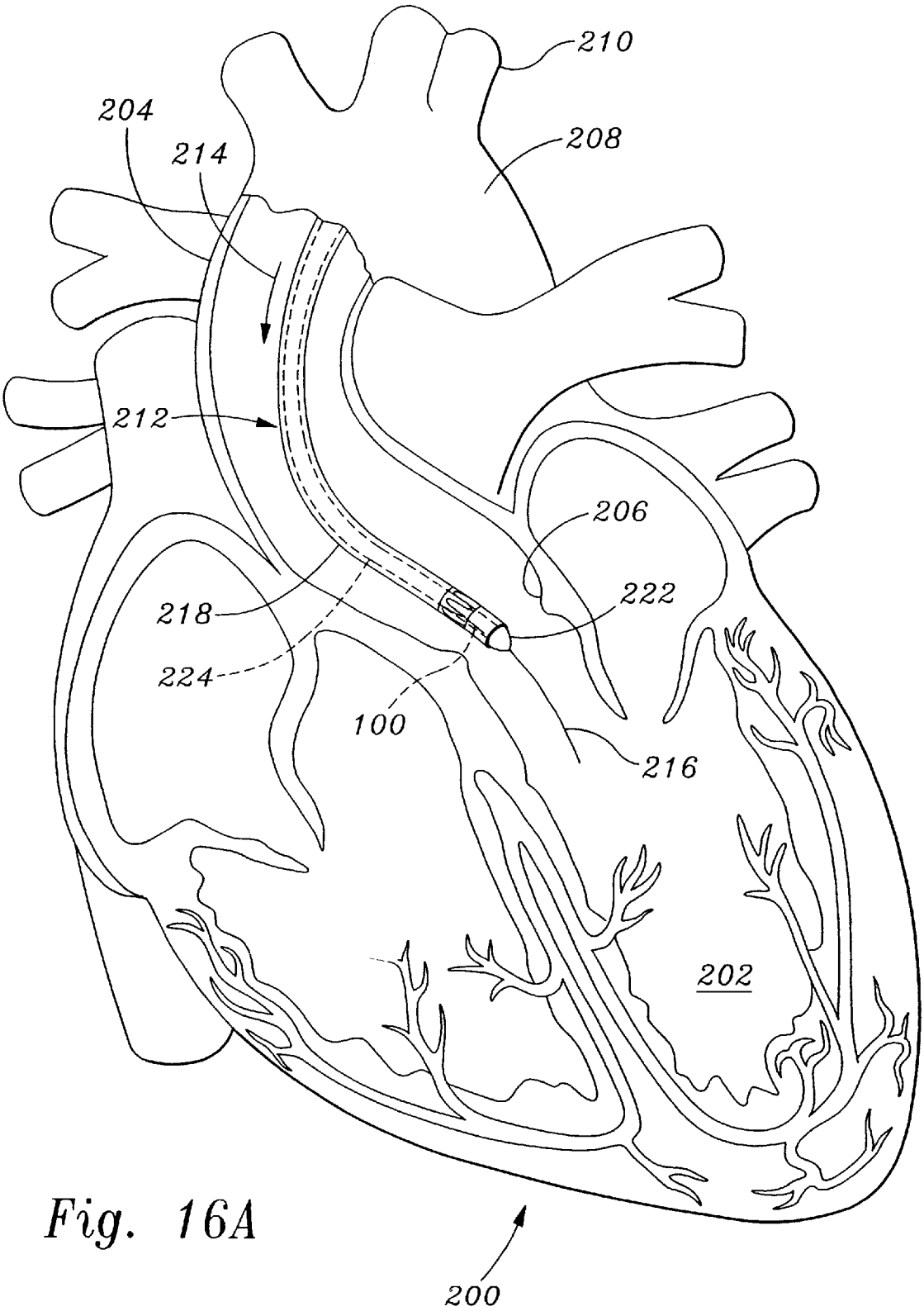


Fig. 16A

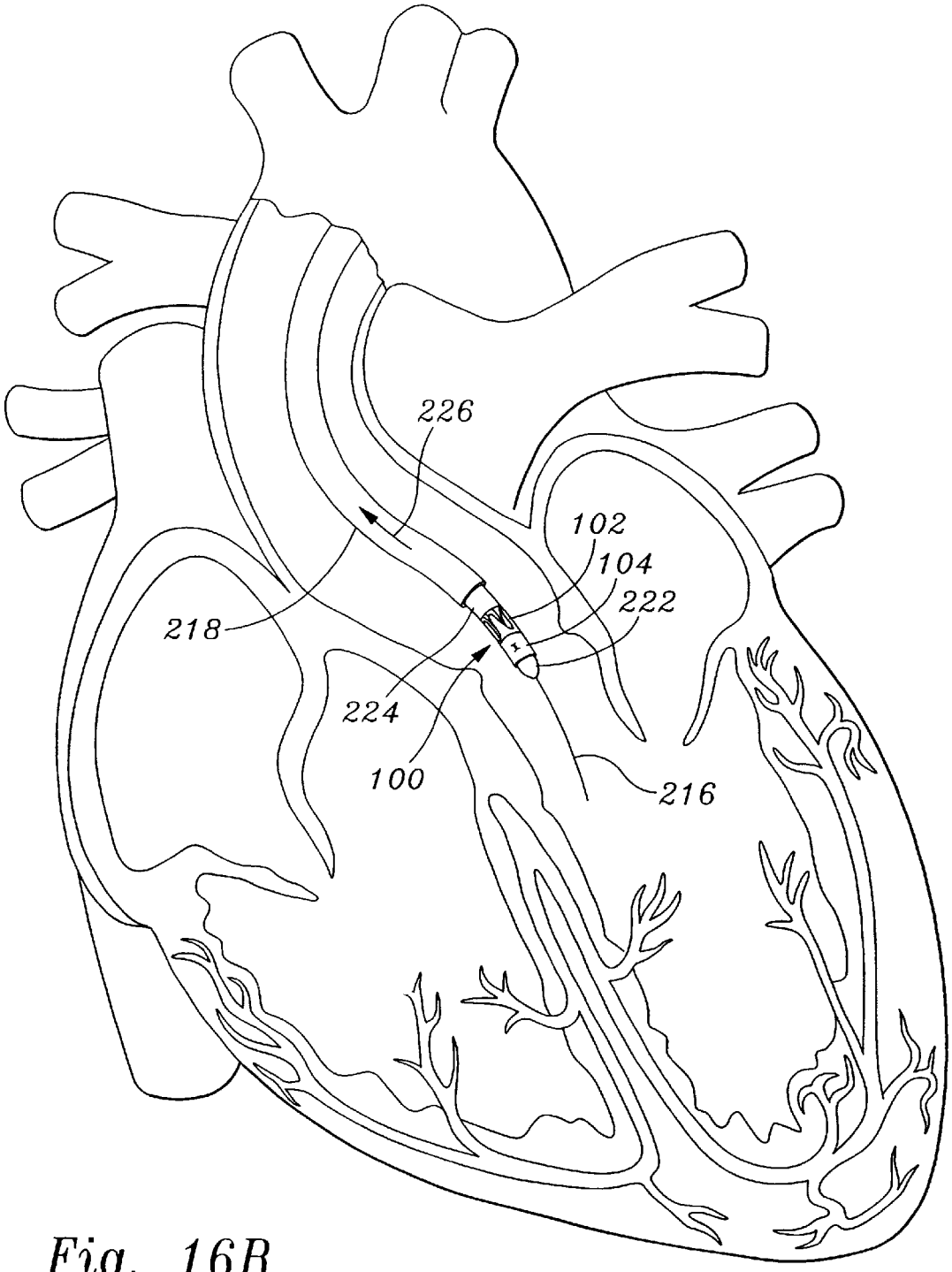


Fig. 16B

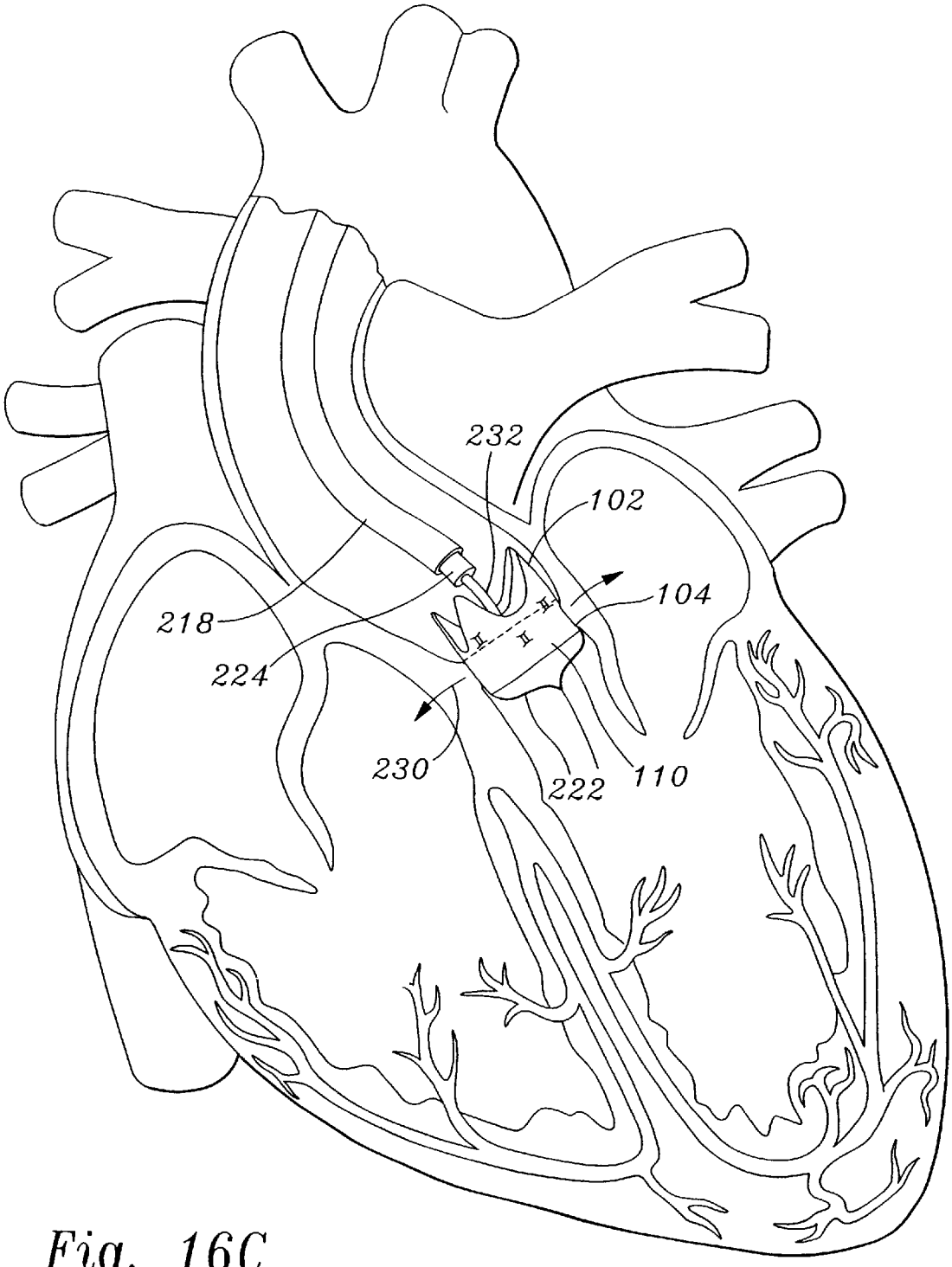


Fig. 16C

MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE

FIELD OF THE INVENTION

The present invention relates generally to medical devices and particularly to expandable heart valve prostheses especially for use in minimally-invasive surgeries.

BACKGROUND OF THE INVENTION

Prosthetic heart valves are used to replace damaged or diseased heart valves. In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. Prosthetic heart valves can be used to replace any of these naturally occurring valves, although repair or replacement of the aortic or mitral valves is most common because they reside in the left side of the heart where pressures are the greatest.

Where replacement of a heart valve is indicated, the dysfunctional valve is typically cut out and replaced with either a mechanical valve, or a tissue valve. Tissue valves are often preferred over mechanical valves because they typically do not require long-term treatment with anticoagulants. The most common tissue valves are constructed with whole porcine (pig) valves, or with separate leaflets cut from bovine (cow) pericardium. Although so-called stentless valves, comprising a section of porcine aorta along with the valve, are available, the most widely used valves include some form of stent or synthetic leaflet support. Typically, a wireform having alternating arcuate cusps and upstanding commissures supports the leaflets within the valve, in combination with an annular stent and a sewing ring. The alternating cusps and commissures mimic the natural contour of leaflet attachment. Importantly, the wireform provides continuous support for each leaflet along the cusp region so as to better simulate the natural support structure.

A conventional heart valve replacement surgery involves accessing the heart in the patient's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart, allowing access to the thoracic cavity and heart within. The patient is then placed on cardiopulmonary bypass which involves stopping the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period.

Recently, a great amount of research has been done to reduce the trauma and risk associated with conventional open heart valve replacement surgery. In particular, the field of minimally invasive surgery (MIS) has exploded since the early to mid-1990s, with devices now being available to enable valve replacements without opening the chest cavity. MIS heart valve replacement surgery still requires bypass, but the excision of the native valve and implantation of the prosthetic valve are accomplished via elongated tubes or cannulas, with the help of endoscopes and other such visualization techniques.

Some examples of MIS heart valves are shown in U.S. Pat. No. 5,980,570 to Simpson, U S. Pat. No. 5,984,959 to Robertson, et al., and PCT Publication No. WO 99/334142 to Vesely. Although these and other such devices provide various ways for collapsing, delivering, and then expanding a "heart valve" per se, none of them disclose an optimum structure for tissue valves. For instance, the publication to

Vesely shows a tissue leaflet structure of the prior art in FIG. **1**, and an expandable inner frame of the invention having stent posts in FIGS. **3**A–**3**C. The leaflets are "mounted to the stent posts **22** in a manner similar to that shown in FIG. **1**." Such a general disclosure stops short of explaining how to construct an optimum valve. In particular, the means of attaching the leaflets to the MIS stent is critical to ensure the integrity and durability of the valve once implanted. All of the prior art MIS valves fall short in this regard.

In view of the foregoing, it is evident that an improved sewing ring that addresses the apparent deficiencies in existing expandable heart valves is necessary and desired.

SUMMARY OF THE INVENTION

The present invention provides an expandable prosthetic heart valve for placement in a host heart valve annulus, comprising an expandable stent system adapted to be delivered in a collapsed state to an implantation site and expanded, and a plurality of prosthetic leaflets attached to the stent system. Each leaflet has an approximately semicircular cusp edge terminating at each end in commissure portions, and a coapting edge extending between the commissure portions. Each leaflet is attached to the stent system substantially entirely along the cusp edge and at both commissure portions, with a coapting edge remaining unattached. The stent system may comprise an expandable generally annular tissue-engaging base and an elastic generally annular wireform attached thereto. The base is adapted to be delivered in a radially collapsed state and expanded into contact with the host annulus. The annular wireform defines a plurality of upstanding commissures and a plurality of arcuate cusps between adjacent commissures, and the prosthetic leaflets are attached to the wireform along the cusps and commissures, wherein the wireform and leaflets are configured to be radially compressed.

In one embodiment, the heart valve includes a plurality of upstanding posts attached to one of the tissue-engaging base and elastic wireform, each post having a connector. A plurality of mating connectors are provided on the other of the tissue-engaging base and elastic wireform for mating with the post connectors. The posts and mating connectors may be provided for each commissure and each cusp of the elastic wireform so that the valve includes a number of posts and mating connectors equal to the number of commissures plus the number of cusps. Further, the expandable stent system may include an undulating wireform defining a plurality of commissures and a plurality of cusps between adjacent commissures. The cusp edge of each of the prosthetic leaflets attaches along a wireform cusp, and the commissure portions of each leaflet terminate in outwardly extending tabs that each attach to a wireform commissure, wherein tabs from adjacent leaflets are attached together at each of the wireform commissures.

In another aspect of the invention, an expandable prosthetic heart valve for placement in a host heart valve annulus is provided. The heart valve comprises an expandable stent portion and an elastic leaflet portion connectable to the stent portion. The stent portion defines an inflow end of the valve and is adapted to be delivered in a collapsed state and expanded into contact with the host annulus. The leaflet portion forms a one-way flow occluder on an outflow end of the valve and includes an elastic wireform defining alternating cusps and commissures and prosthetic tissue attached substantially entirely therealong. The stent portion desirably includes a tubular member and a plurality of connectors, and wherein a plurality of connectors are provided on the elastic

wireform for mating with the tubular member connectors. The wireform connectors may be provided on each commissure and on each cusp of the wireform so that the valve includes a number of mating connectors equal to the number of commissures plus the number of cusps. In a preferred embodiment, the prosthetic tissue comprises a plurality of individual leaflets secured along the alternating cusps and commissures of the elastic wireform. Additionally, the wireform may have a fabric covering, wherein the individual leaflets are stitched along the fabric covering. The fabric covering continues toward an inflow end of the valve in a skirt that surrounds the stent portion and is adapted to be captured between the expanded stent portion and the host annulus. A plurality of posts rigidly may connect to the stent portion and extend upward within the skirt into mating connection with the elastic wireform.

In a still further aspect, the present invention provides a two-part expandable prosthetic heart valve for placement in a host heart valve annulus, comprising:

a leaflet subassembly having a wireform defining a plurality of upstanding commissures and a plurality of arcuate cusps extending between adjacent commissures, a midpoint of each cusp being located approximately equidistant from the adjacent commissures;

a generally annular tissue-engaging base defining an axis; and

a system for connecting the leaflet subassembly and the tissue-engaging base, including a plurality of mating connectors on the leaflet subassembly and on the tissue-engaging base, wherein one connector each is provided at each commissure, and one at each cusp midpoint.

In the two-part heart valve, the tissue-engaging base preferably comprises an expandable tubular member that is deliverable to the host annulus in a collapsed state and expandable into contact with the host annulus to secure the valve therein. Furthermore, the tissue-engaging base forms an inflow end of the valve, and the system for connecting the leaflet subassembly and tissue-engaging base includes a plurality of posts coupled to the tubular member and having varying lengths extending away from the inflow end of the valve. A first plurality of posts each having a first length connects with the wireform commissures, and a second plurality of posts each having a second length connects with the wireform cusps shorter than the first length. The mating connectors may be configured to be joined together by axial compression, preferably with a snap-fit configuration.

A further aspect of the invention includes a prosthetic heart valve having a support stent and a flexible tubular member. The support stent includes a tubular base along an inflow end a plurality of generally axially-extending commissure posts disposed evenly around the tubular base on an outflow end thereof. The flexible tubular member has a prosthetic section attached to the commissure posts so as to define a plurality of the prosthetic valve leaflets between the posts, and a fabric section connected to the base. The prosthetic section and fabric section are desirably both generally tubular and attached together at a seam, wherein the seam is spaced from the outflow end of the tubular base so that only the fabric section of the flexible tubular member contacts the tubular base. The commissure posts each may have an axial slot, wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post. A plurality of inserts sized larger than the slots may be provided, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot. In a preferred embodiment, the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180° to extend alongside the base and project beyond the base at the outflow end thereof.

A prosthetic heart valve of the present invention has a support stent including a tubular base along an inflow end. A plurality of generally axially-extending commissure posts each having an axial slot is disposed evenly around the tubular base on an outflow end thereof. A flexible tubular member having an outflow edge is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post. Further, a plurality of inserts sized larger than the slots are provided, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot, the outflow edge of the tubular member defining a plurality of valve leaflets. The tubular base may be plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

A method of minimally-invasive heart valve replacement surgery on a patient is also provided by the present invention. The method includes the steps of:

providing an annular tissue-engaging base, the base being expandable from a collapsed state;

providing a generally annular elastic wireform subassembly having a plurality of prosthetic leaflets connected thereto, the elastic wireform subassembly having a relaxed, expanded size and a compressed, reduced size;

connecting the wireform and leaflets to the base to form a heart valve;

delivering the heart valve with the connected base in its collapsed state and wireform subassembly in its reduced size to an annulus of the patient's heart valve being replaced; and

expanding the base into its expanded state in contact with the annulus.

The step of delivering the heart valve to the annulus may be accomplished by passing the valve through the patient's vasculature or via a minimally-invasive port in the patient's chest. The tissue-engaging base may plastically-expandable from its collapsed state to its expanded state, and the step of expanding the plastically-expandable base comprises inflating a balloon within the annular base.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded perspective view of a first embodiment of an expandable heart valve of the present invention, including a support stent and a flexible tubular member;

FIG. **2** is an assembled perspective view of the expandable heart valve of FIG. **1**;

FIG. **3** is a longitudinal cross-sectional view taken along line **3**—**3** through a commissure of the expandable heart valve of FIG. **2**;

FIG. **4** is a transverse cross-sectional view taken along line **4**—**4** through the commissure of the expandable heart valve of FIG. **2**;

FIG. **5** is a top plan view of the expandable heart valve of FIG. **2**;

FIG. **6** is an exploded perspective view of a second embodiment of an expandable heart valve of present inven-

tion having two detachable components designed to be assembled post-storage, including a tissue-engaging base and a wireform-supported leaflet subassembly;

FIG. **7** is an assembled perspective view of the expandable heart valve of FIG. **6**, with a fabric skirt removed to illustrate details of a connecting system between the base and leaflet subassembly;

FIG. **8** is a plan view of an insert used to both attach individual leaflets to commissures of the wireform, and connect the commissures of the leaflet subassembly to the tissue-engaging base of the expandable heart valve of FIG. **6**;

FIG. **9** is a plan view of an individual leaflet for use in the expandable heart valve of FIG. **6**;

FIG. **10** is a longitudinal cross-sectional view taken along line **10**—**10** of FIG. **7**;

FIG. **11** is a transverse cross-sectional view taken along line **11**—**11** of FIG. **7**;

FIG. **12** is a longitudinal cross-sectional view taken along line **12**—**12** of FIG. **7**;

FIG. **13** is a top plan view of the expandable heart valve taken along line **13**—**13** of FIG. **7**;

FIG. **14** is an enlarged perspective view of a commissure region of the expandable heart valve taken within the circle **14** of FIG. **7**;

FIG. **15** is an enlarged plan view of the commissure region of the expandable heart valve taken within the circle **15** of FIG. **13**; and

FIGS. **16**A–C illustrate a heart in section and several steps in a delivery and implantation procedure of the expandable valve of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention discloses two different expandable heart valves for implantation in a host annulus, or host tissue adjacent the annulus. The valves may be implanted in any of the four valve positions within the heart, but are more likely to be used in replacing the aortic valve because of the circular shape of the annulus.

It should also be noted that the specific constructional details, including materials and shapes, may be varied from those shown. For example, an expandable tubular base is used in both valve embodiments, and is described as being a plastically-expandable structure that radially expands into contact with the annulus tissue. Alternatively, the tubular base may be elastically- or self-expandable, or expandable on the application of heat (i.e., using shape memory material). Further, various means are known for plastically or elastically expanding structures into contact with anatomical passageways, and though the present invention illustrates and describes only one such structure, others may be used to practice the invention. For example, any plastically- or elastically-expandable structure may be modified so as to have a suitable diameter for heart valves and used to practice the present invention. In addition, barbs, flanges, staples, and the like may be added to the tubular base for the purpose of greater attachment to the host tissue. In short, the present invention should not be construed to be limited to the particular structures and materials disclosed, the scope of the invention being solely defined by the appended claims.

With reference to FIGS. **1**–**5**, a first embodiment of an expandable prosthetic heart valve **20** is shown and described. The prosthetic heart valve **20** is assembled prior to storage. In a second embodiment, shown in FIGS. **6**–**15**, a second embodiment of an expandable heart valve is shown and described. Detachable components of the expandable heart valve in the second embodiment are separately stored, and assembled just prior to insertion and delivery to the host annulus, which provides certain advantages to be described.

Pre-Assembled Expandable Heart Valve

FIG. **1** illustrates the first embodiment of the expandable heart valve **20** exploded, with a flexible tubular member **22** separated from a support stent **24** along a central axis **26**. FIG. **2** illustrates the flexible tubular member **22** attached to the support stent **24** to form the assembled heart valve **20**. The heart valve **20** has an inflow end **28** (the lower end in the figure) and an outflow end **30** (the upper end in the figure).

The flexible tubular member **22** comprises a leaflet section **32** connected to a fabric section **34** at a seam **36**. As illustrated, both the leaflet section **32** and fabric section **34** are desirably formed as tubes, such that the seam **36** defines a circle therebetween. Alternatively, the seam **36** may be other than circular if areas of the leaflet section **32** or fabric section **34** need to be expanded around their circumferential juncture. For example, the fabric section **34** may need to be increased in the commissure region of the valve **20**, such as indicated by the dashed line **38** in FIG. **1**. Whatever the configuration, the fabric section **34** has a minimum axial height indicated at A.

Desirably, the leaflet section **32** is formed from pericardial tissue, such as bovine or equine pericardium, suitably treated to render it biocompatible. Of course, any suitable leaflet material, including synthetics, may be used. The fabric section **34** is desirably a woven polyester, such as polyethylene terepthalate. Alternatively, the fabric section **34** may be formed of polytetrafluoroethylene (PTFE), or other suitable biocompatible sheet material. Still further, the leaflet section **32** may extend the entire axial height of the flexible tubular member **22**, with the fabric section **34** being wrapped around and attached to the inflow end.

As seen in FIG. **1**, the support stent **24** comprises a tubular base **40** and a plurality of upstanding commissure posts **42** distributed evenly around the periphery thereof. That is, the tubular base **40** is provided at the inflow end **28** of the support stent **24**, with the commissure posts **42** extending in the outflow direction. Desirably, there are three such commissure posts **42** disposed at 120° intervals about the circumference of the stent **24**. The tubular base **40** has an axial height indicated at B, which height is less than the axial height A of the fabric section **34** of the flexible tubular member **22**. The commissure posts **42** extending upward a sufficient distance such that the entire axial dimension of the support stent **24** is slightly greater than the axial dimension of the flexible tubular member **22**, as indicated in the assembled view of FIG. **2**.

The tubular base **40** comprises a plastically-expandable material that can be expanded into the configuration shown in the figures from a radially compressed configuration (not shown). In this regard, the illustrated tubular base **40** essentially comprises a non-self expanding stent that can be expanded from its compressed state using a balloon inflated from within the base, for example. Numerous configurations of such plastically-expandable tubes are available in the prior art, and as mentioned above, the present invention should not be considered limited to any one configuration. Moreover, in other configurations the base **40** may be self- or heat-expandable.

With reference to FIG. **1**, each commissure post **42** attaches to or extends from an inflow rim **44** of the tubular

base **40**, continuing on the outside of the tubular base toward the outflow end in an elongated axially-extending lower section **46**, and terminating in an axially extending upper section **48**. The upper section **48** commences at a predetermined distance above an outflow rim **50** of the tubular base **40** and is stepped radially inward from the lower section **46** at a transition region **52**. An axial slot **54** is provided in the upper section **48** and in the transition region **52**. The width of the axial slot **54** is desirably constant in the upper section **48**, but increases at a relief region **56** in the transition region **52**.

In a preferred embodiment, the commissure posts **42** are formed of a biocompatible, elastic material, preferably metallic. For example, each commissure post **42** may be formed of stainless-steel, titanium, or Elgiloy. Alternatively, the commissure posts **42** may be a biocompatible polymer, such as Delrin or polyacetyl.

In a preferred embodiment, the support stent **24** is formed from a single piece of flat material. Specifically, the tubular base **40** initially comprises a flat, narrow strip of uniform width material with the commissure posts **42** extending from one long side thereof. Using conventional means, the narrow strip of material is then rolled into the tubular shape shown in the figures, and the juxtaposed narrow ends joined by, for example, crimping. Each of the commissure posts **42** is then bent 180° outward to project in the opposite direction from their original direction. FIG. **1** illustrates such a configuration in which a 180° bend **60** joins each commissure post **42** to the inflow rim **44**. The radius of the bend **60** is such that a narrow space **62** is defined between the lower section **46** of each commissure post **42** and the exterior of the tubular base **40**.

The flexible tubular member **22** attaches to the support stent **24** as seen in FIG. **2**,with the leaflet section **32** connected to the commissure posts **42**, and the fabric section **34** connected to the tubular base **40**. More specifically, the fabric section **34** surrounds the tubular base **40** and extends toward the inflow rim **44** in the spaces **62** created inboard of each commissure post **42**. Although not shown, the fabric section **34** may be attached to the exterior of the tubular base **40**, such as by sutures passed through the fabric and through openings in the tubular base. Because the axial dimension A of the fabric section **34** is greater than the axial dimension B of the tubular base **40**, the seam **36** is disposed above the outflow rim **50** (FIG. **1**) of the base. This is more clearly shown in the cross-section of FIG. **3**.

The leaflet section **32** is disposed substantially between the commissure posts **42**, except for a number of loops **70** threaded outward through the axial slots **54**. As seen FIGS. **2–3**, the loops **70** comprises regions of the tubular leaflet section **32** pinched and threaded through the axial slots **54**. A plurality of inserts **72** are used to secure the loops **70** to the exterior of the commissure posts **42**. That is, as seen FIG. **4**, the inserts **72** each have a width W that is greater than the circumferential width of the axial slots, **54**. Because the inserts **72** are disposed within the loops **70**, they prevent the loops from pulling inward again through the axial slot **54**. A plurality of stitches **74** are preferably provided to secure the leaflet section **32** to the inserts **72**. In addition, as seen in FIG. **3**, stitching **76** passes through an aperture **78** in each insert **72**, and through an aperture **80** provided in the outflow end of each commissure post **42**. In this manner, each insert **72** is secured with respect to the support stent **24**.

With reference to FIGS. **2** and **5**, a plurality of leaflets **82**, are defined between the support stents **24** by the leaflet section **32**. Specifically, where there are three stent post **24**, a generally triangular arrangement of leaflets **82** remains unconstrained in the middle portion of the valve **20** and opens and closes depending on blood flow forces. Furthermore, the continuous flexible tubular member **22** provides a flow channel for blood through the valve **20**. When the pressure differential is such that blood flows into the inflow end **28** of the valve **20**, the leaflets **82** spread apart and the valve opens. Conversely, when the pressure differential reverses, the leaflets **82** come together, or coapt, to close the valve **20**.

When the pressures are such that the valve closes, radially inward forces are imposed on the free edge of the leaflet section **32**, which may tend to cantilever the support stents **24** inward a slight amount. Localized stresses on the leaflet section **32** are reduced at the connection with the stent supports **24**, however, because of the use of the inserts **72** within the loops **70**. That is, as best seen in FIG. **4**, radially inward forces on the leaflets **82** as indicated by the arrow **84**, pull the inserts **72** inward such that the leaflet material is clamped between each insert and the respective commissure post **42**. Although stitching **74** through the leaflet section **32** is provided, such stitching is not subjected to direct tensile stresses, and thus is less likely to tear through the leaflet tissue.

Certain features of the valve **20** reduce wear typically associated with stent-leaflet dynamic contact. First, because the axial dimension A of the fabric section **34** is greater than the dimension B of the tubular base **40**, any contact between the flexible tubular member **22** and the tubular base **40** (at the outflow rim **50**) is between fabric and the base. That is, the leaflet section **32** is not placed in contact with the base **40**, thus increasing the life of the valve. Additionally, the enlarged relief region **56** of the slot **54** in the transition region **52** helps reduce the rubbing that might otherwise occur between the commissure posts **42** and the leaflets **80**. That is, the leaflet section **32** continues substantially axially downward from the loops **70**, as seen in FIG. **3**, and the relief region **56** provides a small gap in the transition region **52** between the leaflet tissue and the sides of the slot **54** to help prevent rubbing therebetween.

In use, the assembled heart valve **20** as seen in FIG. **2** is initially provided in a radially compacted configuration (not shown). Preferably, the valve **20** is loaded about a balloon catheter and within a delivery cannula. The balloon catheter with the valve **20** loaded thereon is than passed through the patient's vasculature (or through an access port in the chest) into proximity with the host annulus. Alternatively, where the chest of the patient is opened, the reduced size valve **20** is inserted into position using a holder.

Once in position within the annulus of the valve being replaced, the balloon (or other expanding means) causes the tubular base **40** to expand into contact with the annulus. Actually, because the commissure posts **42** and fabric section **34** surround tubular base **40**, these elements are compressed against the host annulus. Because the tubular base **40** is plastically-expandable, it substantially retains its expanded shape. A slight over-expansion of the tubular base **40** may be required to compensate for any elastic spring-back character of the material used. Again, barbs or staples may also be utilized to further secure the valve **20** and in place. Ultimately, the balloon catheter is deflated and removed from within the valve **20**.

Expandable Heart Valve Assembled Post-Storage

FIGS. **6–15** illustrate an expandable prosthetic heart valve **100** including, as best seen in FIG. **6**, a leaflet subassembly **102** adapted to connect to a tissue-engaging base **104**. The two components are both shown in FIG. **6** in their radially expanded configurations, though both are designed to be

radially compressed and delivered through a catheter or cannula, for example. In contrast with the first embodiment, however, the two components are stored separately, and connected just prior to delivery into the body of the patient. In general, the two components provide a tissue-engagement ring and a relatively more flexible valve member having fluid occluding surfaces. It should be understood that configurations of these two connectable components other than those specifically shown may be encompassed by the appended claims.

As seen in FIG. **6**, the leaflet subassembly **102** comprises an elastic wireform **106** supporting a plurality of prosthetic leaflets **108**, and a fabric skirt **110**. The wireform **106** comprises a continuous undulating pattern of alternating commissures **112** and cusps **114**. Preferably, the valve **100** is a tri-leaflet type, such that the wireform **106** has three commissures **112** and three cusps **114**, with three leaflets **108** support thereby. In particular, each leaflet **108** is desirably attached to adjacent commissures **112**, and along the entire arcuate cusp **114** therebetween. As will be described in more detail below, the leaflets **108** each attach to a fabric covering **1 16** around the wireform cusps **114**. In a preferred embodiment, the elastic wireform **106** is formed of a biocompatible, elastic material, preferably metallic. For example, the elastic wireform **106** may be formed of stainless-steel, titanium, or Elgiloy. Alternatively, the elastic wireform **106** may be formed from a biocompatible polymer, such as Delrin or polyacetyl. In this sense, therefore, the term "wire" in wireform should not be construed as limiting the material to metallic.

FIG. **7** illustrates an assembled valve **100** with the fabric skirt **110** shown in FIG. **6** removed for clarity. That is, the fabric skirt **119** is sized to drape outside of and surround the tissue-engaging base **104**, but is removed in FIG. **7** to show the connection details between the base and the leaflet subassembly **102**. The valve **100** defines an inflow end **120** and an outflow end **122**.

FIG. **9** illustrates an exemplary leaflet **108** having an arcuate cusp edge **124** opposite a linear coapting edge **126**. The cusp edge **124** is generally semi-circular, and terminates at commissure portions **128**. A pair of oppositely-directed tabs **130** extend outward from both ends of the coapting edge **126**, and are seen in FIG. **6** prior to attachment to the wireform **106**. That is, the tabs **130** from adjacent leaflets **108** join together and pass through the inverted U-shaped commissures **112** of the elastic wireform **106**. In a preferred embodiment, each leaflet **108** is formed from pericardial tissue, such as bovine or equine pericardium, or a synthetic material, that has been suitably treated to render it biocompatible.

With reference again to FIG. **6**, the cusp edge **124** of each leaflet **108** is shaped so as to follow a cusp **114** of the elastic wireform **106**. The fabric skirt **110** extends to an inflow edge **132** from each of the cusps **114**, and when the skirt is assembled to the tissue-engaging base **104**, the inflow edge extends substantially to the inflow end **120** (FIG. **7**) of the valve. The fabric skirt **110** further terminates at outflow edges **134** between adjacent wires of the wireform commissures **112**, below the leaflet tabs **130** extending therethrough. The skirt **110** may be made of a biocompatible fabric such as polyester, or of other suitable biocompatible sheet material.

The leaflet subassembly **102** attaches to the tissue-engaging base **104** at discrete locations, securely coupling each of the commissures **112** and cusps **114** of the elastic wireform **106** to the base. As seen best in FIG. **6**, the tissue-engaging base **104** comprises a tubular plastically-expandable member **140** having an inflow rim **142** and outflow rim **144**. A plurality of commissure posts **146** are either rigidly attached to, or securely coupled to, the tubular member **140** so as to extend generally axially beyond the outflow rim **144** in the outflow direction. Likewise, a plurality of cusp posts **148** are rigidly attached to, or securely coupled to, the tubular member **140** so as to extend beyond the outflow rim **144**. Because the commissure posts **146** couple to the wireform commissures **112**, they are longer than the cusp posts **148** that couple to the wireform cusps **114**.

As illustrated, both the commissure posts **146** and cusp posts **148** extend through upper and lower sleeves **150***a*, **150***b*, respectively provided on the exterior of the tubular member **140**, and are desirably axially secured therein. It should be noted that this is only one of numerous possible ways to rigidly couple upstanding posts to a plastically-expandable tubular member. However, the posts **146,148** are desirably located on the outside of the tubular member **140** so as not to interfere with a balloon for expanding the tubular member from the inside, nor to interfere with blood flowing through the valve. It should also be noted that in a reverse configuration, the posts **146, 148** may be initially attached to the wireform commissures **112** and cusps **114**, respectively, as part of the leaflet subassembly **102** and subsequently connected to mating structures (not shown) provided on the tissue-engaging base **104**.

A plurality of connectors are provided for attaching the elastic wireform **106** to the posts **146, 148** of the tissue-engaging base **104**. In particular, as seen in FIG. **6**, each commissure post **146** provides a lower commissure connector **160** thereon. Likewise, each cusp posts **148** provides a lower cusp connector **162**. In the illustrate embodiment, the outflow end of each of the posts **146, 148** is bent 90° to face radially inward and a groove formed therein defines the respective connectors **160,162**.

FIGS. **9–11** illustrate the configuration of the connection between the leaflet subassembly **102** and tissue-engaging base **104** at the commissures of the valve. With specific reference to FIG. **10**, the lower commissure connector **160** of the commissure post **146** mates with an upper commissure connector **164** of an insert **166** (isolated in FIG. **8**) secured to the wireform is commissure **112**. As seen in FIG. **11**, adjacent leaflets **130** extend radially outward between spaced wires of the wireform **106** and wrap around the insert **166** to be connected on an outer side thereof with a plurality of stitches **168**. FIG. **8** illustrates one form of the insert **166** wherein the upper commissure connector **164** comprises a downwardly opening partial circle which mates with the groove of the lower commissure connector **160**, as seen in FIG. **10**. In this manner, the commissures **112** are securely fastened with respect to the tissue-engaging base **104** by virtue of the interaction between the lower commissure connector **160** and upper commissure connector **164**.

With reference again to FIGS. **6** and **7**, a plurality of upper cusp connectors **170** attach to the approximate midpoint of each of the cusps **114** of the wireform **106**. Each upper cusp connectors **170** is configured and positioned to mate with the lower cusp connector **162** formed on each of the cusp posts **140**. Again, the upper cusp connector **170** may be provided with a downwardly opening partial circle that mates with the groove of the lower cusp connector **162**.

With specific reference to FIG. **12**, certain constructional details of the valve cusps are further illustrated. The fabric covering **116** of the wireform **106** is shown as a tube having an upper fabric extension **180** and a lower fabric extension **182** sandwiched around a radial portion **184** of the upper

cusp connector **170**. The upper cusp connector **170** extends outward and bends 90° downward to mate with the lower cusp connector **162**. The upper fabric extension **180** continues outward and downward in the fabric skirt **110**. The lower fabric extension **182** bends 180° underneath the cusp edge **124** of the respective leaflet **108**. Stitching **186** secures the combined layers of the upper extension **180**, radial portion **184**, first part of the lower extension **182**, leaflet cusp **124**, and wrapped-around portion of the lower extension **182**.

Desirably, both the insert **166** and upper cusp connector **170** are made from a suture-permeable material having sufficient strength to maintain the connections between the leaflet subassembly **102** and tissue-engaging base **104**. For example, the insert **166** and connector **170** may be made of Delrin, or other suitable polymer. As illustrated, each of the connectors **164** and **170** are partial circles that fit around tubular grooves in the respective posts **146**,**148**. Of course, other arrangements are possible, and the present invention should not be considered limited to those connectors illustrated.

As with the earlier embodiment, the valve **100** utilizes a low-stress connection between the leaflets **108** and the elastic wireform **106**. In particular, as seen in FIG. **11**, the provision of the insert **166** provides a clamping force during diastole between the insert and the wireform **106** against the portion of the leaflets **108** therebetween. The stitching **168** is not subjected to direct tensile stresses, and there is thus less chance for tearing.

Leaflet subassembly **102** is desirably stored in its expanded state, as seen in FIG. **6** (which, as mentioned, does not illustrate the commissure attachment structure). That is, the wireform **106** and leaflets **108** may be stored immersed in a preservative such as glutaraldehyde in a sterile container until needed. In this regard, the prosthetic leaflets **108** remain in their functional shape during storage. This greatly reduces adverse wrinkling or other permanent or semi-permanent damage to the leaflets over time, and improves the quality of the valve **100**. At the same time, the base **104** desirably does not include any bioprosthetic or otherwise perishable components, and thus may be stored in a separate dry sterile container. This method also permits the combination of different bases with any one leaflet subassembly **102**, or visa versa. For example, the type of attachment mechanism (i.e., staples, barbs, sutures, etc.) of the base **104** to the annulus may be selected by the surgeon, with different bases being attached in different ways, and all being combinable with a particular leaflet subassembly **102**. Also, the type of base may be selected based on patient indications; with a self-expanding base being preferred in some situations and a balloon-expanded base in others.

In use, the leaflet subassembly **102** is compressed from its expanded configuration to a size corresponding to the tissue-engaging base **104** in its compressed state (not shown). If the tissue-engaging base **104** is plastically deformable then it is initially supplied in its compressed state. Alternatively, a self-expandable base **104** will have to be compressed either before or after connection to the similarly configured leaflet subassembly **102**. Compression of the leaflet subassembly **102** (and base if necessary) may be accomplished using a tapered mandrel through which the subassembly is passed, or with a cinch or other direct constricting means. The two components are then connected together, just prior to insertion into the patient's body, and the valve **100** delivered simultaneously to the host annulus site. To connect the two components, the fabric skirt **110** is passed around the outside of the commissure posts **146** and around the tubular member **140**. Each of the upper connectors **164** and **170** are caused to mate with the lower connectors **160**, **162**. In the illustrated embodiment, such a mating operation simply requires forcing each of the partial circles defining the upper connectors over the grooves defining the lower connectors. The partial circles open slightly, but then spring inward when the connectors snap together and the groove is fully seated.

There are a number of ways to deliver the valve **100** to the aortic annulus. For one, the tubular member **140** may be mounted around a balloon catheter and inserted via an introducer or other cannula into the patient's vasculature and to the aorta. Alternatively, an open-heart procedure or less-invasive port procedure may be utilized, with the tissue-engaging base **104** being delivered to the host annulus using a holder or other such means.

FIG. **16A** depicts a sectional view of a heart **200** having a left ventricle chamber **202** opening to an ascending aorta **204** through an aortic annulus **206**. The ascending aorta **204** continues over an aortic arch **208**, and branches off into several upper body arteries **210** before descending to the abdominal aorta (not shown). As mentioned above, the expandable valves of the present invention can be delivered into proximity of the aortic annulus **206** in several ways, including through the patient's vasculature as shown.

In particular, a valve delivery catheter **212** is shown in the cutaway portion of the ascending aorta **204**, having been introduced along the direction of the arrow **214** so that a distal end thereof lies adjacent the aortic annulus **206**. The catheter **212** can be introduced percutaneously into the patient's arterial system (e.g. into a peripheral artery such as the fermeral artery) and advanced to the ascending aorta **204**. The catheter shaft preferably has a length of at least about 80 cm, usually about 90–100 cm, to allow transluminal positioning of the shaft from the femoral and iliac arteries to the ascending aorta. Alternatively, the shaft may have a shorter length, e.g. 20–60 cm, for introduction through the iliac artery, through the brachial artery, through the carotid or subclavian arteries, or through a penetration in the aorta itself. In the femoral approach, the catheter is long enough and flexible enough to traverse the path through the femoral artery, iliac artery, descending aorta and aortic arch. At the same time, the catheter has sufficient pushability to be advanced to the ascending aorta by pushing on the proximal end, and has sufficient axial, bending, and torsional stiffness to allow the physician to control the position of the distal end, even when the catheter is in a tortuous vascular structure. Alternatively, the catheter **212** may be passed through a port between ribs in the patient's thorax above the heart and through an incision in the aortic arch **208**, in a so-called minimally-invasive procedure.

Techniques for introducing catheters into the human vasculature are well-known, and typically involve the introduction of a guidewire **216** first, followed by an obturator or dilator (not shown) within a sheath **218**. The dilator facilitates introduction of the catheter sheath **218** into the vasculature, and is then removed, though the guidewire **216** typically remains in place. Subsequently, a valve of the present invention, such as valve **100** seen in FIGS. **6–15**, is delivered over the guidewire **216** and to the distal end of the sheath **218**. In accordance with one aspect of the present invention, the valve **100** includes a balloon-expandable portion and thus is mounted over an expansion balloon **222**. To facilitate passage of the valve **100** through the sheath **218**, a pusher **224** may be used.

FIG. **16B** illustrates a second step in the exemplary valve delivery procedure in which the sheath **218** is retracted in a proximal direction as indicated by arrow **226**. Retraction of the sheath **218** exposes the valve **100**, which is positioned

within the aortic annulus **206** with the assistance of fluoroscopy and radiopaque markers, ultrasonic imaging, or the like. If the valve **100** includes self-expanding components, retraction of the sheath **218** releases the outer restraint on the valve and permits it to expand into contact with the annulus **206**. In the illustrated embodiment, however, the tubular member **140** of the tissue-engaging base **104** is plastically-deformable and retains its radially constricted configuration after retraction of the sheath **218**. Because of the rigid connections between the leaflet subassembly **102** and the base **104**, the subassembly also remains in its constricted configuration.

Finally, in FIG. **16**C, the balloon **222** is inflated to cause the tissue-engaging base **104** to radially expand into contact with the aortic annulus **206**, as indicated by the arrows **230**. Simultaneously, the leaflet subassembly **102** radially expands by virtue of the rigid connection with the base **104**, and by virtue of its spring bias. A balloon inflation catheter **232** is seen projecting from the pusher **224** and through the leaflet subassembly **102**. With reference back to FIG. **6**, the fabric skirt **110** is captured between the tubular member **140** and the surrounding tissue, and is in direct contact therewith. Therefore, by virtue of the continuous connection between the cusp edges **124** of the leaflets **108** and the fabric skirt **110**, the skirt forms a flow channel for blood entering the inflow end **120** of the valve **100**. Again, the plastically-expandable tubular member **140** may be slightly over-expanded to account for any spring-back in the material. Further, as mentioned above, the tubular member **140** may include staples or barbs or other such attachment structure for securely locating the valve **100** within the annulus **206**.

Once the valve **100** is fully expanded and securely attached to the annulus **206**, the balloon **222** is deflated and removed. Such an operation may include elongating the balloon **222** in the distal direction and reducing its radial dimension by, for example, twisting. Care must be taken so as not to damage the leaflets within the subassembly **102** during retraction of the balloon **222** therethrough. After the balloon **222** has been retracted within the sheath **218**, the entire catheter **212** is removed from the patient.

The fully formed valve **100** has a number of distinct advantages over prior expandable valves. For example, as mentioned above, the prosthetic leaflets **108** may be stored in the final, uncompressed implantation shape. This is in contrast to prior expandable valves where the entire valve may be initially compressed such that the leaflets are stored in a compressed state. Consequently, valves of the prior art can be stored for years prior to use, and permanent wrinkling of the compressed leaflets may be a real problem.

Furthermore, each of the leaflets **108** is supported substantially entirely around the undulating wireform **106**, which has proven to provide optimal valve performance. Also, separate leaflets are used as opposed to a continuous tube, as in the first embodiment. Additionally, the advantageous low-stress attachment structure of the leaflet tabs **130** to the wireform commissures **112** further increases the durability of the valve.

While the foregoing is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Moreover, it will be obvious that certain other modifications may be practiced within the scope of the appended claims.

What is claimed is:

1. A prosthetic heart valve, comprising:

a support stent including a tubular base along an inflow end and a plurality of generally axially-extending commissure posts disposed evenly around the tubular base on an outflow end thereof, each commissure post having an axial slot, wherein the base is plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus; and

a flexible tubular member having a prosthetic section attached to the commissure posts so as to define a plurality of prosthetic valve leaflets between the posts, and a fabric section connected to the base, and wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post, and further including a plurality of inserts sized lager than the slots, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot.

2. The heart valve of claim **1**, wherein the prosthetic section and fabric section are both generally tubular and attached together at a seam.

3. The heart valve of claim **2**, wherein the seam is spaced from the outflow end of the tubular base so that only the fabric section of the flexible tubular member contacts the tubular base.

4. The heart valve of claim **2**, wherein the seam is other than circular.

5. The heart valve of claim **1**, wherein the fabric section of the flexible tubular member attaches along a seam to the outflow end of the tubular base.

6. The heart valve of claim **1**, wherein the prosthetic section of the flexible tubular member is pericardial tissue.

7. The heart valve of claim **1**, wherein the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180° to extend alongside the base and project beyond the base at the outflow end thereof.

8. The heart valve of claim **7**, wherein the fabric section of the flexible tubular member extends around the exterior of the tubular base and within spaces created between each of the commissure posts and the tubular base.

9. The heart valve of claim **1**, wherein the commissure posts each comprise:

a first axial section extending from the inflow end of the base and spaced radially therefrom;

a second axial section defining the outflow extent of the post and a portion of the axial slot, the second section being radially inwardly offset from the first section; and

a transition region between the first and second sections, wherein an enlarged portion of the axial slot is defined in the transition region.

10. The heart valve of claim **1**, further including a plurality of stitches securing each loop of the flexible tubular member to the corresponding insert.

11. The heart valve of claim **10**, further including stitching securing each insert to the corresponding commissure post of the base.

12. A prosthetic heart valve, comprising:

a support stent including a tubular base along an inflow end and a plurality of generally axially-extending commissure posts each having an axial slot and being disposed evenly around the tubular base on an outflow end thereof; and

a flexible tubular member having an outflow edge,

wherein the tubular member is primarily located within the posts except for a plurality of loops that extend

outward through each slot on each post, and further including a plurality of inserts sized larger than the slots, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot, the outflow edge of the tubular member defining a plurality of valve leaflets.

13. The heart valve of claim **12**, wherein the tubular base is plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

14. The heart valve of claim **12**, wherein the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180 degrees to extend alongside the base and project beyond the base at the outflow end thereof.

15. The heart valve of claim **12**, wherein the flexible tubular member has a prosthetic section attached to the commissure posts and a fabric section connected to the base at a seam.

16. The heart valve of claim **15**, wherein the seam is other than circular.

17. The heart valve of claim **15**, wherein the fabric section of the flexible tubular member extends around the exterior of the tubular base and attaches along a seam to the outflow end of the tubular base.

18. The heart valve of claim **15**, wherein the prosthetic section of the flexible tubular member is pericardial tissue.

19. The heart valve of claim **12**, further including a plurality of stitches securing each loop of the flexible tubular member to the corresponding insert.

20. The heart valve of claim **19**, further including stitching securing each insert to the corresponding commissure post of the base.

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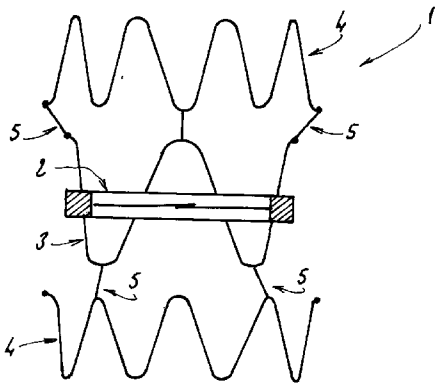
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(54) SUPPORT TUBULAIRE DE MISE EN PLACE, PAR VOIE PERCUTANEE, D'UNE VALVE CARDIAQUE DE REMPLACEMENT.

(57) Ce support (1) comprend une structure susceptible d'être contractée radialement pour permettre l'introduction de l'ensemble support (1) - valve (2) dans le corps du patient, et d'être déployée pour permettre la prise d'appui de cette structure contre la paroi du site à équiper de la valve.

Selon l'invention, la structure du support (1) comprend:

- une portion axiale (3) de support de valve (2), présentant une structure en fil ou en réseau de fils propre à prendre appui contre l'anneau cardiaque (10) subsistant après le retrait de la valve native déficiente;
- au moins une portion axiale de calage (4), présentant une structure en fil ou en réseau de fils distincte de la structure de ladite portion axiale (3) de support de valve, et de diamètre supérieur au diamètre de ladite portion axiale (3) lui permettant de prendre appui contre la paroi bordant ledit anneau cardiaque subsistant (10); et
- au moins un fil (5) reliant ponctuellement lesdites portions (3, 4).



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La présente invention concerne un support tubulaire de mise en place, par voie percutanée, d'une valve cardiaque de remplacement. Elle concerne également un instrument de mise en place de ce support.

La technique classique de remplacement d'une valve cardiaque consiste à opérer à cœur ouvert. Cette technique oblige à une anesthésie générale, à un large abord, et à un arrêt du cœur impliquant la mise du patient sous circulation extracorporelle. Elle est donc particulièrement lourde à mettre en œuvre et induit des risques opératoires importants pour le patient.

Pour remédier à cet inconvénient, il a été envisagé d'opérer l'ablation d'une valve cardiaque déficiente par voie percutanée, avec un abord vasculaire périphérique. La demande de brevet n°FR 99 14462 illustre une technique et un dispositif utilisables à cette fin.

En ce qui concerne la mise en place d'une valve cardiaque de remplacement, il a été envisagé de fixer cette valve sur un support présentant une structure en fil ou en réseau de fils, couramment dénommé "stent". Ce support peut être contracté radialement pour pouvoir être introduit dans le corps du patient par voie percutanée, au moyen d'un cathéter, et peut être déployé radialement une fois positionné au niveau du site à équiper de la valve pour assurer ainsi le montage de cette valve. Le brevet n°US 5 411 552 illustre une technique de ce genre.

Les systèmes de "stent" envisagés à ce jour pour la mise en place d'une valve cardiaque induisent des incertitudes plus ou moins importantes en ce qui concerne leur maintien en position dans les sites à traiter. En particulier, la forme des stents connus n'apparaît pas adaptée à celle de ces sites, dans lesquels la paroi cardiaque s'évase de part et d'autre de l'anneau cardiaque.

En outre, l'anneau cardiaque subsistant après ablation de la valve native peut gêner la mise en place de ces stents.

Ces systèmes connus induisent également, dans certains cas, des problèmes d'étanchéité de la valve de remplacement. En effet, ledit anneau cardiaque subsistant peut présenter une surface plus ou moins irrégulière et plus ou moins calcifiée, qui non seulement amoindrit la qualité de l'appui du stent contre cet anneau mais également peut être à l'origine de fuites entre la valve et cet anneau.

Certains matériels existants présentent par ailleurs des inconvénients en ce qui concerne leur implantation proprement dite. En particulier, ces matériels ne peuvent plus guère être déplacés après déploiement du support même si leur position n'est pas optimale.

La présente invention vise à remédier à ces inconvénients importants.

Son objectif principal est de fournir un support ("stent") procurant une meilleure certitude de maintien en position après implantation.

Un autre objectif de l'invention est de fournir un support permettant d'éliminer la gêne qu'induisent, au moment de la mise en place de la valve de remplacement, les feuillets valvulaires natifs volontiers calcifiés, épaissis et indurés, ou les restes des feuillets valvulaires après résection valvulaire.

Un autre objectif encore de l'invention est de fournir un support permettant une parfaite étanchéité de la valve de remplacement, même en cas d'un anneau cardiaque subsistant qui présente une surface plus ou moins irrégulière et/ou plus ou moins calcifiée.

L'invention a également pour objectif de fournir un support dont la position puisse être adaptée et/ou corrigée le cas échéant au moment de l'implantation.

Le support concerné comprend, de manière connue en soi, une structure en fil ou en réseau de fils susceptible d'être contractée radialement pour permettre l'introduction de l'ensemble support–valve dans le corps du patient, au moyen d'un cathéter, et d'être déployée pour permettre la prise d'appui de cette structure contre la paroi du site à équiper de la valve.

Selon l'invention, cette structure comprend :

- une portion axiale de support de valve, présentant une structure en fil ou en réseau de fils propre à recevoir la valve de remplacement montée sur elle, et propre à prendre appui contre l'anneau cardiaque subsistant après le retrait de la valve native déficiente ;

- au moins une portion axiale de calage, présentant une structure en fil ou en réseau de fils distincte de la structure de ladite portion axiale de support de valve, et dont au moins une partie présente, à l'état déployé, un diamètre supérieur au diamètre à l'état déployé de ladite

portion axiale de support de valve, tel que cette portion axiale de calage est propre à prendre appui contre la paroi bordant ledit anneau cardiaque subsistant ; et

- au moins un fil de liaison desdites portions, ce ou ces fils étant reliés ponctuellement à ces portions, de manière à ne pas faire obstacle au déploiement desdites portions axiales selon leurs diamètres respectifs.

L'invention fournit ainsi un support en au moins deux portions axiales individualisées l'une par rapport à l'autre en ce qui concerne leur structure, qui sont reliées de manière localisée par au moins un fil ; ce ou ces fils ne font pas obstacle à un déploiement différent de la portion axiale comportant la valve et de la ou des portions axiales de calage.

La présence d'une structure en fil ou en réseau de fils au niveau de la portion axiale de support de valve permet un parfait assemblage de cette valve à cette structure, et la forme ainsi que le diamètre de cette portion axiale peuvent être adaptés à une prise d'appui dans les meilleures conditions contre l'anneau cardiaque subsistant. En particulier, cette portion axiale de support de valve peut présenter une force d'expansion radiale telle qu'elle repousse ("impacte") les feuillets valvulaires volontiers calcifiés, ou les restes des feuillets valvulaires après résection valvulaire sur ou dans les tissus sous-jacents, de sorte que ces éléments ne constituent pas une gêne à la mise en place de la valve de remplacement. Cette structure permet également de supporter d'éventuels moyens d'ancrage du support et/ou d'éventuels moyens d'étanchéité de l'espace existant entre l'anneau cardiaque subsistant et la valve de remplacement, comme indiqué plus loin.

La forme et/ou le diamètre de chaque portion axiale de calage peuvent être adaptés à une prise d'appui dans les meilleures conditions contre la paroi cardiaque située aux abords de l'anneau cardiaque subsistant. Notamment, cette portion axiale de calage peut présenter une forme tubulaire de diamètre constant supérieur à celui de la portion axiale de support de valve, ou une forme tronconique dont le diamètre va en augmentant en s'éloignant de la portion axiale de support de valve.

De préférence, le support tubulaire présente une portion axiale de support de valve en au moins deux parties, dont au moins une est adaptée à supporter la valve et dont au moins une autre est adaptée à repousser les feuillets valvulaires natifs ou les restes des feuillets

valvulaires natifs après résection valvulaire, dans ou sur le tissu adjacent afin de rendre cette zone apte à recevoir le support tubulaire.

Cette portion axiale de support de valve élimine la gêne qu'induisent ces éléments valvulaires ou annulaires cardiaques au moment de la mise en place de la valve de remplacement. La force radiale de cette portion axiale de support de valve assure en effet, en impactant tout ou partie du tissu valvulaire dans ou au voisinage de la paroi, une surface plus régulière et plus apte à recevoir l'axe de support de valve. Elle assure également une meilleure solidarisation avec la paroi tout en réduisant le risque de fuite para prothétique.

La portion axiale de support de valve peut notamment comprendre une partie en fil ondulé à larges ondes, pour supporter la valve, et une partie en fil ondulé à ondes réduites, adjacente à ladite partie à larges ondes, présentant une force radiale relativement importante pour permettre de repousser ledit tissu valvulaire contre ou dans la paroi du conduit.

De préférence, le support selon l'invention présente deux portions axiales de calage, l'une étant reliée à une extrémité axiale de ladite portion de support de valve et l'autre à l'autre extrémité axiale de cette même portion de support de valve.

Ces deux portions axiales de calage permettent ainsi un calage du support de part et d'autre de l'anneau cardiaque subsistant, et permettent par conséquent un parfait calage du support dans deux directions opposées par rapport au site traité.

Si nécessaire, par exemple dans le cas où le conduit comprenant la valve présenterait un anévrisme, le support selon l'invention comprend :

- une portion axiale de maintien, propre à prendre appui à l'état déployé contre la paroi du conduit, et

- des fils de liaison tels que précités, reliant ladite portion axiale de support de valve et ladite portion axiale de maintien, ces fils ayant une longueur telle que la portion axiale de maintien soit située après implantation à distance de la portion axiale de support de valve.

Cette distance permet à ladite portion axiale de maintien de prendre appui contre une zone de la paroi du conduit non concernée par une éventuelle affection pouvant exister aux abords de la valve, en particulier un anévrisme. La longueur des fils de liaison peut également être

calculée afin d'éviter que la portion axiale de maintien soit au contact des ostia des artères coronaires.

Les portions axiales précitées (de support de valve, de calage, de maintien) peuvent présenter une structure en fil ondulé, en zig-zag ou, de préférence, une structure en mailles ayant une forme de losange, les mailles étant juxtaposées dans le sens de la circonférence de ces portions.

Cette dernière structure permet une force radiale adaptée, permettant d'assurer une parfaite prise d'appui dedites portions contre la paroi qui les reçoit.

Le support selon l'invention peut être réalisé en un métal plastiquement déformable. L'instrument de mise en place du support comprend alors un ballonnet présentant une portion axiale d'un diamètre prédéterminé, adaptée à réaliser le déploiement de ladite portion axiale de support de valve, et au moins une portion axiale conformée pour présenter, à l'état gonflé, une section supérieure à celle du conduit à traiter, de manière à réaliser le déploiement de la portion axiale de calage placée sur elle jusqu'à ce que cette portion axiale de calage rencontre la paroi contre laquelle elle doit venir en appui.

Le support selon l'invention peut également être réalisé en un matériau à mémoire de forme, tel qu'un alliage nickel–titane du genre dénommé "NITINOL", pouvant être contracté radialement à une température différente de celle du corps du patient et retrouvant une forme originelle lorsque sa température approche ou atteint celle du corps du patient.

Selon une autre possibilité, le support est réalisé en un matériau à mémoire de forme mais susceptible de déformation plastique, ou comprend des parties en un matériau à mémoire de forme et des parties en un matériau susceptible de déformation plastique, et est conformé de manière telle qu'il puisse être amené, par mémoire de forme ou par déformation plastique, d'un état de contraction à un état de déploiement intermédiaire stable entre l'état de contraction et l'état de déploiement total, puis, par déformation plastique ou par mémoire de forme respectivement, dudit état de déploiement intermédiaire audit état de déploiement total ; dans ledit état de déploiement intermédiaire, le support présente des dimensions telles qu'il reste mobile par rapport au site à traiter.

Le support est ainsi amené au niveau du site à traiter puis est déployé dans ledit état intermédiaire ; sa position peut alors éventuellement être adaptée et/ou corrigée puis le support est amené dans son état de déploiement total.

Le matériau à mémoire de forme mais susceptible de déformation plastique précité peut notamment être un alliage nickel–titane du genre dénommé "NITINOL martensitique", susceptible d'être déformé plastiquement au moyen d'un ballonnet.

Avantageusement, le support selon l'invention comprend des moyens d'ancrage propres à s'insérer dans la paroi du site à traiter, conformés de manière à être mobiles entre une position inactive, dans laquelle ils ne font pas obstacle à l'introduction du support dans le corps du patient, et une position active, dans laquelle ils s'insèrent dans la paroi du site à traiter.

Une parfaite immobilisation du support au niveau du site est ainsi obtenue.

En particulier, ces moyens d'ancrage peuvent présenter la forme d'aiguilles et peuvent être montés sur le support entre des positions de rétractation radiale et des positions de saillie radiale.

Avantageusement, la portion axiale de support de valve comporte, au niveau de sa face extérieure, un moyen d'étanchéité conformé de manière à absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau cardiaque subsistant.

Ce moyen d'étanchéité peut être constitué par une bande périphérique en un matériau compressible ou par une bande périphérique délimitant une chambre et ayant une structure radialement expansible, cette chambre pouvant recevoir un fluide de gonflage propre à se figer dans un délai déterminé après introduction dans ladite chambre. Ce moyen d'étanchéité peut également comprendre un matériau pouvant être appliqué entre l'anneau cardiaque subsistant et la portion axiale de support de valve, ce matériau étant propre à se figer dans un délai déterminé après cette application. Dans ce cas, ce matériau peut notamment être thermoactivable, par exemple au moyen d'un laser, à travers le ballonnet, ou activable par émission de lumière d'une fréquence déterminée, par exemple au moyen d'un laser à ultra-violets, à travers le ballonnet. Ledit moyen d'étanchéité peut également se présenter sous forme d'un insert

gonflable ayant une section transversale en diabolo à l'état gonflé, pouvant être inséré entre l'anneau cardiaque subsistant et la portion axiale de support de valve. Ladite forme en diabolo permet à cet insert de se conformer au mieux aux structures irrégulières adjacentes et d'assurer une meilleure étanchéité.

Pour sa bonne compréhension, l'invention est à nouveau décrite ci-dessous en référence au dessin schématique annexé représentant, à titre d'exemples non limitatifs, plusieurs formes de réalisation possibles du support tubulaire qu'elle concerne.

La figure 1 est une vue en développé de la structure de ce support, selon une première forme de réalisation ;

la figure 2 est une vue en coupe du support à l'état déployé, avec la valve cardiaque qu'il comporte ;

la figure 3 est une vue en bout de ce support à l'état déployé ;

la figure 4 est une vue en bout de ce support à l'état contracté ;

la figure 5 est une vue d'un coeur en coupe partielle, sur lequel une valve cardiaque de remplacement a été mise en place au moyen du support selon l'invention ;

la figure 6 est une vue en développé de la structure du support selon une deuxième forme de réalisation ;

la figure 7 est une vue en développé de la structure du support selon une troisième forme de réalisation ;

la figure 8 est une vue de détail d'une partie de cette structure, à échelle agrandie ;

la figure 9 est une vue du support selon la figure 7, après mise en place dans un conduit corporel présentant un anévrisme ;

la figure 10 est une vue en développé de la structure du support selon une quatrième forme de réalisation ;

la figure 11 est une vue de détail d'une variante de réalisation d'un crochet d'ancrage que comprend le support selon la quatrième forme de réalisation ;

la figure 12 est une vue du même détail, en coupe selon la ligne XII-XII de la figure 11 ;

la figure 13 est une vue similaire à la figure 11, la structure étant dans un état expansé ;

la figure 14 est une vue similaire à la figure 12, la structure étant dans ce même état expansé ;

la figure 15 est une vue partielle d'une portion de structure du support selon une cinquième forme de réalisation ;

la figure 16 est une vue agrandie d'une zone de montage d'une valve prothétique sur cette portion ;

la figure 17 est une vue partielle, en coupe longitudinale, du support selon la première forme de réalisation et d'un anneau cardiaque calcifié ;

la figure 18 est une vue similaire à la figure 17, selon une variante ;

la figure 19 est une vue similaire à la figure 17, selon une autre variante ;

les figures 20 et 21 sont des vues similaires à la figure 17, selon encore une autre variante, dans deux phases de mise en place du support ;

la figure 22 est une vue en coupe longitudinale d'un ballonnet permettant l'expansion de la structure du support représenté aux figures 7 à 9 ;

la figure 23 est une vue en coupe longitudinale d'un ballonnet selon une variante de réalisation, et

la figure 24 est une vue similaire à la figure 5, montrant un coeur sur lequel une valve cardiaque de remplacement a été mise en place au moyen du support selon l'invention, selon une sixième forme de réalisation.

Par simplification, les parties ou éléments de ces différentes formes de réalisation qui sont identiques ou similaires d'une forme de réalisation à une autre sont définis par les mêmes références numériques.Les figures 1 à 4 représentent un support tubulaire 1 de mise en place, par voie percutanée, d'une valve cardiaque 2 de remplacement.

La structure du support 1 comprend une portion médiane 3 comportant la valve 2, deux portions extrémales 4 de calage et des fils 5 de liaison de ces portions 3 et 4. La portion médiane 3 comporte en outre une bande périphérique 6 pourvue d'aiguilles d'ancrage 7 et d'un bandage 8 en matériau compressible.

Ainsi que cela apparaît plus particulièrement sur la figure 1, les portions 3 et 4 sont formées chacune par un fil ondulé, et les fils 5 relient ponctuellement les extrémités des ondulations de la portion 3 à l'extrémité d'une ondulation adjacente d'une portion 4. Les portions 4, vues en développé, ont des longueurs supérieures à la longueur de la portion 3, de sorte que, lorsque les extrémités des fils formant respectivement les portions 3 et 4 sont reliées pour constituer la structure tubulaire du support 1, le diamètre de la portion 3 est inférieur au diamètre des portions 4.

Le diamètre de la portion 3 est tel que cette portion 3 peut, comme le montre la figure 5, prendre appui contre l'anneau cardiaque 10 subsistant après le retrait de la valve native déficiente, tandis que les portions 4 peuvent prendre appui contre les parois 11 bordant l'anneau 10. Ces diamètres respectifs sont de préférence tels que lesdites prises d'appui se font avec une légère contrainte radiale de l'anneau 10 et des parois 11.

La portion 3 présente à l'état déployé un diamètre constant. Les portions 4 peuvent présenter un diamètre constant ou une forme tronconique dont le diamètre va en augmentant en s'éloignant de la portion 3.

L'ensemble de la structure du support 1 est réalisé en un matériau à mémoire de forme, tel qu'un alliage nickel-titane du genre dénommé "NITINOL". Ce matériau permet à cette structure d'être contractée radialement, comme montré sur la figure 4, à une température différente de celle du corps du patient et de retrouver la forme originelle montrée sur les figures 2 et 3 lorsque sa température approche ou atteint celle du corps du patient. L'ensemble de la structure du support 1 peut également être réalisé en un matériau expandable sur ballonnet comme par exemple en acier inoxydable médical (acier 316 L).

La valve 2 peut être en tissu biologique ou synthétique. Elle est reliée à la portion 3 par des sutures ou par tous autres moyens de fixation appropriés. Elle peut également être moulée sur la portion 3.

La bande 6 est en "NITINOL". Elle est reliée aux ondulations de la portion 3, à mi-hauteur de celles-ci, et comporte les aiguilles 7 au niveau de ses zones reliées à ces ondulations.

Les aiguilles 7 sont constituées par des brins de fil métallique acérés à leurs extrémités libres, et font saillie radialement vers l'extérieur de la bande 6.

Cette dernière peut prendre la forme ondulée visible sur la figure 4 à l'état contracté du support 1 et la forme circulaire visible sur la figure 3 à l'état déployé de ce support 1. Dans sa forme ondulée, la bande 6 forme des ondulations 6a faisant saillie radialement sur l'extérieur du support 1, au-delà des aiguilles 7, de sorte que ces aiguilles 7, dans cette position de rétractation, ne gênent pas l'introduction du support 1 dans un cathéter ni, une fois le support 1 introduit dans le coeur à l'aide de ce cathéter, le déploiement de ce support 1. Le retour de la bande 6 dans sa forme circulaire amène les aiguilles 7 dans une position de déploiement, leur permettant de s'insérer dans l'anneau 10 afin de compléter l'ancrage du support 1.

Le bandage 8 est fixé sur la bande 6. Son matériau compressible lui permet d'absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau 10 et d'assurer ainsi une parfaite étanchéité de la valve 2.

La figure 6 montre une structure du support 1 comprenant une seule portion 4, reliée à la portion 3 par des fils 5. Cette portion 4 est formée par deux fils 14 ondulés reliés entre eux par des fils 15.

La figure 7 montre une structure du support 1 présentant une portion 3 et une portion 4 reliées par des fils de liaison 5.

Ces portions 3 et 4 ont des structures à mailles en forme de losange, ces mailles étant juxtaposées dans le sens de la circonférence de ces portions et étant reliées les unes aux autres au niveau de deux de leurs angles opposés dans le sens de la circonférence de ces portions 3 et 4. Les fils 5 sont reliés à ces structures au niveau de la zone de jonction de deux mailles consécutives. Ces mailles comportent en outre des crochets d'ancrage 7 s'étendant à travers elles à partir de l'un de leurs angles situés dans le sens longitudinal du support 1.

La figure 8 illustre, à échelle agrandie, la structure de cette portion 4 et d'une partie des fils 5, tels que découpés par exemple au laser dans une plaque d'acier inoxydable, et après recourbement des extrémités 7a acérés des crochets 7. Ces derniers ont, vu de profil, une forme telle que montrée sur les figures 12 ou 14.

La structure représentée sur la figure 7 comprend également une portion axiale de maintien 20, ayant une structure identique à celle de la portion 4 mais à maille plus grosses, et trois fils 5 de longueur

importante, reliant cette portion 20 à la portion 3. Ces fils 5 ont, du côté de la portion 20, une suture unitaire 5a et, du côté de la portion 3, une structure double 5b. Leur nombre correspond aux trois commissures que forment les trois valvules de la valve 2, ce qui facilite le montage de la valve 2 sur le support 1 ainsi conformé.

Le support selon la figure 7 est destiné à être utilisé, ainsi cela apparaît sur la figure 9, lorsque le conduit corporel comprenant la valve à remplacer, en particulier l'aorte, présente un anévrisme aux abords de la valve. La longueur des fils 5 reliant les portions 3 et 20 est prévue de manière telle que, après implantation, la portion 20 soit située dans une zone non dilatée dudit conduit corporel, et cette portion 20 est prévue de manière à prendre appui contre la paroi de ce conduit.

La figure 10 montre une structure similaire à la figure 7 mais non expansé, et sinon que les trois fils 5 ont une structure unitaire mais comportent un fil ondulé 21 assurant un appui complémentaire à proximité de la portion 3. Ce fil 21 est conçu pour supporter une valve 2 à trois valvules.

Les figures 11 à 14 montrent une variante de réalisation de la structure des portions 3, 4 ou 20, lorsque cette structure est équipée de crochets 7. Dans ce cas, la structure est en zig-zag et chaque crochet 7 comprend deux branches 7b ; chacune de ces branches 7b est reliée à l'autre branche 7b par une extrémité et à une branche de la structure 1 par son autre extrémité. La zone de jonction des deux branches 7b présente un ergot recourbé 7a d'accrochage.

La figure 15 montre une portion 3 comprenant deux fils ondulés 25, 26 s'étendant l'un à proximité de l'autre et un fil ondulé secondaire 27. Ainsi que le représente la figure 16, les fils 25, 26 peuvent être utilisés pour réaliser l'insertion d'une valve 2 en matériau biologique entre eux et la fixation de cette valve 2 à eux au moyen de sutures 27.

La figure 17 montre une partie du support 1 selon les figures 1 à 5, et la façon dont le matériau compressible constituant le bandage 8 peut absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau 10, qui résultent de calcifications.

La figure 18 montre un support 1 dont la bande 6 est dépourvue de bandage compressible. Un matériau peut alors être appliqué, au moyen d'une canule appropriée (non représentée), entre l'anneau 10 et cette

bande 6, ce matériau étant propre à se figer dans un délai déterminé après cette application.

La figure 19 montre un support 1 dont la bande 6 présente une section en ligne brisée, délimitant, du côté radialement extérieur, un épaulement inférieur. Dans le redan formé par cet épaulement et la paroi circonférientielle adjacente, est logée une bande périphérique 8, gonflable au moyen d'un cathéter (non représenté). Cette bande 8 délimite une chambre et a une structure radialement expansible, telle qu'elle présente en section transversale, à l'état gonflé, deux extrémités élargies faisant saillie de part et d'autre de la bande 6. Cette chambre peut recevoir un fluide de gonflage propre à se figer dans un délai déterminé après introduction dans ladite chambre. Une fois ce matériau figé, le cathéter de gonflage est sectionné.

Les figures 20 et 21 montrent un support 1 dont la bande 6 reçoit un insert gonflable 8 ayant une section transversale en diabolo à l'état gonflé, cet insert 8 pouvant être gonflé au moyen d'un cathéter 29. L'insert 8 est mis en place à l'état dégonflé (figure 20) aux emplacements dans lesquels il existe un espace entre la bande 6 et l'anneau cardiaque subsistant 10. Sa forme en diabolo permet à cet insert 8 (cf. figure 21) de se conformer au mieux aux structures irrégulières adjacentes et d'assurer une meilleure étanchéité.

La figure 22 montre un ballonnet 30 permettant de déployer le support 1 selon les figures 7 à 9. Ce ballonnet 30 comprend une portion cylindrique 31 dont le diamètre à l'état gonflé permet l'expansion de la portion de maintien 20, une portion cylindrique 32 de diamètre moindre, adaptée à réaliser l'expansion de la portion 3, et une portion tronconique 33, permettant l'expansion de la portion 4.

Ainsi que montre la figure 23, la portion 32 peut être limitée à ce qui est strictement nécessaire pour déployer la portion 3, ce qui permet de réaliser le ballonnet 30 en deux parties au lieu d'une seule, limitant ainsi le volume de ce ballonnet 30.

La figure 24 montre un support 1 dont la portion médiane 3 est en deux parties 3a, 3b. La partie 3a est en fil ondulé à larges ondes, pour supporter la valve 2, et la partie 3b, adjacente à ladite partie 3a et reliée à celle-ci par des ponts 35, est en fil ondulé à ondes réduites. Cette partie 3b, par sa structure, présente une force radiale d'expansion relativement

élevée et est destinée à être placée en regard de l'anneau 10 afin de repousser les feuillets valvulaires natifs volontiers calcifiés, épaissis et indurés, ou les restes des feuillets valvulaires après résection valvulaire contre ou dans la paroi du conduit.

Cette portion axiale 3a, 3b élimine ainsi la gêne qu'induisent ces feuillets ou résidus de feuillets au moment de la mise en place de la valve 2.

Il apparaît de ce qui précède que l'invention fournit un support tubulaire de mise en place, par voie percutanée, d'une valve cardiaque de remplacement procurant, grâce à ses portions 3 et 4, une parfaite certitude de maintien en position après implantation. Ce support permet également une parfaite étanchéité de la valve de remplacement, même en cas d'un anneau cardiaque présentant une surface plus ou moins irrégulière et/ou plus ou moins calcifiée, et sa position peut être adaptée et/ou corrigée le cas échéant au moment de l'implantation.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle en embrasse au contraire toutes les variantes de réalisation couvertes par les revendications ci-annexées.

REVENDICATIONS

1 - Support tubulaire de mise en place, par voie percutanée, d'une valve cardiaque de remplacement (2), comprenant une structure en fil ou en réseau de fils susceptible d'être contractée radialement pour permettre l'introduction de l'ensemble support (1) – valve (2) dans le corps du patient, au moyen d'un cathéter, et d'être déployée pour permettre la prise d'appui de cette structure contre la paroi du site à équiper de la valve (2) ;

support (1) caractérisé en ce que sa structure comprend :

- une portion axiale (3) de support de valve (2), présentant une structure en fil ou en réseau de fils propre à recevoir la valve de remplacement (2) montée sur elle, et propre à prendre appui contre l'anneau cardiaque (10) subsistant après le retrait de la valve native déficiente ;

- au moins une portion axiale de calage (4), présentant une structure en fil ou en réseau de fils distincte de la structure de ladite portion axiale (3) de support de valve, et dont au moins une partie présente, à l'état déployé, un diamètre supérieur au diamètre à l'état déployé de ladite portion axiale (3) de support de valve, tel que cette portion axiale de calage (4) est propre à prendre appui contre la paroi bordant ledit anneau cardiaque subsistant (10) ; et

- au moins un fil (5) de liaison desdites portions (3, 4), ce ou ces fils (5) étant reliés ponctuellement à ces portions (3, 4), de manière à ne pas faire obstacle au déploiement desdites portions axiales (3, 4) selon leurs diamètres respectifs.

2 - Support tubulaire selon la revendication 1, caractérisé en ce qu'il présente une portion axiale (3) de support de valve en au moins deux parties (3a, 3b), dont au moins une adaptée à supporter la valve (2) et dont au moins une autre adaptée à repousser les feuillets valvulaires natifs ou les restes des feuillets valvulaires natifs après résection valvulaire, dans ou sur le tissu adjacent afin de rendre cette zone apte à recevoir le support tubulaire.

3 - Support tubulaire selon la revendication 1 ou la revendication 2, caractérisé en ce qu'au moins une portion axiale de calage (4) présente

une forme tubulaire de diamètre constant supérieur à celui de la portion axiale (3) de support de valve.

4 - Support tubulaire selon la revendication 1 ou la revendication 2, caractérisé en ce qu'au moins une portion axiale de calage (4) présente une forme tronconique dont le diamètre va en augmentant en s'éloignant de la portion axiale (3) de support de valve.

5 - Support tubulaire selon l'une des revendications 1 à 4, caractérisé en ce qu'il comprend :

- une portion axiale de maintien (20), propre à prendre appui à l'état déployé contre la paroi du conduit comprenant la valve, et
- des fils de liaison (5), reliant ladite portion axiale (3) de support de valve et ladite portion axiale de maintien (20), ces fils (5) ayant une longueur telle que la portion axiale de maintien (20) soit située après implantation à distance de la portion axiale (3) de support de valve.

6 - Support tubulaire selon l'une des revendications 1 à 5, caractérisé en ce que chaque portion axiale de support de valve (3), de calage (4) ou de maintien (20) présente une structure en mailles ayant une forme de losange, les mailles étant juxtaposées dans le sens de la circonférence de cette portion (3, 4, 20).

7 - Support tubulaire selon l'une des revendications 1 à 6, caractérisé en ce qu'il présente deux portions axiales de calage (4), l'une étant reliée à une extrémité axiale de ladite portion (3) de support de valve et l'autre à l'autre extrémité axiale de cette même portion (3) de support de valve.

8 - Support tubulaire selon l'une des revendications 1 à 7, caractérisé en ce qu'il est réalisé en un métal plastiquement déformable.

9 - Support tubulaire selon l'une des revendications 1 à 7, caractérisé en ce qu'il est réalisé en un matériau à mémoire de forme, tel qu'un alliage nickel–titane du genre dénommé "NITINOL", pouvant être contracté radialement à une température différente de celle du corps du patient et retrouvant une forme originelle lorsque sa température approche ou atteint celle du corps du patient.

10 - Support tubulaire selon l'une des revendications 1 à 7, caractérisé en ce qu'il est réalisé en un matériau à mémoire de forme mais susceptible de déformation plastique, ou comprend des parties en un matériau à mémoire de forme et des parties en un matériau susceptible de

déformation plastique, et en ce qu'il est conformé de manière telle qu'il puisse être amené, par mémoire de forme ou par déformation plastique, d'un état de contraction à un état de déploiement intermédiaire stable entre l'état de contraction et l'état de déploiement total, puis, par déformation plastique ou par mémoire de forme respectivement, dudit état de déploiement intermédiaire audit état de déploiement total ; dans ledit état de déploiement intermédiaire, le support présente des dimensions telles qu'il reste mobile par rapport au site à traiter.

11 - Support tubulaire selon l'une des revendications 1 à 10, caractérisé en ce qu'il comprend des moyens d'ancrage (7) propres à s'insérer dans la paroi du site à traiter, conformés de manière à être mobiles entre une position inactive, dans laquelle ils ne font pas obstacle à l'introduction du support (1) dans le corps du patient, et une position active, dans laquelle ils s'insèrent dans la paroi du site à traiter.

12 - Support tubulaire selon l'une des revendications 1 à 11, caractérisé en ce que ladite portion axiale (3) de support de valve comporte, au niveau de sa face extérieure, un moyen d'étanchéité (8) conformé de manière à absorber les irrégularités de surface pouvant exister au niveau ou à proximité de l'anneau cardiaque subsistant (10).

13 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) comprend un bandage périphérique en un matériau compressible.

14 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) comprend un bandage périphérique délimitant une chambre et ayant une structure radialement expansible, cette chambre pouvant recevoir un fluide de gonflage propre à se figer dans un délai déterminé après introduction dans ladite chambre.

15 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) comprend un matériau pouvant être appliqué entre l'anneau cardiaque subsistant (10) et la portion axiale (3) de support de valve, ce matériau étant propre à se figer dans un délai déterminé après cette application.

16 - Support tubulaire selon la revendication 12, caractérisé en ce que le moyen d'étanchéité (8) se présente sous forme d'un insert gonflable ayant une section transversale en diabolo à l'état gonflé, pouvant

être inséré entre l'anneau cardiaque subsistant (10) et la portion axiale (3) de support de valve.

17 - Instrument de mise en place du support selon l'une des revendications 8 ou 10 à 16, caractérisé en ce qu'il comprend un ballonnet (30) présentant une portion axiale (32) d'un diamètre prédéterminé, adaptée à réaliser le déploiement de ladite portion axiale de support de valve, et au moins une portion axiale (31, 33) conformée pour présenter, à l'état gonflé, une section supérieure à celle du conduit à traiter, de manière à réaliser le déploiement de la portion axiale de calage placée sur elle jusqu'à ce que cette portion axiale de calage rencontre la paroi contre laquelle elle doit venir en appui.

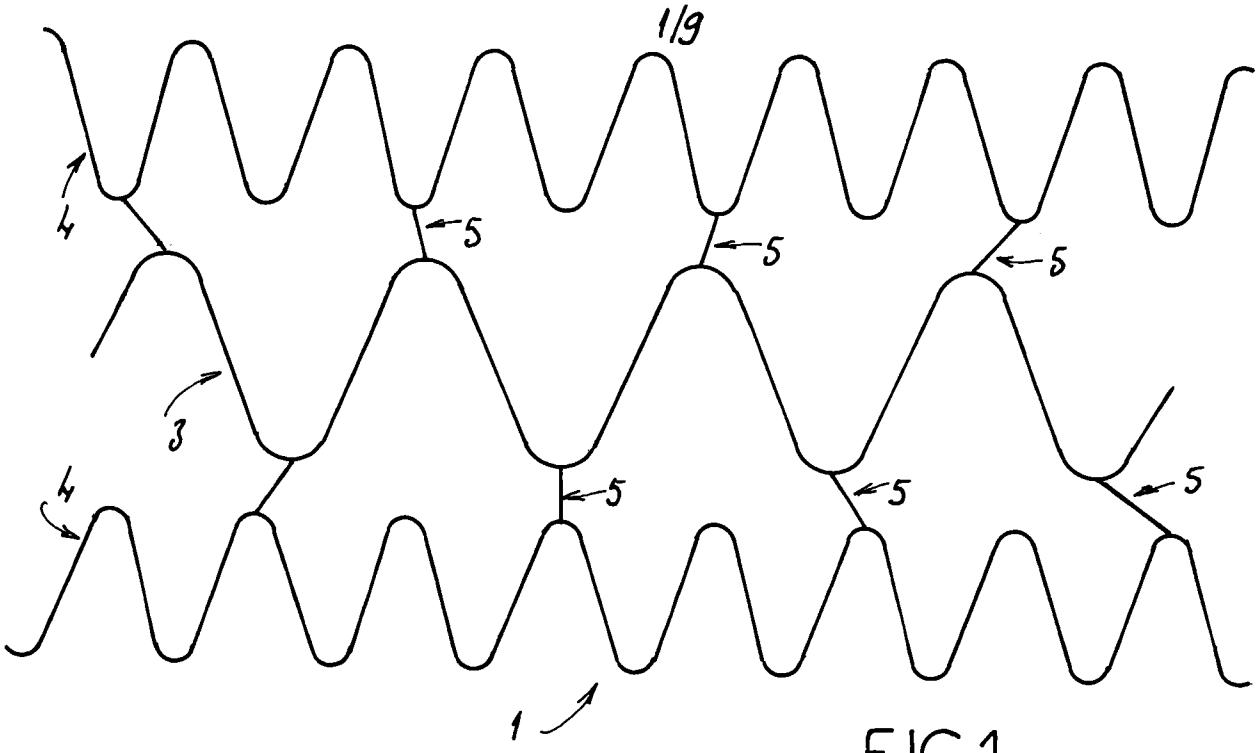


FIG 1

FIG 2

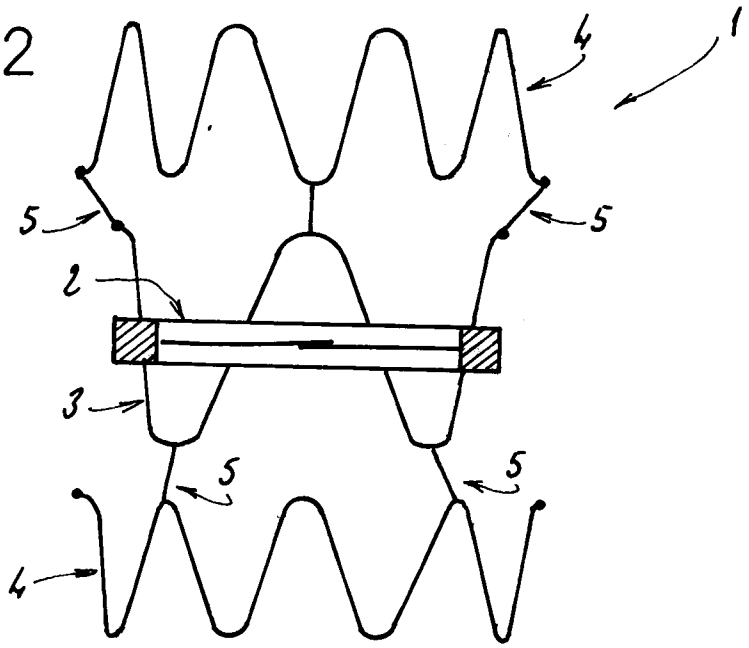


FIG 3

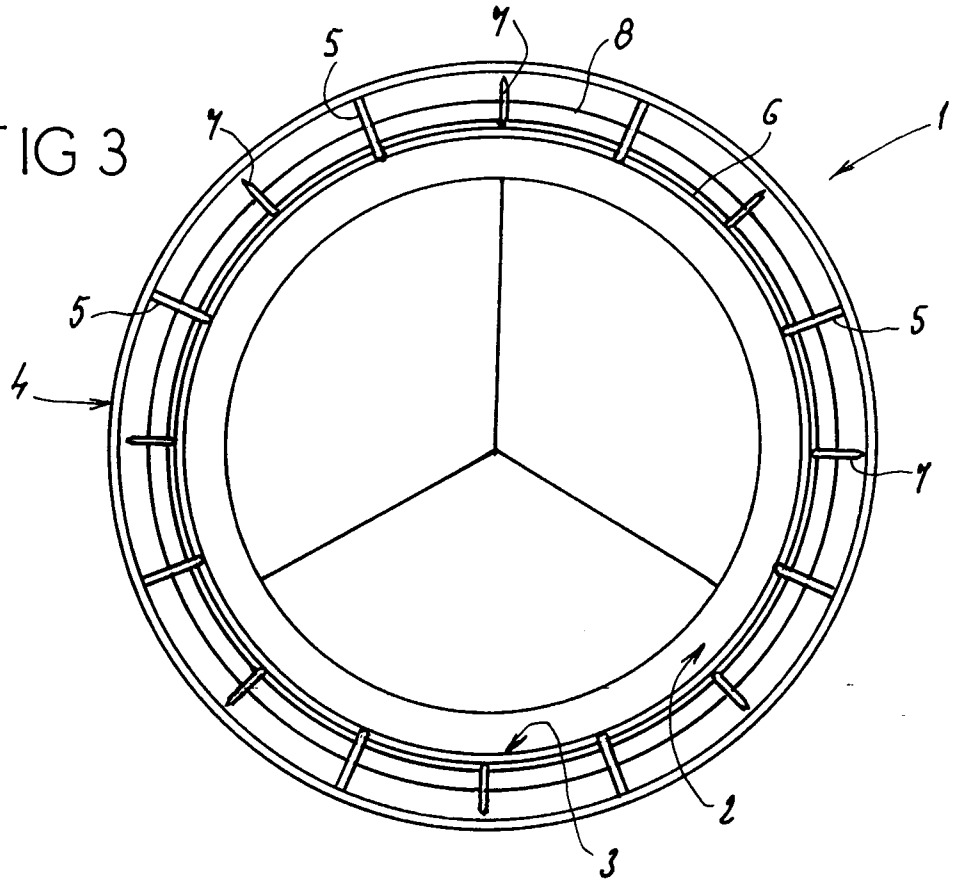


FIG 4

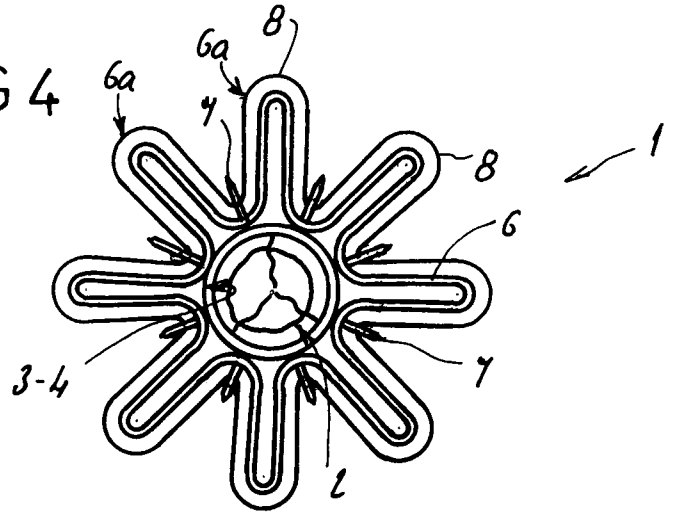


FIG 5

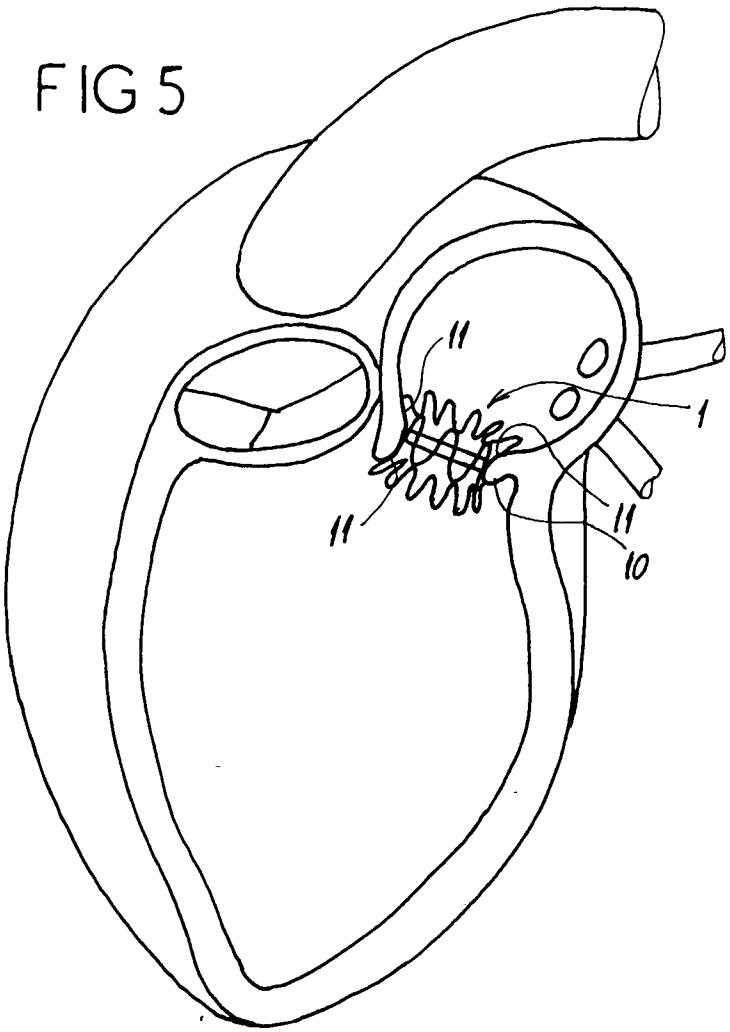


FIG 6

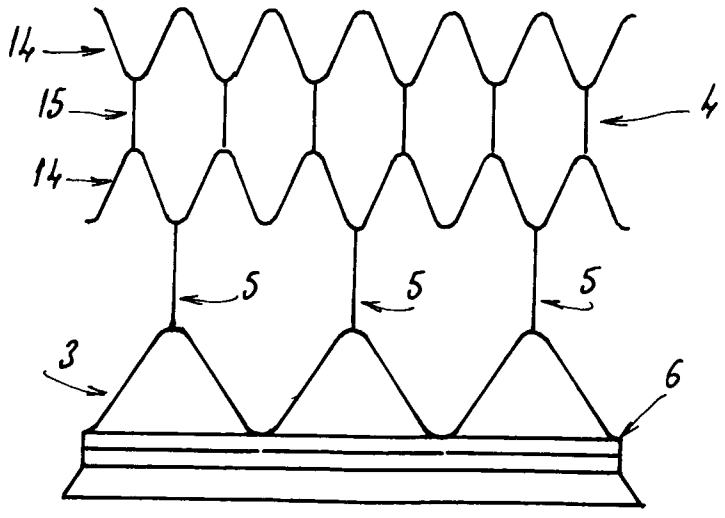


FIG 7

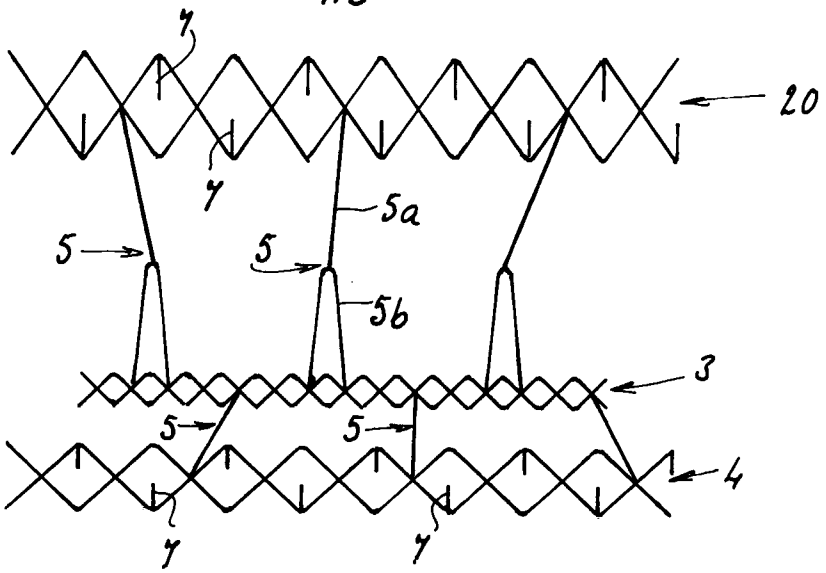


FIG 8

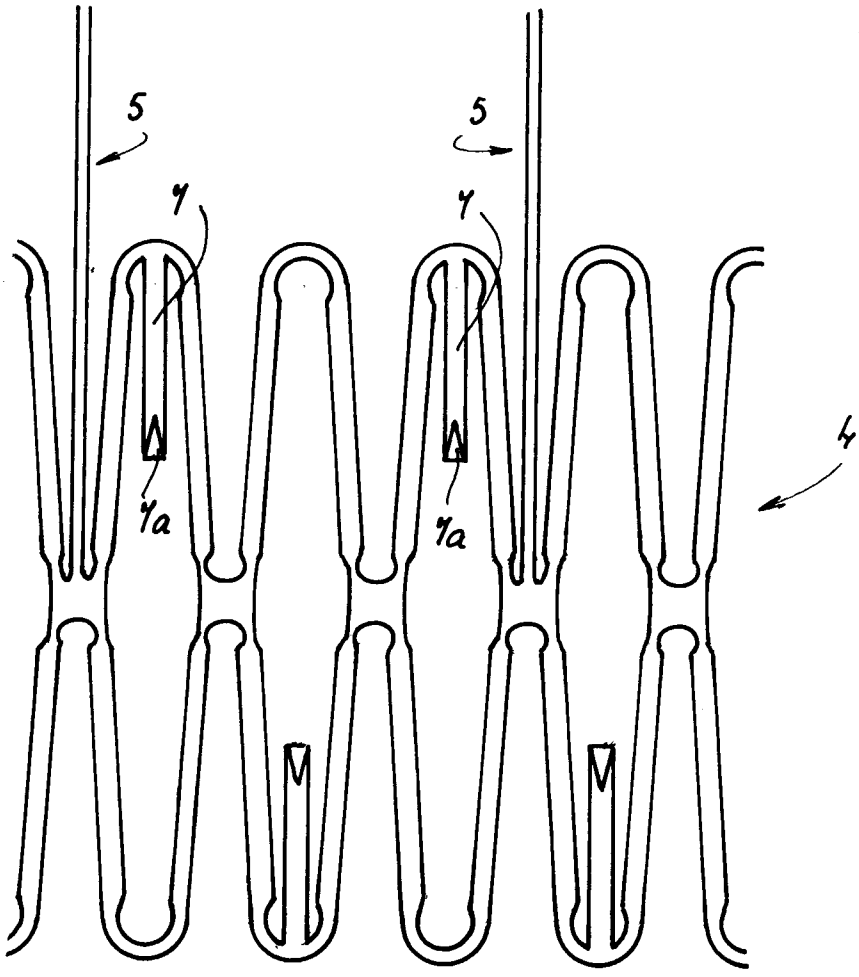


FIG 9

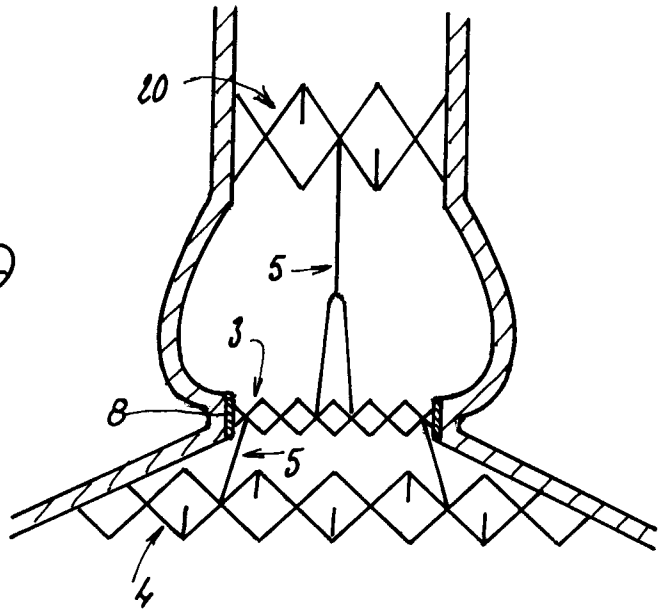


FIG 10

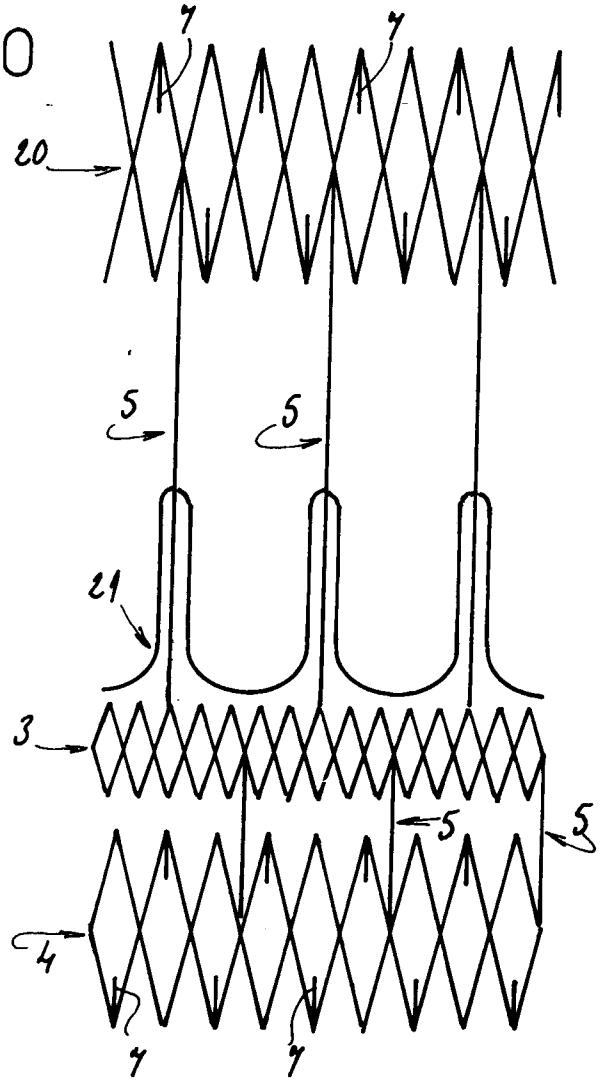


FIG 11

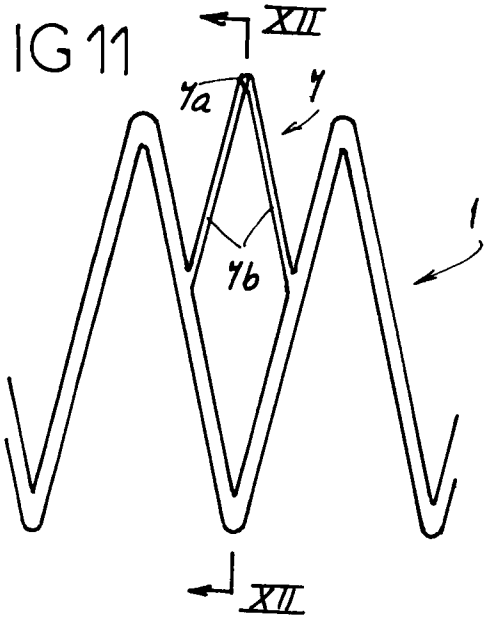
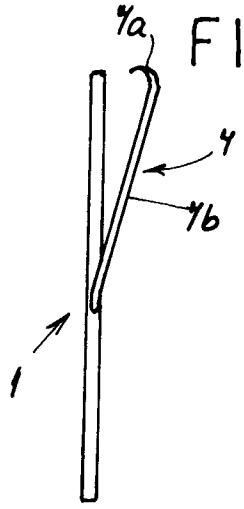


FIG 12



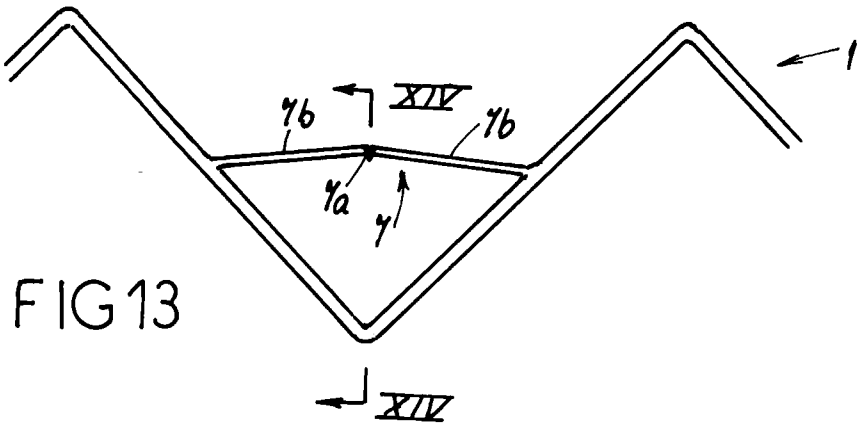


FIG 13

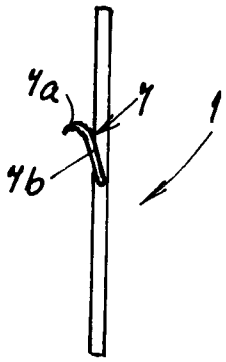


FIG 14

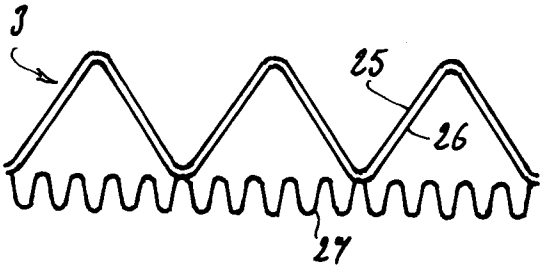


FIG 15

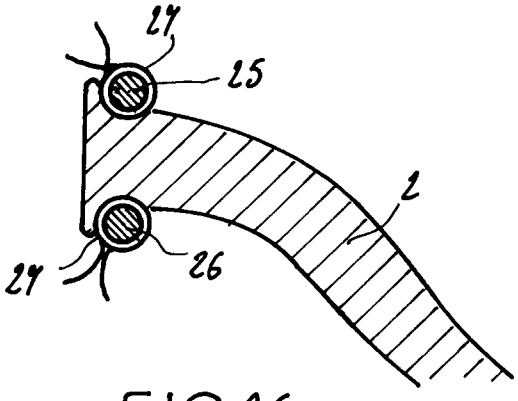


FIG 16

FIG 17

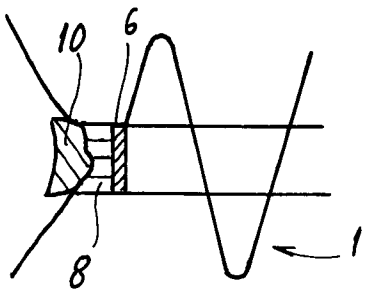


FIG 18

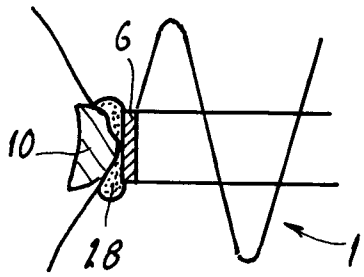


FIG 19

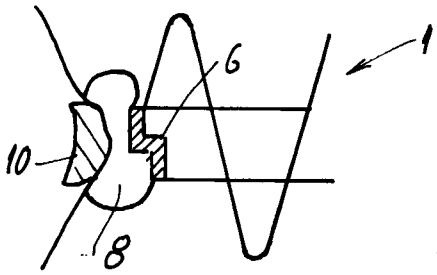


FIG 20

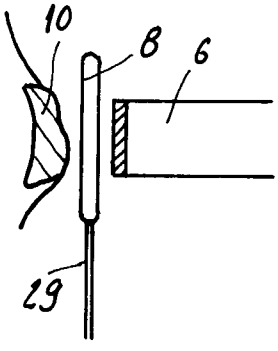


FIG 21

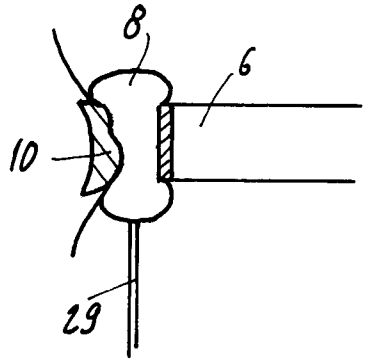


FIG 22

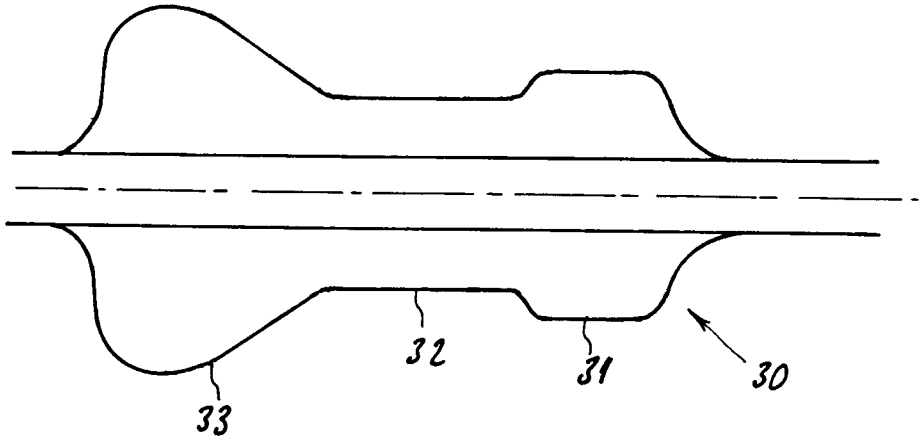


FIG 23

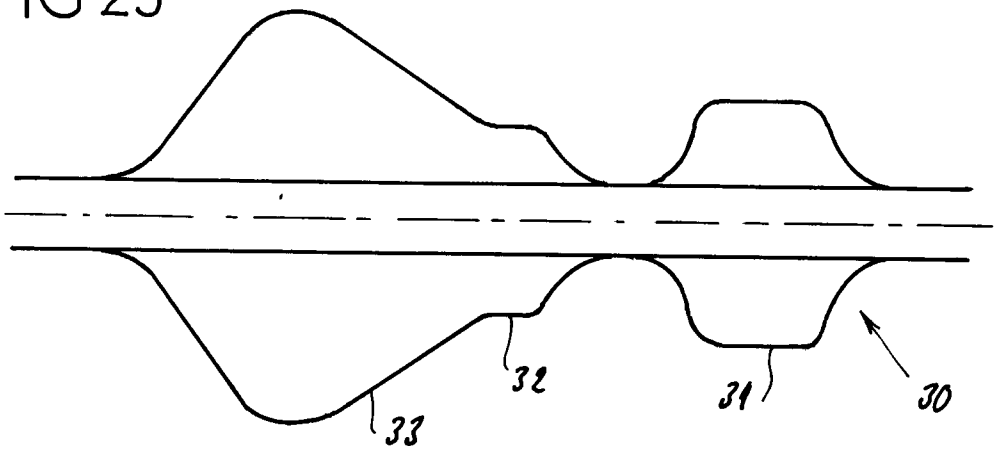
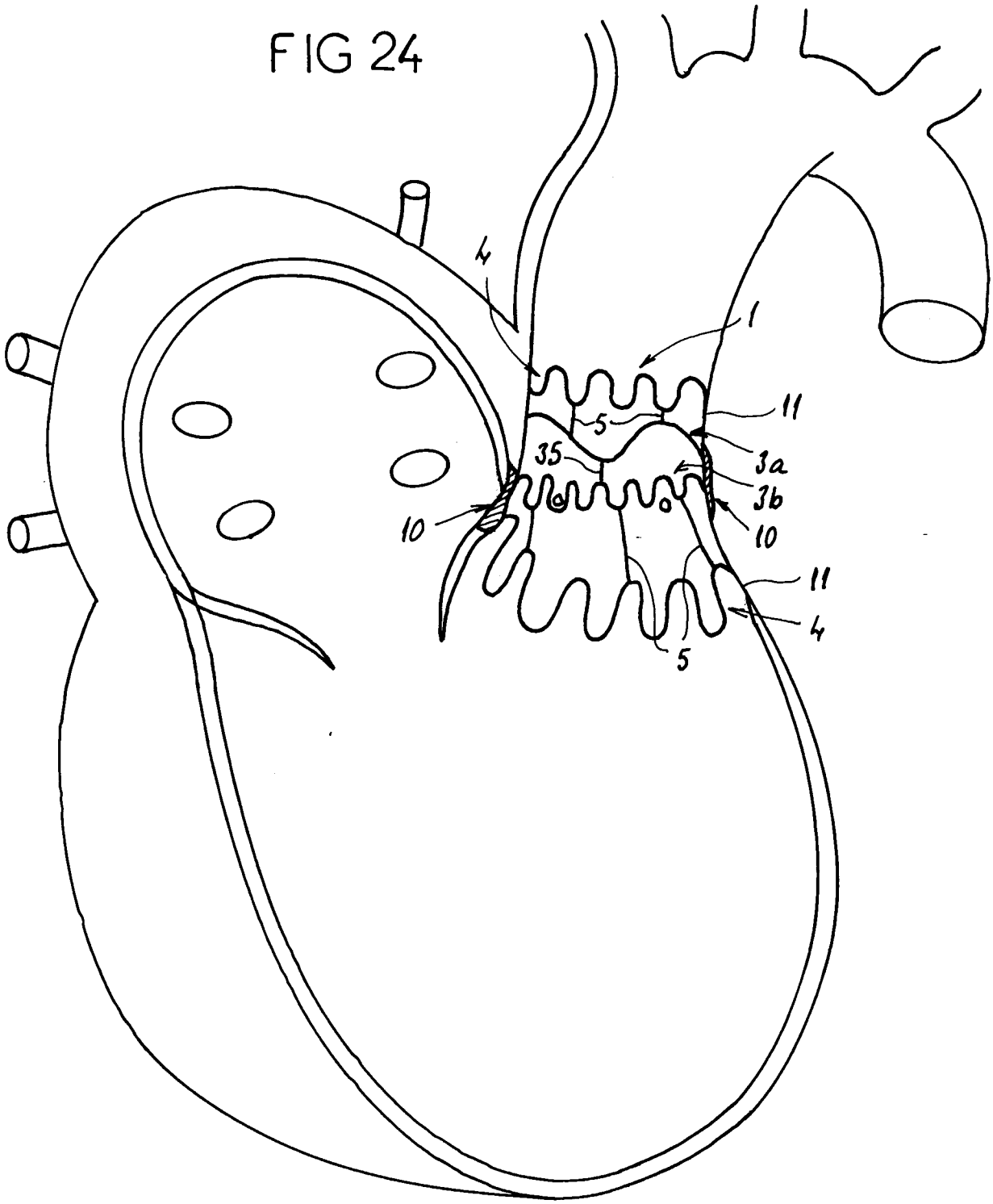


FIG 24



RÉPUBLIQUE FRANÇAISE

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N° d'enregistrement national

FA 593994
FR 0014028

RAPPORT DE RECHERCHE PRÉLIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

DOCUMENTS CONSIDÉRÉS COMME PERTINENTS		Revendication(s) concernée(s)	Classement attribué à l'invention par l'INPI
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes		
A	US 5 957 949 A (LEONHARDT ET AL) 28 septembre 1999 (1999-09-28) * le document en entier * ---	1,17	A61F2/24
A	US 5 855 601 A (BESSLER ET AL) 5 janvier 1999 (1999-01-05) -----		
			DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7)
			A61F

Date d'achèvement de la recherche	Examinateur
24 juillet 2001	Smith, C

CATÉGORIE DES DOCUMENTS CITÉS

X : particulièrement pertinent à lui seul
Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
A : arrière-plan technologique
O : divulgation non-écrite
P : document intercalaire

T : théorie ou principe à la base de l'invention
E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
D : cité dans la demande
L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

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EPO FORM 1503 12.99 (P04C14)

US 20050137698A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0137698 A1**

Salahieh et al. (43) **Pub. Date: Jun. 23, 2005**

(54) **LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF**

(76) Inventors: **Amr Salahieh**, Saratoga, CA (US); **Brian D. Brandt**, Santa Clara, CA (US); **Robert A. Gleshlider**, San Francisco, CA (US); **Dwight P. Morejohn**, Davis, CA (US); **Tom Saul**, El Granada, CA (US)

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PALO ALTO, CA 943041050

(21) Appl. No.: **10/972,287**

(22) Filed: **Oct. 21, 2004**

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/746,240, filed on Dec. 23, 2003.

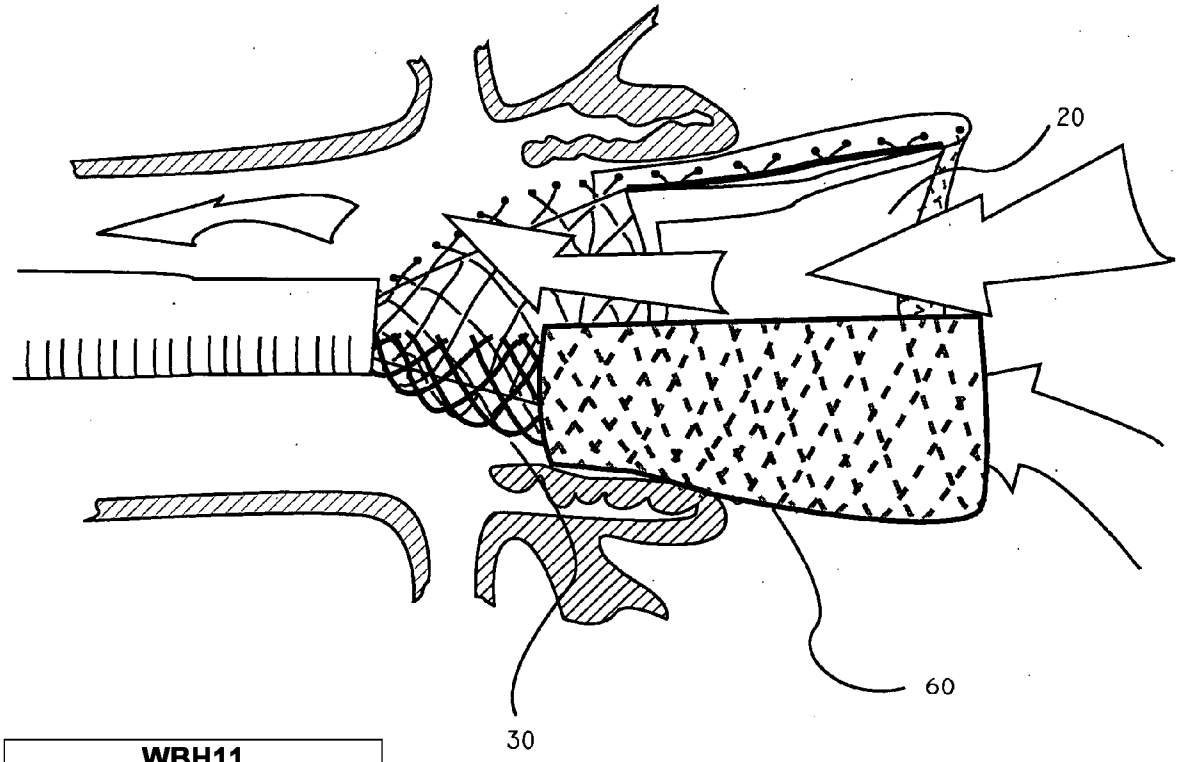
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/24**

(52) **U.S. Cl.** **623/2.11**; 623/2.18; 623/2.38

(57) **ABSTRACT**

The present invention relates to apparatus for methods for endovascularly replacing a patient's heart valve. The apparatus includes an expandable anchor with leaflet engagement elements on the proximal end of the anchor and a replacement valve. The leaflet engagement elements can be used to prevent distal migration and insure proper positioning of the apparatus.



WBH11
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

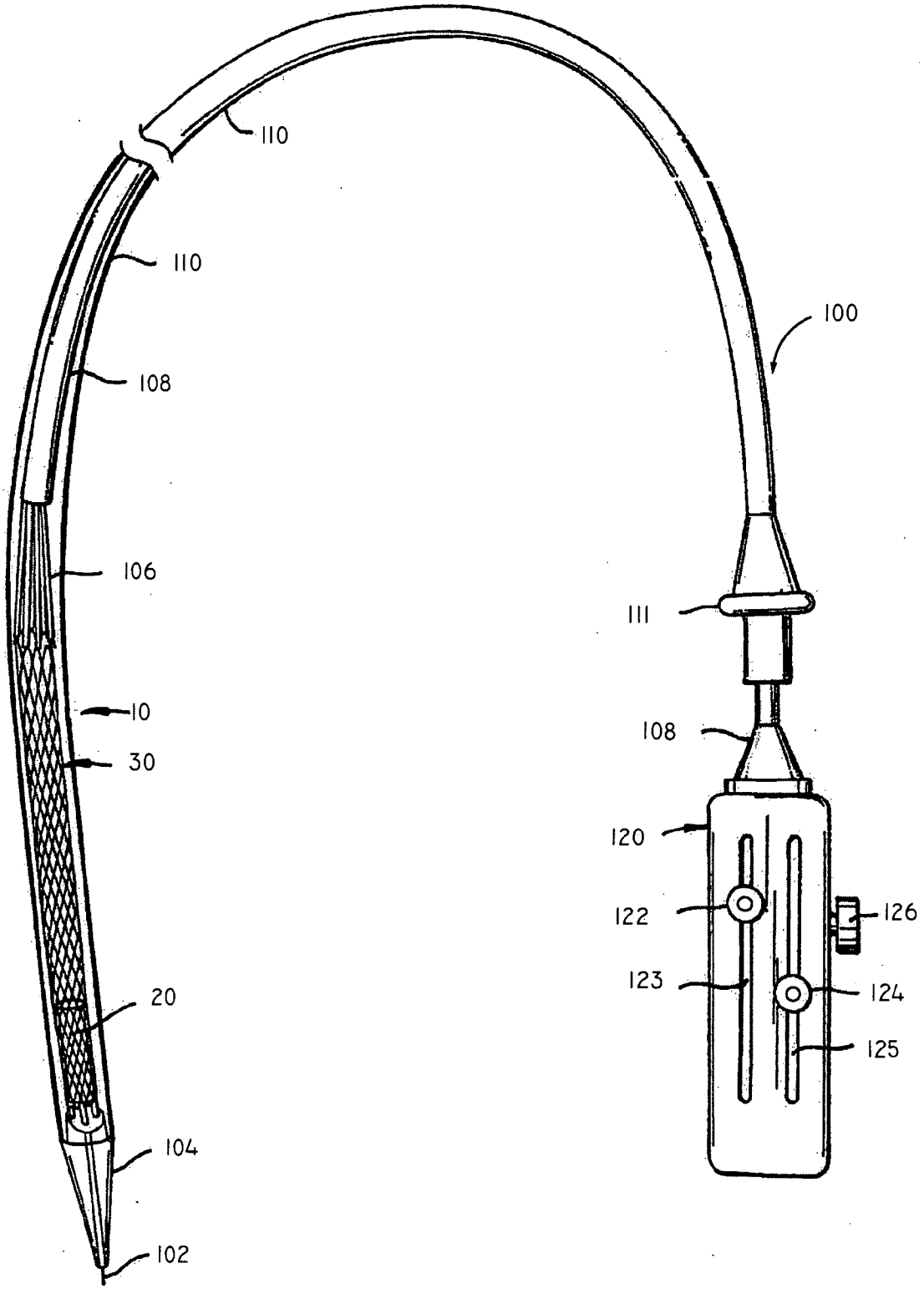

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FIG 1A

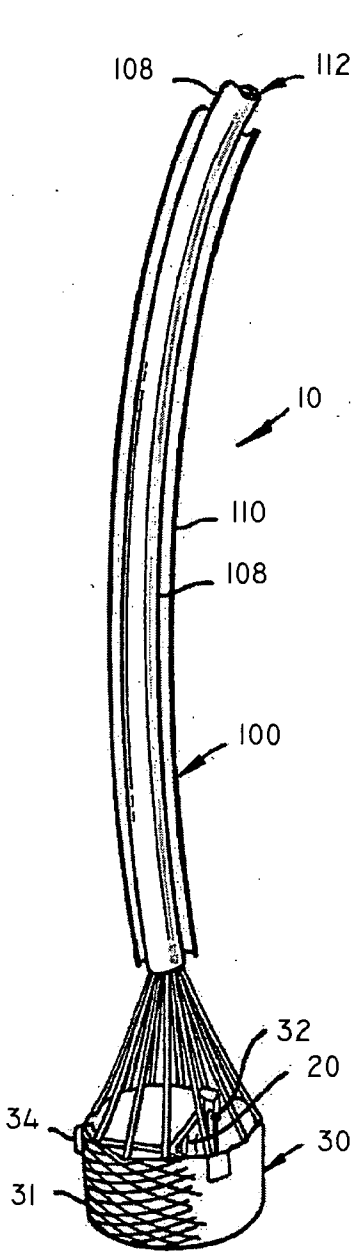


FIG 1B

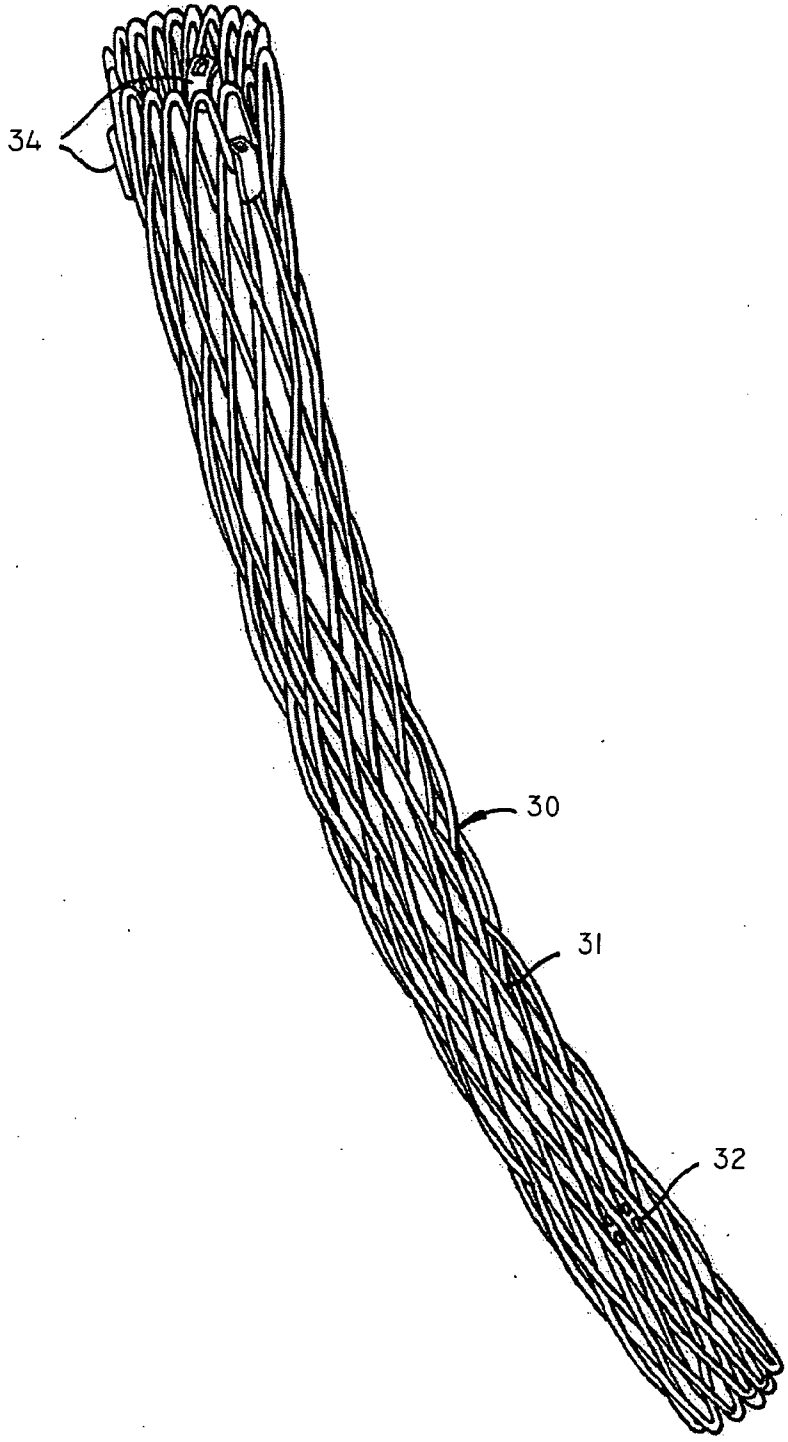


FIG 2

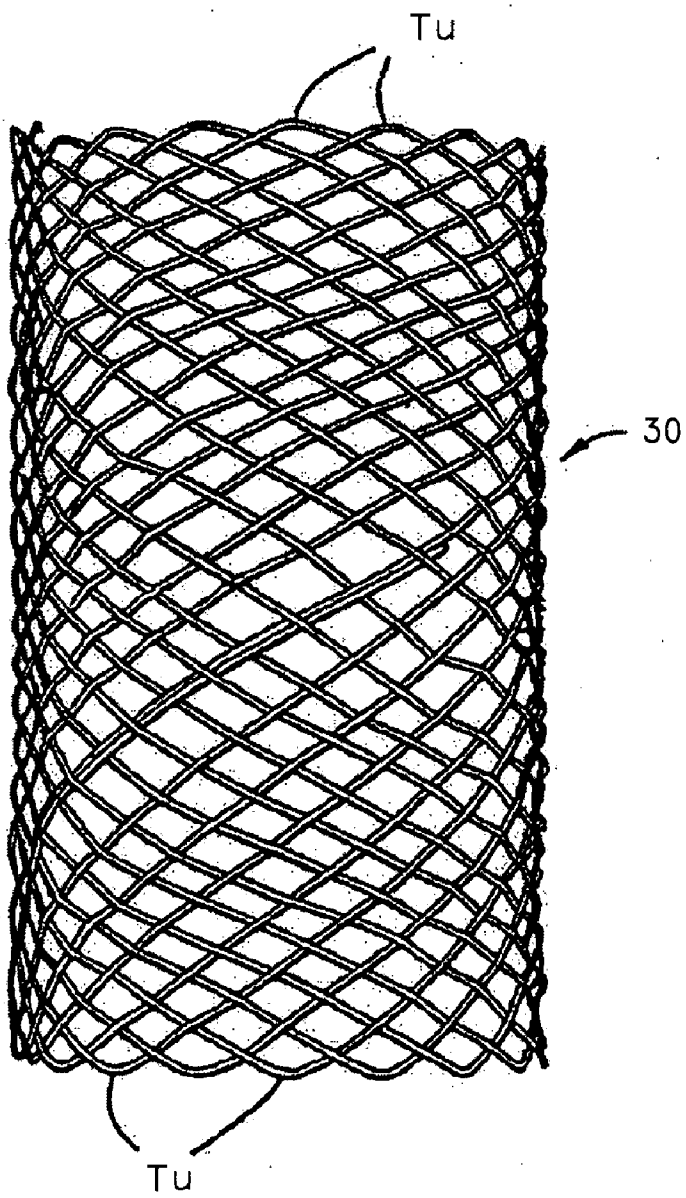


FIG 3

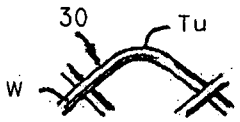


FIG 4A

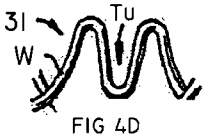


FIG 4D

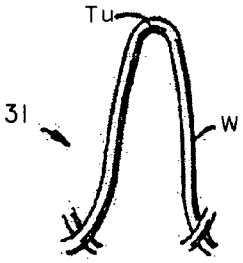


FIG 4B

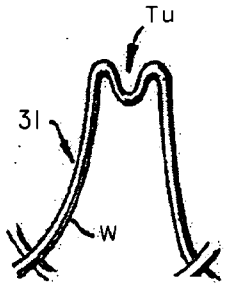


FIG 4C

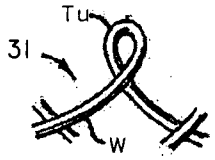


FIG 4E

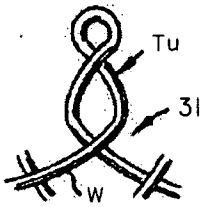


FIG 4F

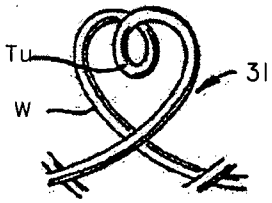


FIG 4G

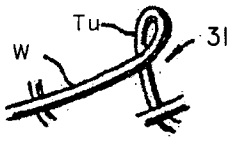


FIG 4H

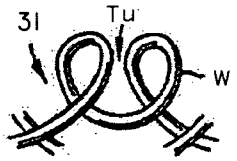


FIG 4I

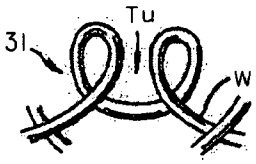


FIG 4J

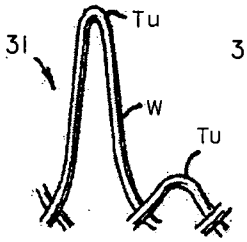


FIG 4K

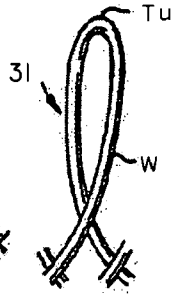


FIG 4L

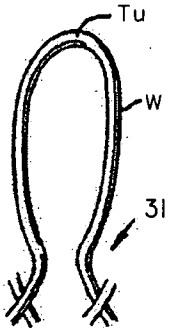


FIG 4M

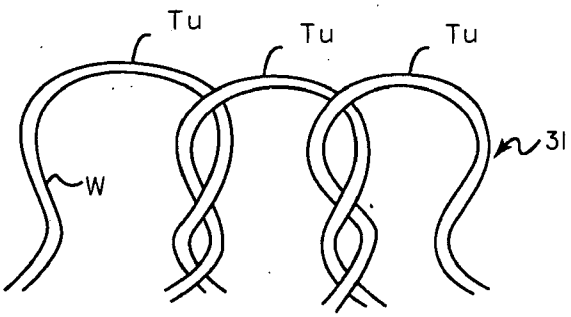


FIG 4N

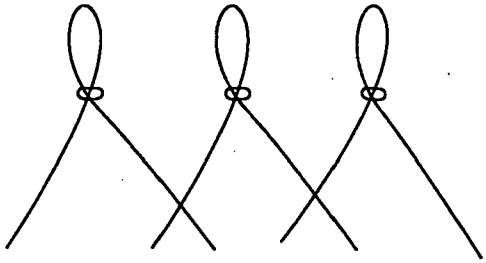


FIG 4O

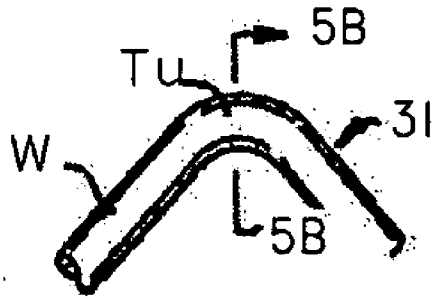


FIG 5A



FIG 5B

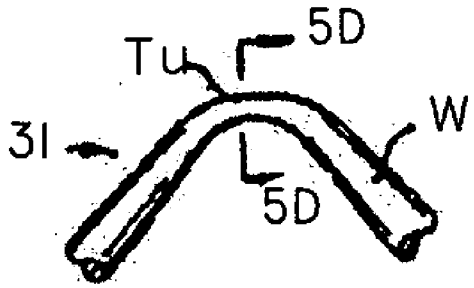


FIG 5C



FIG 5D



FIG 5E

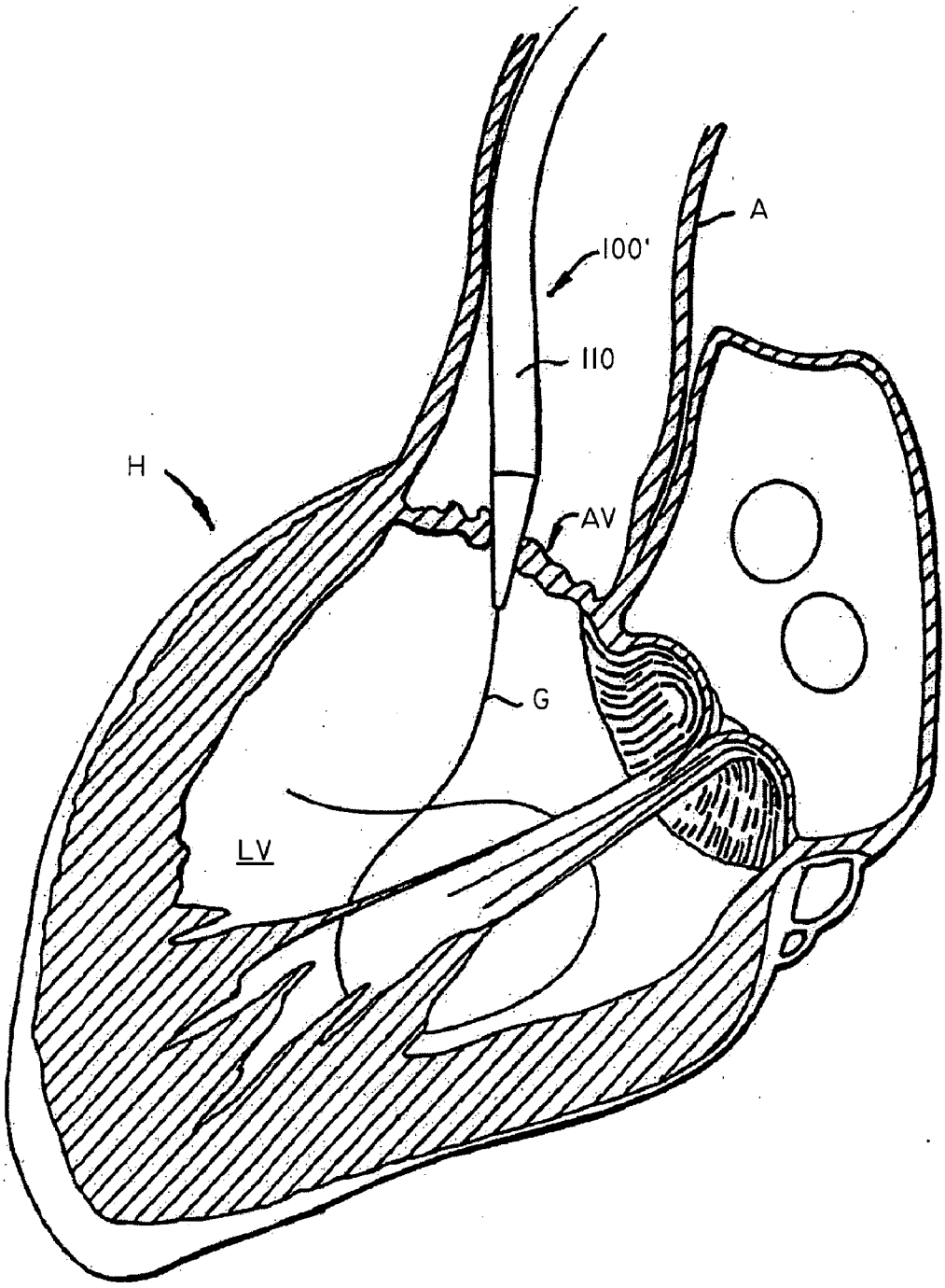


FIG 6A

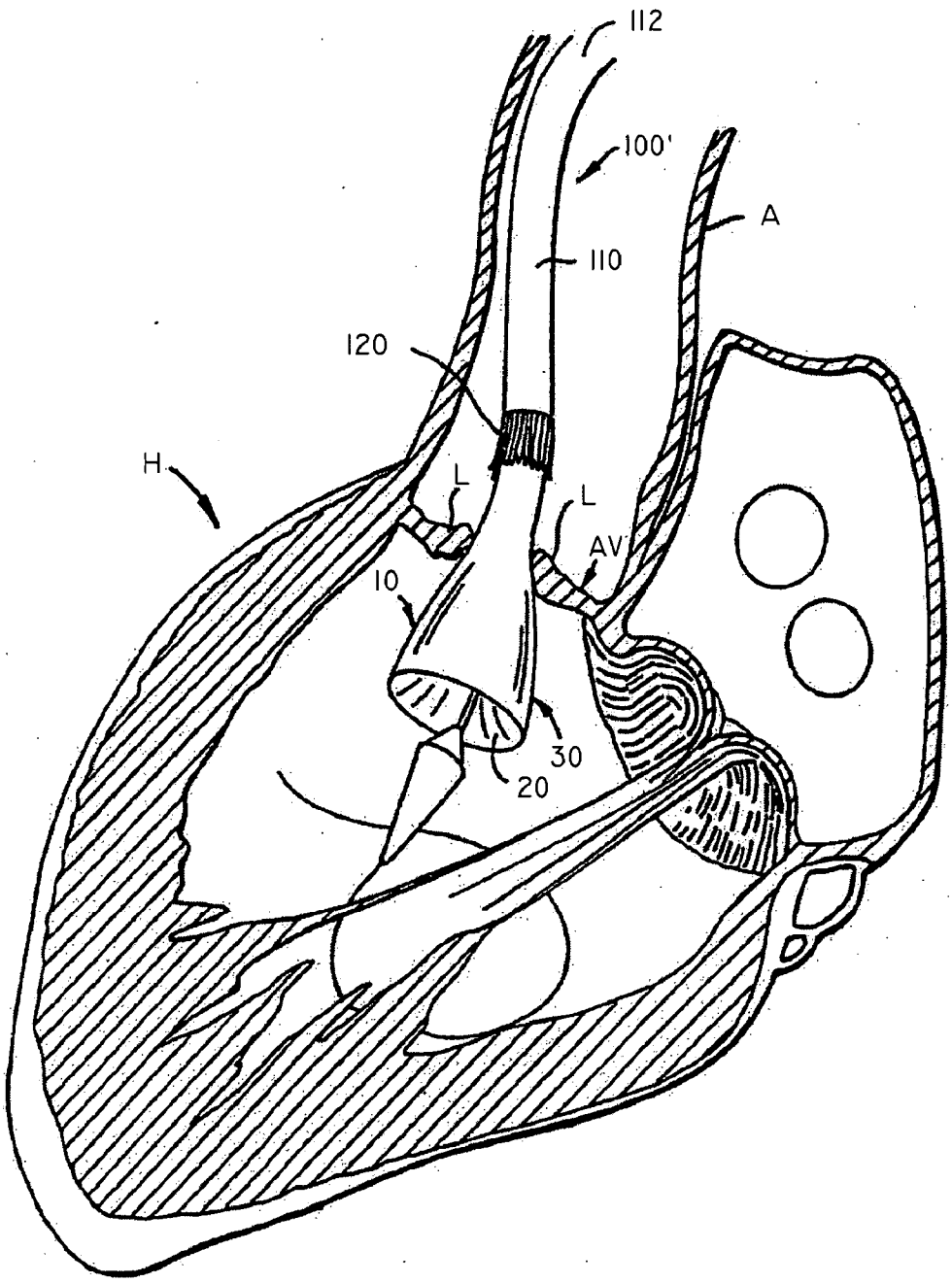


FIG 6B

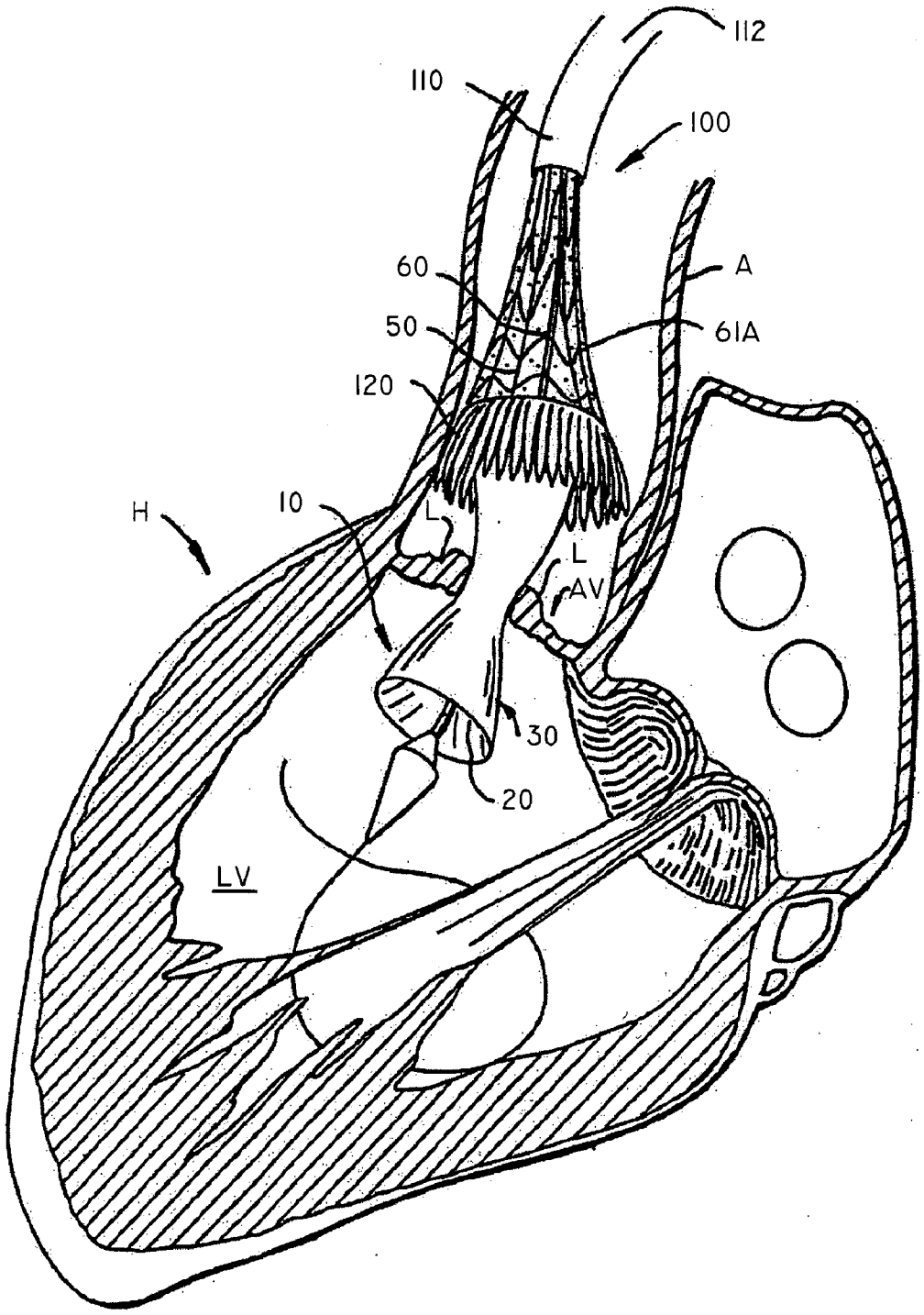


FIG 6C

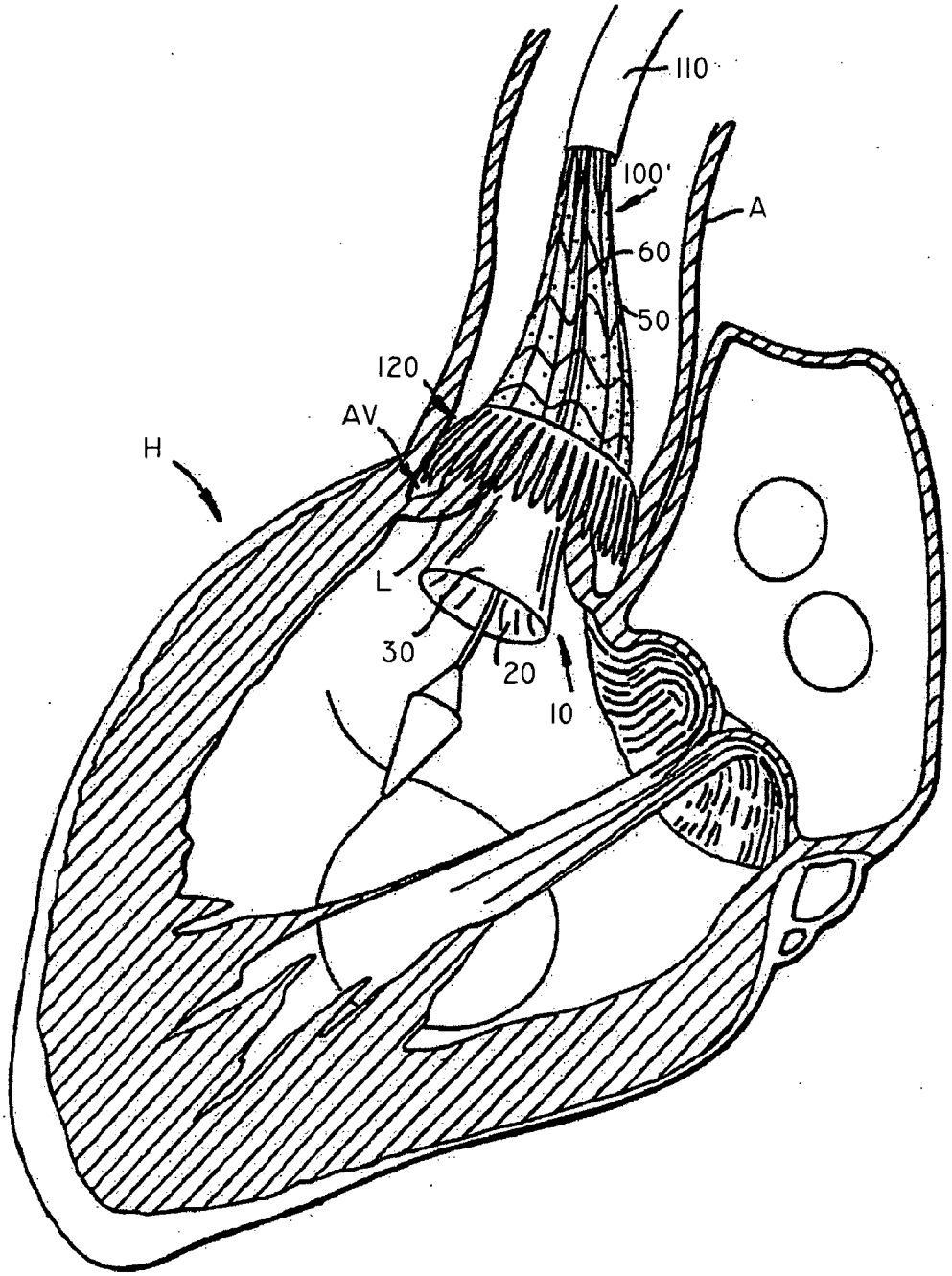


FIG 6D

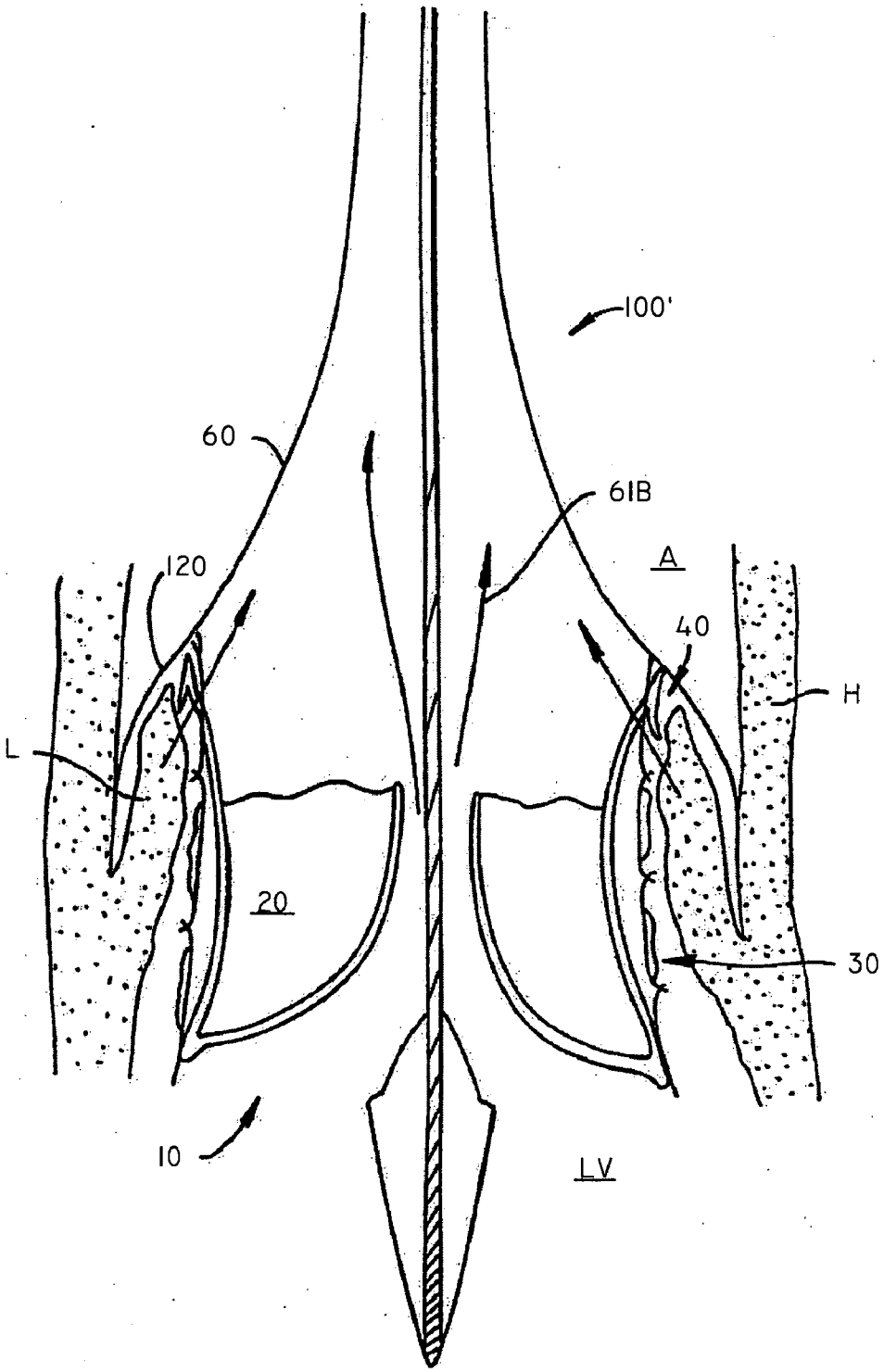


FIG 6E

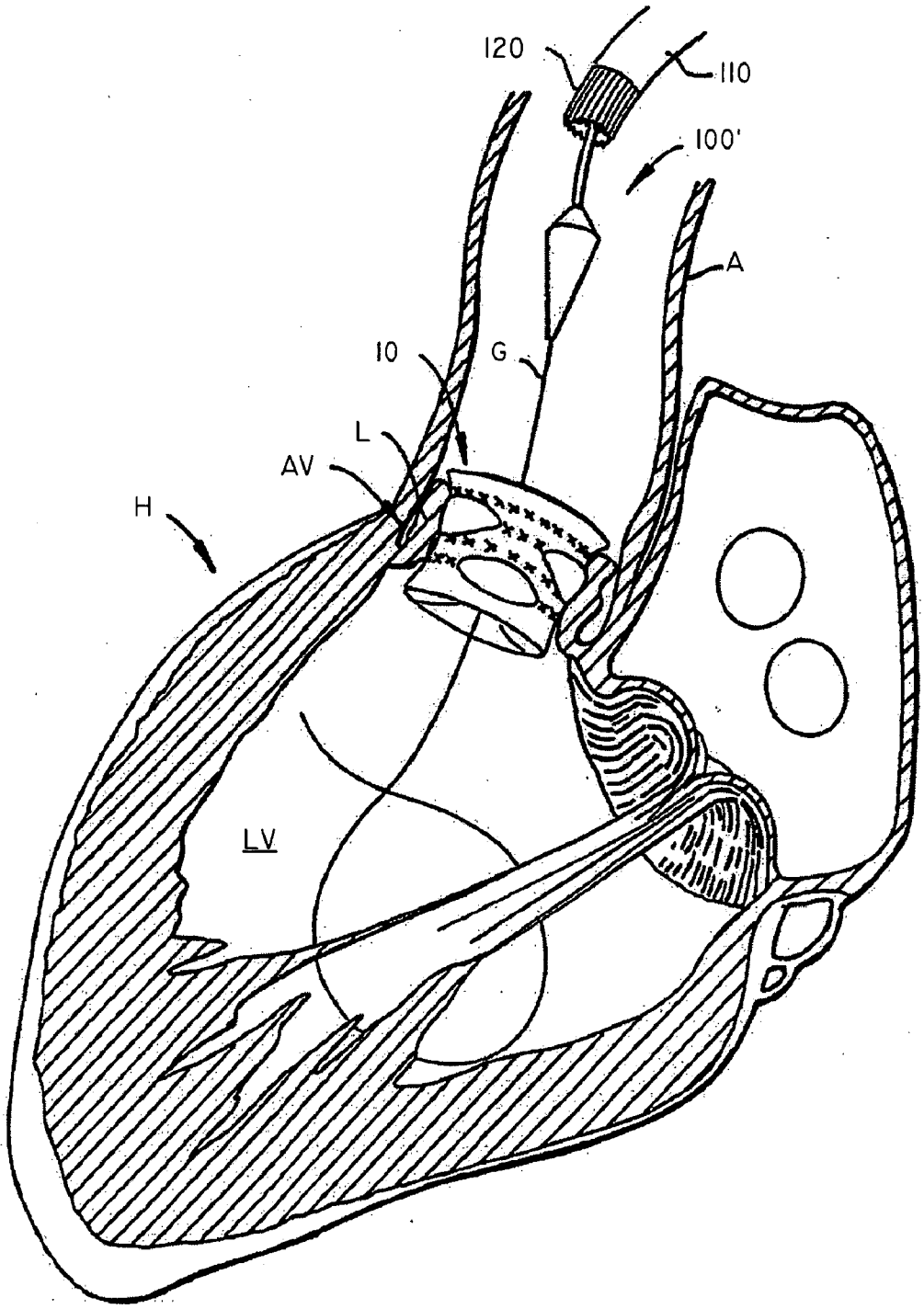


FIG 6F

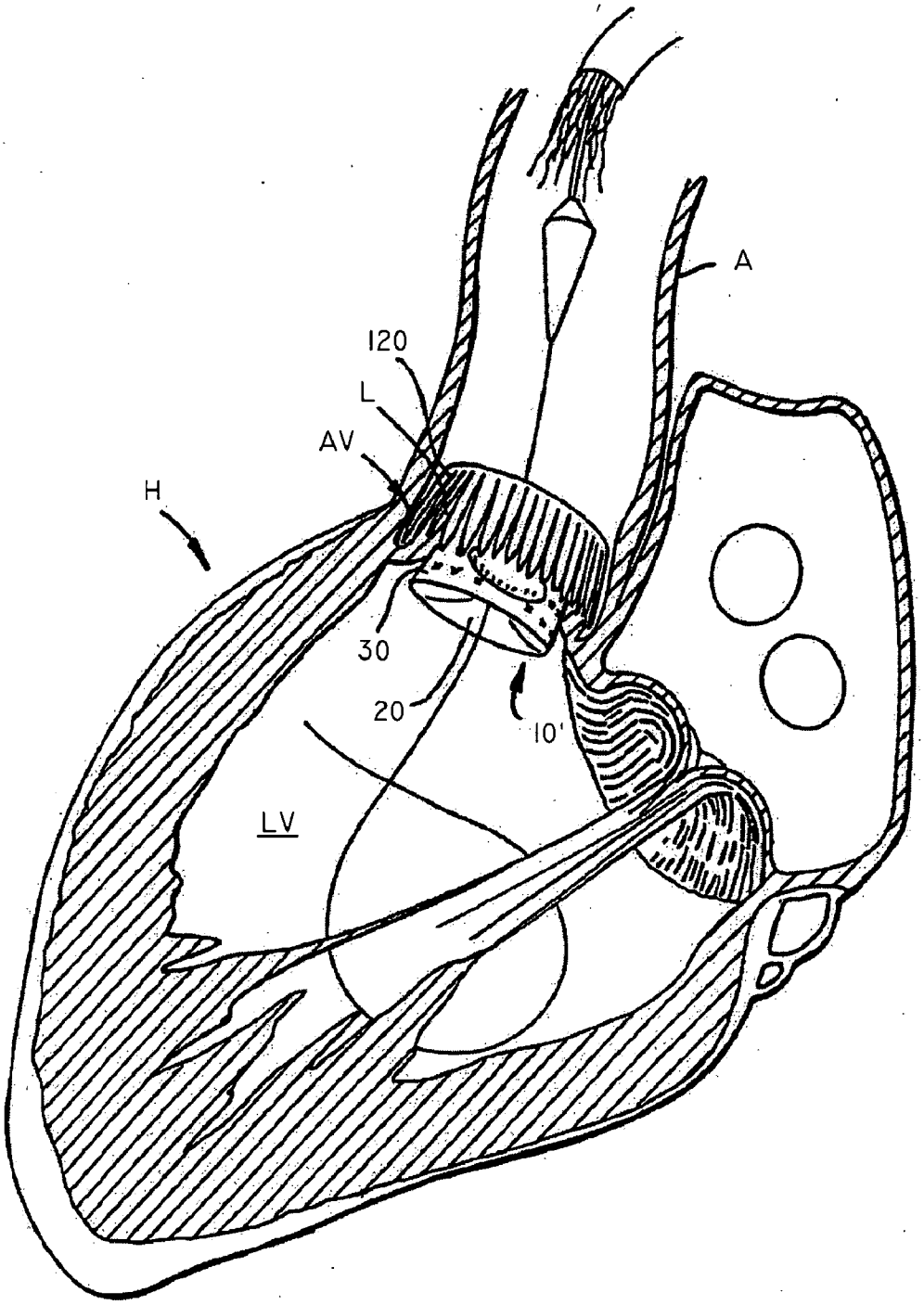


FIG 7

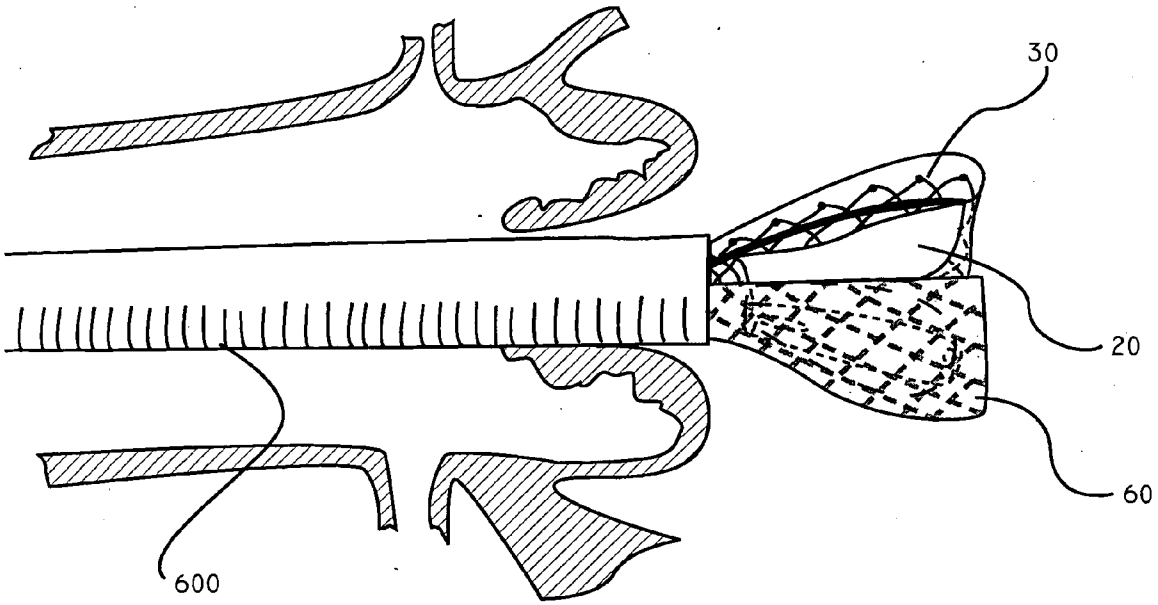


FIG 8A

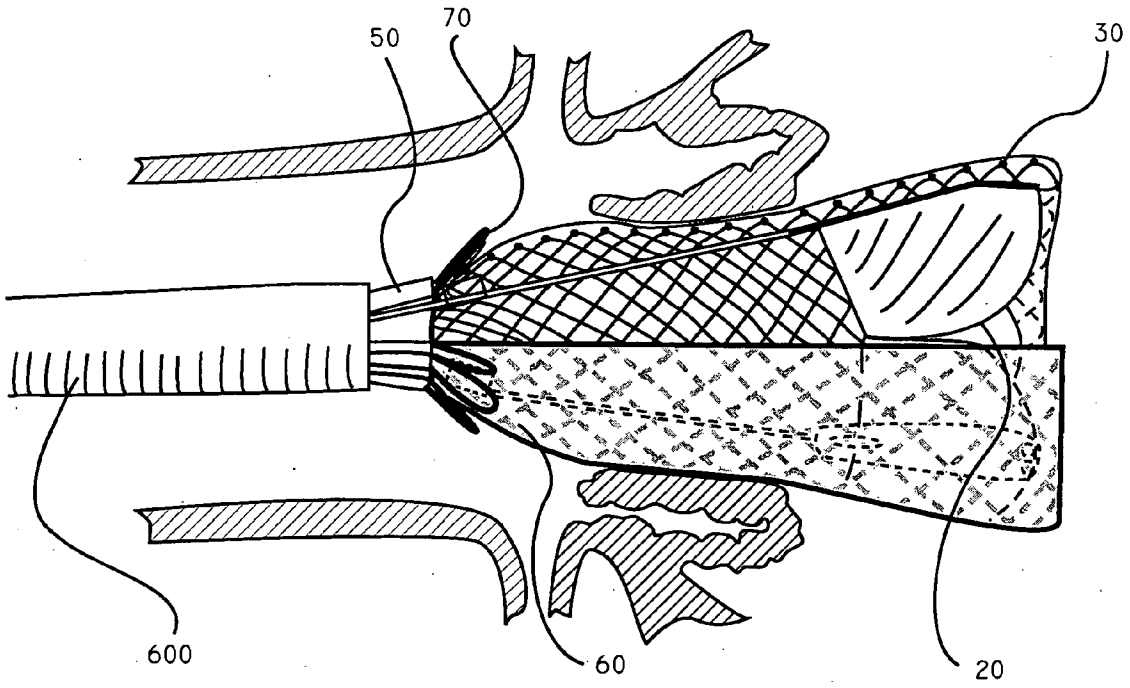


FIG 8B

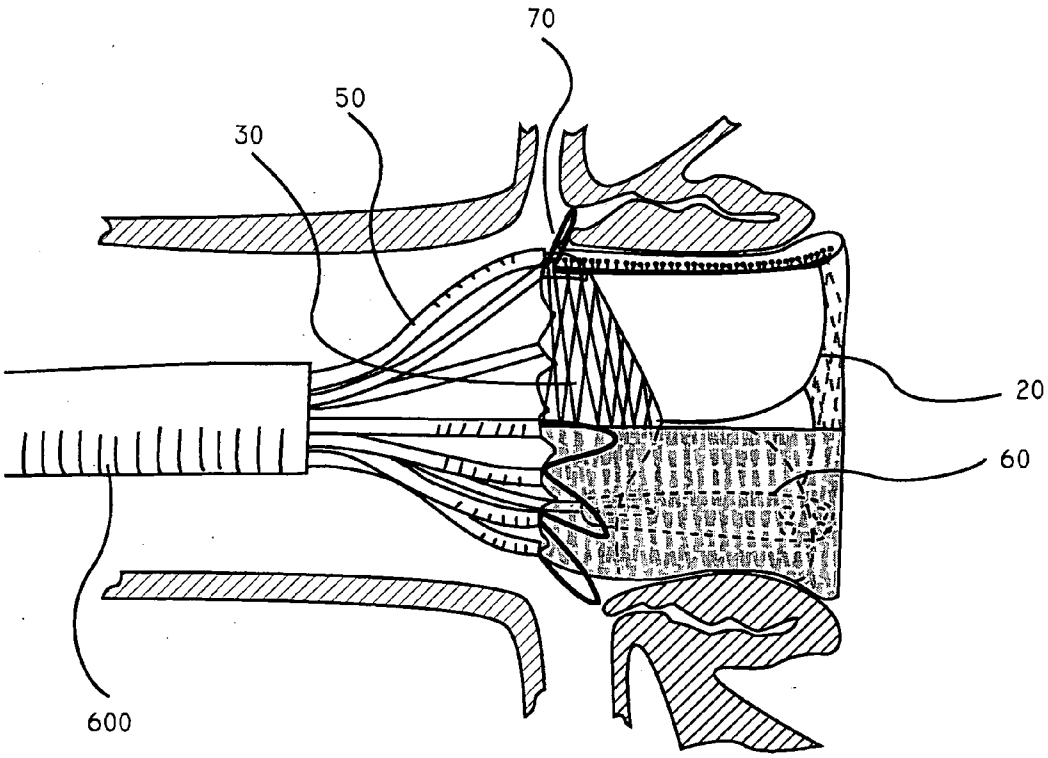


FIG 8C

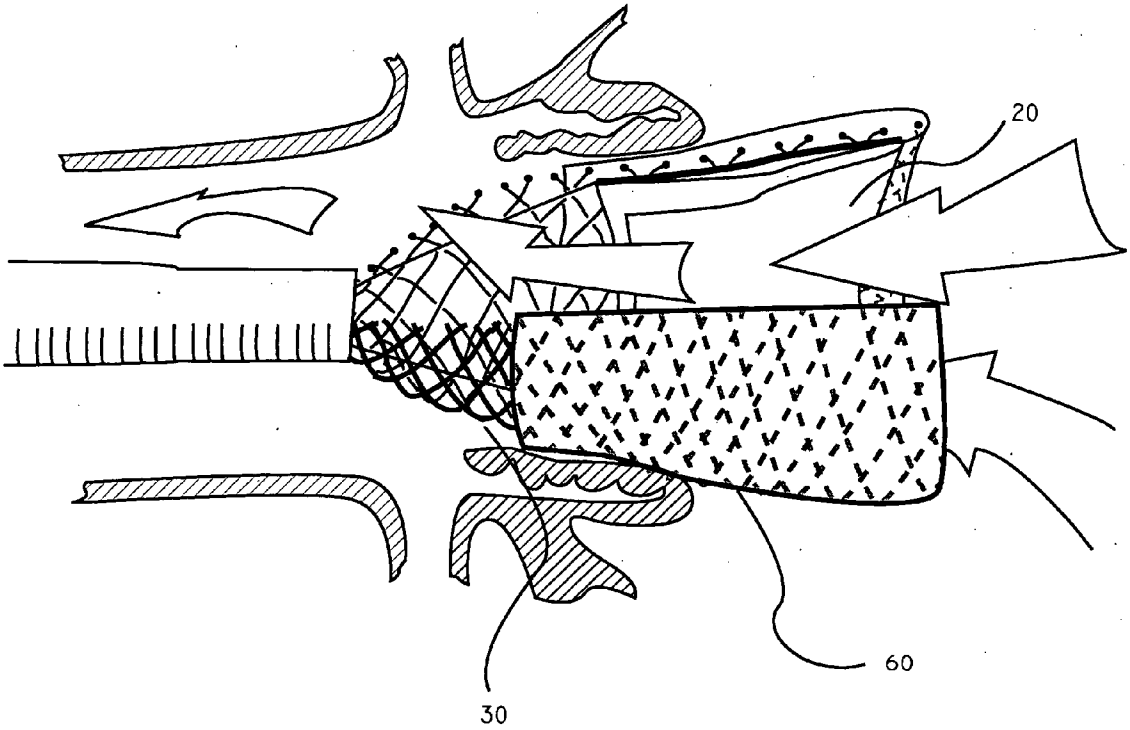


FIG 9A

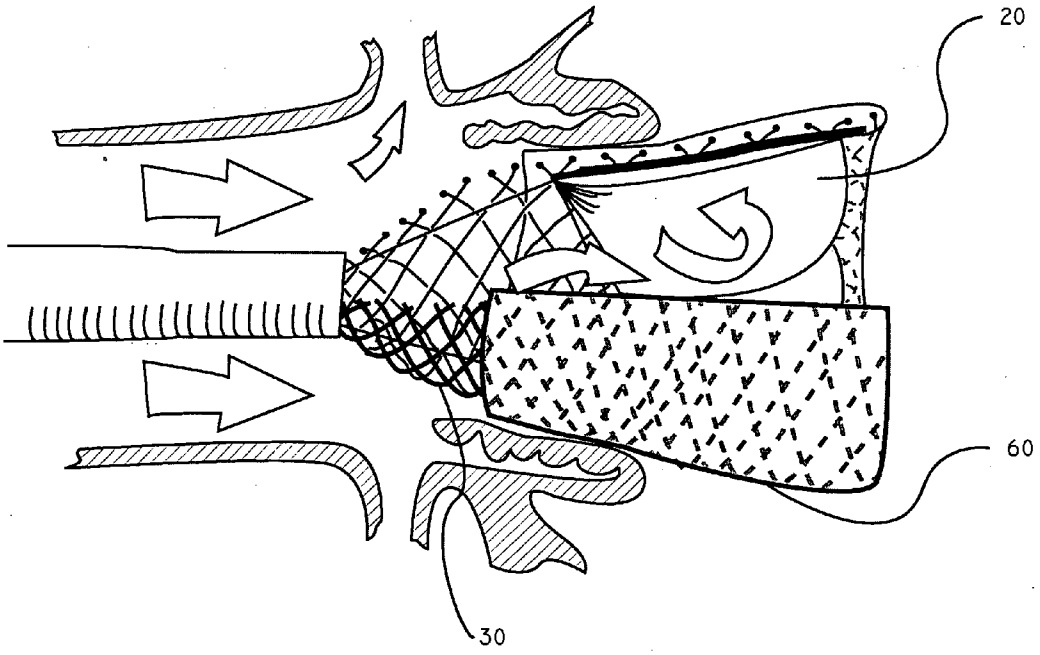


FIG 9B

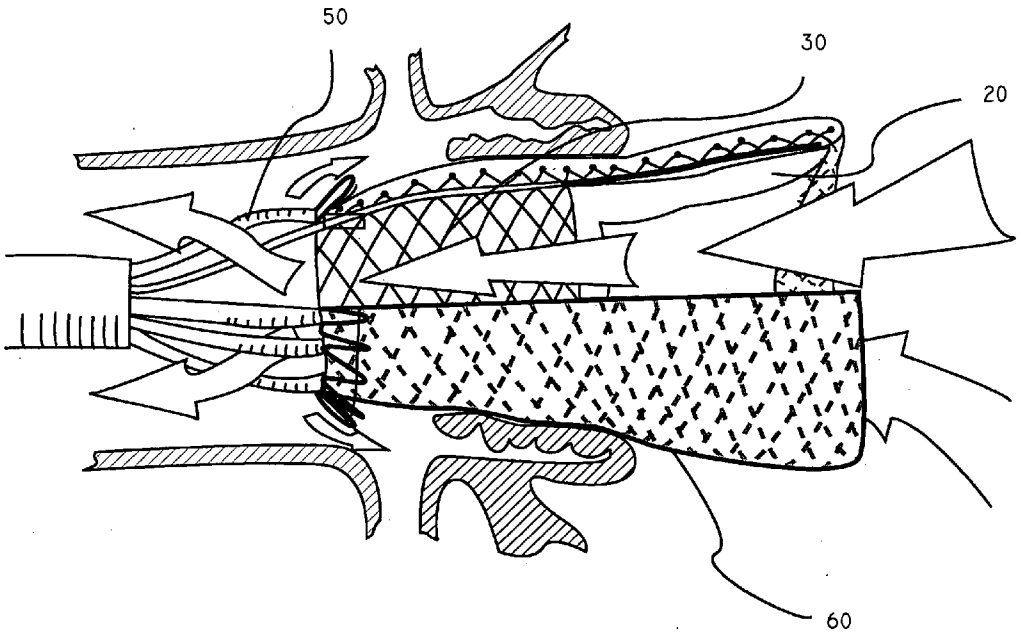


FIG 10A

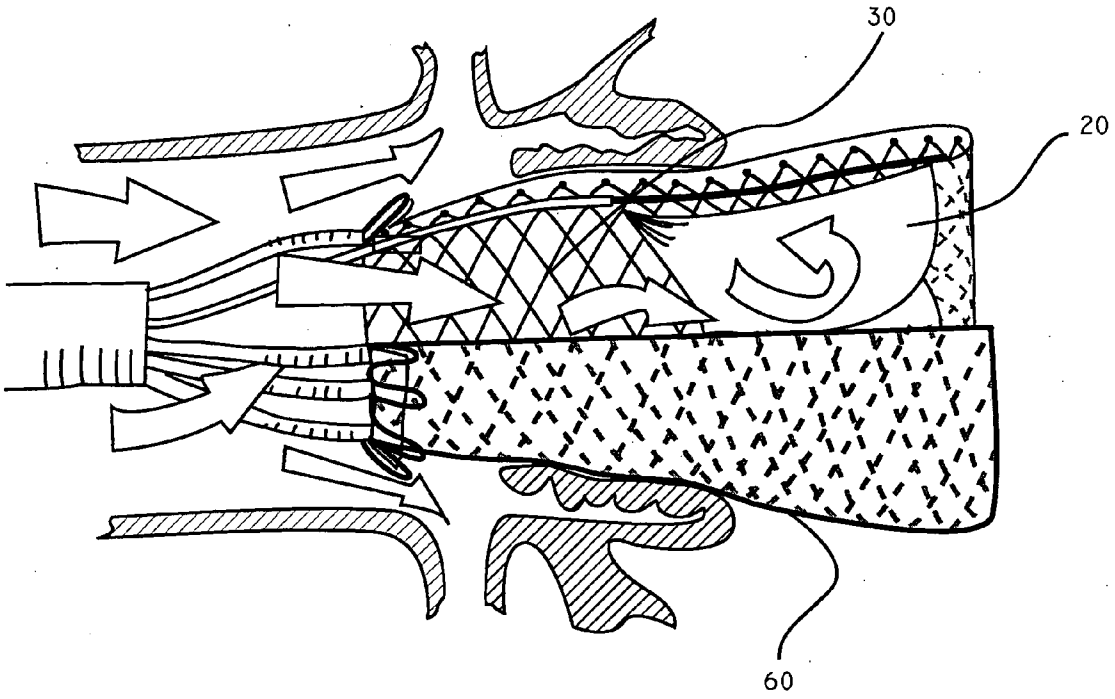


FIG10B

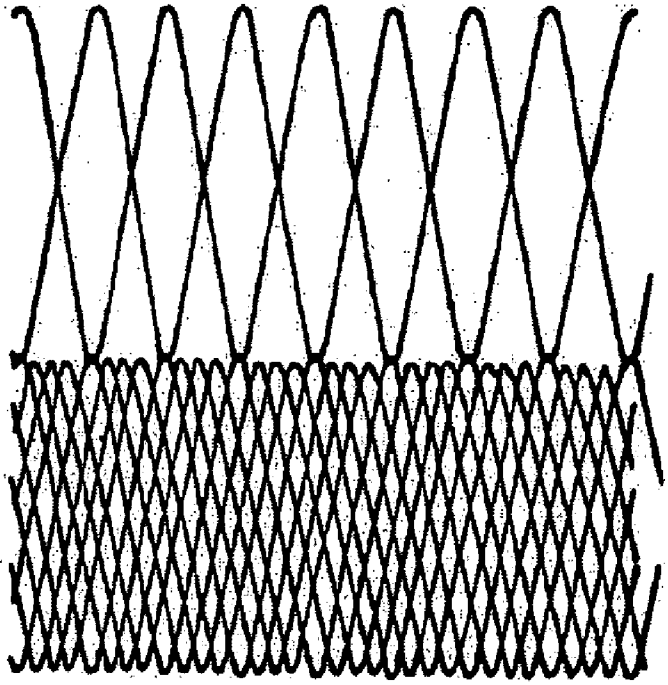


FIG IIA

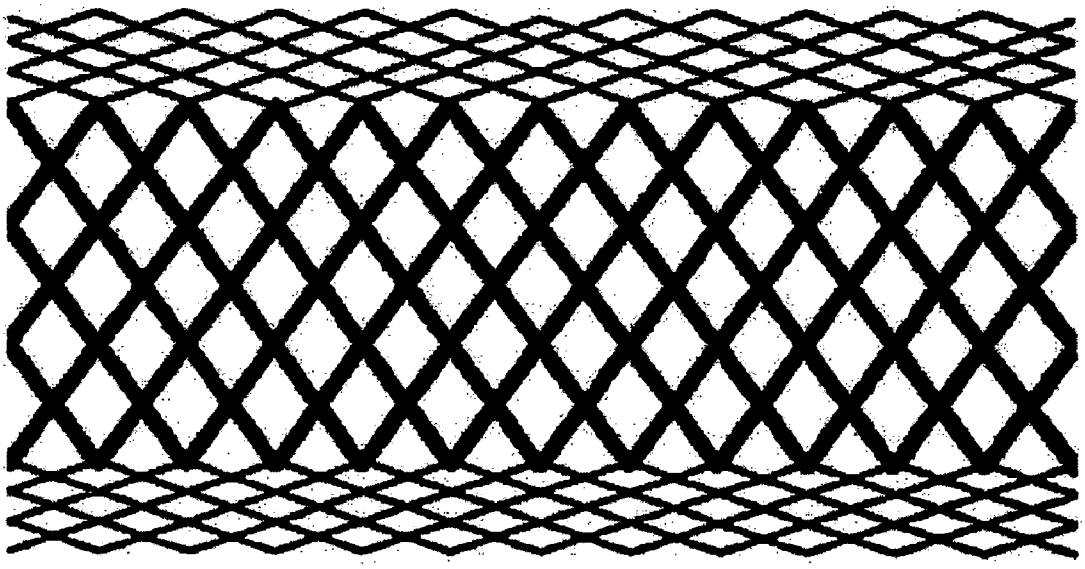


FIG IIB

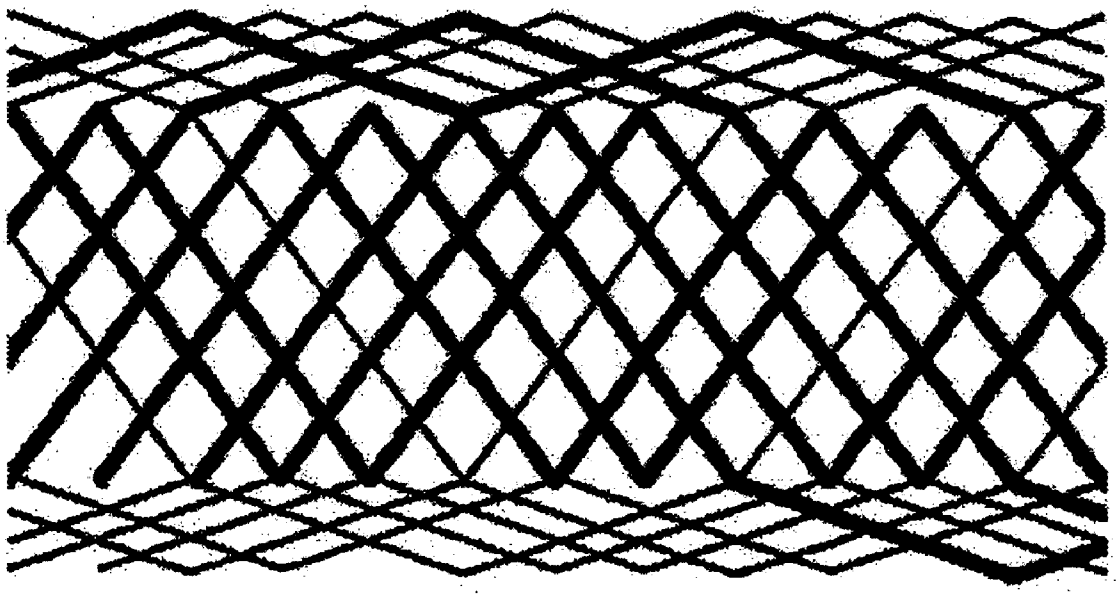


FIG IIC

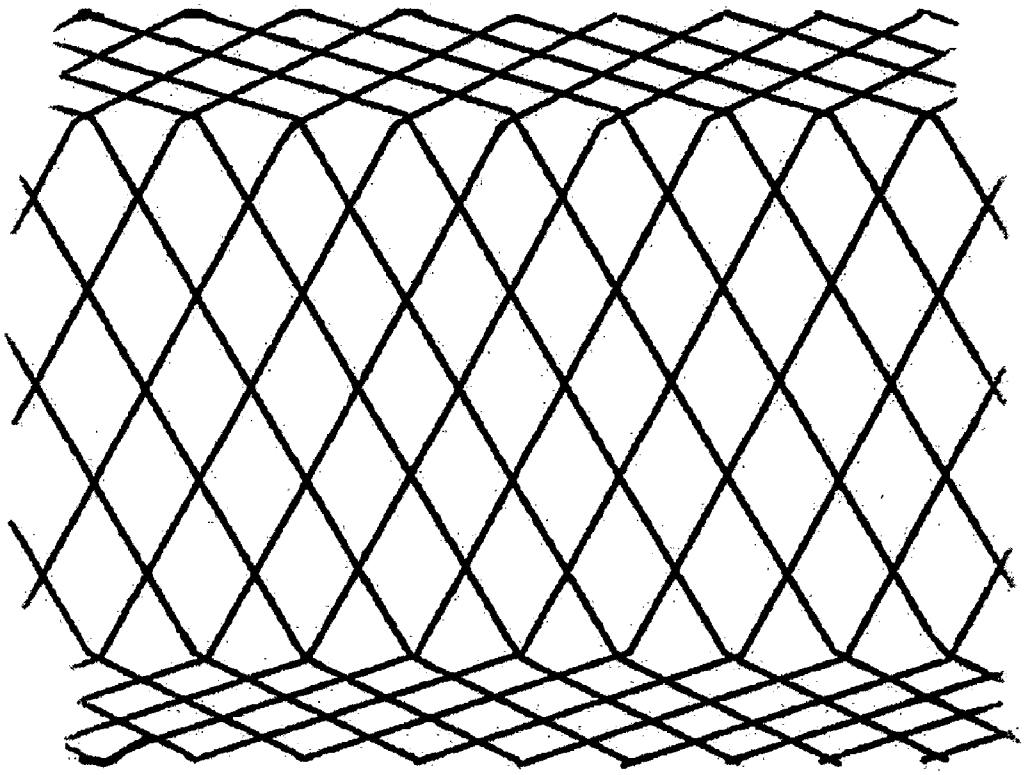


FIG IID

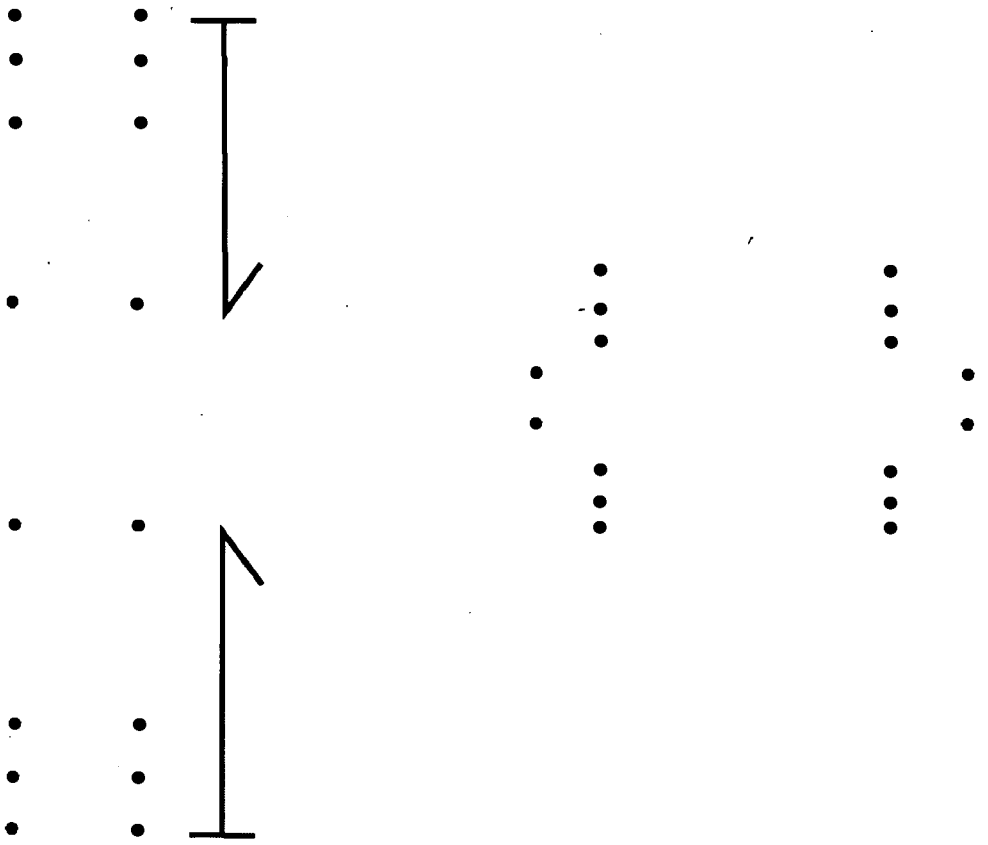


FIG 12A



FIG 12B

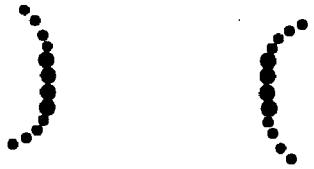


FIG 12C



FIG 12D



FIG 12E

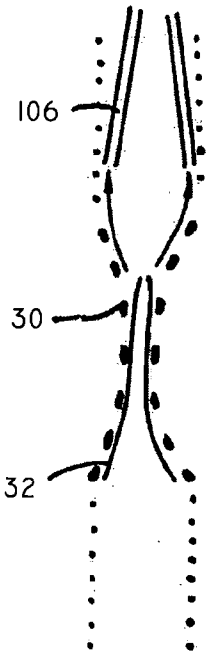


FIG 13A

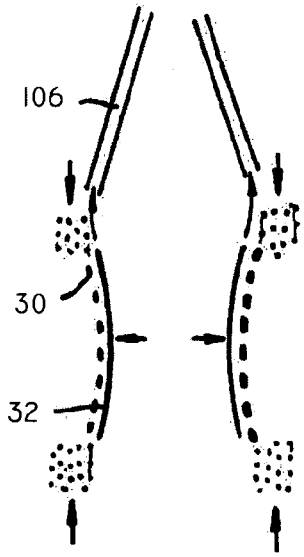


FIG 13B

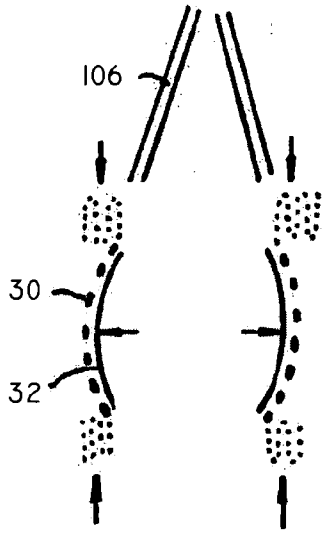


FIG 13C



FIG 13D

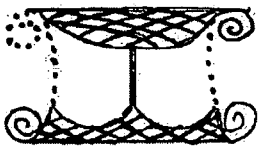


FIG 13E

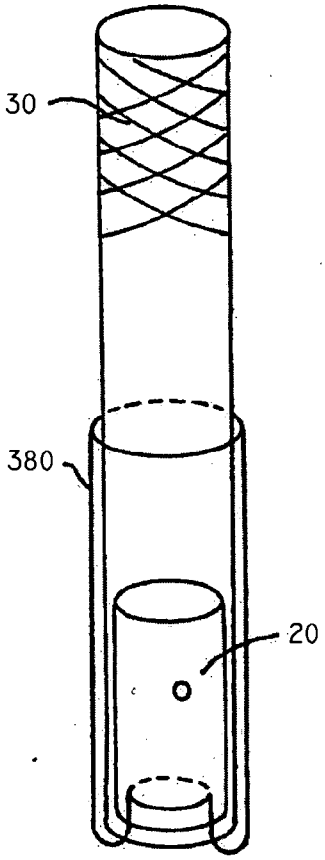


FIG 14A

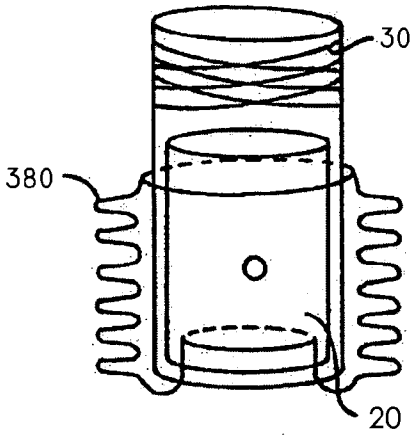


FIG 14B

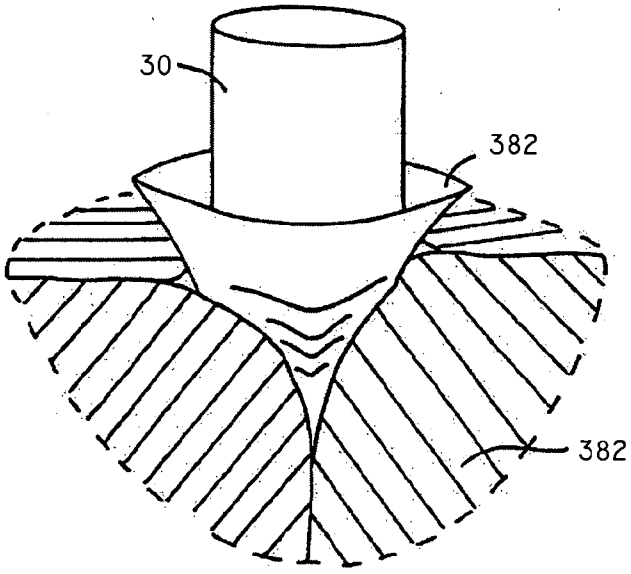


FIG 14C

LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

CROSS-REFERENCE

[0001] This application is a continuation-in-part application of application Ser. No. 10/746,240, filed Dec. 23, 2003, which is incorporated herein by reference in its entirety and to which application we claim priority under 35 USC § 120.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for endovascularly replacing a heart valve with a replacement valve using an expandable and retrievable anchor.

[0003] Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

[0004] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

[0005] Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. 2-5% of patients die during surgery.

[0006] Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

[0007] In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. However, the current devices suffer from several drawbacks.

[0008] First, many of the devices available today can become mispositioned with respect to the native valve. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

[0009] Moreover, some stent/valve devices simply crush the native valve leaflets against the heart wall and do not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation.

[0010] Another drawback of the devices known today is that during implantation they may still require the patient to be on life support as the valve does not function for a portion of the procedure. This further complicates the implantation procedure.

[0011] Furtherstill, the stent comprises openings or gaps, thereby increasing a risk of improper seating of the valve within the stent and increasing the risk of paravalvular leaks. The interface between the stent and the native valve may additionally comprise gaps which again would increase the risks of paravalvular leaks.

[0012] In view of drawbacks associated with previously known techniques for endovascularly replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

SUMMARY OF THE INVENTION

[0013] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable anchor further includes a leaflet engagement element on its proximal end to engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

[0014] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its

deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

INCORPORATION BY REFERENCE

[0015] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0017] **FIGS. 1A and 1B** are schematic views of an anchor and valve apparatus in accordance with the present invention. **FIG. 1A** illustrates the apparatus in a collapsed delivery configuration within a delivery system. **FIG. 1B** illustrates the apparatus in an expanded configuration partially deployed from the delivery system.

[0018] **FIG. 2** illustrates an anchor of **FIG. 1** in the collapsed delivery configuration with locking elements separated.

[0019] **FIG. 3** illustrates a braided anchor of the present invention with closed end turns Tu.

[0020] **FIGS. 4A-4O** are schematic detail views illustrating end turns for a braided anchor.

[0021] **FIGS. 5A-5E** illustrate additional features for end turns of a braided anchor.

[0022] **FIGS. 6A-6F** illustrate deployment of an anchor with leaflet engagement elements on the deployment system.

[0023] **FIG. 7** illustrates a deployed anchor with leaflet engagement elements on the proximal end of the anchor.

[0024] **FIGS. 8A-8C** illustrate deployment of an anchor with anchor registration elements and a seal.

[0025] **FIGS. 9A-9B** illustrate an embodiment of the apparatus with a seal that does not reach the proximal end of the anchor during both systole and diastole.

[0026] **FIGS. 10A-10B** illustrate an embodiment of the apparatus with a seal that reaches the proximal end of the anchor during both systole and diastole.

[0027] **FIGS. 11A-11D** are schematic side views of various braided anchor configurations.

[0028] **FIGS. 12A-12E** are schematic side views of a deployment process for an anchor braid.

[0029] **FIGS. 13A-13E** are schematic views of different weave configurations for an anchor braid.

[0030] **FIGS. 14A-14C** illustrate an embodiment of a replacement heart valve and anchor in the undeployed and deployed configurations.

DETAILED DESCRIPTION OF THE INVENTION

[0031] The present invention relates to an apparatus and methods for endovascularly delivering and deploying an aortic prosthesis within a patient's native heart valve, referred to here out as "replacing" a patient's heart valve. The delivery system includes a sheath assembly, a multi-lumen shaft, and a guide wire for placing the apparatus endovascularly within a patient and a user control allowing manipulation of the aortic prosthesis. The apparatus includes an anchor and a replacement valve. The anchor and the replacement valve are adapted for percutaneous delivery and deployment within a patient's heart valve. In preferred embodiments, the anchor includes a leaflet engagement element and/or a seal inverting element situated on its proximal end. The leaflet engagement element is adapted for engaging the native leaflets of the patient's heart, or more preferably the proximal edge and/or the commissural attachments of the native leaflets. The leaflet engagement element need not extend all the way into the pocket or the distal end of the native leaflet. Preferred embodiments of the apparatus herein are depicted in **FIGS. 1-14**, which are discussed in more detail below.

[0032] **FIGS. 1A and 1B** illustrate one embodiment of a delivery system and the apparatus of the present invention.

[0033] As illustrated by **FIG. 1A**, apparatus **10** may be collapsed for delivery within a delivery system **100**. Delivery system **100** includes a guidewire **102**, a nosecone **104**, anchor actuation elements **106** (in this case fingers) coupled to a multi-lumen shaft **108**, an external sheath **110** having a proximal handle **111**, and a control handle **120**. Delivery system **100** further comprises distal region control elements (not shown), comprised of or actuated by control wires **112**, which pass through one or more lumens of shaft **108** and are reversibly coupled to posts **32** of anchor **30** for manipulating a distal region of apparatus **10**. Thus, the distal region control elements may function as a distal actuation element.

[0034] The delivery system also comprises proximal region control elements comprised of or actuated by control wires **112** that pass through one or more lumens of shaft **108** and anchor actuation elements **106** to reversibly couple the control tubes to a proximal region of anchor **30**. The control wires may comprise, for example, strands of suture, or metal or polymer wires. Control handle **120** is coupled to multi-lumen shaft **108**. In some embodiments, these fingers and wires may be referred to as proximal actuation elements. A knob **122** disposed in slot **123** is coupled to the distal region control wires for controlling movement of the distal region of apparatus **10**. Likewise, a knob **124** disposed in slot **125** is coupled to proximal region control wires **112** for control of the proximal region of apparatus **10**. Handle **120** may also have a knob **126** for, e.g., decoupling the proximal and/or distal region control wires from apparatus **10**, or for performing other control functions.

[0035] As illustrated by **FIG. 1B**, apparatus **10** comprises an anchor **30** and a replacement valve **20**. Anchor **30** preferably comprises a braid. Such braid can have closed ends at either or both of its ends but preferably at least in its

proximal end. Replacement valve **20** is preferably coupled to the anchor at posts **32** attached at distal region of the anchor. Post **32** therefore, may function as valve support and may be adapted to support the replacement valve within the anchor. In the embodiment shown, there are three posts, corresponding to the valve's three commissure attachments. The posts can be attached to braid portion of anchor **30**. The posts can be attached to the braid's distal end, as shown in **FIG. 2**, central region, or proximal end. Replacement valve **20** can be composed of a metal, a synthetic material and/or may be derived from animal tissue. Replacement valve **20** is preferably configured to be secured within anchor **30**.

[**0036**] In preferred embodiments, anchor **30** is collapsible and/or expandable and is formed from material such as Nitinol™, cobalt-chromium steel or stainless steel wire. More preferably, an anchor **30** is self-collapsing and/or self-expanding and is made out of shape memory material, such as Nitinol™. An anchor composed of shape memory material may self-expand to or toward its "at-rest" configuration. This "at rest" configuration of an anchor can be, for example its expanded configuration, its collapsed configuration, or a partially expanded configuration (between the collapsed configuration and the expanded configuration). In preferred embodiments, an anchor's at-rest configuration is between its collapsed configuration and its expanded configuration. Depending on the "at rest" diameter of the anchor and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

[**0037**] Anchor **30** may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor **30** during endovascular deployment. Active foreshortening is described in more detail in U.S. patent application Ser. No. 10/746,280, which is incorporated herein by reference in its entirety. During active foreshortening, the distal region of anchor **30** may be pulled proximally via a proximally directed force applied to posts **32** via a distal deployment system interface comprised of the distal system control elements. The distal deployment system interface is adapted to expand radially during application of a proximally directed force on the distal end of the anchor when opposed by a distally directed force applied to the proximal end of the anchor.

[**0038**] In some embodiments, actuating foreshortening of the apparatus involves applying a proximally directed force on a deployment system interface at the distal end of the anchor, while maintaining the proximal end of the anchor in the same location. In other embodiments, foreshortening of the apparatus involves applying a distally directed force on proximal end of the anchor (e.g., by applying a distally directed force on the anchor actuation elements).

[**0039**] Anchor actuation elements **106** (e.g., fingers, tubes, posts, and control wires connecting to posts) are preferably adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

[**0040**] The distal deployment system interface may include control wires that are controlled, e.g., by control knob **122** of control handle **120**. Similarly, the proximal regions of anchor **30** may be pushed distally via a proximal deployment system interface at the proximal end of the anchor. The proximal deployment system interface is adapted to permit deployment system to apply a distally directed force to the proximal end of anchor **30** through, e.g., fingers, which are controlled by, e.g., control knob **124** of control handle **120**. The proximal deployment system interface may be further adapted to expand radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal deployment system interface is adapted to permit deployment system to apply a distally directed force on the proximal end of the anchor system through a plurality of deployment system fingers or tubes **160**. Such expansion optionally may be assisted via inflation of a balloon catheter (not shown) reversibly disposed within apparatus **10**, as described in U.S. patent application Ser. No. 10/746,280.

[**0041**] Once anchor **30** is fully deployed, posts **32** and buckles **34** of anchor **30** may be used to lock and maintain the anchor in the deployed configuration. In one embodiment, the control wires attached to posts **32** are threaded through buckles **34** so that the proximally directed force exerted on posts **32** by the control wires during deployment pulls the proximal locking end of posts **32** toward and through buckles **34**. Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus **10** during or post-deployment. Apparatus **10** may be repositioned or retrieved from the patient until the two-part locking mechanism of posts **32** and buckles **34** of anchor **30** have been actuated. When the lock is selectively reversible, the apparatus may be repositioned and/or retrieved as desired, e.g., even after actuation of the two-part locking mechanism. Once again, further details of this and other anchor locking structures may be found in U.S. patent application Ser. No. 10/746,280. Locking mechanisms used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion. **FIG. 2** illustrates a braided anchor of **FIG. 1** in the collapsed delivery configuration with locking elements separated.

[**0042**] **FIG. 3** provides a detail view of a front side region of anchor braid **30** with closed end turns Tu. Anchor braid **30** includes various cells, some having an end turn (Tu). End turns can serve various functions. For example, end turns can be configured to reduce the sheathing force, to reduce stress within the braid during delivery and deployment, to prevent distal migration during expansion of the anchor, and/or to positively register the anchor against the native valve during deployment. In preferred embodiments, an end turn feature functions to prevent distal migration and to

register the anchor by engaging the native leaflets. In preferred embodiments, the proximal end of an anchor comprises embodiments (Tu).

[0043] **FIGS. 4A-4N** provide multiple examples of edge cells having end turn feature. The end turn features disclosed and others known in the art may be used as leaflet engagement elements to engage the native heart leaflets with the anchor. The leaflet engagement elements are preferably integral with the anchor, or more preferably part of a braided anchor. The end turn features can occur at the proximal end, the distal end, or both proximal and distal ends of the anchor.

[0044] For example, **FIG. 4A** illustrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape.

[0045] **FIG. 4B** illustrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts and then heat setting the wire.

[0046] **FIG. 4C** illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn may be bent out of a cylindrical shape defined by the braid of anchor braid **30**. This may be achieved, for example, via a combination of routing of wire W within a fixture and then heat setting. Such a turn Tu in the anchor edge cells in **FIG. 4C** may reduce stress in some configurations without increasing height, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus **10** during deployment.

[0047] In **FIG. 4D**, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid **30** about a central inner post and two flanking outer posts. As with the elongated braid cells of **FIGS. 4B and 4C**, the W-shape may better distribute stress about turn Tu.

[0048] The anchor edge cell configuration in **FIG. 4E** includes a loop formed in braid **30** at the turn, which may be formed by looping wire W around an inner or outer post.

[0049] **FIG. 4F** provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post and an aligned outer post in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0050] In **FIG. 4G**, the edge cells of braid **30** include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post in the desired manner.

[0051] In **FIG. 4H**, the edge cells of braid **30** have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid **30** during expansion and collapse of the braid, in addition to affecting stress concentration.

[0052] In **FIG. 4I**, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts. Additional loops may also be employed.

[0053] The double loop turn feature may be formed with a smooth transition between the loops, as in **FIG. 4I**, or may be heat set with a more discontinuous shape, as in **FIG. 4J**.

[0054] **FIG. 4K** illustrates that the edge cells of braid **30** may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in **FIG. 4K** have extended length cells as in **FIG. 4B** disposed adjacent to standard size edge cells, as in **FIG. 4A**.

[0055] The anchor edge cells of **FIG. 4L** have an extended turn configuration having an extended loop.

[0056] The anchor edge cells shown in **FIG. 4M** have an alternative extended configuration with a specified heat set profile.

[0057] In **FIG. 4N**, some or all anchor edge cells are interwoven. When interwoven, one or more edge cells may be shorter or longer than an adjacent edge cell. This permits one or more edge cells to extend into one or more leaflet pocket(s). For example, in **FIG. 4N** the middle Tu may be taller than the two adjacent edge cells thus permitting the edge cell to be situated within a leaflet pocket.

[0058] In any of the embodiments herein, edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in **FIG. 4O**. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0059] The anchor and any of its features may be heat set at different configurations. For example, the anchor may be heat set ay its "at rest" configuration such that upon unsheathing it expands radially. The end turn features/leaflet engagement elements may be heat set at a different "at rest" configuration than the rest of the anchor. In preferred embodiment, end turn features are heat set to "flower" and then "evert" upon unsheathing.

[0060] The end turn features of **FIG. 4** are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of **FIG. 4**. Furthermore, combinations of any such end turn features may be provided to achieve the desired characteristics of anchor **30**.

[0061] Referring now to FIGS. **5**A-E, additional configurations for reducing stress concentration and/or circumferential stiffness of an anchor braid and/or leaflet engagement elements are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in **FIGS. 5A and 5B**, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in **FIG. 5C**, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid **30** from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

[0062] In any of the embodiments herein, localized reduction of an anchor wire may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized.

Additional processing techniques will be apparent to those of skill in the art. As seen in **FIGS. 5D-5E**, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

[0063] With reference now to FIGS. **6**A-F, a method of endovascularly replacing a patient's diseased aortic valve is provided. The method involves endovascularly delivering an anchor/valve apparatus and properly positioning such apparatus via positive registration with the patient's native valve leaflets. Registration with the native valve leaflet preferably occurs using the leaflet engagement elements.

[0064] In **FIG. 6A**, modified delivery system **100'** delivers apparatus **10** to diseased aortic valve AV within sheath **110**. Apparatus **10** is delivered in a collapsed delivery configuration.

[0065] As seen in **FIGS. 6B and 6C**, apparatus **10** is deployed from lumen **112** of sheath **110**, for example, under fluoroscopic guidance. Sheath **110** includes at its distal end leaflet engagement elements **120**. Upon deployment, anchor **30** of apparatus **10** dynamically self-expands to a partially deployed configuration. This causes tubes **60** to also dynamically expand, as well as membrane filter (or braid) **61**A and leaflet engagement elements **120**. As when deployed via delivery system **100**, deployment of apparatus **10** via delivery system **100'** is fully reversible until locks **40** have been actuated.

[0066] Thus, delivery system **100'** comprises leaflet engagement element **120**, which preferably self-expands along with anchor **30**. In preferred embodiments, the distal end of leaflet engagement elements **120** expands a greater radial distance than anchor **30**. Moreover, engagement elements **120** may be disposed between tubes **60** of delivery system **100'** and lip region **32** of anchor **30**. However, leaflet engagement elements **120** may also be disposed on the proximal end of an anchor (as is illustrated in **FIG. 7**). Leaflet engagement elements **120** releasably engage the anchor. As seen in **FIG. 6C**, the leaflet engagement elements **120** are initially deployed proximal of the patient's native valve leaflets L. Apparatus **10** and element **120** then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus **10**. The leaflet engagement element engages with the proximal edges of the native valve leaflets and/or the commissural attachments. The leaflet engagement element need not extend all the way to the distal edge of the native leaflets (the leaflet pockets). In preferred embodiments, a leaflet engagement element length is less than about 20 mm, more preferably less than about 15 mm, or more preferably less than about 10 mm. Once leaflet engagement element **120** is registered against the native valve leaflets and/or commissural attachments, apparatus **10** deploys substantially distal to the coronary ostia of the heart.

[0067] In any of the embodiments herein, delivery system **100'** can include filter structure **61**A (e.g., filter membrane or braid) as part of push tubes **60** to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage. Arrows **61**B in **FIG. 6C** show blood flow through filter structure **61**A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[0068] Active foreshortening may be imposed upon anchor **30** while element **120** is disposed proximal of the leaflets, as is illustrated in **FIG. 6D**. Active foreshortening can be accomplished by actuating distal anchor actuation elements (e.g., wires **50**) and/or proximal anchor actuation elements (e.g., tubes **60**). Upon positive registration of element **120** against leaflets L, element **120** precludes further distal migration of apparatus **10** during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. **FIG. 6E** details engagement of element **120** against the native leaflets.

[0069] As seen in **FIG. 6F**, once apparatus **10** is fully deployed, anchor **30** may be locked (reversibly or irreversibly). Subsequently, structure **61**A leaflet engagement, elements **120**, wires **50** and/or tubes **60** may be decoupled from the apparatus, and delivery system **100'** may be removed from the patient, thereby completing the procedure.

[0070] **FIG. 7** illustrates an alternative embodiment of the apparatus of FIGS. **6**A-F described above, wherein leaflet engagement elements **120** are coupled to anchor **30** of apparatus **10'** rather than to delivery system **100**. In the embodiment illustrated in **FIG. 7**, leaflet engagement elements **120** remain implanted near the patient's native heart valve after the deployment of apparatus **10'** and removal of delivery system **100**. Leaflets L may be sandwiched between the proximal region of anchor **30** and leaflet engagement element **120** in the fully deployed configuration. In this manner, element **120** positively registers apparatus **10'** relative to the leaflets L and precludes distal migration of the apparatus over time.

[0071] **FIGS. 8A-8C** illustrate another embodiment for endovascularly delivering an apparatus of the present invention. In **FIG. 8A**, a catheter **600** is delivered percutaneously in a retrograde fashion to the aortic valve. The catheter passes through the native aortic valve before an operator actuates the unseathing of the anchor/valve apparatus. As the sheathing catheter is pulled proximally out of the native valve, anchor **30** and replacement valve **20** become unsheathed. Immediately the portion of the unsheathed anchor **30** dynamically self-expands to its "at rest" position, and replacement valve **20** within the anchor regains an uncollapsed structure, allowing it to begin to function. In preferred embodiments in its "at rest" position, anchor **30** presses against the native leaflets limiting blood from flowing in between the anchor and leaflet. Also, in preferred embodiments, anchor **30** portions relatively adjacent to the valve is externally covered by a seal **60**, more preferably the entire exterior contour of anchor **30** excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor **30** including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric. The seal can

be attached by any means known in the art to the anchor and, in some embodiments, to the distal end of the valve. In preferred embodiments, a seal is attached to the anchor by suturing.

[0072] In **FIG. 8B**, as the catheter is further pulled proximally, the proximal end of anchor **30** and fingers **50** are unsheathed. In this embodiment, it is possible to visualize that the seal covers the entire contour of the anchor including the external face of the leaflet engagement element **70**. As soon as the proximal end of the anchor is exposed, it also dynamically expands. Furthermore, when fingers **50** become exposed, replacement valve **20** begins to function permitting blood to flow through replacement valve **20**, between fingers **50**, and around the catheter **600**. This also permits blood to flow into the coronary ostias. In other embodiments where the seal does not cover the proximal end of the anchor, the replacement valve can begin to function as soon as the unsealed portion of the anchor is unsheathed. This causes the leaflet engagement elements **70** to radially expand to their heat set position and engage with the native heart leaflets.

[0073] Next, **FIG. 8C**, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., wires **55**), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal **60** to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently withdrawn, leaving behind valve **20**, seal **60** and anchor **70**. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

[0074] **FIGS. 9A-9B** illustrate an embodiment wherein only a distal portion anchor **30** is covered by seal **60** and wherein anchor **30** is only partially deployed since the blood can escape through the proximal end of the anchor braid. As anchor **30** in this embodiment is unsheathed, it presses against the native valve leaflets. At this point replacement valve **20** is functional even though anchor **30** is not fully deployed since blood can escape through the proximal end of the anchor braid. This allows blood to flow through replacement valve **20** and out of holes in the distal end of anchor **30** during systole (**FIG. 9A**) while preventing backflow during diastole (**FIG. 9B**).

[0075] **FIGS. 10A-10B** illustrate a similar embodiment wherein seal **60** around anchor **30** surrounds the entire contour of anchor **30**. In this embodiment, valve **20** does not become functional until both anchor **30** and a portion of fingers **50** are unsheathed. As soon as a portion of fingers **50** is unsheathed, replacement valve **20** is fully functional. This allows blood to flow through replacement valve **20** and anchor **30**, out of fingers **50**, and around catheter **60** into the aorta and coronary ostias during systole. Similarly, during diastole, replacement valve **20** closes preventing blood backflow from entering the chamber.

[0076] In any of the embodiments herein the anchor is preferably a self-expanding anchor braid. Anchor braid of the present invention can be made from one or more wires, more preferably 2-20 wires, more preferably 3-15 wires, or more preferably 4-10 wires. Moreover, the density of the braid can be modified by various forms of weave used.

[0077] **FIGS. 11A-11D** illustrate various anchor braid embodiments contemplated by the present invention.

[0078] **FIG. 11A** illustrates two groups of cells or two braids interwoven in the center. The top group of cells forms a more open weave than the bottom group of cells, which forms a denser weave.

[0079] **FIG. 11B** illustrates another embodiment of an anchor braid having three groups of cells. The top and bottom (proximal and distal) edges of the anchor braid have denser cells than the central portion of the anchor. Also, the edges of the anchor are woven from a thinner filament than the central portion.

[0080] In another embodiment illustrated by **FIG. 11C**, all three sections of an anchor valve are woven by more than one wire. The wires of each section are made of a different material and/or thickness. Wires at the sectional boundaries may or may not interconnect with wires from a different section. Each of the sections of the braid anchor may be composed of a different number of wires.

[0081] **FIG. 11D** illustrates another embodiment of a braided anchor having three sections. In this embodiment, all sections are composed of a single wire. The proximal and distal sections/edges of the braided anchor have the same pitch. The central region of the braided anchor has a different pitch than the edge sections.

[0082] **FIGS. 12A-12E** illustrate side views of braided anchor having more than one braid pitch. Varying pitch within the anchor allows localized variations in foreshortening across the anchor, as greater foreshortening is achieved by higher pitch of the braid. Moreover, the localized foreshortening features allow for the design of a braid which incorporates various diameters depending upon the amount of foreshortening. (The greater the foreshortening, the greater the diameter increase upon deployment.)

[0083] **FIG. 12A**, is a side view representation of the braided anchor of **FIG. 11D**. On the left side of the figure, the expanded anchor is illustrated having a denser weave (shorter pitch) at the distal and proximal ends; hence the dots are located closer to each other. The middle section of the anchor is composed of a looser weave that is generated by a higher pitch braid and is represented by dots that are farther away from each other. On the right side of the figure, the braided anchor is foreshortened and the dots are collapsed closer to each other. In this case, the central portion of the anchor foreshortened more than the proximal and distal edges.

[0084] **FIG. 12B** illustrates a side view of a foreshortened braided anchor that is created by low pitch at the edges and high pitch in the middle.

[0085] **FIG. 12C** illustrates a side view of a foreshortened braided anchor that is created by high pitch edges and low pitch middle section.

[0086] **FIG. 12D** illustrates a side view of a foreshortened braided anchor that includes a sealing feature or space filling feature at both ends. This type of anchor can be created by

a high pitch braid at edges, low pitch braid in the middle and heat setting the edges to curl upon unsheathing. These end features can be useful in facilitating anchoring by functioning as a locator and/or sealing. In preferred embodiment the curled ends of the anchor in **FIG. 12D** can be used as leaflet engagement elements.

[**0087**] **FIG. 12E** illustrates a side view of a foreshortened braided anchor that is associated with an everting valve or locational features. In preferred embodiments, the middle section of the anchor may be composed of thicker wire(s) than edge section(s). The everting feature at the proximal end can function as a leaflet engagement element as disclosed herein.

[**0088**] **FIGS. 13A-13E** illustrate an example of the process of deploying an anchor, such as the one illustrated in **FIG. 12B** above.

[**0089**] **FIG. 13A** illustrates a braided anchor **30** in its expanded or elongated configuration. The anchor is composed of three sections. The distal and proximal sections of the anchor are made of a fine weave, low pitch braid and the middle section of the anchor is made of a thicker thread and higher pitch braid. The distal and proximal section are preferably heat set to roll upon unsheathing, though some rolling may occur simply from active for shortening of the fine weave braid. In preferred embodiments, the filaments of the fine weave braid are less than 0.01 cm, or more preferably less than 0.005 cm in thickness. On the other hand, thicker filaments of the middle section are preferably 0.01 cm or greater in thickness or more preferably 0.015 cm or greater in thickness. Posts **32** are coupled to the middle section of the anchor. For deployment, tubes (or fingers) **106** are coupled to the anchor's middle section.

[**0090**] **FIG. 13B** illustrates an anchor during the process of deployment after the anchor is unsheathed. The anchor is pushed distally by tubes and pulled proximally by wires and begins foreshortening. In some embodiment the distal section rolls up and can act as a locator, assisting the operator in locating the aortic valve, or as a seal preventing leakage. In some embodiments, the proximal section may roll down and be used as a leaflet engagement element to prevent distal migration or as a proximal seal.

[**0091**] In **FIG. 13C**, the device may be configured such that the middle section of the valve may form an hour glass shape or a round shape. The tubes may subsequently be removed as described before.

[**0092**] **FIG. 13D** is another illustration of the braided anchor in its elongated configuration.

[**0093**] **FIG. 13E** is another illustration of the braided anchor in its foreshortened configuration.

[**0094**] **FIGS. 14A-14C** illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. **FIG. 14A** illustrates a fabric seal **380** prior to deployment and foreshortening of the anchor/valve apparatus. In **FIG. 14A**, the fabric seal **380** extends from the distal end of valve **20** proximally over anchor **30** during delivery. During deployment, as illustrated in **FIG. 14B**, anchor **30** foreshortens and the fabric seal **380** bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets **382**. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement valve. **FIG. 14C** illustrates anchor **30**, surrounded by fabric seal **380** in between native valve leaflets **382**. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is fully deployed.

What is claimed is:

1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage leaflets of the patient's heart valve.

2. The apparatus of claim 1 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

3. The apparatus of claim 1 wherein the anchor is further adapted to be actively foreshortened during deployment.

4. The apparatus of claim 3 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

5. The apparatus of claim 3 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

6. The apparatus of claim 3 further comprising a lock adapted to lock the anchor in a deployed shape.

7. The apparatus of claim 1 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

8. The apparatus of claim 1 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

9. The apparatus of claim 1 wherein the leaflet engagement elements are integral with the anchor.

10. The apparatus of claim 9 wherein the anchor comprises a braid, the leaflet engagement elements being part of the braid.

11. The apparatus of claim 1 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow to the chamber of the heart through the replacement valve during deployment of the anchor and replacement valve.

12. The apparatus of claim 1 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

13. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter but before the anchor completely exits the catheter.

14. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor.

15. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration,

the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

16. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

17. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

18. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

19. The apparatus of claim 1 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

20. The apparatus of claim 19 wherein the seal comprises a pleated seal.

21. The apparatus of claim 19 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

22. A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native valve leaflets;

expanding the anchor; and

engaging the leaflet engagement elements with native valve leaflets.

23. The method of claim 22 further comprising expanding the anchor into engagement with the patient's heart such that the anchor is substantially distal to coronary ostia of the heart.

24. The method of claim 23 wherein the expanding step comprises actively foreshortening the anchor.

25. The method of claim 24 wherein the actively foreshortening step comprises actuating distal anchor actuation elements.

26. The method of claim 24 wherein the actively foreshortening step comprises actuating proximal anchor actuation elements.

27. The method of claim 24 further comprising locking the anchor in a deployed configuration.

28. The method of claim 22 further comprising resisting distal movement of the proximal end of the anchor after the engaging step.

29. The method of claim 22 further comprising moving the leaflet engagement elements further apart radially during the anchor expanding step.

30. The method of claim 22 further comprising permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve during deployment of the anchor and replacement valve.

31. The method of claim 22 further comprising:

delivering the anchor and replacement valve to a vicinity of the heart in a delivery catheter;

removing the anchor and the replacement valve from the catheter; and

permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

32. The method of claim 31 wherein the permitting and preventing steps are performed before the anchor completely exits the catheter.

33. The method of claim 31 wherein the permitting step comprises allowing the anchor to self-expand.

34. The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

35. The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

36. The method of claim 22 further comprising sealing between the replacement valve and the heart.

37. The method of claim 36 wherein the sealing step comprises pleating a seal.

38. The method of claim 36 wherein the sealing step comprises capturing at least a portion of a seal between the leaflets and a wall of the heart.

39. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising a braid, the braid comprising leaflet engagement elements adapted to engage leaflets of the patient's heart valve.

40. The apparatus of claim 39 wherein the leaflet engagement elements extend from a proximal end of the anchor.

41. The apparatus of claim 39 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

42. The apparatus of claim 39 wherein the anchor is further adapted to be actively foreshortened during deployment.

43. The apparatus of claim 42 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

44. The apparatus of claim 42 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

45. The apparatus of claim 42 further comprising a lock adapted to lock the anchor in a deployed shape.

46. The apparatus of claim 40 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

47. The apparatus of claim 40 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

48. The apparatus of claim 40 wherein the anchor and the replacement valve are further adapted to permit blood flow

from a chamber of the heart through the replacement valve and to prevent blood flow through the replacement valve during deployment of the anchor and replacement valve.

49. The apparatus of claim 40 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

50. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before the anchor completely exits the catheter.

51. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor.

52. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

53. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

54. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

55. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

56. The apparatus of claim 40 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

57. The apparatus of claim 56 wherein the seal comprises a pleated seal.

58. The apparatus of claim 56 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

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A1

DEMANDE DE BREVET D'INVENTION

(21) **N° 76 36928**

(54) **Valve cardiaque bioprothétique supportée par un cadre souple.**

(51) Classification internationale (Int. Cl.²). **A 61 F 1/22.**

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(71) Déposant : Société dite : AMERICAN HOSPITAL SUPPLY CORPORATION, résidant aux Etats-Unis d'Amérique.

(72) Invention de :

(73) Titulaire : *Idem* (71)

(74) Mandataire : Cabinet Maulvault.

WBH2
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

Les valvules bioprothétiques supportées, c'est-à-dire les greffes valvulaires supportées qui peuvent être soit des hétérogreffes (xénogreffes) soit des homogreffes (allogreffes) sont considérées comme possédant des avantages cliniques importants par rapport aux valvules prothétiques mécaniques non tissulaires. Les rapports établis concernant l'application de valvules hétérogreffes indiquent que les risques de thromboembolie sont plus faibles, que le traitement prolongé par anti-coagulants est réduit au minimum et que le risque d'une défaillance éventuelle de la valvule est progressif, ce qui permet une réopération élective dans des conditions optimales. Voir à cet égard les ouvrages de Carpentier et al "J. Thorac. Cardiovasc. Surg." 68:771 (1974), de "Zuhdi et al", Ann. Thorac Surg." 17:479 (1974) et de Horowitz et al, "J. Thorac. Cardiovasc. Surg." 67:885 (1974).

De façon générale, ces greffes ont été placées sur des montures de support qui forment des anneaux circulaires rigides (voir les brevets des Etats Unis d'Amérique N° 3.570.014, N° 3.755.823 et l'ouvrage de Weldon et al, "J. Surg. Research 6:548 (1966)), même si certains cadres comportent des branches capables de s'infléchir vers l'intérieur dans une mesure limitée, en réduisant par là même les contraintes imposées à ces greffes pendant le fonctionnement de la valvule et en diminuant l'érosion éventuelle des tissus environnants du patient (voir Sugie et al, J. Thorac. Cardiovasc. Surg" 57:455 (1969), Hardy, Human Organ Support and Replacement, 338 et suivantes (Thomas 1971) et le brevet des Etats Unis d'Amérique N° 3.755.823). Malgré des résultats encourageants en ce qui concerne l'utilisation de greffes valvulaires supportées et les avantages très marqués des valvules cardiaques bioprothétiques par rapport aux valvules prothétiques entièrement artificielles, il est encore nécessaire d'améliorer en particulier la durabilité et la fiabilité pendant une longue durée des greffes valvulaires supportées.

La présente invention concerne un cadre perfectionné pour valvules cardiaques bioprothétiques (hétérogreffes ou homogreffes) qui est flexible et en particulier capable de céder dans une

mesure limitée, en réponse aux forces qui tendent à modifier la configuration et la circonférence de l'anneau. Cette flexibilité et cette déformabilité permettent aux valves de se fermer avec un mouvement glissant le long de leurs bords libres qui est semblable à celui qui est observé physiologiquement et elles sont considérées comme importantes pour l'amélioration de la fiabilité des valvules pendant une longue durée.

La conformabilité de la partie délimitant l'orifice de la valvule prothétique est assurée en premier lieu par l'utilisation d'une monture de support flexible constituée essentiellement d'un seul brin de fil métallique flexible préformé. Le cadre en fil métallique est conformé de manière à définir trois supports de commissure faisant saillie axialement et circonférentiellement espacés. Chaque support de commissure présente une configuration généralement en U inversé dont les branches se raccordent à leurs extrémités inférieures espacées avec les parties de liaison curvilignes du cadre en fil métallique qui s'étendent circonférentiellement entre les branches des supports de commissure adjacents. Chaque partie de liaison curviligne peut subir une flexion lui imprimant une courbure plus ou moins prononcée, en permettant ainsi une déformation limitée des éléments du cadre délimitant l'orifice. En outre, chacune des parties de liaison curvilignes peut être déplacée d'une distance faible, mais définie, indépendamment des autres parties. Etant donné que la monture en fil métallique de chaque support de commissure est profilée en U inversé, et que les extrémités inférieures de ses branches sont normalement espacées d'une certaine distance, les parties curvilignes avec lesquelles les extrémités inférieures des branches se raccordent peuvent être sollicitées circonférentiellement de façon à se rapprocher et à s'éloigner en réponse aux forces exercées pendant le fonctionnement du coeur. Il en résulte un cadre flexible qui peut changer de dimensions et de forme dans une mesure limitée pendant le fonctionnement du coeur.

Des éléments rapportés s'étendent entre les supports de commissure circonférentiellement espacés, chacun de ces éléments présentant une bordure supérieure curviligne qui s'élève à ses

extrémités pour épouser le contour des supports de commissure. Les éléments rapportés en question peuvent être réalisés d'une seule pièce et constituer des parties d'une bande de matière plastique perforée flexible circonscrivant le cadre en fil métallique. Un revêtement d'étoffe poreuse entoure le cadre et les éléments rapportés pour constituer un moyen permettant de suturer la valvule et favorisant la croissance des tissus. Une garniture annulaire d'amortissement est également enfermée dans le revêtement externe pour faciliter la coaption, la configuration de cette garniture dépendant de l'application de la valvule en position mitrale, aortique ou tricuspide.

L'invention sera décrite plus en détail en regard des dessins annexés à titre d'exemple nullement limitatif et sur lesquels :-

La fig. 1 est une vue en perspective d'une valvule cardiaque bioprothétique conforme à la présente invention.

La fig. 2 est une vue en perspective montrant la monture en fil métallique de support de la valvule.

La fig. 3 est une vue par-dessus du cadre en fil métallique.

La fig. 4 est une vue en élévation latérale du cadre.

Les fig. 5-7 sont des vues en perspective à échelle réduite mettant en évidence les phases de la fabrication du cadre.

La fig. 8 est une vue en plan à échelle réduite montrant les éléments rapportés mutuellement reliés de la valvule.

La fig. 9 est une coupe verticale à grande échelle d'une valvule aortique bioprothétique complète conforme à l'invention.

La fig. 10 est une coupe à plus grande échelle d'une valvule mitrale conforme à l'invention.

Si l'on examine la fig. 1, on voit que le numéro de référence 10 désigne généralement une valvule bioprothétique destinée à être implantée en position aortique. Le fait que cette valvule soit destinée à remplacer une valvule aortique naturelle ou une valvule mitrale ou tricuspide, dépend principalement des dimensions de la valvule et de la construction de son manchon ou anneau de suturation. En ce qui concerne l'invention, les trois types de valvules présentent les mêmes caractéristiques essen-

tielles et, par conséquent, une valvule aortique a été choisie simplement à titre illustratif.

La valvule 10 comprend un cadre 11 et une greffe valvulaire 12. Par exemple, la greffe est une hétérogreffe conservée d'origine porcine. Toutefois, le cadre peut être utilisé pour supporter des greffes provenant d'autres espèces et peut constituer éventuellement le support d'une homogreffe.

La greffe 12 comporte trois valves 13-15 qui se touchent le long de commissures 15. Le traitement et la conservation de la greffe sont bien connus, comme indiqué dans l'ouvrage de Carpentier et al, "J. Thorac. Cardiovasc. Surg." 68:771 (1974) et les références citées dans le présent mémoire et n'ont pas besoin d'être décrits en détail.

Le cadre 11 consiste essentiellement en une monture 16 en fil métallique flexible qui est recouverte et garnie d'un tissu ou étoffe poreux biologiquement compatible formant des goussets de telle sorte que la valvule complète puisse être suturée à l'intérieur d'un coeur humain et permette la croissance des tissus dans le revêtement d'étoffe. La monture 16 est de configuration généralement annulaire et est constituée essentiellement d'une seule pièce de fil métallique flexible façonnée de manière à définir trois supports de commissure 17 à 19 circonférentiellement espacés. Comme représenté sur la fig. 2, chaque support de commissure est généralement profilé en U inversé et comporte des branches 20 en fil métallique se raccordant en arrondi à leurs extrémités inférieures espacées avec des parties de liaison curvilignes 21. Ces dernières s'étendent circonférentiellement et se raccordent aux branches adjacentes des supports de commissure voisins.

Les extrémités 22 du fil métallique qui constitue la monture sont réunies le long d'une des parties de liaison curvilignes 21 au moyen d'un manchon serti 23. L'emplacement et le mode de liaison sont tous deux importants si l'on veut obtenir une grande durabilité du cadre. On a constaté que la zone médiane d'une partie de liaison curviligne 21 forme une zone de contrainte relativement faible et l'utilisation d'un manchon ou tube d'accouplement serti sur chacune des parties terminales évite les difficultés

dues à la dégradation de la matière et à une défaillance rapide résultant de la fatigue, qu'entraîne un soudage.

Le fil métallique est de section circulaire et, sauf en ce qui concerne le manchon 23, a un diamètre sensiblement uniforme dans toute sa longueur. Chaque support de commissure en U inversé comporte une extrémité supérieure arrondie ou de courbure régulière. De même, les extrémités inférieures des branches 20 des supports de commissure s'incurvent vers l'extérieur pour se raccorder régulièrement en arrondi avec les parties de liaison 21.

La monture en fil métallique peut être en toute matière flexible non corrosive, résistant bien à la fatigue et biologiquement compatible. Une patière particulièrement efficace est l'acier qui est mis sur le marché sous la marque "Elgiloy" par la firme Elgiloy Company, Elgin (Illinois), bien que d'autre aciers ou alliages inoxydables possédant des propriétés semblables puissent être utilisés.

On remarquera que les parties de liaison curvilignes 21 définissent dans l'ensemble le pourtour de l'anneau de la valvule. Etant donné que les parties ou segments de liaison sont interrompus par des supports de commissure 17 à 19 et que les extrémités inférieures de chaque paire de branches 20 sont espacées, la flexion vers l'intérieur des branches (comme le montre la fig. 4) réduit l'écartement des segments de liaison adjacents 21 et diminue donc le périmètre effectif de l'anneau. Ainsi, la monture 16 peut subir une contraction et une expansion limitée lorsque les branches flexibles des supports de commissure subissent une flexion vers l'intérieur et vers l'extérieur.

De plus, les parties ou segments de liaison 21 sont eux-mêmes capables de subir une flexion limitée. Ainsi, en particulier, la courbure de chaque segment curviligne 21 peut augmenter ou diminuer légèrement. Cette flexion permet des changements légers, mais notables, des positions des supports de commissure les uns par rapport aux autres et par rapport à l'axe de la valvule, comme indiqué en traits interrompus sur la fig. 3. De façon générale, la configuration de l'anneau peut être modifiée en réponse aux forces exercées lors de chaque battement du coeur

dans lequel est implantée la valvule bioprothétique. Il en résulte un cadre de valvule capable de subir une déformation limitée, c'est-à-dire qui peut se déployer et se contracter dans une mesure faible mais définie, pendant le fonctionnement du coeur. Cette souplesse est considérée comme importante non seulement pour l'obtention d'une plus grande durabilité ou d'une fiabilité prolongée de l'hétérogreffe ou de l'homogreffe, mais également pour permettre aux valves de se fermer en glissant le long de leurs bords libres, qui est plus semblable au phénomène observé physiologiquement.

La monture en fil métallique est recouverte d'un revêtement poreux rembourré et formant des goussets pour faciliter la fixation, l'invasion des tissus et l'enrobage. Les fig. 5-7 représentent plusieurs phases de la fabrication du cadre final. Un manchon 27 constitué par une étoffe poreuse biologiquement compatible est ajusté autour de la monture en fil métallique et est fixé à celle-ci par des piqûres, comme indiqué sur la fig.5. Des éléments rapportés qui, sous la forme représentée, sont constitués par des parties 25 d'une bande 26 de matière plastique, sont ensuite placés à l'extérieur du manchon 27 entre chacun des supports de commissure 17 à 19. Le manchon est rogné et fixé par piquage en 27 aux bordures des éléments rapportés. Un revêtement d'une étoffe poreuse 28 biologiquement compatible est ensuite ajusté autour du cadre pour envelopper complètement la monture en fil métallique et les éléments rapportés, comme le montre la fig. 7. Alors que l'étoffe peut être repliée sur elle-même autour du cadre pour former une bordure de suture rembourrée, il est préférable que ce rembourrage soit effectué en enfermant un anneau de caoutchouc mousse 29 (Fig.9) à l'intérieur du revêtement d'étoffe 28. La réalisation et la fonction de ces bordures rembourrées de suturation sont bien connues d'ailleurs dans la construction des valvules prothétiques et sont décrites, par exemple, dans les brevets des Etats Unis d'Amérique N° 3.099.016, N° 3.365.728 et N° 3.371.352.

Les couches d'étoffe 24 et 28 peuvent être constituées par un tissu ou tricot poreux de "Teflon", bien que d'autres matières

telles que le "Dacron", puissent être utilisées. Les éléments rapportés 25 peuvent être constitués par une ou plusieurs feuilles de téréphtalate de polyglycol ("Mylar"), bien que d'autres matières inertes biologiquement compatibles, telles que le polypropylène, puissent être utilisées.

Les éléments rapportés 25 forment des goussets pour augmenter les dimensions axiales du cadre dans les zones comprises entre les supports de commissure 17 à 19 et pour assurer la fixation de l'étoffe 24 et de l'hétérogreffe ou homogreffe 12. Chaque élément rapporté 25 de la bande représentée sur la fig. 8 est percé d'ouvertures 30 par lesquelles les fils de piqûre 27 passent pendant la fabrication du cadre. La bordure supérieure 31 de chaque élément rapporté est de forme incurvée pour établir une transition régulière à partir de l'extérieur de la partie supérieure de chaque support de commissure.

Les trois éléments rapportés 25 pourraient être des composants distincts fixés individuellement à la monture en fil métallique recouverte d'étoffe mais, pour faciliter la fabrication, il est préférable de constituer ces éléments sous la forme d'une bande continue 26, les éléments successifs étant reliés par des parties de liaison 32 (Fig.8). Il doit être entendu que ni les parties de liaison 32, ni les autres parties des éléments rapportés ne modifient de façon notable les caractéristiques de flexion de la monture en fil métallique précédemment décrites.

La fig. 9 représente les détails de la valvule complète dont la greffe est fixée au cadre par des points de suture 33. La configuration et l'emplacement de la garniture 29 en mousse conviennent particulièrement à l'utilisation de la valvule pour remplacer une valvule aortique. La valvule représentée dans la fig.10 est destinée à remplacer la valvule mitrale et par conséquent présente des proportions assez différentes. La garniture annulaire 29' en mousse est placée et conformée pour s'engager dans l'orifice mitral, comme ceci est bien connu d'ailleurs dans la technique chirurgicale. Sauf pour les différences évidentes qui ressortent des fig. 9 et 10 et les différences dues aux caractéristiques anatomiques des parties du coeur humain auxquelles les

valvules respectives doivent être fixées, les valvules représentées sur ces figures sont essentiellement les mêmes et utilisent toutes des montures en fil métallique comme celle représentée généralement sur les fig. 2-4.

Les détails de réalisation peuvent être modifiés, sans s'écarter de l'invention, dans le domaine des équivalences techniques.

REVENDICATIONS

1.- Valvule cardiaque bioprothétique supportée, caractérisée en ce qu'elle comprend un cadre auquel est fixée une greffe valvulaire, ce cadre présentant une monture annulaire constituée essentiellement d'un seul tronçon de fil métallique flexible préformé, ladite monture étant conformée de manière à constituer trois supports de commissure circonférentiellement espacés faisant saillie axialement, chaque support de commissure étant profilé en U inversé et comportant des branches raccordées en arrondi à leurs extrémités inférieures avec des parties de liaison curvilignes s'étendant circonférentiellement entre les branches des supports de commissure adjacents et reliant ces branches.

2.- Valvule suivant la revendication 1, caractérisée en ce que le cadre comprend des éléments rapportés s'étendant entre les supports de commissure et présentant des bordures supérieures curvilignes au-dessus des parties de liaison de la monture.

3.- Valvule suivant la revendication 2, caractérisée en ce que les éléments rapportés sont percés de plusieurs ouvertures.

4.- Valvule suivant la revendication 2, caractérisée en ce que les éléments rapportés sont constitués par des parties solidaires d'une bande de matière plastique perforée flexible circonscrivant la monture.

5.- Valvule suivant la revendication 4, caractérisée en ce que la bande présente des parties ayant des bordures supérieures incurvées entre les supports de commissure.

6.- Valvule suivant la revendication 2, caractérisée en ce que la greffe est reliée par des lignes de piqûres à la monture et aux éléments rapportés.

7.- Valvule suivant la revendication 1, caractérisée en ce que ledit cadre comprend un revêtement d'étoffe poreuse biologiquement compatible pour assurer la suturation de la valvule et pour permettre la croissance des tissus lorsqu'elle est implantée.

8.- Valvule suivant la revendication 1, caractérisée en ce que les extrémités du fil métallique de la monture sont reliées en un point situé le long d'une des parties de liaison curvilignes.

9.- Valvule suivant la revendication 8, caractérisée en ce que lesdites extrémités sont réunies par un manchon tubulaire s'emboîtant sur elles et auxquelles il est fixé.

10.- Valvule suivant la revendication 9, caractérisée en ce que le manchon est serti autour des deux extrémités.

11.- Valvule suivant la revendication 1, caractérisée en ce que chacun des supports de commissure de la monture est arrondi à son extrémité supérieure.

12.- Cadre flexible pour supporter une greffe valvulaire, caractérisé en ce qu'il comporte une monture annulaire constitué par un fil métallique flexible et comprenant trois supports de commissure faisant saillie axialement et circonférentiellement espacés, chaque support de commissure étant profilé en U inversé ayant des branches en fil métallique normalement espacées à ses extrémités inférieures, qui se raccordent en arrondi avec des segments de liaison curvilignes de la monture s'étendant circonférentiellement entre les branches adjacentes des supports de commissure voisins et les reliant, ces supports de commissure et ces segments de liaison étant constitués d'un seul tenant en fil métallique élastique.

13.- Cadre suivant la revendication 12, caractérisé en ce que les éléments rapportés s'étendent entre les supports de commissure, ces éléments rapportés étant flexibles et comportant des bordures supérieures curvilignes au-dessus des segments de liaison de la monture.

14.- Cadre suivant la revendication 13, caractérisé en ce que les éléments rapportés sont constitués d'une matière foliiforme perforée flexible.

15.- Cadre suivant la revendication 13, caractérisé en ce que les éléments rapportés sont des parties intégrantes d'une bande de matière plastique perforée flexible circonscrivant la monture.

16.- Cadre suivant la revendication 15, caractérisé en ce que la bande présente des bordures supérieures incurvées entre les supports de commissure.

17.- Cadre suivant la revendication 12, caractérisé en ce qu'un revêtement d'étoffe poreuse biologiquement compatible entoure la monture pour permettre de fixer le cadre par suturation et pour favoriser la croissance des tissus.

18.- Cadre suivant la revendication 12, caractérisé en ce que les extrémités du fil métallique de la monture sont réunies en un point intermédiaire situé le long d'un des segments de liaison curvilignes.

19.- Cadre suivant la revendication 18, caractérisé en ce que lesdites extrémités sont reliées par un manchon tubulaire emboîté sur lesdites extrémités auxquelles il est fixé.

20.- Cadre suivant la revendication 19, caractérisé en ce que ce manchon est serti sur lesdites extrémités.

21.- Cadre suivant la revendication 12, caractérisé en ce que chacun des supports de commissure de la monture est arrondi à son extrémité supérieure.

FIG. 2

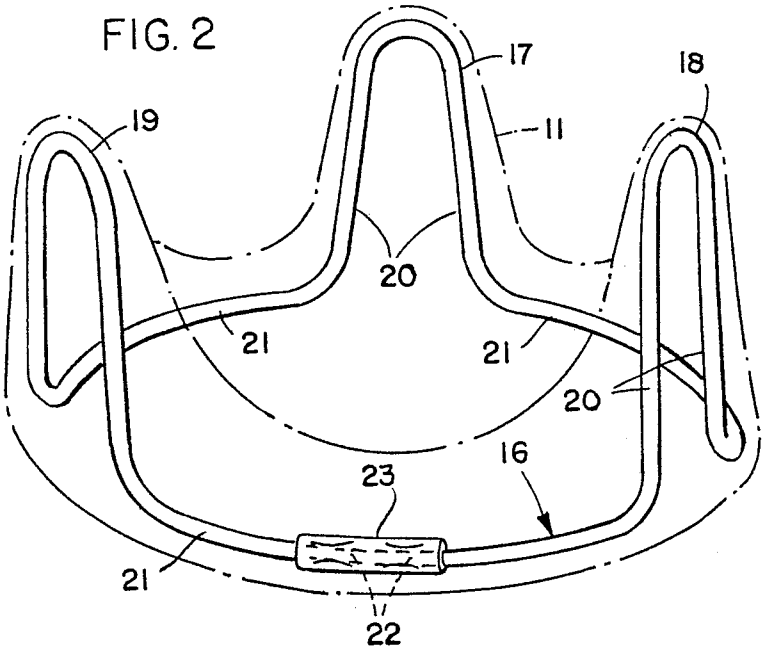


FIG. 3

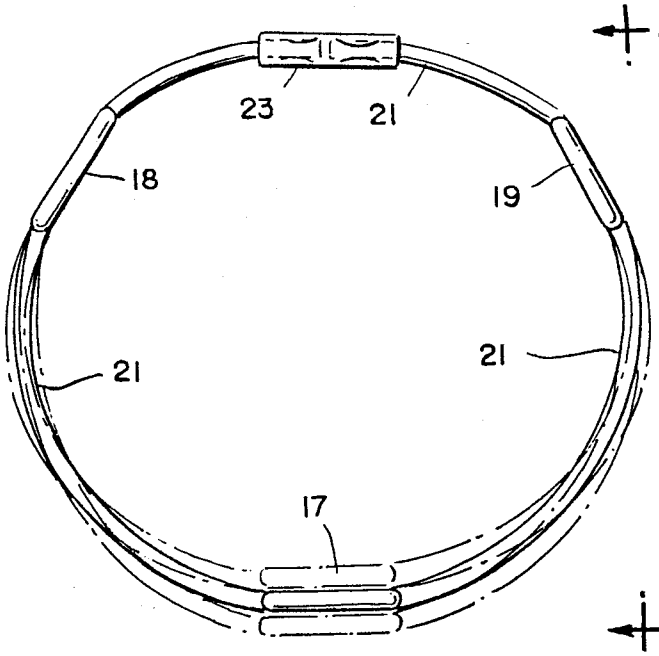
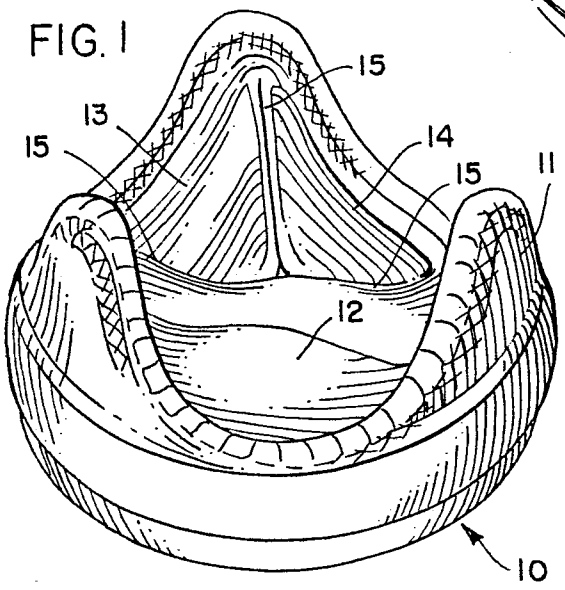


FIG. 1



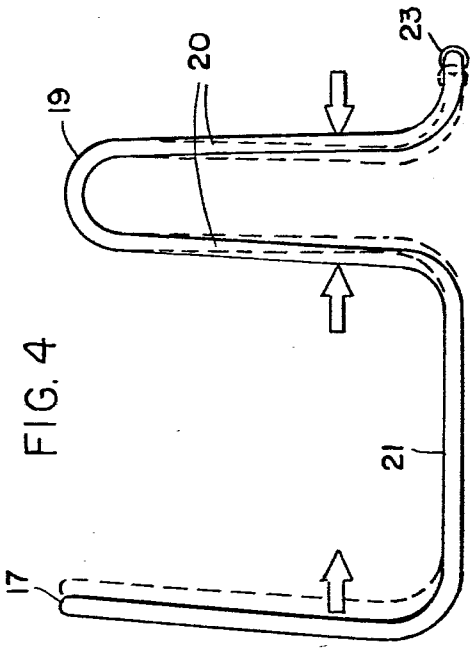


FIG. 4

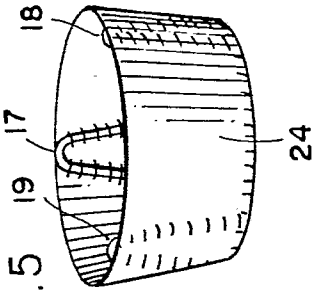


FIG. 5

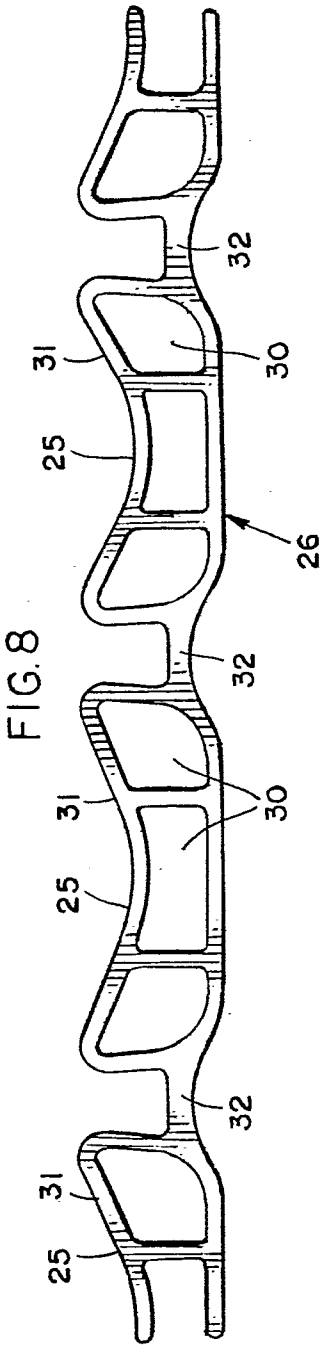


FIG. 8

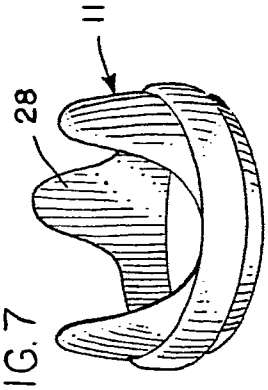


FIG. 7

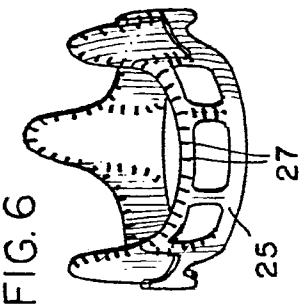


FIG. 6

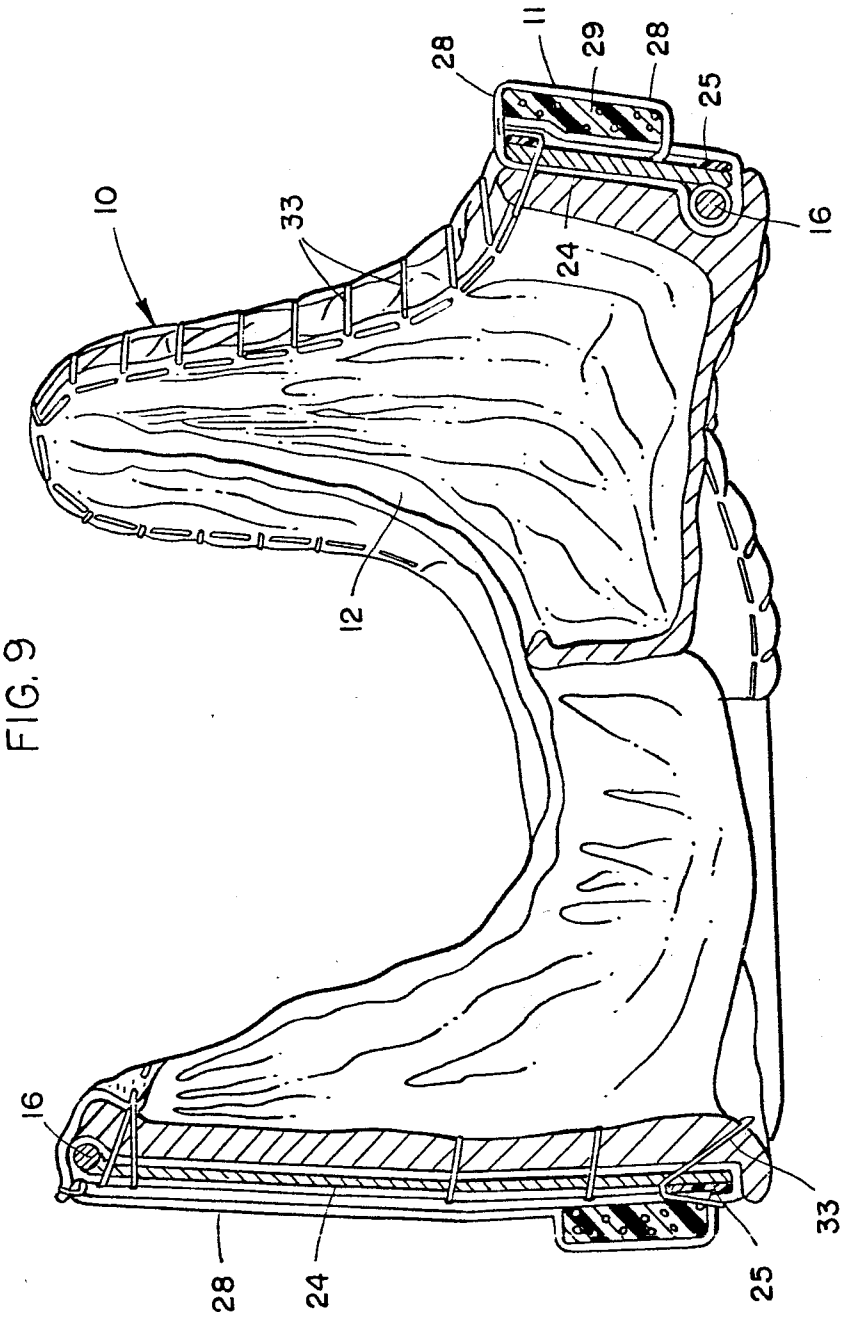


FIG. 9

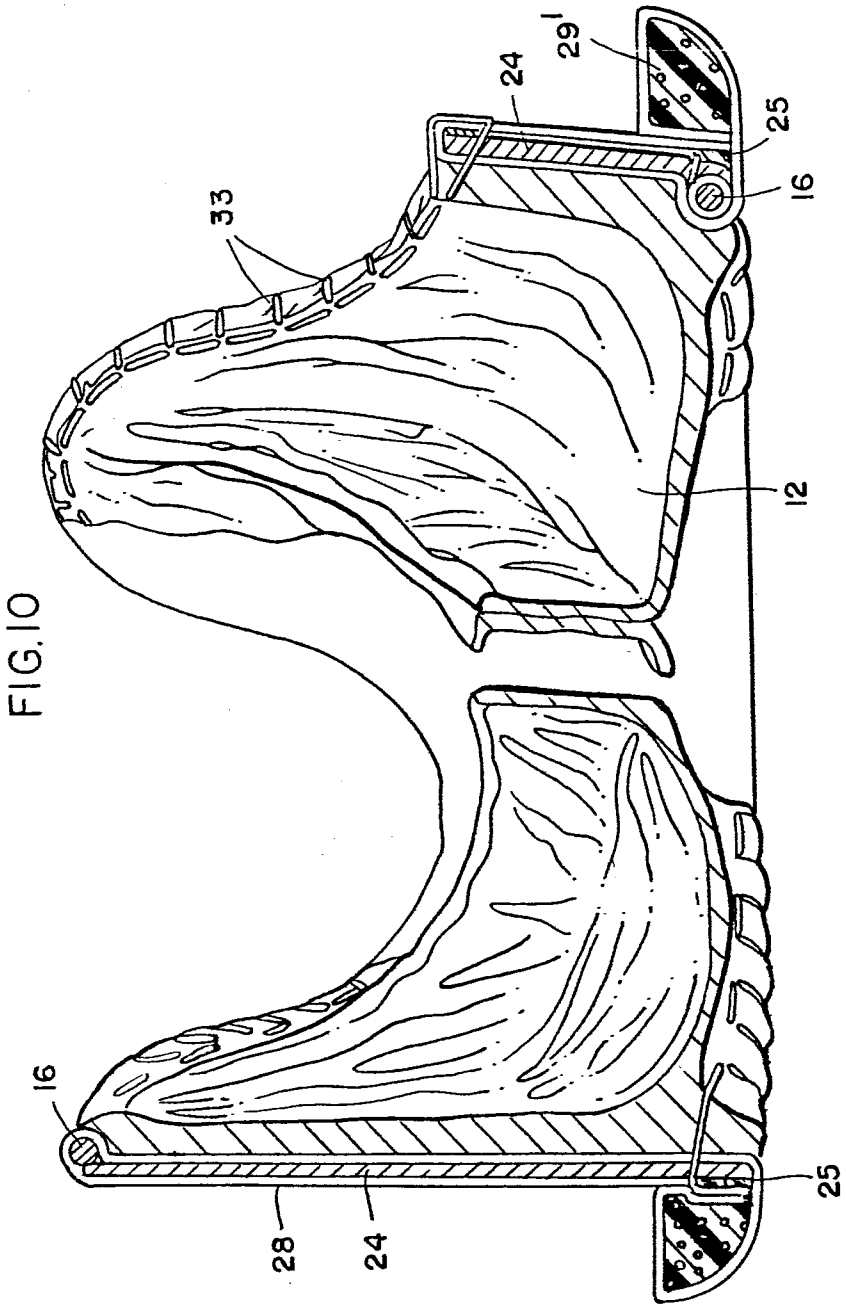


FIG.10

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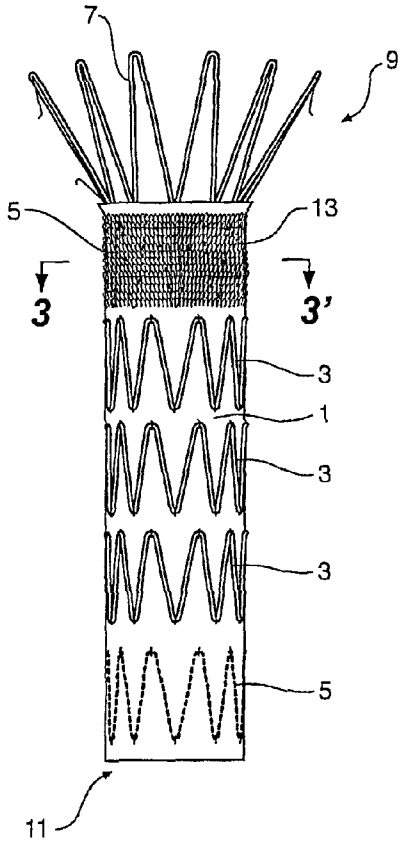
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[Continued on next page]

(54) Title: STENT GRAFT WITH IMPROVED GRAFT ADHESION



(57) Abstract: A graft (1) having a band of fibrous material (13) on an outer surface thereof adjacent its proximal end (9). The band of fibrous material extends circumferentially around the graft to promote adhesion. The band can be continuous around the proximal end of the graft. The band can be formed from a patch of fibrous material, cut or loop pile velour, by fibres woven or knitted into the material of the graft or by brushing of material of the graft to raise fibres of the material of the graft. The band of fibrous material has a length of from 5 mm to 15 mm along the length of the graft.

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./. Edwards Lifesciences
PVT, Inc.

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TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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STENT GRAFT WITH IMPROVED GRAFT ADHESION

Description

Technical Field

This invention relates to endoluminal stent grafts and in particular to a stent graft for improving the adhesion or incorporation of such grafts into the wall of a lumen.

Background of the Invention

Throughout this specification when applied to a blood vessel the term distal, with respect to a stent graft or graft, is the end of the stent graft or graft furthest away in the direction of blood flow from the heart within a body lumen. The term proximal means the end of the stent graft or graft nearest to the heart in the direction of blood flow. Where the invention is applied to other lumens of the human or animal body then corresponding terms such as caudal and cranial should be understood.

A surgical stent graft or graft may be placed into a lumen in the body by endoluminal techniques or by surgical techniques. Such a stent graft or graft is constructed from biocompatible materials but it is desirable in the long term for such grafts to be actually incorporated into the wall of the body lumen and this requires that the tissue of the body lumen grows into the material of the graft.

It is known that tufts of fibrous material may be placed on grafts to enhance blood clotting and adhesion but such tufts do not promote complete circumferential adhesion. Particularly when such grafts are deployed endoluminally it is desirable that the amount of fibrous material be kept to a minimum to ensure that the graft can be compressed into small enough volume to enable deployment while at the same time ensuring good adhesion of the graft.

Summary of the Invention

The object of this invention is to provide a graft with material to ensure good adhesion or incorporation of the graft into a lumen.

In one form therefore the invention is said to reside in a graft or stent graft having a band of fibrous material on an outer surface thereof adjacent a distal or a

proximal end thereof, the band of fibrous material extending circumferentially around the graft to promote adhesion and incorporation. Furthermore, the graft or stent graft can include separate bands of fibrous material extending circumferentially around the graft at both the distal and the proximal ends thereof to promote adhesion and incorporation.

Preferably the band is continuous around the proximal end of the graft.

In one embodiment the band is provided by patches of fibrous material around the proximal end of the graft. Alternatively the band of fibrous material is formed from velour or is provided by fibres woven or knitted into the material of the graft. The velour material may be loop pile material or cut pile material to present either loops of fibres or individual fibres to the wall of the vessel.

The band of fibrous material may alternatively be provided by brushing of the material of the graft to raise fibres of the material to provide the fibrous band.

In an alternative form, the invention may be said to reside in a graft having a continuous band of velour material adjacent a proximal end thereof, the continuous band of velour material extending circumferentially around the graft to promote adhesion.

In a further form, the invention may be said to reside in a continuous band of velour material around one end of a graft to provide adhesion against the wall of a lumen by ingrowth of the tissue of the wall into the velour material, the velour material being a continuous band around the graft.

In a further form, the invention may be said to reside in a stent graft adapted for insertion into an internal lumen of a patient to be incorporated therein, the stent graft comprising a substantially tubular body providing a fluid flow path and having a periphery defined by a biocompatible relatively impervious material wall, the wall having a proximal portion including a continuous external circumferential band of a fibrous biocompatible material.

In a further form, the invention may be said to reside in a stent graft adapted for implantation within a lumen in a human or animal body to reside therein, the stent graft having a proximal end and a distal end and a substantially tubular graft body formed from a relatively impervious biocompatible material, at least one

stent to maintain the patency of the stent graft, and a continuous circumferential band of fibrous material on the outside of the tubular graft body adjacent the proximal end of the stent graft.

It would be seen that by the various forms of the invention there is provided a continuous band of velour material or fibrous material around the outside of the proximal end of a stent graft for good adhesion of that end of the stent graft to the wall of a lumen.

It will be noted that the graft of the present invention is particularly useful in delivery devices when endoluminal deployment is used because the band is of a relatively short length with respect to the length of the graft and hence does not make the device when it is compressed for deployment significantly larger over the entire length of the device.

The band of fibrous material can be a band which is stitched onto the graft at the proximal end, it may be fibres woven or knitted into the material of the graft or where the graft itself is manufactured from a fibrous woven, knitted or non-woven material at which the proximal area of the graft may be brushed to raise the fibres to provide the fibrous band.

To ensure good adhesion the band may be in the region of 5 mm to 15 mm in length along the length of the graft.

In one preferred form of the invention, the invention is particularly related to a stent graft using self-expanding stents such as stainless steel or nitinol stents.

The relatively impervious material may be a knitted or woven biocompatible material such as a dacron or similar material or it may be a non-woven fibrous material or it may be a plastics material sheet formed into a graft tube or extruded into tubular form.

It is desirable that the band be continuous around the proximal end of the graft so that with fibrous ingrowth of the cells of the wall of the lumen into the band of fibrous material on the graft, union of the wall and graft is obtained which provides sealing for blood flow which could occur between the graft and the wall as well as prevention of movement of the graft longitudinally within the lumen. In so doing there is improved incorporation of the graft into the wall of the lumen.

Brief Description of the Drawing

This then generally describes the invention but to assist with understanding reference will now be made to the accompanying drawing which show preferred embodiments of the invention.

In the drawings,

Figure 1 shows a perspective view of a stent graft including the adhesion or incorporation arrangement according to one embodiment of the present invention;

Figure 2 shows a perspective view of a stent graft including the adhesion or incorporation arrangement according to an alternative embodiment of the present invention;

Figure 3A shows a plan view of a stent graft shown in Figure 1 with a first form of velour pile;

Figure 3B shows a plan view of a stent graft shown in Figure 1 with an alternative form of velour pile; and

Figure 4 shows a detailed perspective view of a stent graft including an adhesion or incorporation arrangement of an alternative embodiment.

Detailed Description

Looking more closely at Figure 1 of the drawings it can be seen that in a stent graft comprising a graft material tube 1 which is held into a substantially cylindrical shape by means of external expandable stents 3 in the main body of the graft material 1 and internal stents 5 at each end of the graft. These stents can be self-expanding of, for example, commercially available Gianturco, zigzag or Z stent using a spring like metal such as stainless steel, nitinol, or other alloy metals. These stents can also be balloon or mechanically expandable stents, which are also commercially available.

The graft body has a proximal end 9 and a distal end 11.

In this particular embodiment, a proximally extending stent 7 is provided although this proximally extending stent is not essential to the invention.

Each stent 3, 5 and 7 is a Gianturco zig zag or Z stent manufactured from nitinol or stainless steel and is self expanding from a compressed state, in which the stent graft can be introduced into the lumen, to the expanded state shown.

Extending circumferentially around the graft body 1 at the proximal end 9 is a continuous circumferential region 13 of fibres extending from the graft material. The continuous circumferential region is formed on the material of the graft 1 by portions of the fibrous material woven into the material or extending from the woven graft material. The portions of fibrous material may be in the form of a loop pile or a cut pile to present either loops of fibres or individual fibres to the wall of the vessel when deployed within a body lumen.

The graft may have a diameter in the range of 25 to 50 millimetres and a length of from 100 to 200 millimetres. The band 13 may have a length of from 5 to 15 millimetres and may be adjacent the end of the stent graft or spaced from the proximal end of the graft by a distance of up to 10 millimetres.

Figure 2 shows an alternative embodiment of the invention. In this embodiment the graft 1 is of substantially the same construction as shown in Figure 1 except that it does not have a proximally extending uncovered stent. Around the proximal end 19 of the graft 1 is a continuous band of velour material 20 fastened to the graft 1 by stitching 22 at the proximal end and 21 at the distal end of the velour band 20. The velour provides loops of fibrous material which can be incorporated into the wall of the lumen into which the graft is placed by fibrous ingrowth. This provides adhesion of the graft into the lumen. One again the velour material may be of loop pile or cut pile form.

The provision of the continuous band at the proximal end of the graft provides adhesion and incorporation around the entire circumference of the graft. The adhesion and incorporation around the entire circumference of the graft will prevent blood or other body fluid, depending upon the lumen into which it is introduced, from getting behind the wall of the graft. The adhesion and incorporation will also assist with preventing movement of the graft within the lumen.

Figure 3A and B show cross sectional plan views in the line 3 – 3′ on the stent graft shown in Figure 1 but with different forms of velour pile.

Figure 3A shows loop pile velour as the continuous band 13a of fibrous material around the circumference of the graft 1.

Figure 3B shows cut pile velour as the continuous band 13b of fibrous

material around the circumference of the graft 1.

Figure 4 shows a detailed perspective view of part of a stent graft including an alternative adhesion arrangement for the proximal end of the stent graft. As with Figure 1 the stent graft has a bio-compatible woven material body 1 with a self expanding stent 5 inside the graft body 1 at the proximal end 9 to provide a good contact of the graft material with the wall of a lumen into which it is deployed. In this case the continuous band of fibrous material 25 is provided by brushing or similar means to raise fibres 26 from the material of the graft 1. The brushing can be with a wire brush or a hooking system may be used to raise some of the fibres in a continuous band around the graft.

This brushing or hooking can also be used with non-woven bio-compatible graft materials to raise a fibrous band around the circumference of a graft.

It may be noted that this specification has been particularly directed to the use of a velour band on the proximal end of a graft because that is the end of the graft which it is normally expected to get more blood pressure in the case where the lumen is a blood vessel and the proximal end in the case of an artery being the end nearer the heart. There may be situations, however, where the band of fibrous material may be placed around the distal end of a graft or at both ends and this invention is intended to cover those applications as well.

Throughout this specification various indications have been given as to the scope of this invention but the invention is not limited to any one of these but may reside in two or more of these combined together. The examples are given for illustration only and not for limitation.

Throughout this specification and the claims that follow unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

Claims

1. A stent graft comprising:

a tubular graft having a distal end, a proximal end, and an outer surface;

at least one expandable stent disposed on said tubular graft; and

a band of fibrous material on said outer surface and adjacent at least one of said distal end and said proximal end of said tubular graft, said band of fibrous material extending circumferentially around said graft.

2. The stent graft as in Claim 1 wherein said band is continuous around said proximal end of said tubular graft.

3. The stent graft as in Claim 1 wherein said band comprises a patch of fibrous material fastened around said proximal end of said tubular graft.

4. The stent graft as in Claim 1 wherein said band of fibrous material includes velour material.

5. The stent graft as in Claim 4 wherein said velour material includes a loop pile velour material.

6. The stent graft as in Claim 4 wherein said velour material includes a cut pile velour material.

7. The stent graft as in Claim 1 wherein said band of fibrous material includes fibres woven or knitted into material of said graft.

8. The stent graft as in Claim 1 wherein said graft includes a graft material and wherein said band of fibrous material comprises brushed raised fibres of said graft material.

9. The stent graft as in Claim 1 wherein said band of fibrous material has a length of from 5 mm to 15 mm along the length of said graft.

10. The stent graft as in Claim 1 wherein said at least one expandable stent extends proximally from said proximal end of said tubular graft.

11. The stent graft as in Claim 1 wherein said stent graft further comprises another band of fibrous material on said outer surface and adjacent a remaining one of said distal end and said proximal end of said tubular graft, said other band of fibrous material extending circumferentially around said graft.

12. A stent graft comprising:

a tubular graft having an outer surface and a proximal end;

at least one expandable stent disposed on said tubular graft; and

a continuous band of velour material adjacent said proximal end of said tubular graft, said continuous band of velour material extending circumferentially around said graft.

13. The stent graft as in Claim 12 wherein said continuous band of velour material is disposed on said outer surface of said tubular graft.

14. A stent graft adapted for insertion into an internal lumen of a patient to be incorporated therein, the stent graft comprising a substantially tubular body providing a fluid flow path and having a periphery defined by a biocompatible relatively impervious material wall, the wall having a proximal portion including a continuous external circumferential band of a fibrous biocompatible material.

15. The stent graft as in Claim 14 wherein the stent graft further comprises at least one stent to maintain the patency of the stent graft, and a continuous circumferential band of fibrous material on the outside of the tubular body adjacent the proximal end of the stent graft.

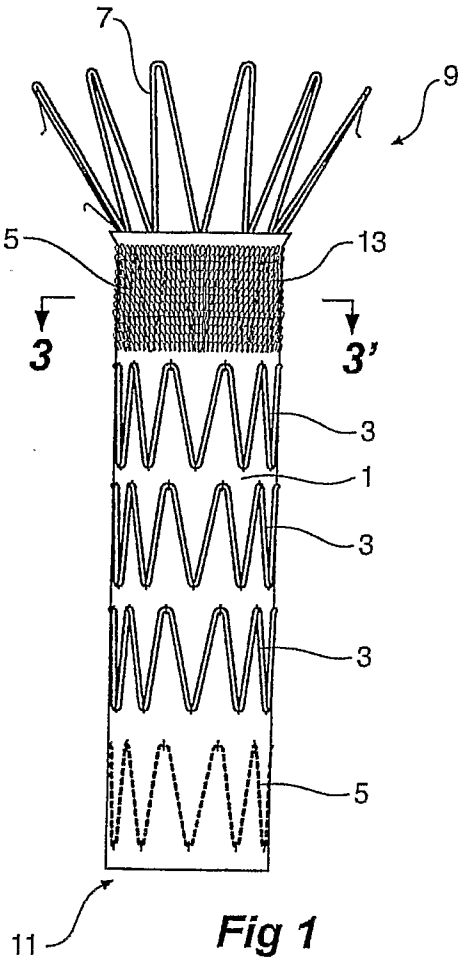


Fig 1

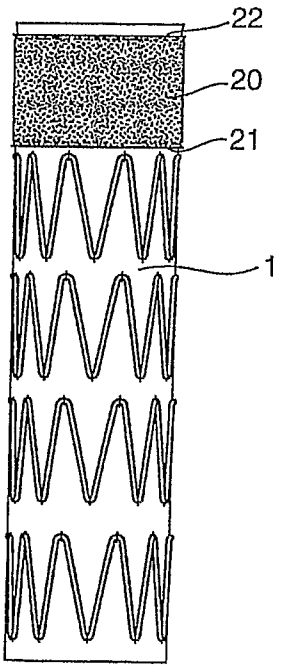


Fig 2

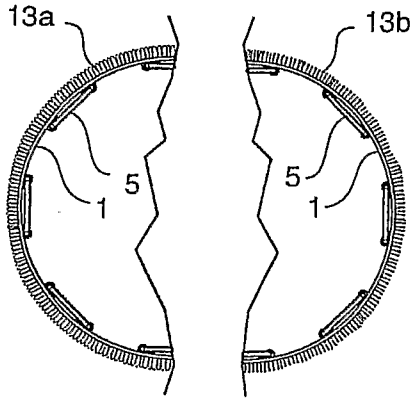


Fig 3A

Fig 3B

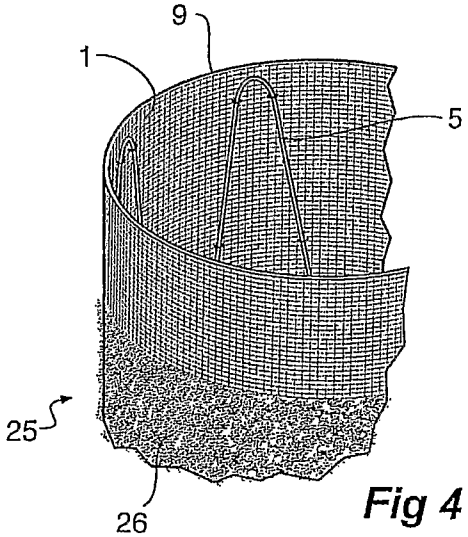


Fig 4

INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/US 02/40663

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2002/052649 A1 (GREENHALGH E SKOTT) 2 May 2002 (2002-05-02) figures 1-9 paragraph '0023! - paragraph '0040!	1-15
X	US 6 152 956 A (PIERCE GEORGE E) 28 November 2000 (2000-11-28) figures 7A,,8 column 7, line 39 -column 8, line 20	1-4,10, 12-15
A	US 4 871 366 A (VON RECUM ANDREAS F ET AL) 3 October 1989 (1989-10-03) column 4, line 34 -column 6, line 55	1-15
P,A	WO 02 22055 A (SCIMED LIFE SYSTEMS INC) 21 March 2002 (2002-03-21) page 8, line 13 -page 14, line 3	1-15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 May 2003	19/05/2003

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati Application No
PCT/US 02/40663

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 20030153974A1

(19) **United States**

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Spenser et al. (43) **Pub. Date: Aug. 14, 2003**

(54) **IMPLANTABLE PROSTHETIC VALVE**

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(21) Appl. No.: **09/975,750**

(22) Filed: **Oct. 11, 2001**

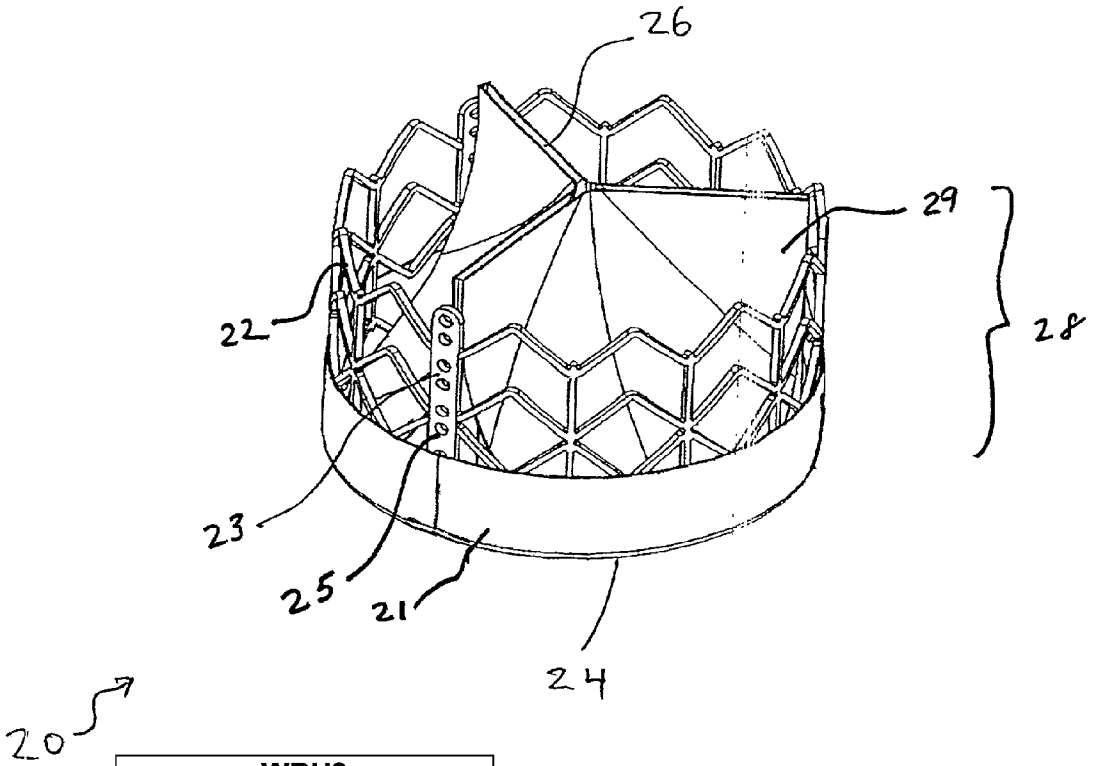
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/24**

(52) **U.S. Cl.** **623/2.11**; 623/1.13; 623/2.18

(57) **ABSTRACT**

A valve prosthesis device is disclosed suitable for implantation in body ducts. The device comprises support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length; valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet. When flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.



WBH9
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

FIG. 1

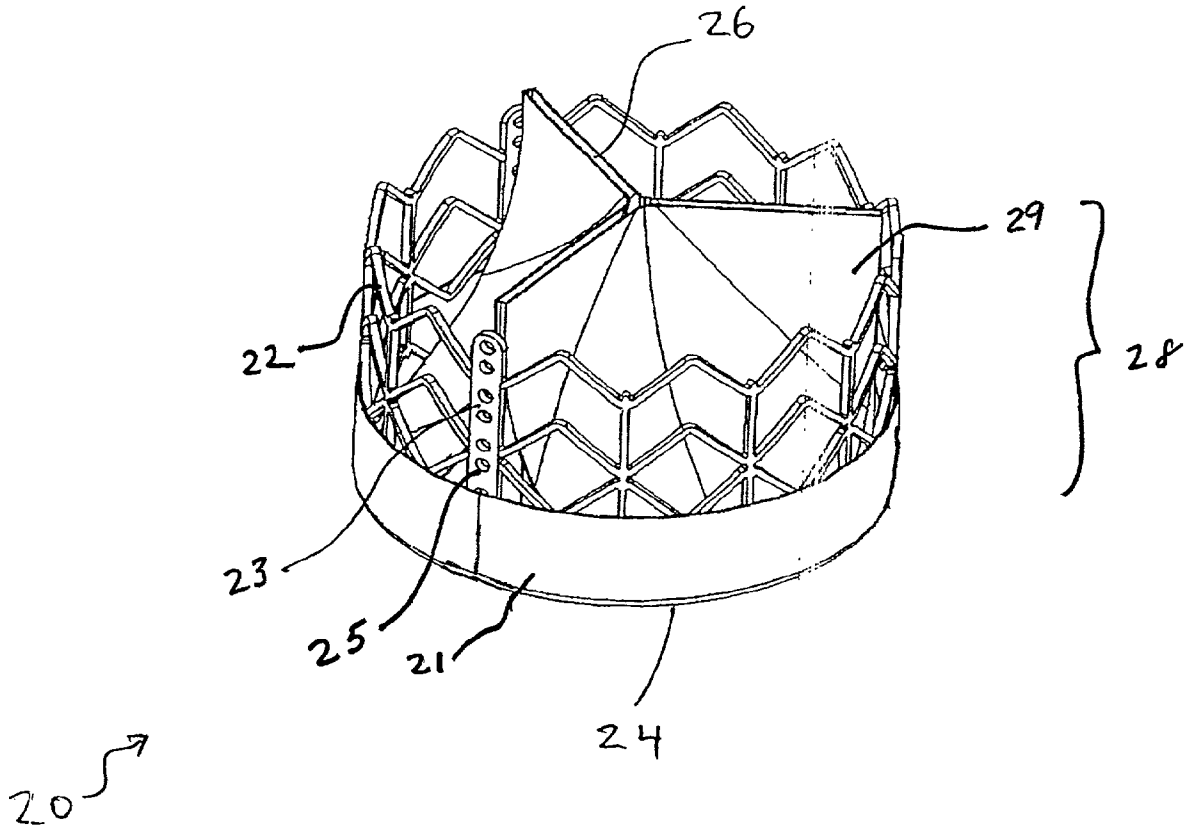


FIG. 2

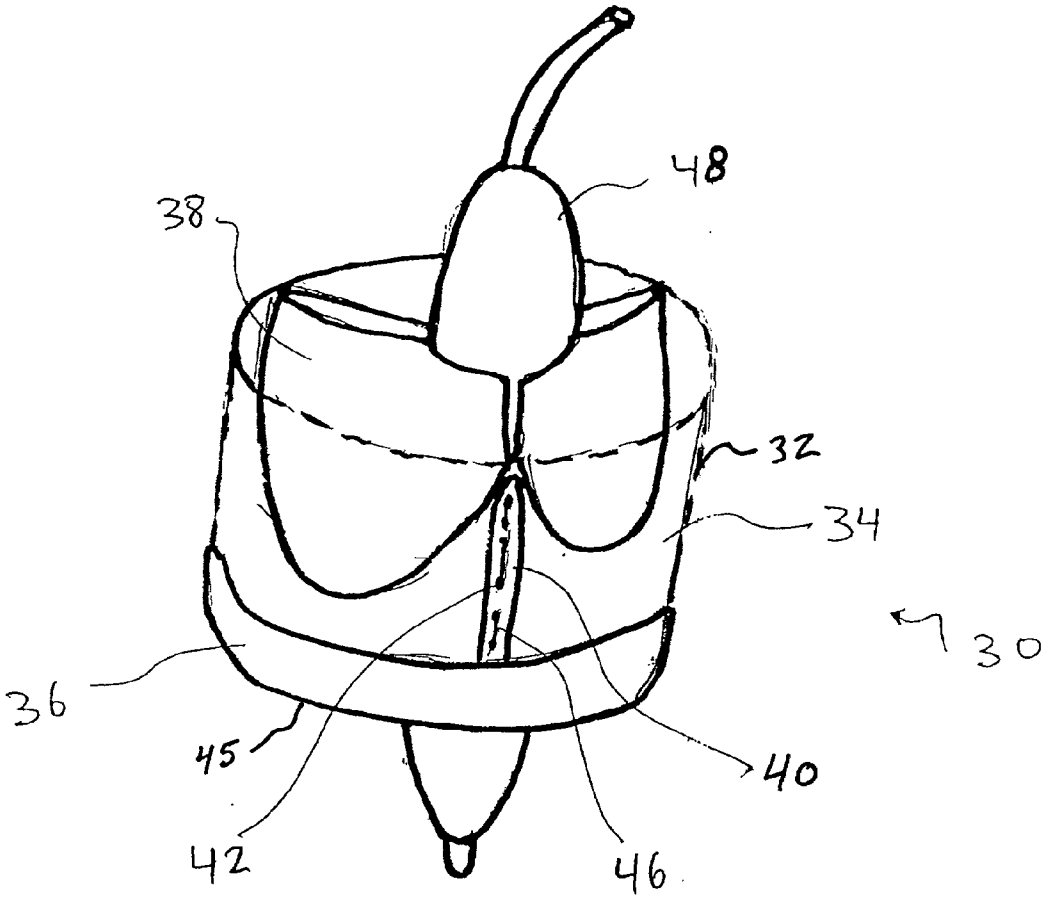


FIG. 3

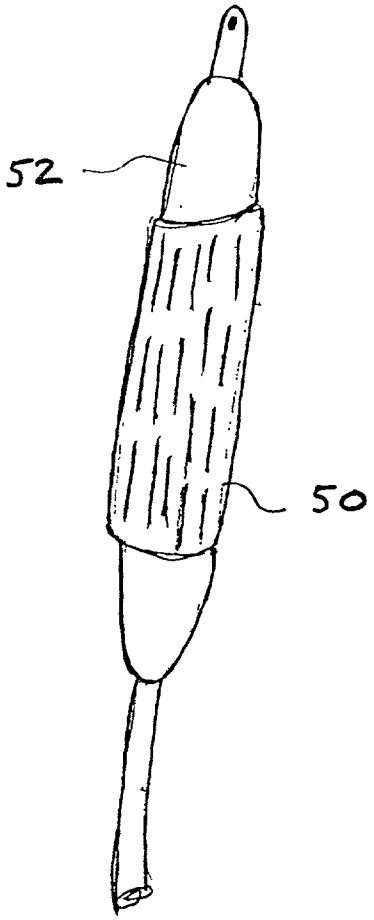


FIG. 4

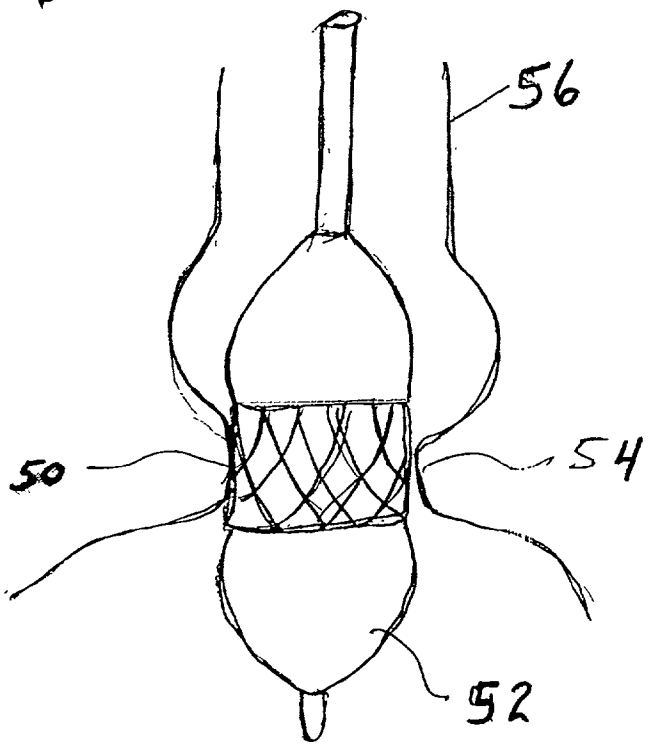
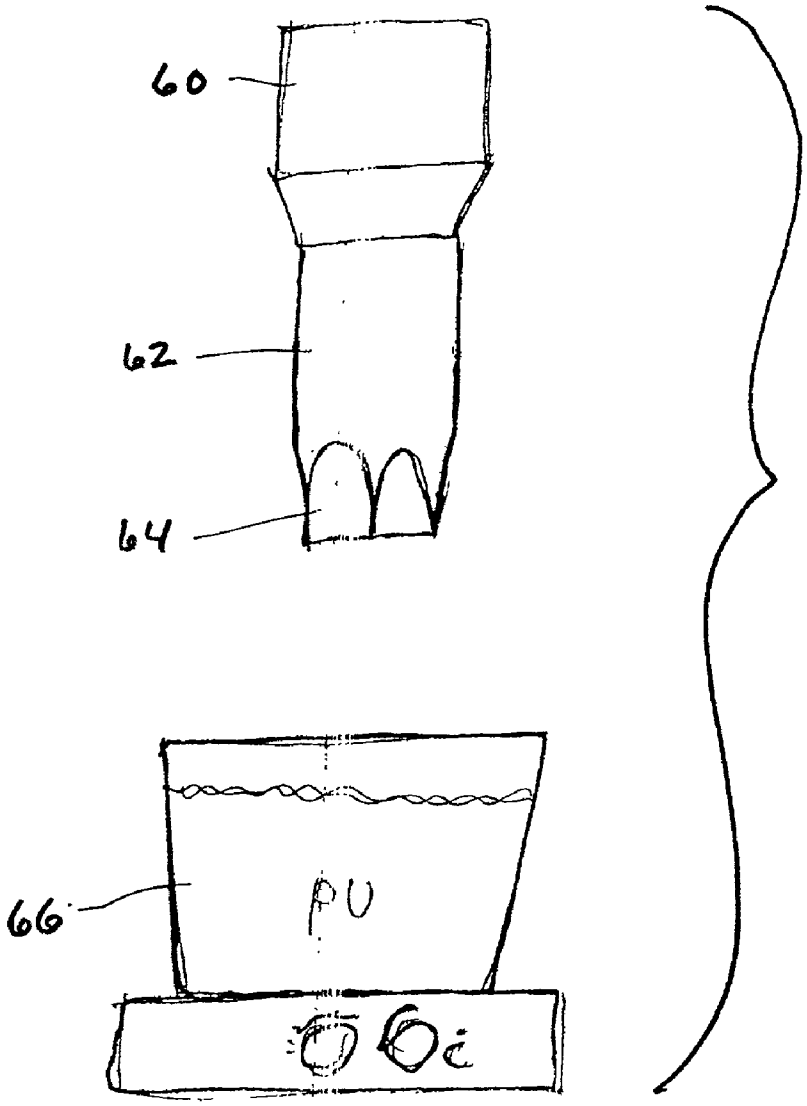


FIG. 5



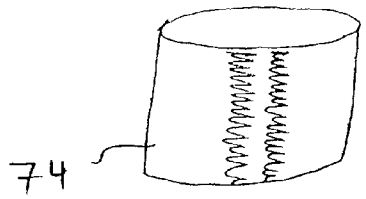


Fig. 6a

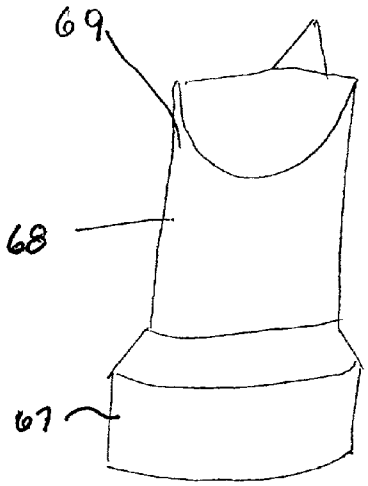


Fig. 6b

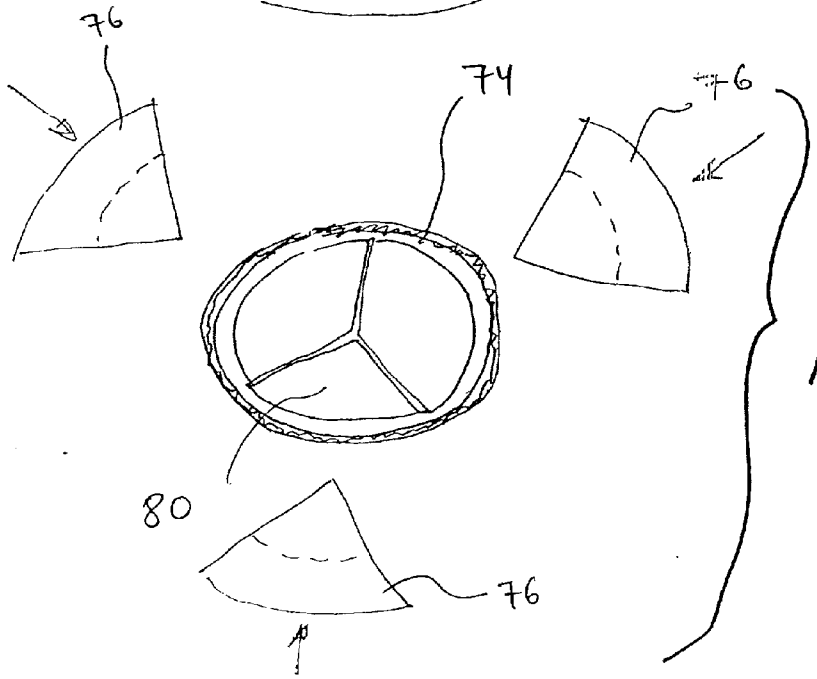


Fig. 6c

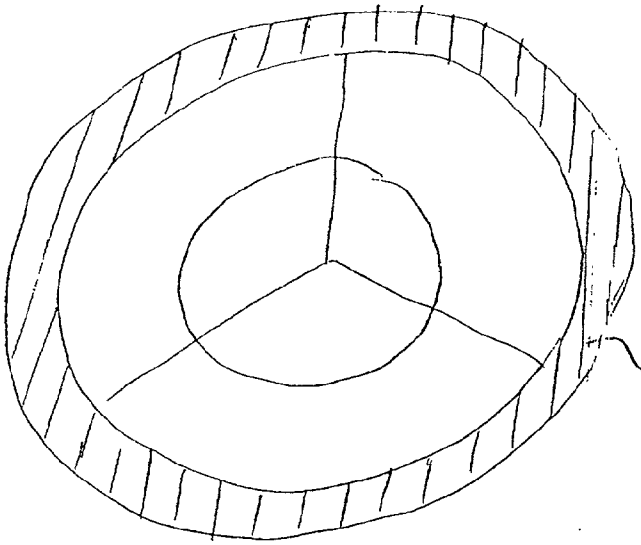


Fig. 6d

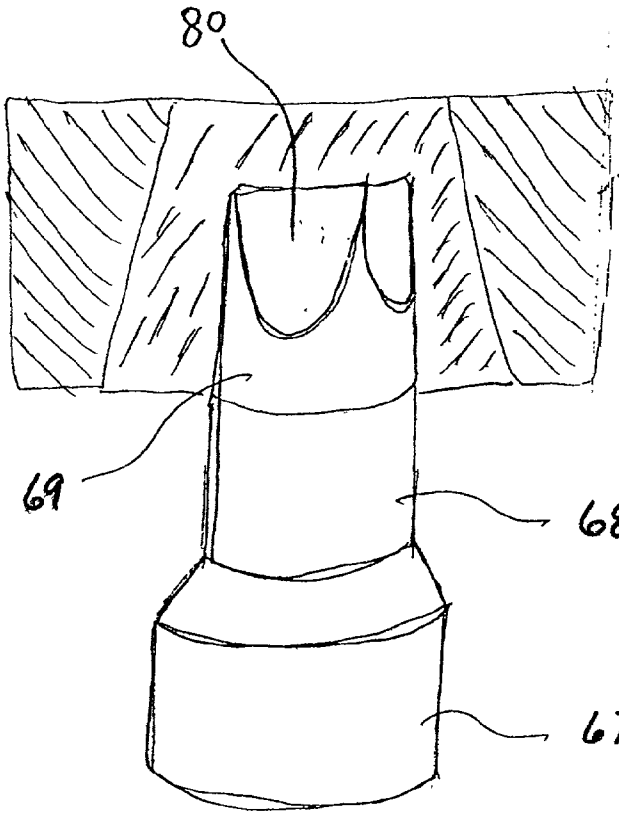


Fig. 6e

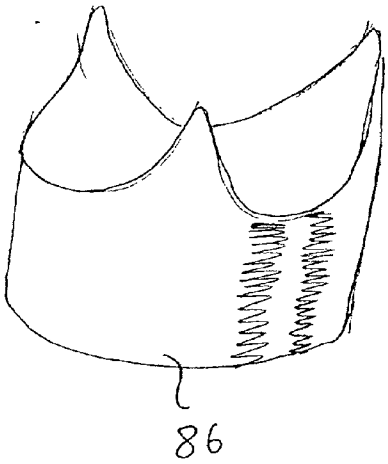


FIG. 7a

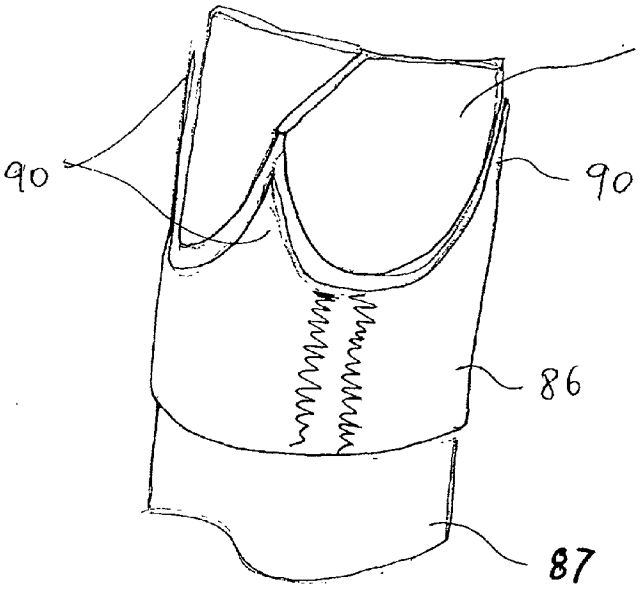


Fig. 7b

FIG 8a

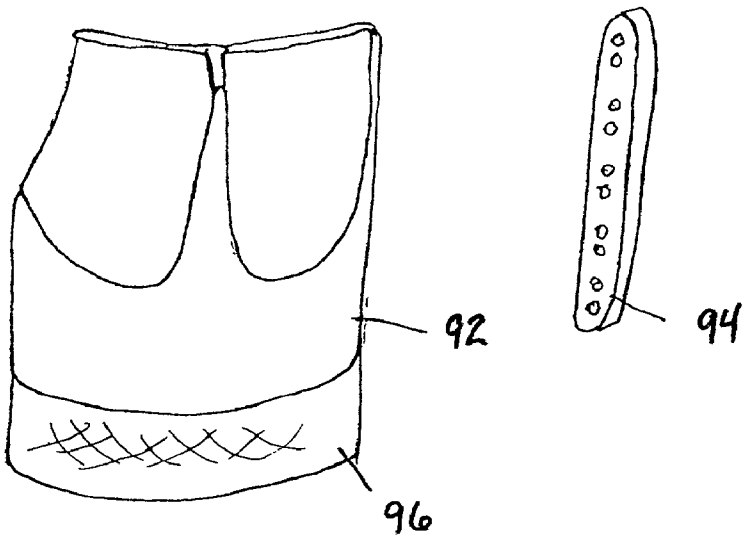


Fig. 8b

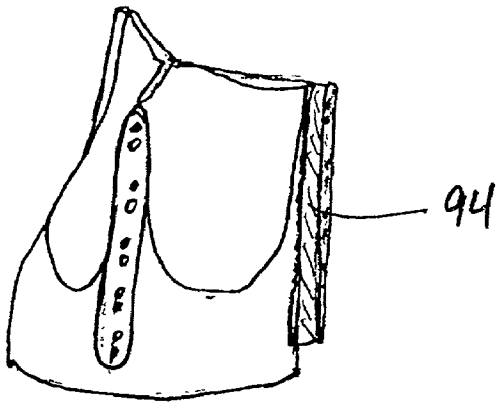
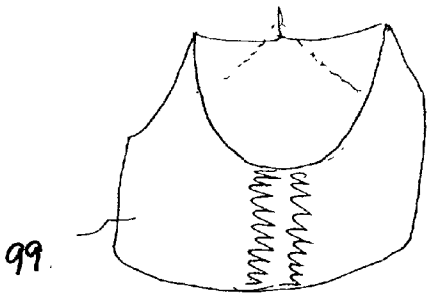


FIG. 9



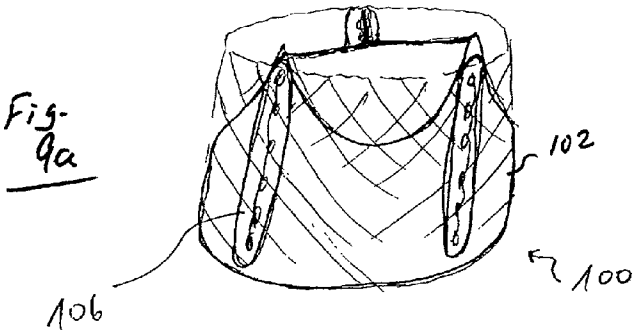


Fig. 9a

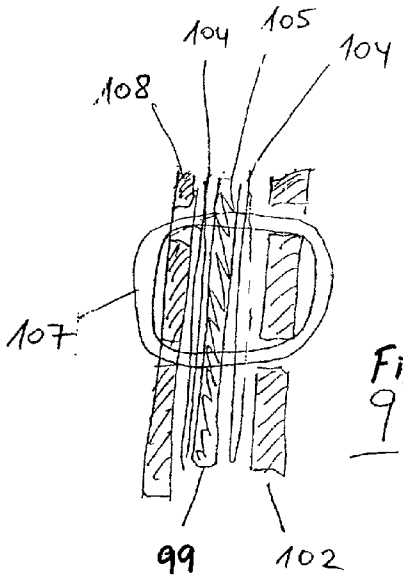


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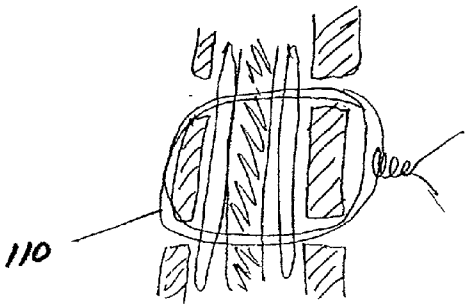


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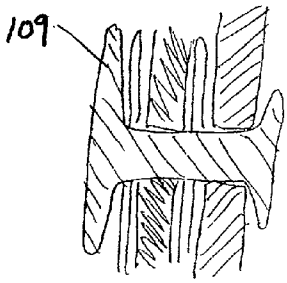


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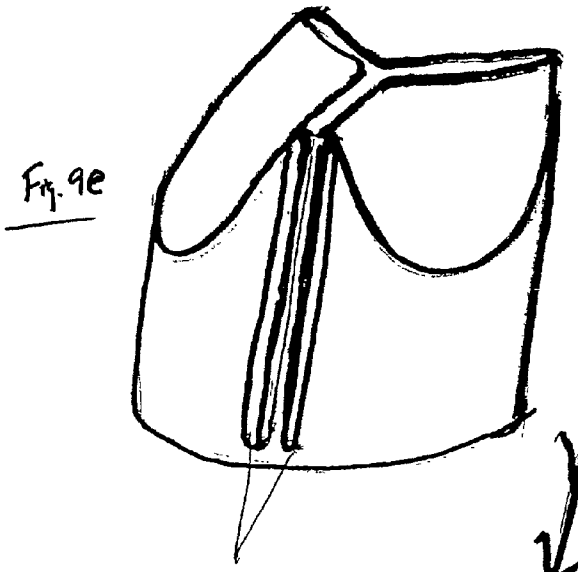


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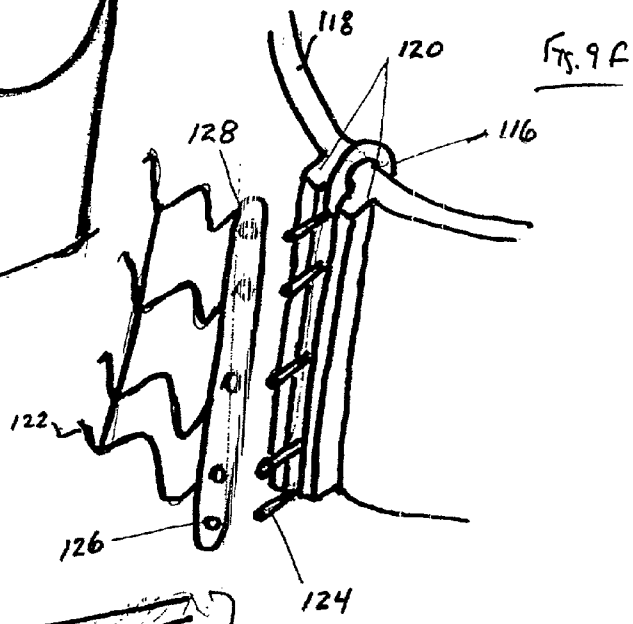


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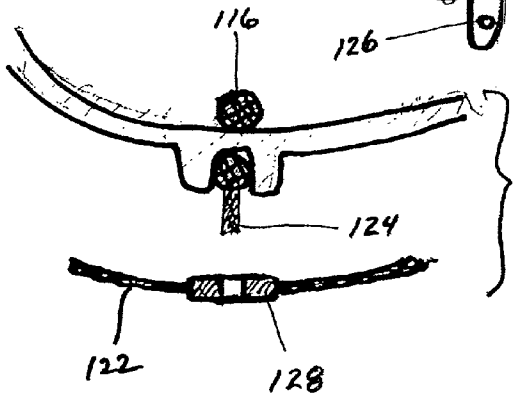


Fig. 9g

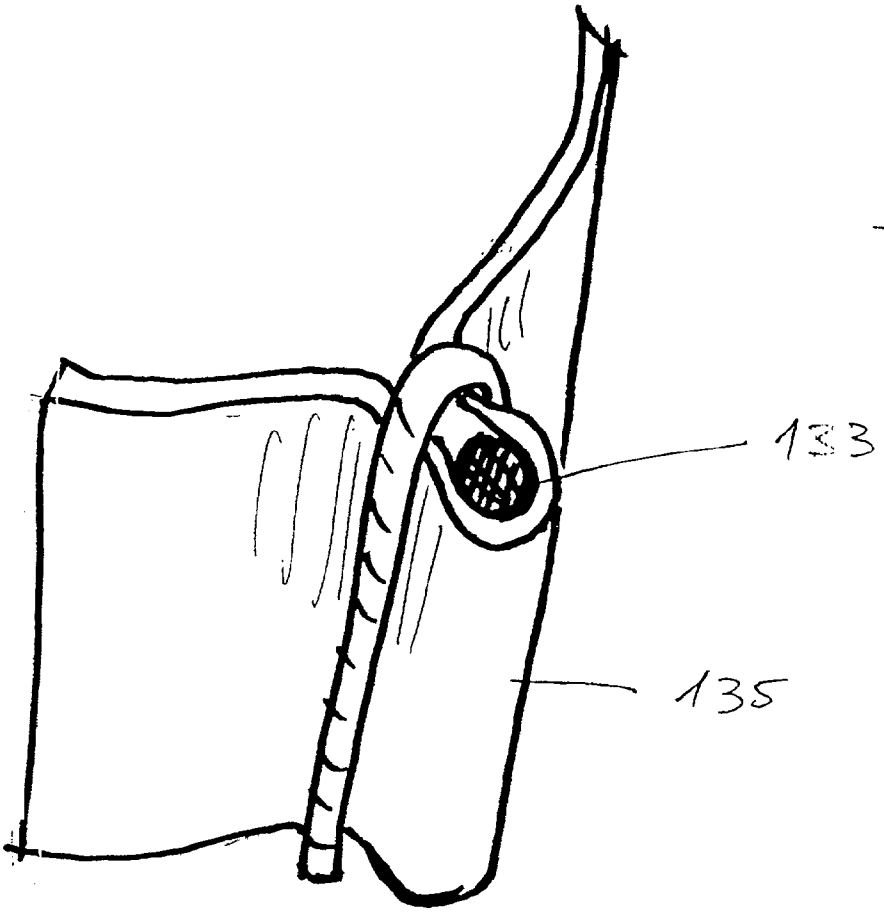


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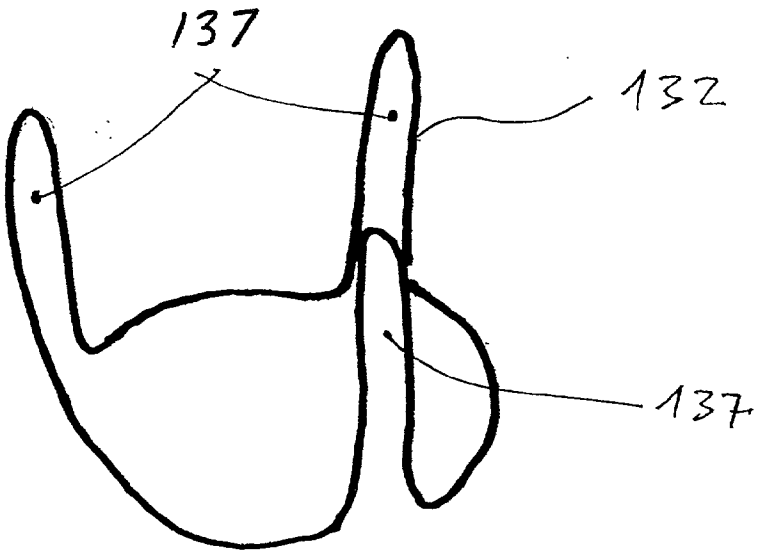
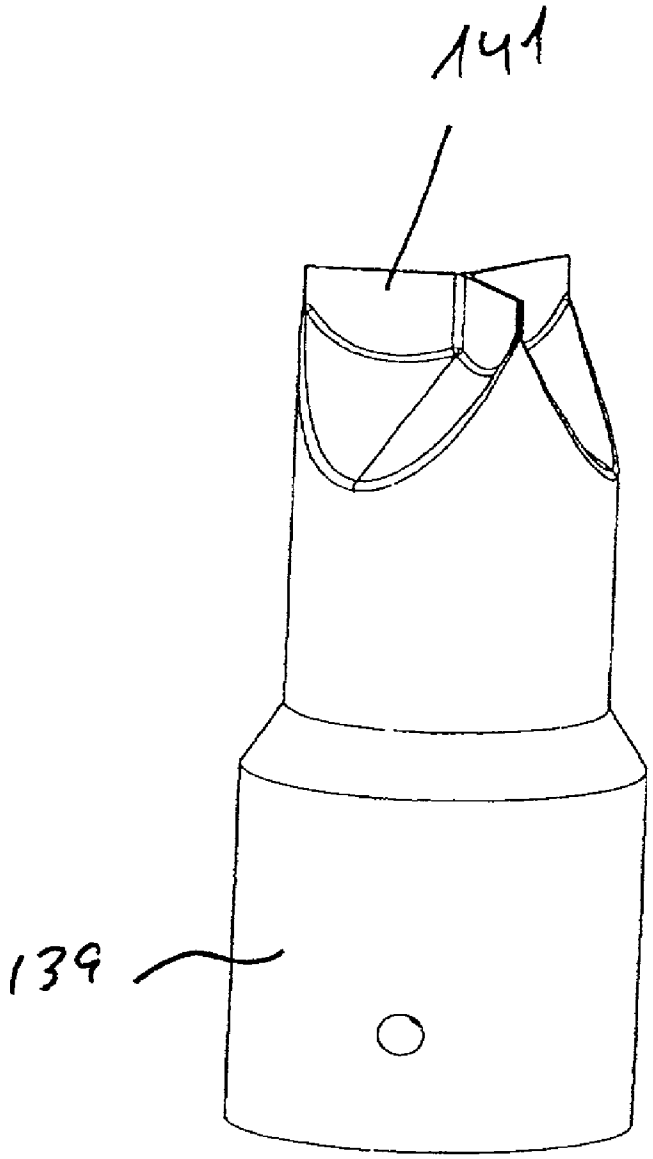


Fig. 9i

FIG 10



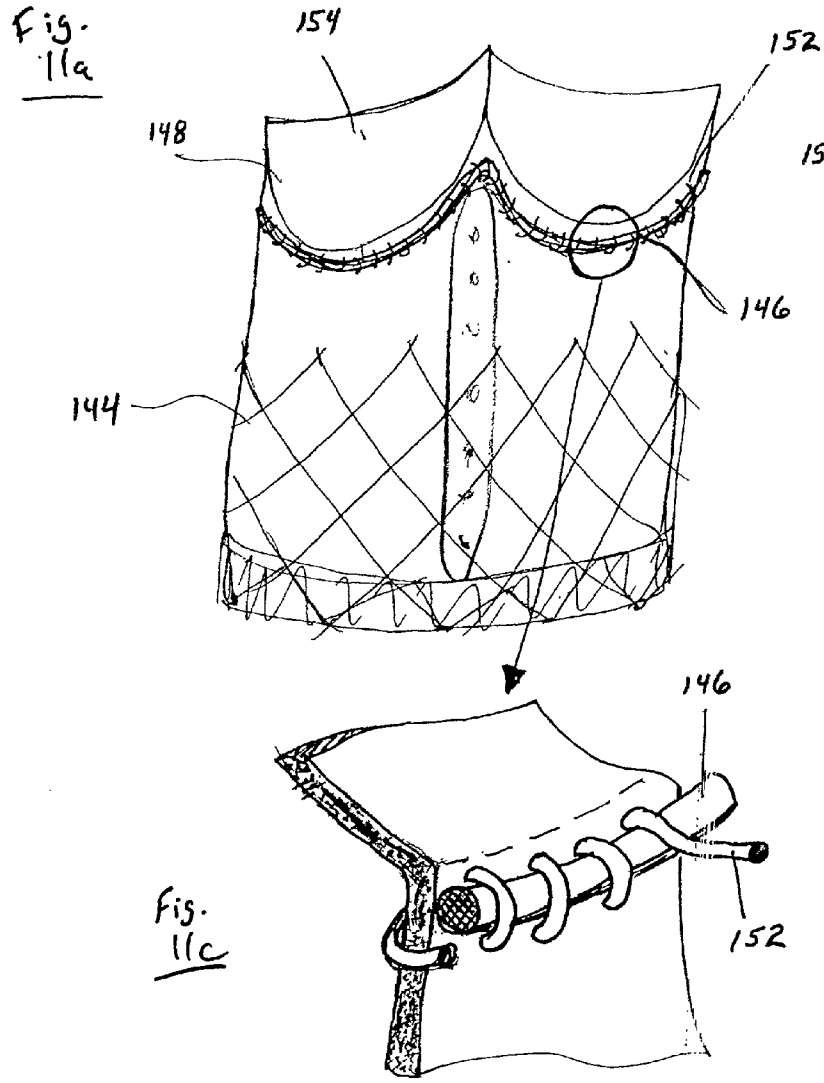


Fig. 11a

Fig. 11c

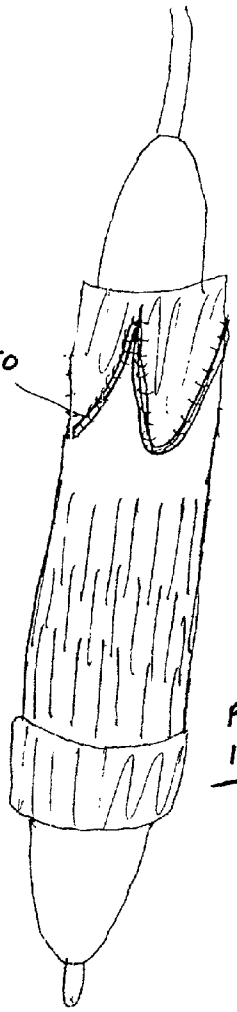


Fig. 11b

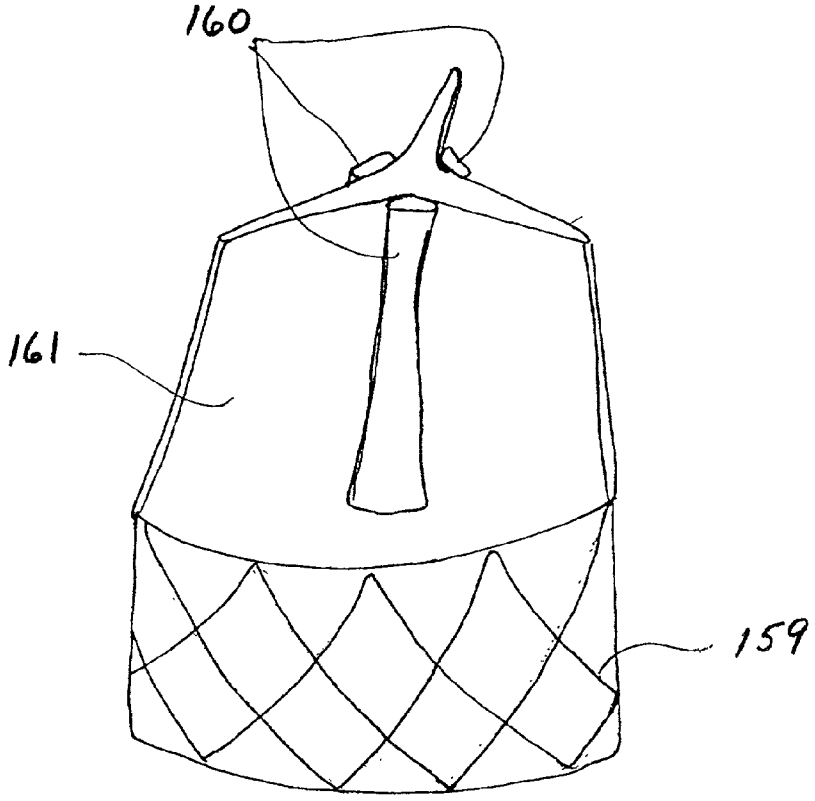
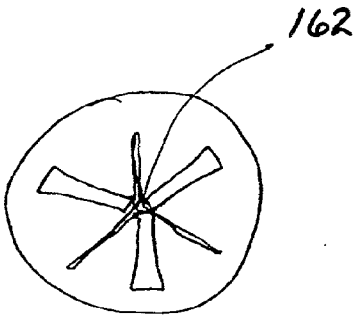
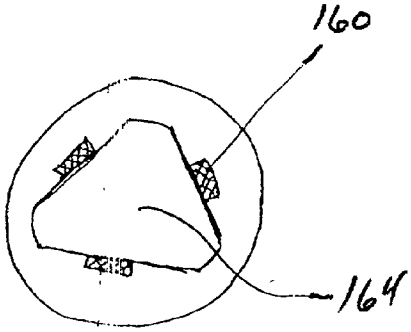


Fig. 12a



closed

Fig. 12b



open

Fig. 12c

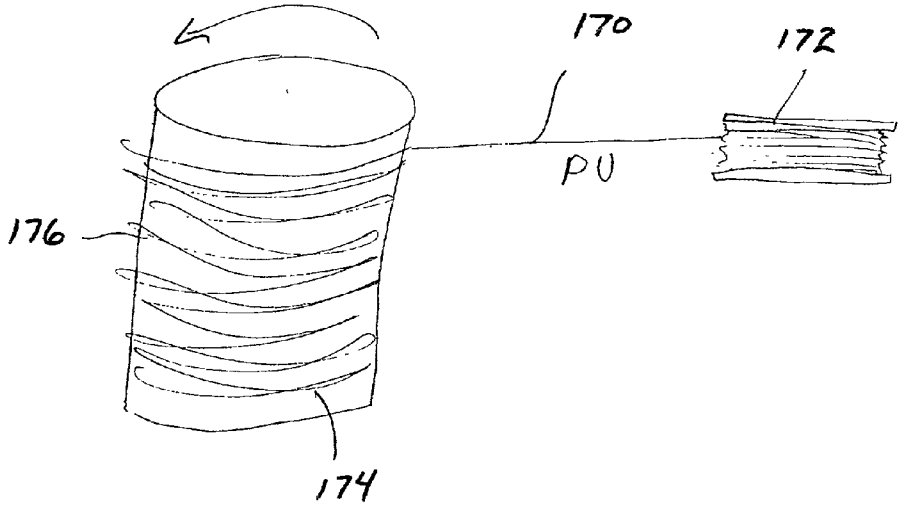


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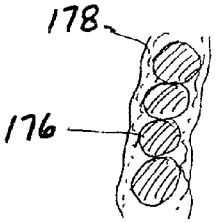


Fig. 13c

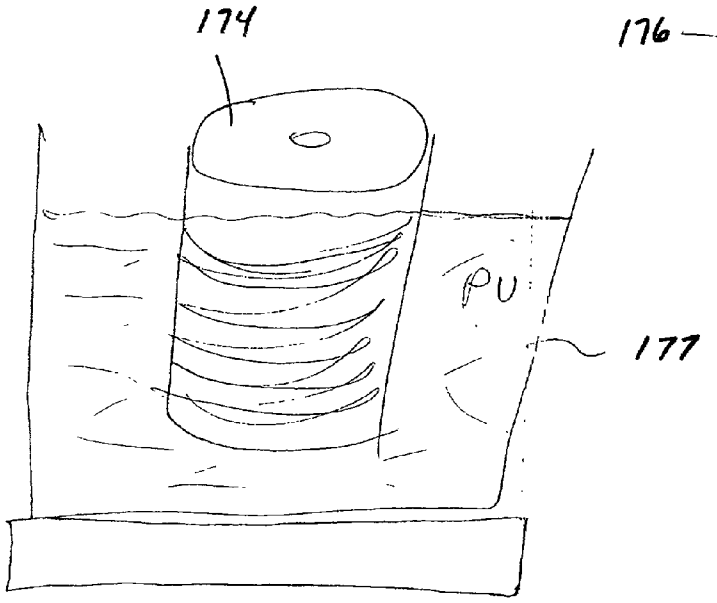


Fig. 13b

FIG 14

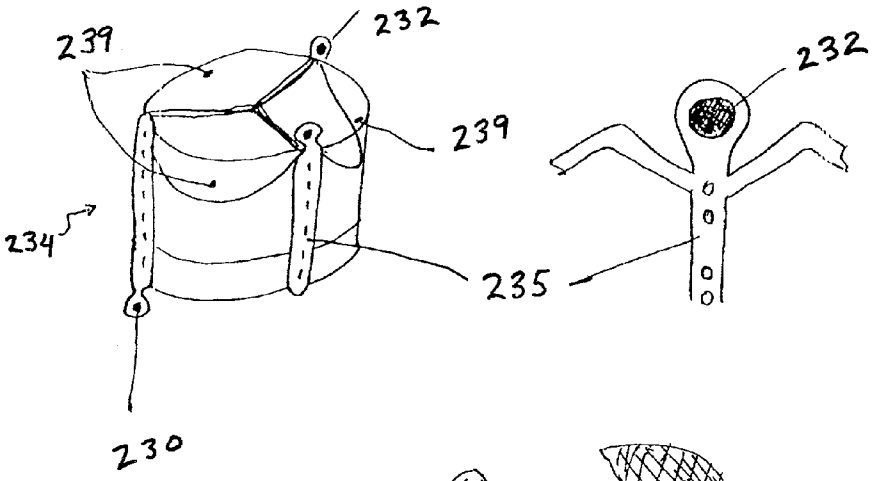


Fig. 14a

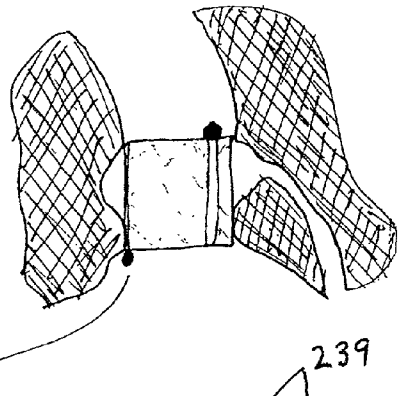


Fig. 14b

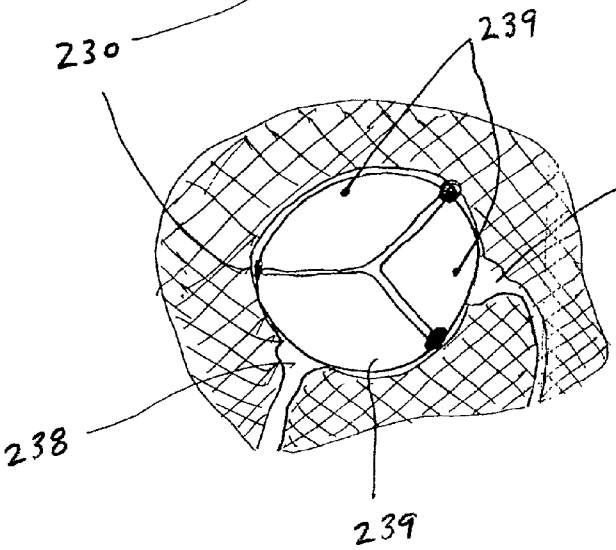


Fig. 14c

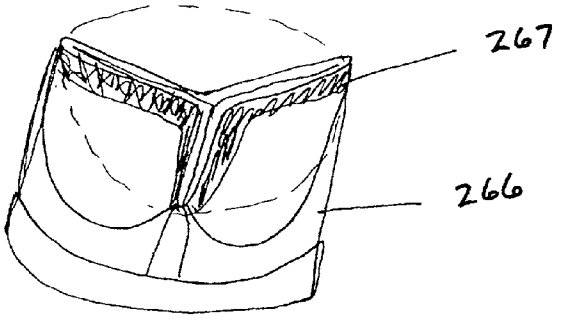


Fig. 15a

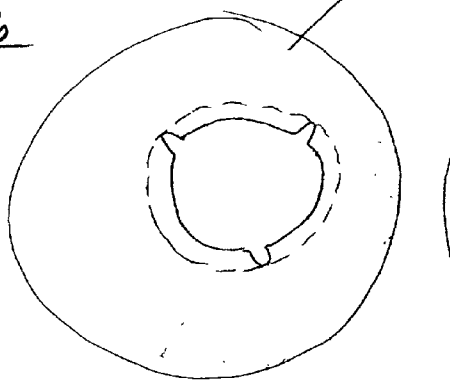


Fig. 15b

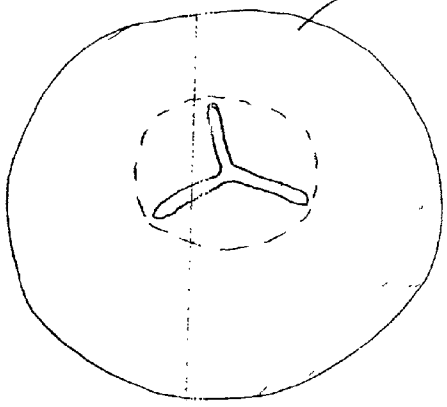


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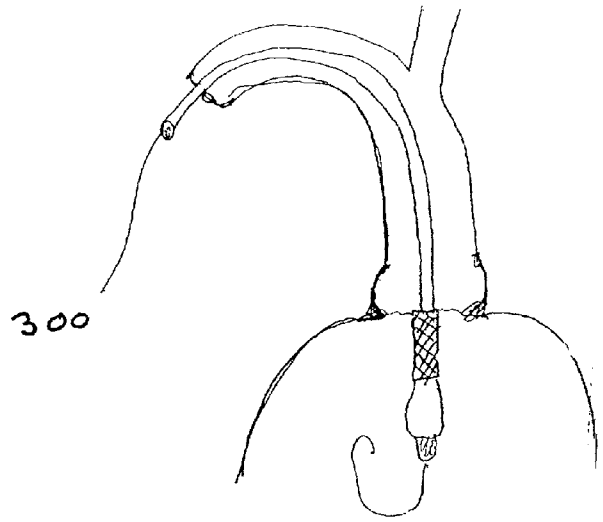


Fig. 16a

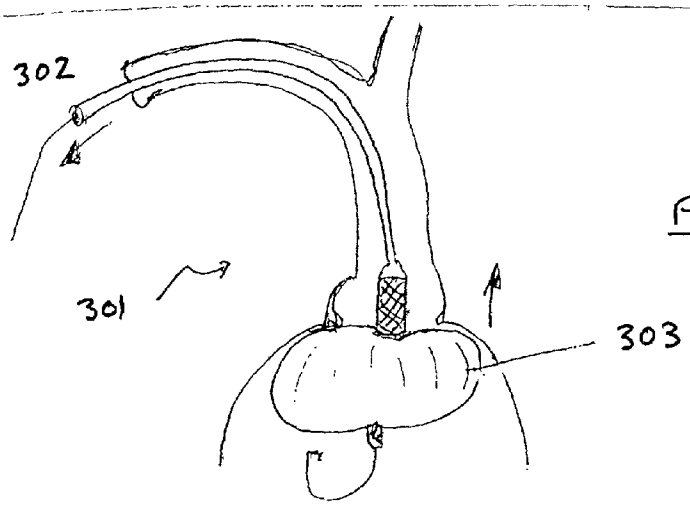


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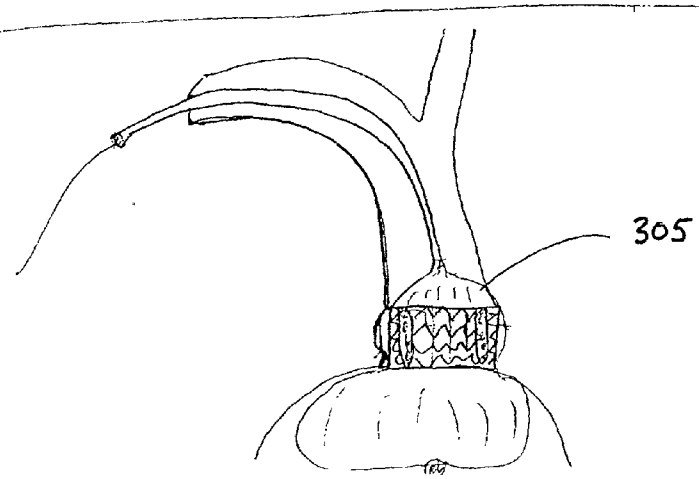


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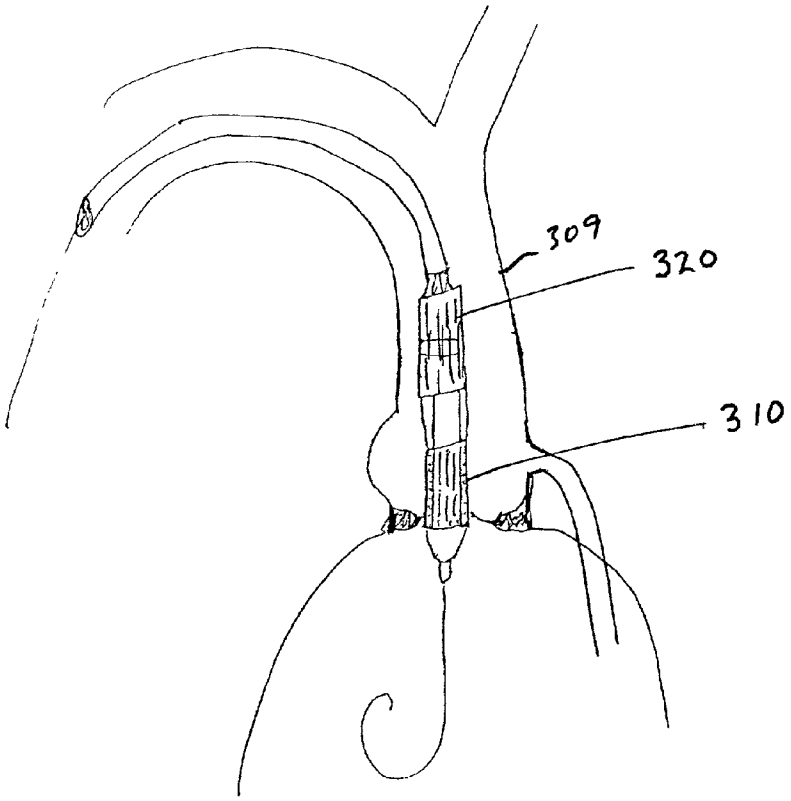


Fig. 17a

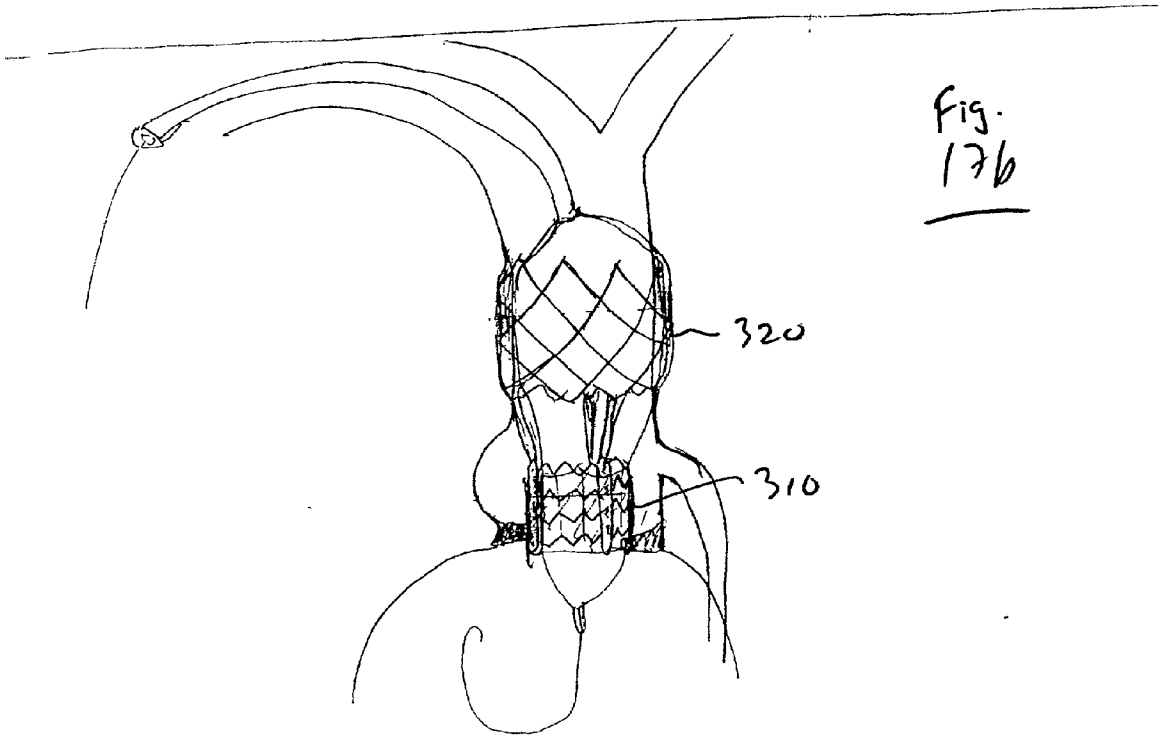


Fig. 17b

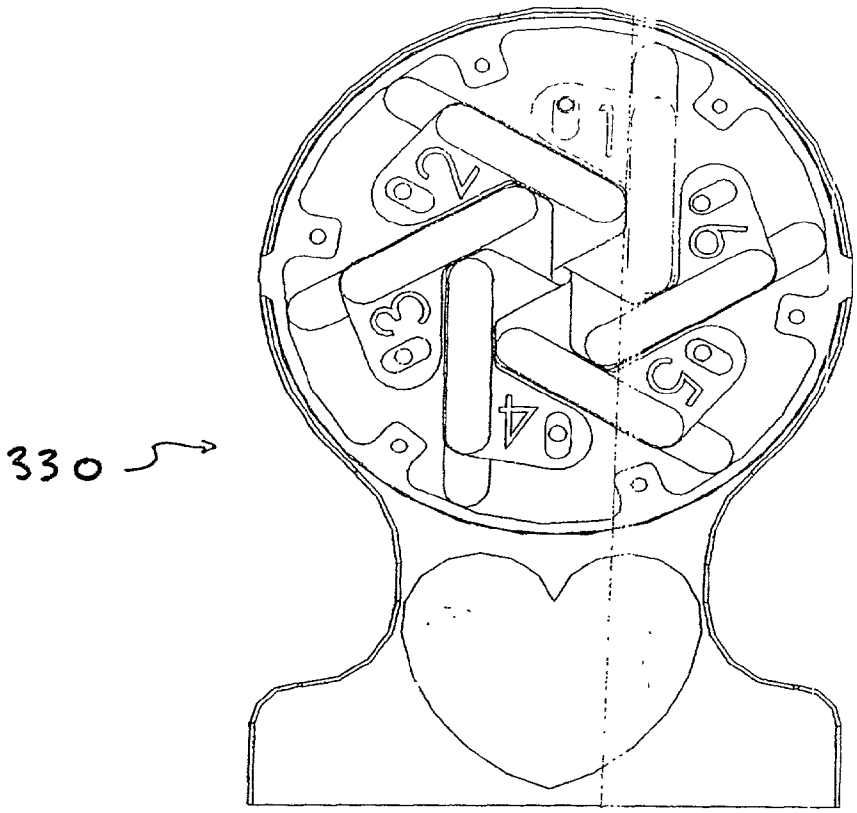


Fig. 18b

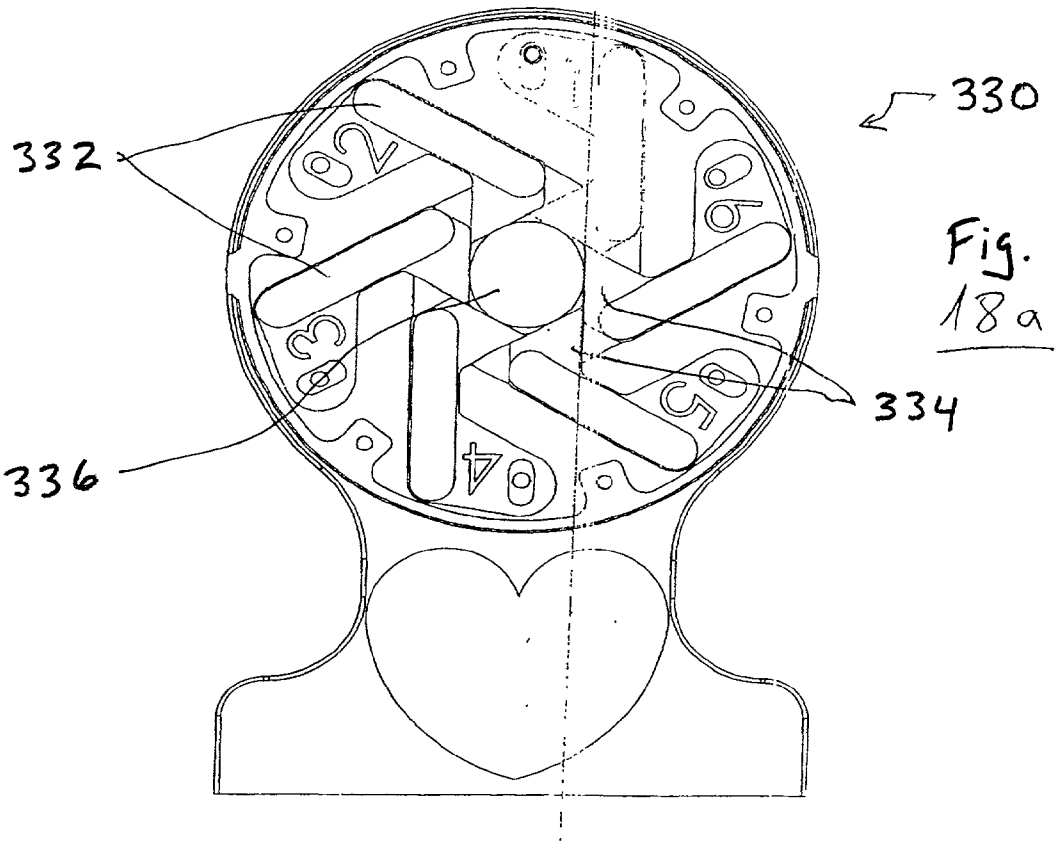


Fig. 18a

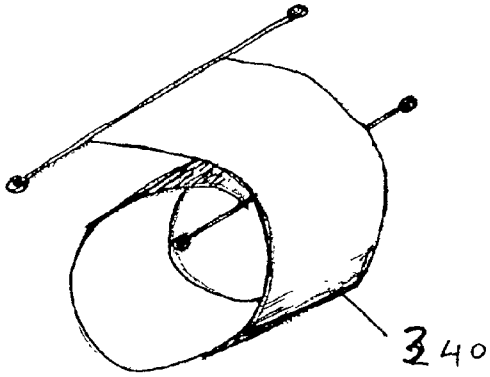


Fig. 19a

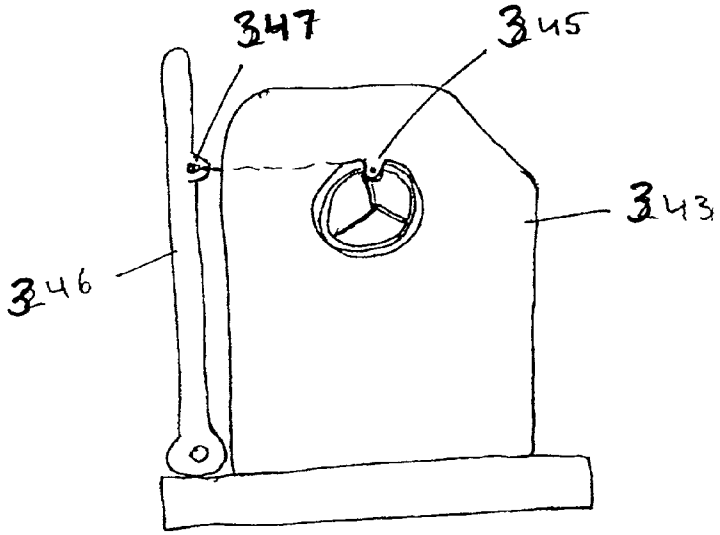


Fig. 19b

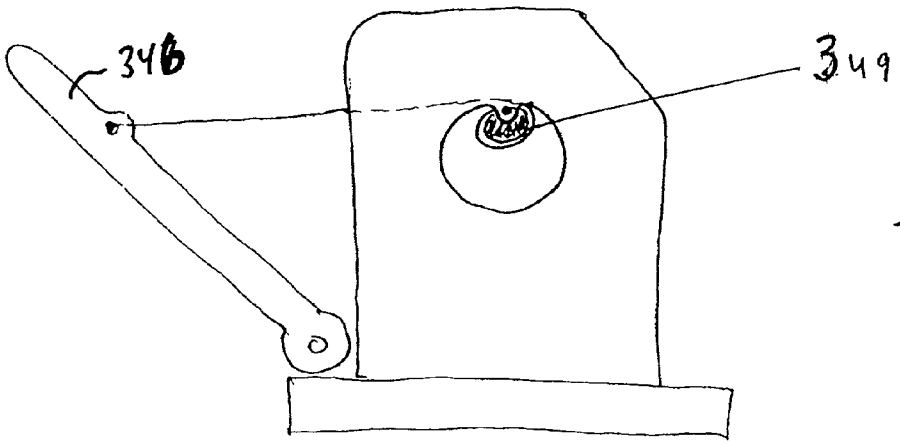


Fig. 19c

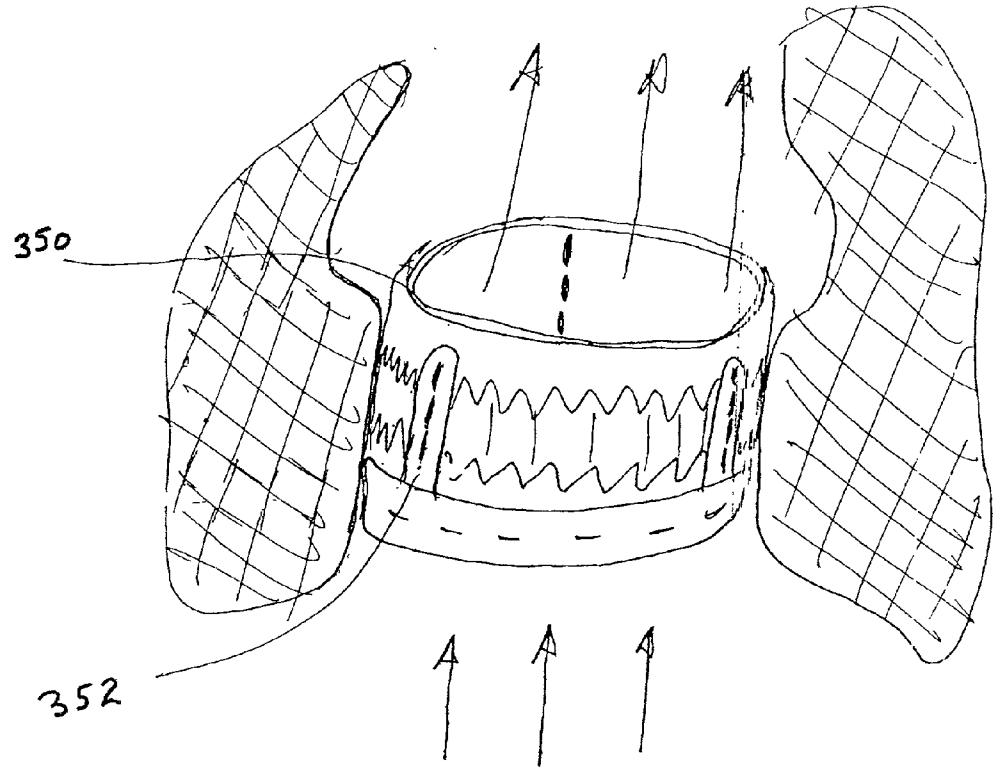


Fig. 20a

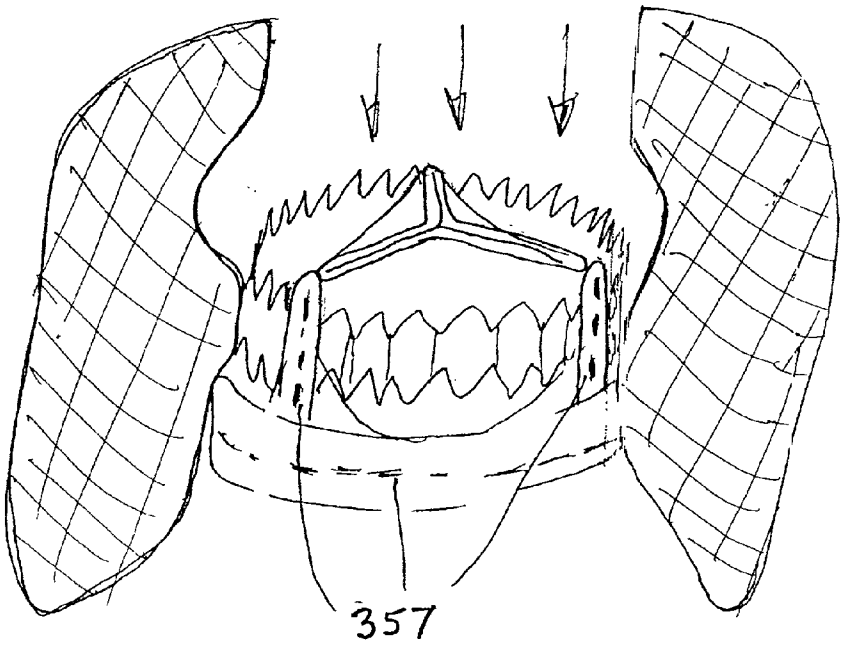


Fig. 20b

FIG 21

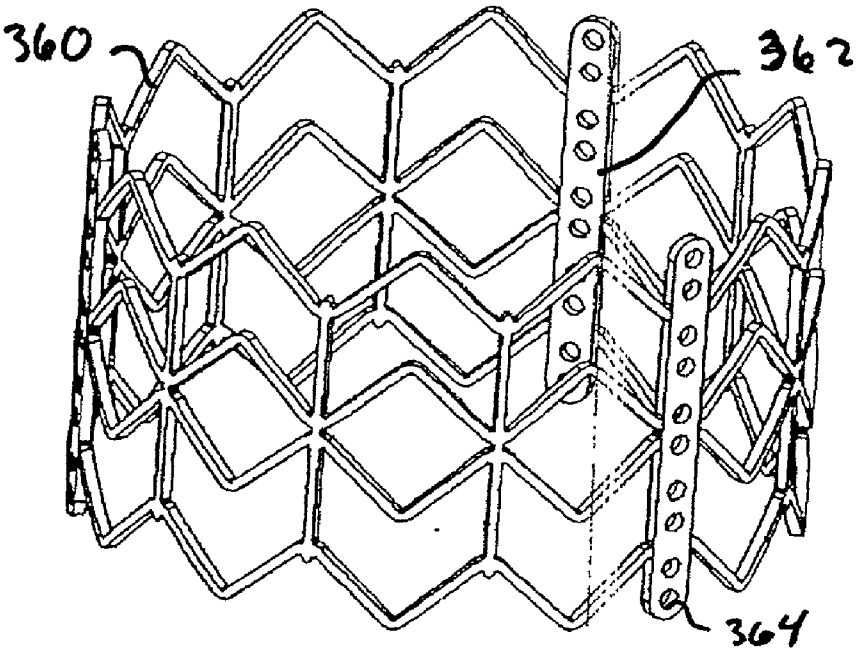


FIG 22

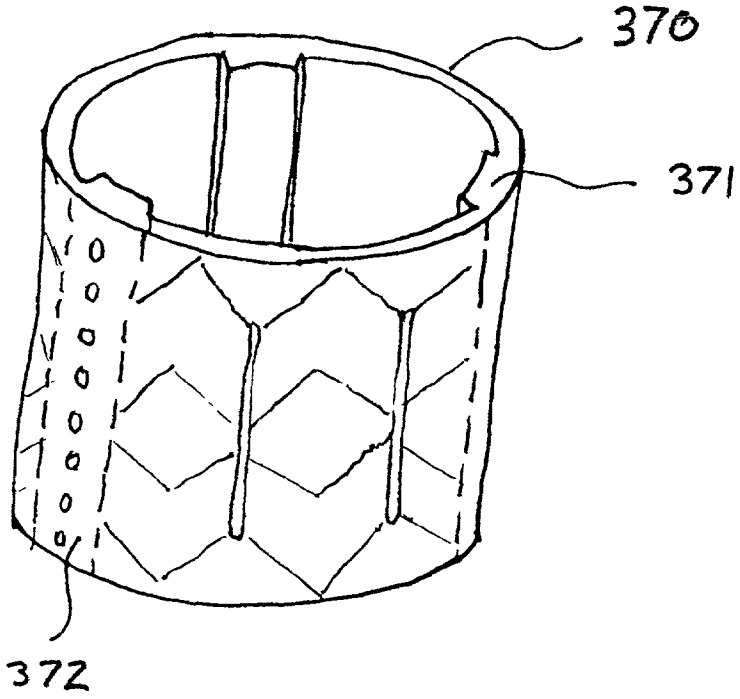




Fig. 23a

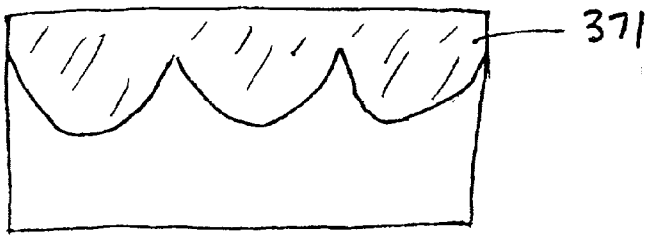


Fig. 23b

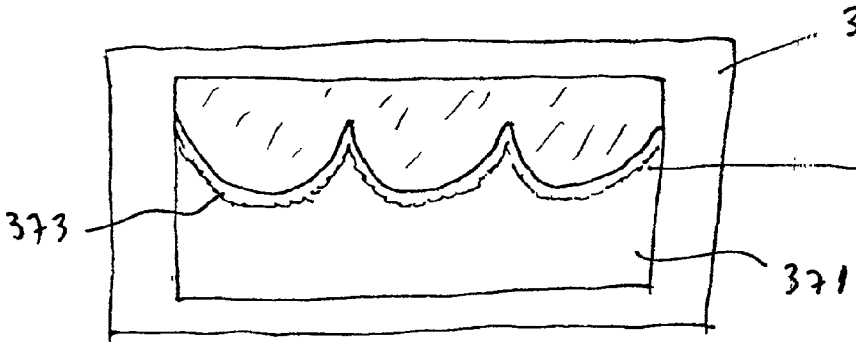


Fig. 23c

Fig. 23d

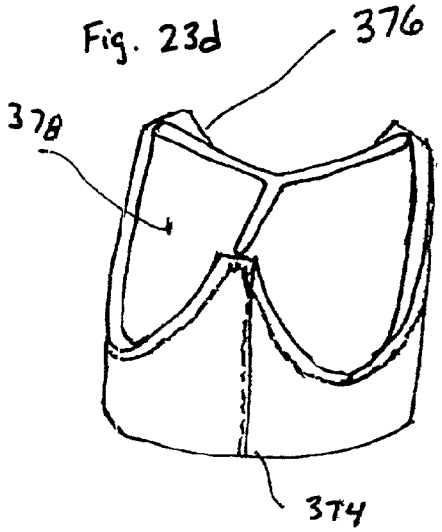
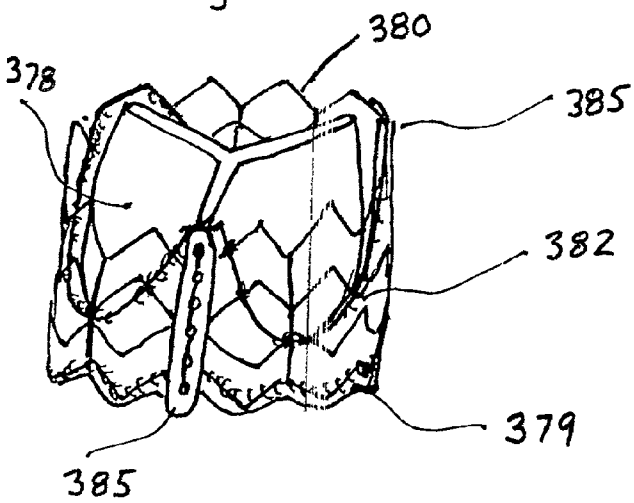


Fig. 23e



IMPLANTABLE PROSTHETIC VALVE

FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly, it relates to a valve prosthesis for cardiac implantation or for implantation in other body ducts.

BACKGROUND OF THE INVENTION

[0002] There are several known prosthesis valves that have been previously described. U.S. Pat. No. 5,411,552 (Andersen et al.), entitled VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS, discloses a valve prosthesis comprising a stent made from an expandable cylinder-shaped thread structure comprising several spaced apices. The elastically collapsible valve is mounted on the stent with the commissural points of the valve secured to the projecting apices, which prevents the valve from turning inside out. Deployment of the valve can be achieved by using an inflatable balloon which in its deflated state is used to carry about it the valve structure to its position and, when inflated, deploys the stent in position to its final size. See, also, U.S. Pat. No. 6,168,614 (Andersen et al.) entitled VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY and U.S. Pat. No. 5,840,081 (Andersen et al.), titled SYSTEM AND METHOD FORIMPLANTING CARDIAC VALVES.

[0003] In PCT/EP97/07337 (Letac, Cribier et al.), published as WO 98/29057, entitled VALVE PROSTHESIS FOR IMPLANTATION IN BODY CHANNELS, there is disclosed a valve prosthesis comprising a collapsible valve structure and an expandable frame on which the valve structure is mounted. The valve structure is composed of a valvular tissue compatible with the human body and blood, the valvular tissue being sufficiently supple and resistant to allow the valve structure to be deformed from a closed state to an opened state. The valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, the guiding means creating stiffened zones which induce the valve structure to follow a patterned movement in its expansion to its opened state and in its turning back to its closed state. The valve structure can be extended to an internal cover which is fastened to the lower part of the valve structure to prevent regurgitation.

[0004] There are several known methods currently used for replacing aortic valves and several types of artificial prosthetic devices. Mechanical valves are commonly used in several different designs (single and double flap) manufactured by well-known companies such as St. Jude, Medtronic, Sulzer, and others. Some of the main disadvantages of these devices are: a need for permanent treatment of anticoagulants, noisy operation, and a need for a large-scale operation to implant.

[0005] There is a wide range of biologically based valves made of natural valves or composed of biological materials such as pericardial tissue. These too are made and marketed by well-known companies such as Edwards Lifesciences, Medtronic, Sulzer, Sorin, and others.

[0006] Polymer valves are new and are not yet in use, but several companies are in the process of developing such products. A new type of prosthesis is being considered, based on artificial polymer materials such as polyurethane.

[0007] The present invention introduces several novel structural designs for implantable valves. An aspect of the present invention deals with the possibility of implanting the valve percutaneously, i.e., inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the desired location via a large blood vessel such as the femoral artery, in a procedure similar to other known interventional cardiovascular procedures. The percutaneous deployment procedure and device has an impact on the product design in several parameters, some of which are explained hereinafter.

[0008] The percutaneous implantation of medical devices, and particularly prosthetic valves, is a preferred surgical procedure for it involves making a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation, as opposed to a large chest surgery incision, which requires general anesthesia, opening a large portion of the chest, and cardiopulmonary bypass. This percutaneous procedure is therefore considered safer.

[0009] The present invention provides a series of new concepts in the field of aortic valves and other human valves.

SUMMARY OF THE INVENTION

[0010] It is therefore thus provided, in accordance with a preferred embodiment of the present invention, a valve prosthesis device suitable for implantation in body ducts, the device comprising:

[0011] a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length; and

[0012] a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

[0013] whereby when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

[0014] Furthermore, in accordance with another preferred embodiment of the present invention, the support stent comprises an annular frame.

[0015] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly has a tricuspid configuration.

[0016] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is made from biocompatible material.

[0017] Furthermore, in accordance with another preferred embodiment of the present invention, the valve assembly is made from pericardial tissue, or other biological tissue.

[0018] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is made from biocompatible polymers.

[0019] Furthermore, in accordance with another preferred embodiment of the present invention, the valve assembly is made from materials selected from the group consisting of polyurethane and polyethylene terphthalane.

[0020] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly comprises a main body made from polyethylene terphthalane and leaflets made from polyurethane.

[0021] Furthermore, in accordance with another preferred embodiment of the present invention, said support stent is made from nickel titanium.

[0022] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

[0023] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

[0024] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are chemically adhered to the support stent.

[0025] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is riveted to the support beams.

[0026] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is stitched to the support beams.

[0027] Furthermore, in accordance with another preferred embodiment of the present invention, said beams are manufactured by injection using a mold, or by machining.

[0028] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is rolled over the support stent at the inlet.

[0029] Furthermore, in accordance with another preferred embodiment of the present invention, said valve device is manufactured using forging or dipping techniques.

[0030] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

[0031] Furthermore, in accordance with another preferred embodiment of the present invention, said valve assembly is made from coils of a polymer, coated by a coating layer of same polymer.

[0032] Furthermore, in accordance with another preferred embodiment of the present invention, said polymer is polyurethane.

[0033] Furthermore, in accordance with another preferred embodiment of the present invention, the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

[0034] Furthermore, in accordance with another preferred embodiment of the present invention, the heavy metal markers are selected from gold, platinum, iridium, or tantalum.

[0035] Furthermore, in accordance with another preferred embodiment of the present invention, the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation in vivo.

[0036] Furthermore, in accordance with another preferred embodiment of the present invention, said radio-opaque material comprises gold thread.

[0037] Furthermore, in accordance with another preferred embodiment of the present invention, the diameter of said support stent, when fully deployed is in the range of from about 19 to about 25 mm.

[0038] Furthermore, in accordance with another preferred embodiment of the present invention, the diameter of said support stent may be expanded from about 4 to about 25 mm.

[0039] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of U-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

[0040] Furthermore, in accordance with another preferred embodiment of the present invention, the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

[0041] Furthermore, in accordance with another preferred embodiment of the present invention, the main body of the valve assembly is made from coiled wire coated with coating material.

[0042] Furthermore, in accordance with another preferred embodiment of the present invention, the coiled wire and the coating material is made from polyurethane.

[0043] Furthermore, in accordance with another preferred embodiment of the present invention, a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

[0044] Furthermore, in accordance with another preferred embodiment of the present invention, the strengthening wire is made from nickel titanium alloy.

[0045] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a valve prosthesis device suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the main body is made from polyethylene terphtalate and collapsible leaflets are made form polyurethane.

[0046] Furthermore, in accordance with another preferred embodiment of the present invention, support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

[0047] Furthermore, in accordance with another preferred embodiment of the present invention, said support beams are chemically adhered to the main body.

[0048] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a valve prosthesis device suitable for implantation in body ducts, the device comprising:

[0049] a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length;

[0050] a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet; and

[0051] substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally.

[0052] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a crimping device for crimping the valve device described above or in claim 1, the crimping device comprising a plurality of adjustable plates that resemble a typical SLR (Single Lens Reflex) camera variable restrictor, each provided with a blade, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening.

[0053] Furthermore, in accordance with another preferred embodiment of the present invention, the multiple plates are adapted to move simultaneously by means of a lever and transmission.

[0054] Furthermore, in accordance with another preferred embodiment of the present invention, there is provided a method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

[0055] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[0056] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[0057] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the second inflatable portion of the balloon catheter;

[0058] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[0059] (e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

[0060] (f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[0061] (g) deflating the first and second inflatable portions of the balloon catheter; and

[0062] (h) retracting the balloon catheter and removing it from the patient's body.

[0063] Furthermore, in accordance with another preferred embodiment of the present invention, the guiding tool comprises a guide wire.

[0064] Finally, in accordance with another preferred embodiment of the present invention, there is provided a method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

[0065] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[0066] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[0067] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

[0068] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[0069] (e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

[0070] (f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[0071] (g) deflating the first and second inflatable portions of the balloon catheter; and

[0072] (h) retracting the balloon catheter and removing it from the patient's body.

BRIEF DESCRIPTION OF THE FIGURES

[0073] To better understand the present invention and appreciate its practical applications, the following Figures are provided and referenced hereafter. It should be noted that the Figures are given as examples only and in no way limit the scope of the invention as defined in the appended claims.

[0074] **FIG. 1** illustrates an implantable prosthetic tricuspid valve in accordance with a preferred embodiment of the present invention, suitable for percutaneous deployment using a stent or similar deploying means, in its deployed-inflated position;

[0075] **FIG. 2** depicts an implantable valve according to the present invention mounted over a deploying stent with an inflatable balloon;

[0076] **FIG. 3** illustrates an implantable valve according to the present invention mounted over a stent with an inflatable balloon, in a crimped position;

[0077] **FIG. 4** depicts implantable valve deployment in a natural aortic valve position in accordance with the present invention;

[0078] **FIG. 5** demonstrates manufacturing a polyurethane implantable valve in a dipping technique according with the present invention;

[0079] **FIGS. 6***a* to **6***e* illustrate manufacturing of an implantable valve by forging according to the present invention;

[0080] **FIGS. 7***a* and **7***b* demonstrate composite valve, which has polyurethane (PU) leaflets and Polyethylene terphthalate (PET) tubular-crown shaped construction, according to the present invention;

[0081] **FIGS. 8***a* and **8***b* depict a manufacture process of a composite valve made of flexible PU leaflets, rigid PU construction for mounting and a PET tubular end;

[0082] FIGS. **9** to **9***i* demonstrate different methods of attachment between the valve and stent according to the present invention;

[0083] **FIG. 10** illustrates a dipping mandrel with an extra portion, which improves the sealing ability of the valve, according to the present invention;

[0084] **FIGS. 11***a* to **11***c* illustrate a valve mounted on a stent with an extra support, which improves the force distribution on the valve material and facilitates prolonged durability of the valve, according to the present invention;

[0085] **FIGS. 12***a* to **12***c* depict a valve with rigid supports according to the present invention, located substantially in the center of its leaflets. This design allows the valve leafs to perform without outer support;

[0086] **FIGS. 13***a* to **13***c* illustrate the manufacturing of a reinforced PU tube composed of strong fiber from PU, PET or other and a softer PU coating, for serving as the supporting structure;

[0087] **FIGS. 14***a* to **14***c* demonstrate incorporation of heavy metal markers on the stent, according to the present invention. These markers allow orientation control while positioning the device at the required location;

[0088] **FIGS. 15***a* to **15***c* demonstrate a valve with radio-opaque coating, according to the present invention, which allows imaging of the valve motion under angiogram;

[0089] **FIGS. 16***a* to **16***c* illustrate a procedure, which helps in accurate positioning the valve device with respect to the longitudinal orientation;

[0090] **FIGS. 17***a* and **17***b* describe a valve device according to the present invention, comprising one valve assembly mounted on a stent and an additional portion with a stent only. This allows placing the device in a way that coronaries are not blocked, longitudinal positioning thus becomes less sensitive and the extra stent decreases the risk of device migration within the vasculature;

[0091] **FIGS. 18***a* and **18***b* demonstrate a crimping device according to the present invention, which can crimp a valve device in the operating theater as part of the implantation procedure;

[0092] **FIGS. 19***a* to **19***c* depict a crimping machine according to the present invention, similar to the one described in **FIG. 18** with a different mechanical method;

[0093] **FIGS. 20***a* and **20***b* demonstrate a valve according to the present invention, made of a tube mounted on a stent. During systole the tube is fully open and during diastole the tube collapses according to the mounting geometry providing tight sealing;

[0094] **FIG. 21** depicts a stent structure according to the present invention, with built-in mounting portions of constant length, which allow valve mounting;

[0095] **FIG. 22** depicts yet another preferred embodiment a valve assembly in accordance with the present invention, having dilated supports; and

[0096] **FIGS. 23***a* to **23***e* depict stages in a method of manufacturing an implantable prosthetic valve in accordance with another preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0097] A main aspect of the present invention is the introduction of several novel designs for an implantable prosthesis valve. Another aspect of the present invention is the disclosure of several manufacture methods for the manufacturing of implantable prosthesis valves in accordance with the present invention. A further aspect of the present invention is the provision of novel deployment and positioning techniques suitable for the valve of the present invention.

[0098] Basically the implantable prosthetic valve of the present invention comprises a leafed-valve assembly, preferably tricuspid but not limited to tricuspid valves only,

consisting of a conduit having an inlet end and an outlet, made of pliant material arranged so as to present collapsible walls at the outlet. The valve assembly is mounted on a support structure such as a stent adapted to be positioned at a target location within the body duct and deploy the valve assembly by the use of deploying means, such as a balloon catheter or similar devices. In embodiments suitable for safe and convenient percutaneous positioning and deployment the annular frame is able to be posed in two positions, a crimped position where the conduit passage cross-section presented is small so as to permit advancing the device towards its target location, and a deployed position where the frame is radial extended by forces exerted from within (by deploying means) so as to provide support against the body duct wall, secure the valve in position and open itself so as to allow flow through the conduit.

[0099] The valve assembly can be made from biological matter, such as a natural tissue, pericardial tissue or other biological tissue. Alternatively, the valve assembly may be made form biocompatible polymers or similar materials. Homograph biological valves need occasional replacement (usually within 5 to 14 years) and this is a consideration the surgeon must take into account, when selecting the proper valve implant according to the patient type. Metal mechanical valves, which have better durability qualities, carry the associated risk of long-term anticoagulation treatment.

[0100] The frame can be made from shape memory alloys such as nickel titanium (nickel titanium shape memory alloys, or NiTi, as marketed, for example, under the brand name Nitinol), or other biocompatible metals. The percutaneously implantable embodiment of the implantable valve of the present invention has to be suitable for crimping into a narrow configuration for positioning and expandable to a wider, deployed configuration so as to anchor in position in the desired target location.

[0101] The support stent is preferably annular, but may be provided in other shapes too, depending on the cross-section shape of the desired target location passage.

[0102] Manufacturing of the implantable prosthetic valve of the present invention can be done in various methods, for example, by dipping, injection, electrospinning, rotation, ironing, or pressing.

[0103] The attachment of the valve assembly to the support stent can be accomplished in several ways, such as by sewing it to several anchoring points on the support stent, or riveting it, pinning it, or adhering it, to provide a valve assembly that is cast or molded over the support stent, or use any other suitable way of attachment.

[0104] To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet.

[0105] Furthermore, floating supports may be added to enhance the stability of the device and prevent it from turning inside out.

[0106] An important aspect of certain embodiments of the present invention is the provision of rigid support beams incorporated with the support stent that retains its longitudinal dimension while the entire support stent may be longitudinally or laterally extended.

[0107] The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different types of devices are discussed and explained below with reference to the accompanying drawings. Note that the drawings are only given for the purpose of understanding the present invention and presenting some preferred embodiments of the present invention, but this does in no way limit the scope of the present invention as defined in the appended claims.

[0108] Reference is now made to **FIG. 1**, which illustrates a general tricuspid implantable prosthesis valve **20** in accordance with a preferred embodiment of the present invention, suitable for percutaneous deployment using an expandable stent or similar deploying means, shown in its deployed position. A valve assembly **28** comprises a conduit having an inlet **24** and an outlet **26**, the outlet walls consisting of collapsible pliant material **29** that is arranged to collapse in a tricuspid arrangement. The valve assembly **28** is attached to an annular support stent **22**, the one in this figure being a net-like frame designed to be adapted to crimp evenly so as to present a narrow configuration and be radially deployable so as to extend to occupy the passage at the target location for implantation in a body duct. Support beams **23** are provided on annular support stent **22** to provide anchorage to valve assembly **28**. Support beams **23** are optionally provided with bores **25** to allow stitching of valve assembly **28** to support beams **23** by thread, wires, or other attachment means.

[0109] In the embodiment shown in **FIG. 1, a** cuff portion **21** of the valve assembly **28** is wrapped around support stent **22** at inlet **24** to enhance the stability. Preferably cuff portion **21** of valve material **28** is attached to support beams **23**.

[0110] Note that the entire valve structure is adapted to be radially crimped and radially expanded, and this lends to provide ease of navigation through narrow passages in the vasculature during positioning of the device and adequate deployment on the final location. This is made possible by the provision of a collapsible support stent structure. However, the support beams remain at all times constant at their length and thus are suitable for serving as the pliable valve assembly's anchorage. The valve assembly is attached to the support stent at the support beams, and due to their constant length there is no need for slack material as the attachment points **(25)** remain at constant distances regardless of the position of the valve device (crimped or deployed). This is an important feature for this means that the manufacturer of the valve device can make sure the valve assembly is secured and fastened to the support stent at all times. In prior art implantable valve devices the entire support structure changes its dimensions from its initial first crimped position and final deployed position, and this means that in the attachment of the valve assembly to the support structure one must take into consideration these dimension changes and leave slack material so that upon deployment of the device the valve assembly does not tear or deform. In the valve device of the present invention there is no relative movement between the valve assembly and the support beams (along the longitudinal central axis of the device). As a result, the valve device of the present invention acquires greater durability and is capable of withstanding the harsh conditions prevailing within the vasculature and especially the millions of cycles of stress applied by the blood pressure.

[0111] The fixed attachment of the valve assembly to the support stent in the valve device of the present invention results in greater stability, enhanced safety, better sealing and consequently longer lifespan. The novel design of the valve device of the present invention leads to longitudinal strength and rigidity whereas its collapsible support structure results in radial flexibility.

[0112] **FIG. 2** depicts an implantable valve **30** mounted on a deployable stent **32**. The valve assembly **34** is attached to the deployable support stent **32** (dotted lines) along three substantially equidistant and substantially parallel support beams **40** of constant length, which are part of stent **32**. The attachment of valve assembly **34** to stent **32** is facilitated by the support beams **40** to which valve assembly **34** is stitched with thread or fiber **46** (through bores **42** of support beams **40**). Outlet leafs **38**, which are a slack portion of the valve assembly, dangle inwardly, and the whole device is carried by an inflatable balloon **48**, which serves as the deploying device. A portion of the valve assembly **34** at an inlet zone **45** is optionally rolled over support stent **32** at the inlet, making up a rolled sleeve, which enhances the sealing of the device at the valve inlet.

[0113] **FIG. 3** demonstrates an implantable valve mounted to a stent **50** with an inflatable balloon **52**, in a crimped position. The support stent **50** is initially crimped about the balloon **52** so that is presents a narrow cross-section and is thus suitable for percutaneous catheterization and deployment.

[0114] **FIG. 4** depicts an implantable valve deployment in a natural aortic valve position. The implantable valve is advanced while mounted over the balloon **52** until it reaches the desired target location **54** in a body duct, for example, aorta **56**. The balloon is inflated and the support stent **50** expands radially to take up its position.

[0115] **FIG. 5** demonstrates the manufacture of a polyurethane valve in a dipping technique. A dipping mandrel **60** is provided with a tubular portion **62** with surfaces **64** that correspond to the collapsible valve leaflets to be manufactured. Mandrel **60** is dipped into a dissolved polyurethane bath **66** and is coated with a polyurethane coating in the desired form of the valve. Then, after the polyurethane coating has hardened sufficiently, the completed valve is removed from mandrel **60**.

[0116] **FIGS. 6***a* to **6***e* illustrate manufacturing an implantable valve by forging. A suitable tubularly shaped material **74** is placed tightly on a tubular portion **68** of mandrel **67**, covering the cusp portion **69**. Flexible inserts **76** are pressed to mandrel **67**, forging the tubular material to mandrel shape **80**. A tapered ring **70** holds the flexible inserts in place as the whole mold is placed in a hot oven regulated to a desired temperature, which is lower than the material's melting point. **FIG. 6***e* illustrates a sectional side view of the mandrel and a cross cut portion of the mold. The mold is made to press inwardly on the mandrel, which is covered with the valve material. As a result the material takes up the desired shape. The materials used can vary, for example, polyurethane (PU), polyethylene terphthalate (PET), or any other suitable material, which may be formed by heating.

[0117] **FIGS. 7***a* and **7***b* demonstrate a method of manufacturing a composite valve, which has PU leaflets and PET tubular construction with a crown shape. PU is an excellent fatigue resistant material but is sensitive to tear. The PU is reinforced by the PET crown to allow safe attachment to a stent by means of stitching, riveting, or any other suitable attachment method. A PET crown **86** is placed on a mandrel **87**, which is then (turned and) dipped in a container of dissolved PU. The manufactured device is a valve assembly having leaflets **88** composed of pure PU, and thus fatigue resistant, and a main body made of PET with protruding attachment portions **90** suitable for attachment built in the PU.

[0118] **FIGS. 8***a* and **8***b* demonstrate a method of manufacturing a composite valve, which is based on flexible PU **92** for as the main body of the valve, rigid PU support beams **94** serving for the attachment area, and PET sleeve **96** portions for the valve inlet. The need for a rigid portion for attachment (support beams **94**) is explained by the tendency of the flexible, fatigue resistant material to tear as already explained. The advantage of the stiff PU support beams is that they are chemically adhered to the main body, and this improves the overall durability of the valve due to reduction of inner forces and friction in the attachment area specially attachment between two different materials. The valve is dipped in the method mentioned with reference to **FIG. 5**, and the rigid PU support beam **94** is created by way of mold injection, machining or any other suitable way. The rigid PU support beam **94** is placed on the valve and then dipped into the container of dissolved PU. This is done while the valve is positioned on the mandrel (not shown). This method provides the ability to composite several materials into one body and, by that, gain the advantage of the various properties of the materials as they are needed in different areas of the prosthesis.

[0119] FIGS. **9** to **9***i* demonstrate different methods of attachment between a valve assembly and the support stents. A valve assembly **99** shown in **FIG. 9** is incorporated into valve **100** shown in **FIG. 9***a*, where a support stent **102** is attached to valve assembly **99** through support beam **106**. A detail is shown in **FIG. 9***b*, where, in cross-section, it can be seen that layer **108** is an optional inner support made of stainless steel or rigid polymeric material, valve assembly **99** comprises a PET layer **105** coated with a PU layer **104**, with the outer support beam **106**. Connector **107** is a connecting wire made of a strong material, such as stainless steel. **FIG. 9***c* illustrates an alternative arrangement for attachment by a rivet **109**, and in **FIG. 9***d* the attachment is achieved by a suture **110**.

[0120] **FIGS. 9***e* to **9***g* show an attachment method comprising shaped rigid members **116**, preferably made from metal, which tightly hold the PU valve material **118** by fitting in between a PU U-shaped nest **120** and are attached to a stent **122** by extruding portions **124** that are provided on U-shaped rigid member **116**, which fit the bores **126** of the support beam **128** of the stent **122**. **FIGS. 9***h* and **9***i* show another attachment method, where rigid support beams in the form of frame construction **132** are provided, and the valve assembly pliant material **135** made of a tubular material is inserted through a gap **137** in the frame. After insertion, a fastening rod **133** is inserted through the pocket formed between the pliant material and the frame and holds the valve in position.

[0121] **FIG. 10** illustrates a dipping mandrel **139** with an extending portion **141**, which improves the sealing ability of

the valve. Since the valve is attached to a collapsible stent and is itself collapsible, it is difficult to determine the exact shape of the valve after crimping and deploying. It is of major importance that sealing will be achieved. By adding the extension **141** the leaflets are made longer than needed to exactly close the outlet, and therefore when they are in the collapsed state, substantial portions of the leaflets fall on each other creating better sealing.

[**0122**] **FIGS. 11***a* to **11***c* illustrate a valve assembly mounted on a support stent **144** with interlaced strengthening wire **146**, which improves the force distribution on the valve material and facilitates prolonged durability of the valve. The support is in the form of a wire, which has a crown shape as the shape of the three cusp valve base **148**, it also has the ability to be crimped **150** to a small diameter, together with the stent, valve and balloon, as shown in **FIG. 11***b*. The forces applied to the valve edge **148** while working, are applied to the attachment points, by making the attachment line longer we reduce the force on each attachment point. In this support method the valve is attached by suturing **152** the entire line to the extra support wire **146**. This wire can be made of stainless steel, nickel titanium alloy such as nitinol, or polymeric material. The support suture renders the valve assembly default fault lines where the valve material more readily flexes, thus ensuring proper operation of the valve flaps (leaflets). Optionally the valve assembly shown in **FIGS. 11***a* to **11***c* can be mounted on a support stent such as the one described herein or similar supporting structures. The strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion **154** of the valve assembly may flap.

[**0123**] **FIGS. 12***a* to **12***c* depict a valve device provided with a stent **159** and substantially equidistant rigid support beams **160**, interlaced or attached to the slack portion of the valve assembly material **161**, arranged longitudinally. This design allows the valve leaflets to perform without outer support. The support in standard valves is by tying the upper edge of the cusp to a rigid embodiment, so that it reacts to the load as a suspension bridge. In this new design the prevention of collapsing is achieved similar to an Indian tent, i.e., the rigid supports lean on each other **162** when the valve is closed but do not interfere in opening **164** when the valve is open.

[**0124**] **FIGS. 13***a* to **13***c* illustrate the manufacturing of a valve assembly in accordance with another preferred embodiment of the present invention. At first a polyurethane thread line **170** is fed from a PU supply **172**, and coiled around a cylindrical drum **174** to form coil **176**. Then, drum **174** with coil **176** is dipped in a PU bath **177**, and a second layer **178** of the PU coats coil **176**, making it a stronger construction capable of withstanding tearing forces both laterally and in other directions. Incorporating two different types of materials—such as PU and PET—may render greater durability and endurance to the valve assembly. This material is an alternative material to be used in the forging method shown in **FIG. 6**.

[**0125**] FIGS. **14** to **14***c* demonstrate the incorporation of heavy metal markers on the stent, which markers allow observation and thereby adjustment of orientation while placing the device in the required location. Heavy metals are radiopaque, that is, they are conspicuous on an angioscopic image, which is a two-dimensional image. Since the coronary arteries ostia **237** and **238** are located near the typical valve deployment location and must stay open, it is extremely important to make sure that the deployed valve assembly is not blocking a coronary ostium. In some cases the stent is lower than the ostium and in those cases it will stay open, but in some cases as shown in these figures it is necessary to make sure that the stent portion **239** that is connecting the valve supports **235** is opposite the coronary ostia, and in that way the blood supply is preserved through the stent struts. Two heavy metal markers **232** are attached at the outlet side, one marker **230** at the inlet side. It is possible to adjust the angiogscopic view to the plane of the left coronary as shown in **FIG. 14***b* and anatomically locate the other accordingly. If the two upper markers **232** are placed in the radiographic two dimensional image, one on top of the other, and the low marker **230** on the opposite side, we make sure that the coronaries are open to blood flow as seen in **FIG. 14***c*. Gold, platinum, iridium or tantalum are all biocompatible materials suitable for the markers described above.

[**0126**] **FIGS. 15***a* to **15***c* illustrate a valve with a portion of radio-opaque material **267** such as a thread of gold at the sealing edge. When a valve is implanted, it is very important to have clear indications of how the valve is functioning in vivo; pressure measurements, flow visualization, and doppler measurements are utilized. It is also possible to examine the valve by ultrasound methods, however, observing the opening and closing of the valve cusps on a monitor. **FIG. 15***b* is an angiographic image **268** of the open valve, while image **169** in **FIG. 15***c* is the closed position as seen on the angiogram.

[**0127**] **FIGS. 16***a* to **16***c* illustrate a procedure, which helps in placing the device in the longitudinal position. It is very important to place the device in the correct longitudinal position, for if it is too deep in the left ventricle it may interfere with the mitral valve function by improper closing or function of the valve. If it is positioned too high it may migrate, it may leak via the sinus cavities, which are located around it, and/or it may block the coronaries. It is a necessary task to position the valve prosthesis in a narrow target location. In **FIG. 14 a** method of lateral orientation placement is shown, and **FIGS. 16***a* to **16***c* illustrate a longitudinal positioning. The valve device (the valve assembly and the support stent) is placed on an inflatable balloon catheter, comprising double independently inflatable chambers **303**, **305**, and is inserted into the left ventricle **302** in the crimped position and guided over a guiding stylet or guide wire **300**. The balloon, which is larger than the annulus diameter when inflated, is inflated in the left ventricle **302**, and then the whole device is pulled slightly backwards. The balloon is supported on the inner part of the annulus **303**, allowing positioning of the device in the exact desired position. In addition, it temporarily blocks the blood flow, and that improves the ability to hold the device in place while inflating it. The next step is inflating the second balloon **305**, which deploys the valve device in the desired location.

[**0128**] The method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient,

as depicted in **FIGS. 16***a*, **16***b* and **16***c*, comprises the steps of:

[**0129**] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[**0130**] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[**0131**] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the second inflatable portion of the balloon catheter

[**0132**] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[**0133**] (e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

[**0134**] (f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[**0135**] (g) deflating the first and second inflatable portions of the balloon catheter; and

[**0136**] (h) retracting the balloon catheter and removing it from the patient's body.

[**0137**] **FIG. 17** describes a positioning of a valve device **310** using an additional deployable stent **320**. There are several problems that may be encountered while deploying the stent and valve in the aortic valve location: blockage of coronaries may occur that is dangerous if the diameter of the stent is similar to that of the coronaries aortic root **309**. Secondly, migration of the whole device may also occur, which is a dangerous possibility, and there is the problematic challenge of exact positioning of the valve device that is very difficult to accomplish, as already explained. The newly special designed device with a double diameter inflatable balloon and double stent design allows placement of the device in a way that coronaries will not be blocked because of a safe difference that is kept between the diameters, longitudinal placing is less sensitive because of the small diameter which ensures prevents over expansion of the valved prosthesis. The distal stent **320**, which contains no valve, is expanded into the ascending aorta, while the proximal stent **310** is placed simultaneously in the annular position. This placement method is less challenging due to the smaller diameter of the proximal stent **310** which ensures that the mitral valve is safe too dimensions are preserved, and the additional stent decreases the risk of device migration. It is safer to over dilate in the aorta, which is not true for the annulus.

[**0138**] The method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, as depicted in **FIGS. 17***a* and **17***b*, comprises the steps of:

[**0139**] (a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

[**0140**] (b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

[**0141**] (c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

[**0142**] (d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

[**0143**] (e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

[**0144**] (f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

[**0145**] (g) deflating the first and second inflatable portions of the balloon catheter; and

[**0146**] (h) retracting the balloon catheter and removing it from the patient's body.

[**0147**] **FIGS. 118***a* and **18***b* illustrate an accessory crimping device that is adapted to crimp a valve device in the operating theater as part of the implantation procedure. The crimping device **330** comprises several adjustable plates that resemble a typical SLR camera variable restrictor. It is comprised of simultaneously movable plates **332** each provided with a blade **334**, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening **336**. Initially (see **FIG. 18***a*) the plates are drawn apart providing a large enough opening for the implantable valve to be positioned within that opening. When the plates are drawn towards the center (see **FIG. 18***b*), the opening **336** reduces in size but still retains the annular shape, and this facilitates the crimping of the valve frame to a small dimension suitable for percutaneous positioning.

[**0148**] **FIG. 19***a* depicts a crimping method for the support stent of the valve prosthesis device of the present invention, whereby stent **340** is curled. In **FIG. 19***b* a crimping device **343** is shown, comprising a body having an

annular void in which an expanded stent is positioned. Lever **346** is connected to the end **347** of the stent and as the lever is pulled the stent is curled about axle **345** into a curled position **349** (**FIG. 19***c*).

[**0149**] **FIGS. 20***a* and **20***b* depict a valve made of a simple tube mounted to a stent **352**. During systole period the tube is fully open and during diastole period the tube collapses according to the mounting geometry **357** and achieves sealing.

[**0150**] **FIG. 21** describes a newly designed support stent **360** in its open position. Three of the longitudinal struts **362** are full and thick and always stay with their original constant size, serving as anchoring support. Each of these struts **362** is provided with a plurality of bores **364**, which are later used for mounting the valve assembly (not shown) and tying it to stent **360**. Between struts **362** a web-like construction is provided, which is capable of being crimped to a narrow state and capable of being deployed again to a wider state.

[**0151**] **FIG. 22** illustrates another preferred embodiment of an implantable prosthetic valve according to the present invention. It comprises a metal tube **370**, having three portions with a thicker wall **371** than in the rest of the tube **370**, these areas form the longitudinal columns **372** in the construction, after the tube is cut to its final form. The advantage of such a construction is in its superior bending strength, in specific required portions of the construction, with minimal interference to the crimped volume of the whole construction.

[**0152**] **FIGS. 23***a* to **23***c* depict a new method of manufacturing an artificial or biological crimpable valve device. A piece of fabric material **370** (**FIG. 23***a*), is dipped in PU to create a portion which is later formed into valve leaflets **371** (**FIG. 23***b*). This composite material **371** is then attached to an additional piece of fabric such as PET **372** by means of stitching, suturing or other attaching technique **373** (**FIG. 23***c*). The resulting fabric **375** is cut along stitching line **373** leaving enough material to later suture the valve assembly to the support construction. It is then formed to a tubular shape and stitched **374** (**FIG. 23***d*). The tubular valve is then attached to a support construction **380** by suturing the bottom part around the valve **379** tightly to prevent leakage, and around the cut fabric line **376** (**FIG. 23***e*). This open wall structure **378** allows blood flow to the coronary arteries. The valve is later placed with the coronary artery between the support columns **385**. Additional variations of this can be made by replacing the composite material **371**/**370** with a biological patch such as a suitable pericardium patch. In some cases it is possible to make the same valve without cutting the fabric **372** with the shaped cut **376**, and by that create a valve with an outer tubular shape. The embodiment of **FIGS. 23***a* to **23***c* is easy to manufacture as it is generally flat throughout most of the production process and only at the final stage of mounting on the support stent is it given a three-dimensional form.

[**0153**] A typical size of an aortic prosthesis valve is from about 19 to about 25 mm in diameter. A maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter. The present invention introduces a device, which has the ability to change its diameter from about 4 mm to about 25 mm. Artificial valves are not new; however, artificial valves in accordance with the present invention posses the ability to change shape and size for the purpose of delivery and as such are novel. These newly designed valves require new manufacturing methods and technical inventions and improvements, some of which were described herein.

[**0154**] As mentioned earlier, the material of which the valve is made from can be either biological or artificial. In any case new technologies are needed to create such a valve.

[**0155**] To attach the valve to the body, the blood vessels determine the size during delivery, and the requirements for it to work efficiently, there is a need to mount it on a collapsible construction which can be crimped to a small size, be expanded to a larger size, and be strong enough to act as a support for the valve function. This construction, which is in somewhat similar to a large "stent", can be made of different materials such as Nitinol, biocompatible stainless steel, polymeric material or a combination of all. Special requirement for the stent are a subject of some of the embodiments discussed herein.

[**0156**] The mounting of the valve onto a collapsible stent is a new field of problems. New solutions to this problem are described herein.

[**0157**] Another major aspect of the design of the valve of the present invention is the attachment to the body.

[**0158**] In the traditional procedure the valve is sutured in place by a complicated suturing procedure. In the case of the percutaneous procedure there is no direct access to the implantation site therefore different attachment techniques are needed.

[**0159**] Another new problem that is dealt herein is the delivery procedure, which is new and unique. Positioning of the device in the body in an accurate location and orientation requires special marking and measuring methods of the device and surgical site as was disclosed herein.

[**0160**] Artificial polymer valves require special treatment and special conditions when kept on a shelf, as well as a special sterilization procedure. One of the consequences of the shelf treatment is the need to crimp the valve during the implantation procedure. A series of devices and inventions to allow the crimping procedure are disclosed herein.

[**0161**] It should be clear that the description of the embodiments and attached Figures set forth in this specification serves only for a better understanding of the invention, without limiting its scope as covered by the following claims.

[**0162**] It should also be clear that a person skilled in the art, after reading the present specification could make adjustments or amendments to the attached Figures and above described embodiments that would still be covered by the following claims.

1. A valve prosthesis device suitable for implantation in body ducts, the device comprising:

a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the

target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length; and

a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

whereby when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

2. The valve device of claim 1, wherein the support stent comprises an annular frame.

3. The valve device of claim 1, wherein said valve assembly has a tricuspid configuration.

4. The valve device of claim 1, wherein said valve assembly is made from biocompatible material.

5. The valve device of claim 4, wherein the valve assembly is made from pericardial tissue, or other biological tissue.

6. The valve device of claim 1, wherein said valve assembly is made from biocompatible polymers.

7. The valve device of claim 6, wherein the valve assembly is made from materials selected from polyurethane and polyethylene terphthalane.

8. The valve device of claim 7, wherein said valve assembly comprises a main body made from polyethylene terphthalane and leaflets made from polyurethane.

9. The valve device of claim 1, wherein said support stent is made from nickel titanium.

10. The valve device of claim 1, wherein the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

11. The valve device of claim 1, wherein the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

12. The valve device of claim 1, wherein the support beams are chemically adhered to the support stent.

13. The valve device of claim 1, wherein said valve assembly is riveted to the support beams.

14. The valve device of claim 1, wherein said valve assembly is stitched to the support beams.

15. The valve device of claim 1, wherein said beams are manufactured by injection using a mold, or by machining.

16. The valve device of claim 1, wherein said valve assembly is rolled over the support stent at the inlet.

17. The valve device of claim 1, wherein said valve device is manufactured using forging or dipping techniques.

18. The valve device of claim 1, wherein said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

19. The valve device of claim 1, wherein said valve assembly is made from coiled a polymer, coated by a coating layer of same polymer.

20. The valve device of claim 19, wherein said polymer is polyurethane.

21. The valve device of claim 1, wherein the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

22. The valve device of claim 21, wherein the heavy metal markers are selected from gold, platinum, iridium, or tantalum.

23. The valve device of claim 1, wherein the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation in vivo.

24. The valve device of claim 23, wherein said radio-opaque material comprises gold thread.

25. The valve device of claim 1, wherein the diameter of said support stent, when fully deployed is in the range of from about 19 to about 25 mm.

26. The valve device of claim 1, wherein the diameter of said support stent may be expanded from about 4 to about 25 mm.

27. The valve device of claim 1, wherein the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of u-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

28. The valve device of claim 1, wherein the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

29. The valve device of claim 1, wherein the main body of the valve assembly is made from coiled wire coated with coating material.

30. The valve device of claim **31**, wherein the coiled wire and the coating material is made from polyurethane.

32. The valve device of claim 1, wherein a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

33. The valve device of claim 32, wherein the strengthening-wire is made from nickel titanium alloy.

33. A valve prosthesis device suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the main body is made from polyethylene terphtalate and collapsible leaflets are made form polyurethane.

34. The valve device of claim 33, wherein support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

35. The valve device of claim 33, wherein said support beams are chemically adhered to the main body.

36. A valve prosthesis device suitable for implantation in body ducts, the device comprising:

support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by

means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length;

valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet;

substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally.

37. A crimping device for crimping the valve device of claim 1, the crimping device comprising a plurality of adjustable plates that resemble a typical SLR camera variable restrictor, each provided with a blade, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening.

38. The crimping device of claim 37, wherein the multiple plates are adapted to move simultaneously by means of a lever and transmission.

39. A method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

(a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

(b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

(c) providing a deployable implantable valve prosthesis device adapted to be mounted on the second inflatable portion of the balloon catheter

(d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

(e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

(f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

(g) deflating the first and second inflatable portions of the balloon catheter; and

(h) retracting the balloon catheter and removing it from the patient's body.

40. The method of claim 39, wherein the guiding tool comprises a guide wire.

41. A method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

(a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

(b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

(c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

(d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

(e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

(f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

(g) deflating the first and second inflatable portions of the balloon catheter; and

(h) retracting the balloon catheter and removing it from the patient's body.

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Remarks:
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(54) Repositionable heart valve

(57) An apparatus is described for endovascularly replacing a patient's heart valve comprising: a replacement valve; an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor, wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

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Opposition against
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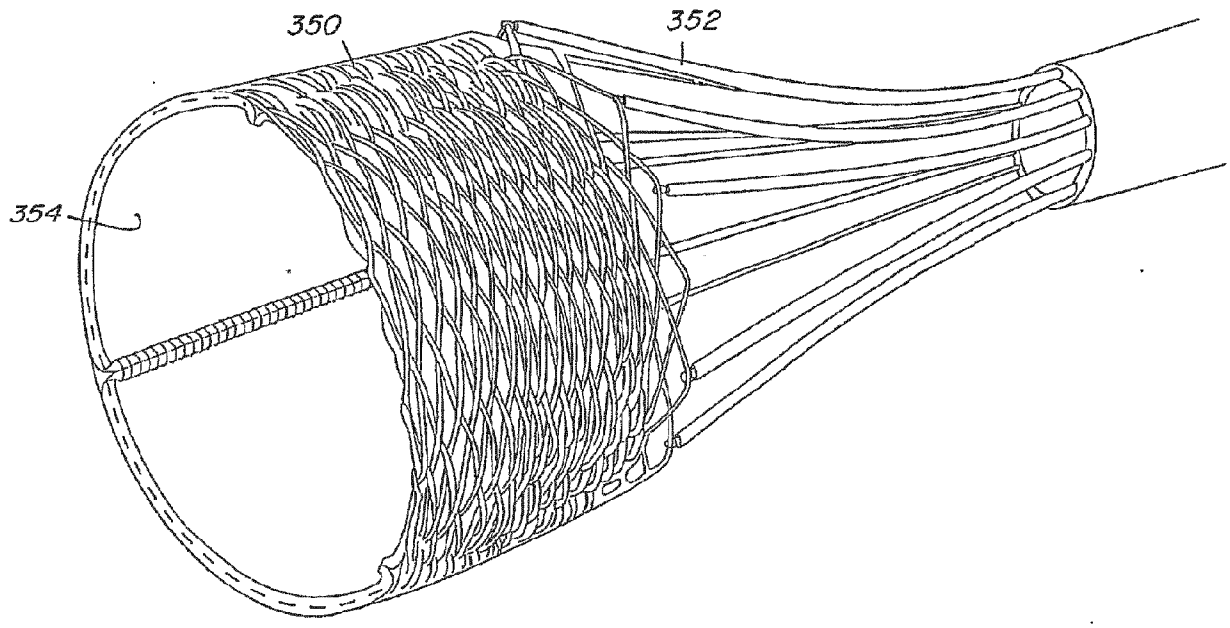


FIG. 24

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Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for percutaneously replacing a heart valve with a replacement valve using an expandable and retrievable anchor.

[0002] Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

[0003] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates.

[0004] When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

[0005] Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. 2-5% of patients die during surgery.

[0006] Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

[0007] In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. Percutaneous Valve Technologies ("PVT") of Fort Lee, New Jersey, has developed a balloon-expandable stent integrated with a bioprosthetic valve. The stent/valve device is deployed across the native diseased valve to permanently hold the valve open, thereby alleviating a need to excise the native valve and to position the bioprosthetic valve in place of the native valve. PVT's device is designed for delivery in a cardiac catheterization laboratory under local anesthesia using fluoroscopic guidance, thereby avoiding general anesthesia and open-heart surgery. The device was first implanted in a patient in April of 2002.

[0008] PVT's device suffers from several drawbacks. Deployment of PVT's stent is not reversible, and the stent is not retrievable. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

[0009] Another drawback of the PVT device is its relatively large cross-sectional delivery profile. The PVT system's stent/valve combination is mounted onto a delivery balloon, making retrograde delivery through the aorta challenging. An antegrade transseptal approach may therefore be needed, requiring puncture of the septum and routing through the mitral valve, which significantly increases complexity and risk of the procedure. Very few cardiologists are currently trained in performing a transseptal puncture, which is a challenging procedure by itself.

[0010] Other prior art replacement heart valves use self-expanding stents as anchors. In the endovascular aortic valve replacement procedure, accurate placement of aortic valves relative to coronary ostia and the mitral valve is critical. Standard self-expanding systems have very poor accuracy in deployment, however. Often the proximal end of the stent is not released from the delivery system until accurate placement is verified by fluoroscopy, and the stent typically jumps once released. It is therefore often impossible to know where the ends of the stent will be with respect to the native valve, the coronary ostia and the mitral valve.

[0011] Also, visualization of the way the new valve is functioning prior to final deployment is very desirable. Visualization prior to final and irreversible deployment cannot be done with standard self-expanding systems, however, and the replacement valve is often not fully functional before final deployment.

[0012] Another drawback of prior art self-expanding replacement heart valve systems is their lack of radial strength. In order for self-expanding systems to be easily delivered through a delivery sheath, the metal needs to flex and bend inside the delivery catheter without being plastically deformed. In arterial stents, this is not a challenge, and there are many commercial arterial stent systems that apply adequate radial force against the vessel wall and yet can collapse to a small enough of a diameter to fit inside a delivery catheter without plastically deforming.

[0013] However when the stent has a valve fastened inside it, as is the case in aortic valve replacement, the anchoring of the stent to vessel walls is significantly challenged during diastole. The force to hold back arterial pressure and prevent blood from going back inside the ventricle during diastole will be directly transferred to the stent/vessel wall interface. Therefore the amount of radial force required to keep the self expanding stent/valve in contact with the vessel wall and not sliding will be much

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higher than in stents that do not have valves inside of them. Moreover, a self-expanding stent without sufficient radial force will end up dilating and contracting with each heartbeat, thereby distorting the valve, affecting its function and possibly migrating and dislodging completely. Simply increasing strut thickness of the self-expanding stent is not a practical solution as it runs the risk of larger profile and/or plastic deformation of the self-expanding stent.

[0014] U.S. patent application Serial No. 2002/0151-970 to Garrison et al. describes a two-piece device for replacement of the aortic valve that is adapted for delivery through a patient's aorta. A stent is percutaneously placed across the native valve, then a replacement valve is positioned within the lumen of the stent. By separating the stent and the valve during delivery, a profile of the device's delivery system may be sufficiently reduced to allow aortic delivery without requiring a transseptal approach. Both the stent and a frame of the replacement valve may be balloon-expandable or self-expanding.

[0015] While providing for an aortic approach, devices described in the Garrison patent application suffer from several drawbacks. First, the stent portion of the device is delivered across the native valve as a single piece in a single step, which precludes dynamic repositioning of the stent during delivery. Stent foreshortening or migration during expansion may lead to improper alignment.

[0016] Additionally, Garrison's stent simply crushes the native valve leaflets against the heart wall and does not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation. FurtherstiU, the stent comprises openings or gaps in which the replacement valve is seated post-delivery. Tissue may protrude through these gaps, thereby increasing a risk of improper seating of the valve within the stent.

[0017] In view of drawbacks associated with previously known techniques for percutaneously replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

SUMMARY OF THE INVENTION

[0018] One aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at an anchor site; repositioning the anchor in the anchor site; and deploying the anchor at the anchor site. The repositioning step may include the step of contracting the anchor and re-expanding the anchor at the anchor site for finer repositioning. The contracting step may include the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

[0019] In another aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of endovascularly or percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to a deployed configuration in which the anchor contacts tissue at a first anchor site; repositioning the anchor to a second anchor site; and deploying the anchor at the second anchor site. The repositioning step may include the step of contracting the anchor and reexpanding the anchor at the second anchor site. The contracting step may includes the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor.

[0020] In some embodiments the deploying step includes the step of releasing the anchor from a deployment tool. The delivering step may include the step of delivering the replacement heart valve coupled to the anchor or, alternatively, separate from the anchor, in which case the method further includes the step of attaching the replacement valve to the anchor.

[0021] In instances in which the heart valve is an aortic valve, the delivering step may include the step of endovascularly or percutaneously delivering the expandable anchor and replacement valve to the vicinity of the aortic valve along a retrograde approach.

[0022] In some embodiments the deploying step may include the step of expanding a balloon within the anchor, and in some embodiments the deploying step may include the step of locking the anchor in an expanded configuration. Proximal and distal regions of the anchor may be expanded separately.

[0023] The invention may also include the step of registering the anchor with the first or second anchor site, such as by contacting tissue of the heart valve to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

[0024] Another aspect of the invention provides a method for percutaneously replacing a heart valve of a patient. The method includes the steps of percutaneously delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; expanding the anchor to an expanded configuration in which the anchor contacts tissue at an anchor site, such as first a force of at least one pound; visually observing the anchor location; and releasing the anchor from a deployment tool. The replacement valve may be delivered coupled to the anchor or separate from the anchor, in which case the method also includes the step of attaching the valve to the anchor.

[0025] In some embodiments the method further includes the step of repositioning the anchor to a second anchor site after the observing step and before the releasing step. In some embodiments the expanding step includes the step of applying an external non-hydraulic or non-pneumatic actuation force on the anchor, and in

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some embodiments the method further includes the step of expanding a balloon within the anchor after the observing step. The method may include the step of registering the anchor with the anchor site.

[0026] One aspect of the present invention provides an apparatus for endovascularly replacing a patient's native heart valve. The apparatus comprises an anchor having an expandable braid and a replacement valve adapted to be secured within the patient. In some embodiments, the expandable braid of the anchor is fabricated from a single strand of wire. In some embodiments, the expandable braid comprises at least one edge feature. The anchor and the replacement valve preferably are configured for endovascular delivery and deployment.

[0027] The present invention relates to an apparatus for replacing a patient's native heart valve. The apparatus comprises an anchor having an expandable braid adapted for endovascular delivery. The anchor is further adapted for expansion via active foreshortening at an anchor site within the native valve. The apparatus also includes a replacement valve adapted to be secured within the patient. In some embodiments, the anchor braid is further adapted to remain substantially undeformed in response to a pressure up to 0.5 arm or 2 arm directed substantially radially inward toward the central axis. In some embodiments, the anchor braid comprises a first region and a second region having a diameter larger than a diameter of the first region when the anchor is expanded. In some embodiments, the anchor braid is configured to have an expanded shape that is radially symmetrical, bilaterally symmetrical, or asymmetrical. In some embodiments, the anchor comprises first and second wires, the first wire having a diameter smaller than a diameter of the second wire. In some embodiments, the anchor comprises first and second wires formed from different materials. In some embodiments, the anchor has a collapsed delivery configuration, an at-rest configuration and an expanded deployed configuration.

[0028] In some embodiments, the apparatus herein further comprises a lock or a plurality of locks configured to maintain expansion of the braid. In some embodiments, the apparatus herein further comprises a valve support adapted to support the replacement valve within the anchor. In some embodiments, the anchor herein comprises a distal deployment system interface at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor. In some embodiments, the anchor comprises a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor.

[0029] One aspect of the present invention provides methods for replacing a native aortic valve. Such methods involve endovascularly delivering a replacement valve and an anchor having an expandable braid. Delivery is preferably made to a site within the native aortic valve. Delivery is preferably made by actively foreshortening the anchor to radially expand the anchor to an expanded shape to secure the anchor at the anchor site. In some embodiments, the methods further include the step of locking the anchor in an expanded shape. In some embodiments, the methods include expanding a first step region of the anchor to a first diameter and a second region of the anchor to a second diameter larger than the first diameter.

[0030] In some embodiments, the foreshortening step of the methods herein comprises actively foreshortening the anchor to radially expand the anchor to an expanded shape to secure the anchor at the anchor site while avoiding interference with a mitral valve. In some embodiments, the foreshortening step comprises actively foreshortening the anchor to radially expand the anchor to a radially symmetrical expanded shape, a bilaterally symmetrical expanded shape or an asymmetrical expanded shape.

[0031] In some embodiments, the anchor is allowed to self-expand prior to the foreshortening step. In some embodiments, the foreshortening step comprises applying a proximally directed force on a deployment system interface at a proximal end or a distal end of the anchor. In some embodiments, the foreshortening step comprises applying a distally directed force on a deployment system interface at a proximal end of the anchor.

[0032] The present invention relates to an apparatus for replacing a native aortic valve, the apparatus includes an expandable anchor adapted to be endovascularly delivered and secured at a site within the native aortic valve. The expandable anchor has a delivery length in a delivery configuration substantially greater than a deployed length in a deployed configuration. The apparatus may also include and a replacement valve configured to be secured within the anchor.

[0033] In some embodiments, the delivery length is between about 15 mm and about 150 mm and the deployed length is between about 5 mm and about 40 mm. In some embodiments, the apparatus has a ratio of delivery length to deployed length that is between about 0.05 and about 0.5; between about 0.1 and about 0.35; or between about 0.15 and about 0.25. hi some embodiments, the apparatus herein includes an anchor that has an at-rest configuration and wherein the anchor includes a shape memory material that is heat set in the at-rest configuration. The at-rest configuration may have a length between the delivery length and the deployed length.

[0034] In some embodiments, the apparatus herein has an anchor that is configured for active foreshortening during endovascular deployment. The apparatus may also include a lock or a plurality of locks configured to maintain expansion of the anchor. The lock(s) may also be configured to maintain expansion of the anchor at a plurality of amounts of expansion, thereby conferring non cylindrical shapes to the apparatus.

[0035] In any of the embodiments herein, the apparatus may further include a valve support adapted to sup-

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port the replacement valve within the anchor. The valve support may also include a lock that is an extension of the valve support.

[0036] In any of the embodiments herein, the apparatus may include a distal deployment system interface disposed at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor. The distal deployment system interface may further be adapted to expand radially during application of a proximally directed force on the distal end of the anchor. The distal deployment system interface may further be adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor without passing any portion of a deployment system through a center opening of the replacement valve.

[0037] In some embodiments, the apparatus herein may include an anchor, wherein the anchor includes a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor. The proximal deployment system interface may further be adapted to expand radially during application of a distally directed force on the proximal end of the anchor. The proximal deployment system interface may further be adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor through a plurality of deployment system fingers.

[0038] The invention provides apparatus and methods for endovascularly replacing a patient's heart valve. One aspect of the invention provides an apparatus including: an expandable anchor with a lip region and a skirt region; and a replacement valve, wherein the lip region and skirt region are configured for percutaneous expansion (e.g., independent expansion or concurrent expansion) to engage leaflets of the heart valve. The lip and/or skirt regions may be adapted to preclude migration of the apparatus post-deployment and expansion. Expansion of the anchor and replacement valve may be by balloon-expansion, self-expansion, and combinations thereof. A locking element may be provided to maintain expansion.

[0039] The invention also includes a delivery system that facilitates deployment and expansion of the apparatus to endovascularly replace the heart valve and, in some embodiments, retrieve the apparatus.

[0040] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering apparatus having an anchor having lip and skirt regions, and a replacement valve coupled to the anchor, to a vicinity of the heart valve in a collapsed delivery configuration; and expanding the apparatus such that leaflets of the heart valve are captured between the lip and skirt regions of the anchor. The expanding step of the method may include the step of dynamically repositioning the apparatus relative to the heart valve prior to capturing the leaflets. The expanding step may also include the steps of expanding either the lip region or the skirt region, positively engaging the heart valve with the expanded lip or skirt region, and then expanding the unexpanded region. The apparatus may be retrieved, repositioned and redeployed, and the apparatus may be locked in its expanded configuration.

[0041] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable anchor further includes a leaflet engagement element on its proximal end to engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

[0042] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

[0043] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable an-

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chor further includes a leaflet engagement element on its proximal end to engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

[0044] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

[0045] The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method including the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; and applying an external non-hydraulic or non-pneumatic actuation force on the anchor to change the shape of the anchor, such as by applying proximally and/or distally directed force on the anchor using a releasable deployment tool to expand and contract the anchor or parts of the anchor. The method may also include the step of applying a radially outwardly directed force comprises expanding a balloon within the anchor, such as by expanding a balloon. The anchor may be locked in its expanded configuration.

[0046] Some embodiments of the method may include the step of registering the anchor with an anatomical landmark in an anchor location and deploying the anchor at the anchor location, such as by contacting tissue of the heart valve (e.g., a native valve leaflet) to resist movement of the anchor in at least a proximal or a distal direction prior to deploying the anchor.

[0047] Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve; an anchor; and a deployment tool adapted to apply a non-hydraulic or non-pneumatic actuation force on the anchor to reshape the anchor, such as a proximally or distally directed force to expand or contract regions of the anchor. The deployment tool may be releasable. An anchor lock may be provided to lock the anchor in a deployed configuration, and there may also be a lock prevention element actuatable from outside the patient.

[0048] The apparatus may also include a registration element adapted, e.g., to extend radially outward from the anchor to entrap at least part of the heart valve.

[0049] Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: an anchor having a collapsed delivery configuration and an expanded deployed configuration; and a replacement valve coupled to the anchor, wherein the anchor comprises enhanced radial strength in the expanded deployed configuration as compared to the collapsed delivery configuration due to imposed foreshortening. The apparatus may include a locking mechanism for maintaining imposed foreshortening, and it may be configured for retrieval prior to actuation of the locking mechanism. The apparatus may also include a delivery system configured for percutaneous delivery, deployment and foreshortening of the anchor.

[0050] In some embodiments the anchor is at least partially covered by a biocompatible film and perhaps an element configured to reduce paravalvular leakage or regurgitation.

[0051] Yet another aspect of the invention provides a method for endovascularly replacing a patient's heart valve, h some embodiments the method includes the steps of: providing apparatus comprising an expandable anchor having a replacement valve coupled thereto; endovascularly delivering the apparatus to a vicinity of the heart valve in a collapsed delivery configuration; expanding the apparatus to a partially deployed configuration; and actively foreshortening the anchor to a fully deployed configuration comprising enhanced radial strength, such that the anchor displaces the patient' s heart valve, and the replacement valve regulates blood flow.

[0052] Still another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, with the apparatus including: an anchor; a replacement valve coupled to the anchor; and a delivery system, wherein the delivery system is configured to retrieve the anchor and replacement valve post-deployment. The delivery system may also be further configured for percutaneous delivery, deployment and foreshortening of the anchor.

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[0053] The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method including the steps of" endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; and applying an external non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor through a plurality of anchor actuation elements to change the shape of the anchor, such as by applying a proximally and/or distally directed force on the anchor through anchor actuation elements to change the shape of the anchor. The anchor may be locked in its expanded configuration.

[0054] Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve; an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor. An anchor lock may be provided to lock the anchor in a deployed configuration, and there may also be a lock prevention element actuatable from outside the patient. Optionally, the anchor lock may be reversible.

[0055] Other aspects of the invention include methods and apparatuses for endovascularly, percutaneously and/or endoscopically delivering and deploying expandable devices in a patient and optionally detaching a deployment tool from the device.

[0056] One aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of: endovascularly delivering a replacement valve and an expandable anchor in an unexpanded configuration within a catheter to a vicinity of the heart valve; deploying the anchor from the catheter; expanding the anchor to contact tissue at an anchor site; and retrieving the anchor into the catheter. Expansion of the anchor may include application of an actuation force on the anchor, such as a proximally or distally directed force, to expand or contract at least a region of the anchor.

[0057] Another aspect of the invention provides an apparatus for endovascularly replacing a heart valve, including: a catheter; a replacement valve configured to be disposed within the catheter for delivery to a vicinity of the heart valve; and an expandable anchor configured to be disposed within the catheter for delivery to a vicinity of the heart valve, to be deployed from the catheter, to be expanded to contact tissue at an anchor site and to be retrieved back into the catheter after having been expanded. The apparatus may also include a deployment tool configured to apply an actuation force to the anchor - such as a proximally or distally directed force - when the anchor is in the vicinity of the heart valve.

[0058] The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method for endovascularly replacing a patient's heart valve, including the steps of: endovascularly delivering a replacement valve and an expandable anchor in an unexpanded configuration within a sheath to a vicinity of the heart valve; deploying the anchor from the sheath; expanding the anchor with a deployment tool comprising a plurality of actuation elements to contact tissue at an anchor site; and retrieving the anchor into the sheath.

[0059] Another aspect of the invention provides apparatus for endovascularly replacing a patient's heart valve, including: a sheath; a deployment tool comprising a plurality of anchor actuation elements; a replacement valve configured to be disposed within the sheath for delivery to a vicinity of the heart valve; and an expandable anchor configured to be disposed within the sheath for delivery to the vicinity of the heart valve, to be deployed from the sheath, to be expanded by the deployment tool to contact tissue at an anchor site and to be retrieved back into the sheath after having been expanded.

[0060] Other aspects of the invention include methods and apparatuses for endovascularly, percutaneously and/or endoscopically delivering, deploying and optionally retrieving expandable devices into and from a patient.

[0061] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a delivery catheter having a diameter of 21 french or less; an expandable anchor disposed within the delivery catheter; and a replacement valve disposed within the delivery catheter. The replacement valve may be coupled to the anchor within the catheter, and the catheter may be adapted to deliver the anchor and replacement valve to an aortic valve along a retrograde approach. The apparatus may also include a deployment tool coupled to the anchor within the catheter and an expandable balloon disposed within the delivery catheter, the balloon being adapted to expand the anchor. In some embodiments the balloon is disposed within the catheter apart from the anchor and the replacement valve.

[0062] Another aspect of the invention provides a method for endovascularly replacing a heart valve of a patient. In some embodiments the method includes the steps of: inserting a catheter having a diameter no more than 21 french into the patient; endovascularly delivering a replacment valve and an expandable anchor to a vicinity of the heart valve through the catheter; and deploying the anchor and the replacement valve. In embodiments in which the heart valve is an aortic valve, the inserting step may include the step of inserting the catheter to the vicinity of the aortic valve along a retrograde approach. The method's deploying step may include the steps of endovascularly delivering an anchor deployment tool through the catheter and actuating the anchor with the deployment tool, such as by applying proximally or distally directed forces on the anchor. The method may also include the steps of endovascularly delivering an expandable balloon through the catheter to the vicinity of the heart valve and using the balloon to expand the anchor.

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The balloon may be delivered apart from the anchor. The anchor may be retrieved back into the catheter after having been expanded.

[0063] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve adapted to be delivered endovascularly to a vicinity of the heart valve; an expandable anchor adapted to be delivered endovascularly to the vicinity of the heart valve; and a lock mechanism configured to maintain a minimum amount of anchor expansion. The lock mechanism may include first and second mating interlocking elements. An actuator may be provided to apply an actuation force on the anchor.

[0064] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; expanding the anchor to a deployed configuration; and locking the anchor in the deployed configuration.

[0065] Yet another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: an anchor comprising a lip region and a skirt region; a replacement valve coupled to the anchor; and a lock, wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve, and wherein the lock is configured to maintain such expansion.

[0066] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a custom-designed anchor; and a replacement valve, wherein the custom-designed anchor is adapted to engage native leaflets of the heart valve, and wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the heart valve.

[0067] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: providing apparatus comprising an anchor piece and a replacement valve piece; endovascularly delivering the anchor piece to a vicinity of the heart valve in a collapsed delivery configuration; expanding the anchor piece to a deployed configuration; engaging at least one valve leaflet of the heart valve with the anchor piece; endovascularly delivering the replacement valve piece to the vicinity of the heart valve in a collapsed delivery configuration; expanding the replacement valve piece to a deployed configuration; and coupling the valve piece to the anchor piece in vivo to form composite two-piece apparatus that endovascularly replaces the patient's heart valve.

[0068] Yet another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: an anchor having a first portion of an alignment/locking mechanism; and a replacement valve having a second portion of the alignment/locking mechanism, wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the patient's heart valve.

[0069] Still another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of:

endovascularly delivering an anchor piece having a first portion of an alignment/locking mechanism to a vicinity of the heart valve in a collapsed delivery configuration; expanding the anchor piece to a deployed configuration such that the anchor piece displaces the patient's heart valve; endovascularly delivering a replacement valve piece having a second portion of the alignment/locking mechanism to the vicinity of the heart valve in a collapsed delivery configuration; expanding the replacement valve piece to a deployed configuration; and coupling the valve piece to the anchor piece in vivo by securing the first and second portions of the alignment/locking mechanism to one another, thereby forming composite two-piece apparatus that endovascularly replaces the patient's heart valve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0070]

Figures 1A-B are elevational views of a replacement heart valve and anchor according to one embodiment of the invention.

Figures 2A-B are sectional views of the anchor and valve of Figures 1.

Figures 3A-B show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of Figures 1 and 2.

Figures 4A-F also show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of Figures 1 and 2.

Figures 5 A-I show the use of a replacement heart valve and anchor to replace an aortic valve.

Figures 6A-F show the use of a replacement heart valve and anchor with a positive registration feature to replace an aortic valve.

Figure 7 shows the the use of a replacement heart valve and anchor with an alternative positive registration feature to replace an aortic valve.

Figures 8A-C show another embodiment of a replacement heart valve and anchor according to the invention.

Figures 9A-H show delivery and deployment of the replacement heart valve and anchor of Figures 8.

Figure 10 is a cross-sectional drawing of the delivery system used with the method and apparatus of Figures 8 and 9.

Figures 11A-C show alternative locks for use with replacement heart valves and anchors of this inven-

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tion.

Figures 12 A-C show a vessel wall engaging lock for use with replacement heart valves and anchors of this invention.

Figure 13 demonstrates paravalvular leaking around a replacement heart valve and anchor.

Figure 14 shows a seal for use with a replacement heart valve and anchor of this invention.

Figures 15A-E show alternative arrangements of seals on a replacement heart valve and anchor.

Figures 16 A-C show alternative seal designs for use with replacement heart valves and anchors.

Figures 17 A-B show an alternative anchor lock embodiment in an unlocked configuration.

Figures 18 A-B show the anchor lock of Figure 17 in a locked configuration.

Figure 19 shows an alternative anchor deployment tool attachment and release mechanism for use with the invention.

Figure 20 shows the attachment and release mechanism of Figure 19 in the process of being released.

Figure 21 shows the attachment and release mechanism of Figures 19 and 20 in a released condition.

Figure 22 shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an undeployed configuration.

Figure 23 shows the replacement heart valve and anchor of Figure 22 in a partially deployed configuration.

Figure 24 shows the replacement heart valve and anchor of Figures 22 and 23 in a more fully deployed configuration but with the deployment tool still attached.

Figure 25 shows yet another embodiment of the delivery and deployment apparatus of the invention in use with a replacement heart valve and anchor.

Figure 26 shows the delivery and deployment apparatus of Figure 25 in the process of deploying a replacement heart valve and anchor.

Figure 27 shows an embodiment of the invention employing seals at the interface of the replacement heart valve and anchor and the patient's tissue.

Figure 28 is a longitudinal cross-sectional view of the seal shown in Figure 27 in compressed form.

Figure 29 is a transverse cross-sectional view of the seal shown in Figure 28.

Figure 30 is a longitudinal cross-sectional view of the seal shown in Figure 27 in expanded form.

Figure 31 is a transverse cross-sectional view of the seal shown in Figure 30.

Figure 32 shows yet another embodiment of the replacement heart valve and anchor of this invention in an undeployed configuration.

Figure 33 shows the replacement heart valve and anchor of Figure 32 in a deployed configuration.

Figure 34 shows the replacement heart valve and anchor of Figures 32 and 33 deployed in a patient's heart valve.

Figures 35A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.

Figures 36A-E show more detail of the anchor of the embodiment shown in Figures 35A-H.

Figures 37A-B show further details of the embodiment of Figures 35A-H.

Figures 38A-C illustrate a method for percutaneously replacing a patient's diseased heart valve.

Figures 39A-B show an anchor for use in a two-piece replacement heart valve and anchor embodiment of the invention.

Figures 40A-B show a replacement heart valve for use in a two-piece replacement heart valve and anchor embodiment of the invention.

Figures 41A-D show a method of coupling the anchor of Figures 39 and the replacement heart valve of Figures 40.

Figure 42 shows a delivery system for use with the appartus shown in Figures 39-41.

Figure 43 shows an alternative embodiment of a delivery system for use with the apparatus shown in Figures 39-41.

Figure 44 shows yet another alternative embodiment of a delivery system for use with the apparatus shown in Figures 39-41.

Figures 45 A-I illustrate a method of deliverying and deploying a two-piece replacement heart valve and anchor.

Figures 46A-B shows another embodiment of a two-piece replacement heart valve and anchor according to this invention.

Figure 47 shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

Figure 48 shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

Figures 49A and 49B show replacement valve apparatus in accordance with the present invention. Figure 49 illustrates the apparatus in a collapsed delivery configuration within a delivery system. Figure 49B illustrates the apparatus in an expanded configuration partially deployed from the delivery system.

Figures 50A-50F show an anchor of the apparatus of Figures 49 in the collapsed delivery configuration and the expanded deployed configuration, as well as the full apparatus in the deployed configuration, and optional locking mechanisms for use with the apparatus.

Figure 51 shows a detail view of a variation of an anchor post.

Figures 52A and 52B show an alternative variation of the post having a lock alignment feature.

Figures 53A and 53B show a variation of the post having an alternative lock alignment feature.

Figure 54 shows a variation of the post having an

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expansile element.
Figure 55 shows a variation of the post with an alternative expansile or cable element.
Figures 56A-56C show a variation of the post having an alternative lock alignment feature.
Figure 57 shows the post variation of Figure 51 in combination with an illustrative actuator and release actuator.
Figures 58A-58C show a variation of the post, actuator and release actuator that form an alternative releasable attachment mechanism.
Figures 59A-59C show another variation of the releasable attachment mechanism.
Figures 60A-60C show yet another variation of the releasable attachment mechanism.
Figures 61A and 61B show still another variation of the releasable attachment element.
Figure 62 shows a variation of the post, actuator and anchor lock element having a reversible lock.
Figures 63A-63C show a variation of the actuator, lock actuator and release actuator.
Figure 64 shows a variation of the anchor lock element having a lock alignment feature.
Figures 65A and 65B show expansion, locking and actuation of the releasable attachment mechanism of the apparatus of Figure 64.
Figure 66 shows another variation of the apparatus having an actuable lock prevention mechanism.
Figures 67A and 67B show a variation of the post that is configured to lock against the braid of the anchor.
Figures 68A-68C show actuation and release of a variation of the anchor lock element.
Figures 69A and 69B show another variation of a releasable actuation mechanism having a lock alignment mechanism which can be cut from a tube.
Figures 70A-70D show actuation of a variation of the anchor lock element that may be formed from a cut tube.
Figures 71A-71F show a variation of the post having an unlock actuator.
Figures 72A and 72B show another buckle variation of the anchor lock element.
Figure 73 shows attachment of a variation of the anchor lock element to the anchor.
Figure 74 shows a variation of the post and anchor lock element having a ratcheting lock.
Figures 75A and 75B show variations of the ratcheting lock.
Figures 76A-76H show actuation of another variation of the ratcheting lock.
Figures 77A-77C show a tubular variation of the ratcheting lock element.
Figures 78A-78C show a variation of the anchor lock element of Figures 77.
Figures 79A and 79B show a variation of the apparatus of Figures 78 comprising a lock alignment feature.
Figures 80A-80F show a method of actuating and adjusting the ratcheting lock of the apparatus of Figures 78.
Figures 81A and 81B show a variation of an anchor/actuator.
Figures 82A-82C show detail views of the releasable attachment mechanism of the actuator of Figures 81.
Figures 83A-83C show a variation of the releasable attachment mechanism of Figures 82.
Figures 84A-84C show another variation of the releasable attachment mechanism.
Figures 85A-85C show yet another variation of the releasable attachment mechanism.
Figures 86A-86N show variations of a release actuator used in conjunction with the releasable attachment mechanism of Figures 82.
Figures 87A and 87B show detail views of an embodiment of the delivery system/deployment tool.
Figures 88A and 88B show the delivery system/deployment tool of Figures 87 releaseably attached to apparatus 10, and detached from the apparatus.
Figures 89A and 89B show a variation of the delivery system deployment tool of
Figures 87 and 88 wherein the actuators extend from a unitary structure.
Figures 90A-90C show various ways to connect elements to the anchor of the replacement valve apparatus.
Figure 91 is a schematic top view of an apparatus for fabricating braided anchors in accordance with the present invention.
Figures 92A-92D are schematic top views illustrating a method of using the apparatus of Figure 91 to fabricate a braided anchor of the present invention.
Figures 93A-93O are schematic detail views illustrating features of braid cells at an anchor edge.
Figures 94A-94E illustrate further features of braid cells at an anchor edge.
Figures 95A-95J are schematic detail views terminations for one or more wire strands forming anchors of the present invention.
Figures 96A and 96B are schematic side views of alternative embodiments of the anchor portion of the apparatus of the present invention.
Figures 97A-97E are schematic side views of further alternative embodiments of the of the anchor portion of the apparatus of the present invention.
Figures 98A-98D are schematic views of different weave configurations.
Figures 99A-99E are schematic side views of various braided anchor configurations.
Figures 100A-100E are schematic side views of a deployment process.
Figures 101A and 101B illustrate a braided anchor in the heart.
Figures 102A and 102B illustrate a bilaterally symmetrical anchor and an asymmetric anchor, respectively.

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Figure 103 illustrates a braided anchor of the present invention with closed end turns Tu.
Figures 104A-104E illustrate additional features for end turns of a braided anchor.
Figures 105A-105F illustrate deployment of an anchor with leaflet engagement elements on the deployment system.
Figure 106 illustrates a deployed anchor with leaflet engagement elements on the proximal end of the anchor.
Figures 107A-107C illustrate deployment of an anchor with anchor registration elements and a seal.
Figures 108A-108B illustrate an embodiment of the apparatus with a seal that does not reach the proximal end of the anchor during both systole and diastole.
Figures 109A-109B illustrate an embodiment of the apparatus with a seal that reaches the proximal end of the anchor during both systole and diastole.

DETAILED DESCRIPTION

[0071] The present invention relates to apparatus and methods for endovascularly or percutaneously delivering and deploying a prosthesis, e.g., an aortic prosthesis, within and/or across a patient's native heart valve, referred to hereinafter as replacing the patient's heart valve. A delivery system and/or deployment tool is provided including a sheath assembly and a guidewire for placing the prosthetic apparatus endovascularly within the patient and a user control allowing manipulation of the prosthetic apparatus from external to the patient through the application of a non-hydraulically expanding or non-pneumatically expanding force on the anchor. A hydraulically or pneumatically expanding force would be, for example, a force applied to the anchor by a balloon expanded within the anchor. In certain embodiments, the application of a non-hydraulically expanding or non-pneumatically expanding force could include the use of a hydraulic component transmitting a proximally or distally directed force on an anchor.

[0072] The apparatus includes an anchor and a replacement valve. The anchor includes an expandable anchor such as a braid. In preferred embodiments, the expandable braid includes closed edges, but the edges may alternatively be open. The replacement valve is adapted to be secured within the anchor, and as such, be delivered endovascularly to the patient's heart to replace one of the patient's native heart valves. More preferably, the apparatus and methods of the present invention contemplate replacement of the patient's aortic valve.

[0073] With reference now to Figures 1-4, a first embodiment of replacement heart valve apparatus in accordance with the present invention is described, including a method of actively foreshortening and expanding the apparatus from a delivery configuration and to a deployed configuration. Apparatus 10 comprises replacement valve 20 disposed within and coupled to anchor 30. Figures 1 schematically illustrate individual cells of anchor 30 of apparatus 10, and should be viewed as if the cylindrical anchor has been cut open and laid flat. Figures 2 schematically illustrate a detail portion of apparatus 10 in side-section.

[0074] Anchor 30 has a lip region 32, a skirt region 34 and a body region 36. First, second and third posts 38a, 38b and 38c, respectively, are coupled to skirt region 34 and extend within lumen 31 of anchor 30. Posts 38 preferably are spaced 120° apart from one another about the circumference of anchor 30.

[0075] Anchor 30 preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids, and materials, such as a stainless steel, nickel-titanium ("Nitinol") or cobalt chromium but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to it's final shape by means of balloon expansion. Replacement valve 20 is preferably from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues, alternatively it can be made from tissue engineered materials (such as extracellular matrix material from Small Intestinal Submucosa (SIS)) but alternatively may be prosthetic from an elastomeric polymer or silicone, Nitinol or stainless steel mesh or pattern (sputtered, chemically milled or laser cut). The leaflet may also be made of a composite of the elastomeric or silicone materials and metal alloys or other fibers such Kevlar or carbon. Annular base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to posts 38.

[0076] Anchor 30 may be actuated using external non-hydraulic or non-pneumatic force to actively foreshorten in order to increase its radial strength. As shown below, the proximal and distal end regions of anchor 30 may be actuated independently. The anchor and valve may be placed and expanded in order to visualize their location with respect to the native valve and other anatomical features and to visualize operation of the valve. The anchor and valve may thereafter be repositioned and even retrieved into the delivery sheath or catheter. The apparatus may be delivered to the vicinity of the patient's aortic valve in a retrograde approach in a catheter having a diameter no more than 23 french, preferably no more than 21 french, more preferably no more than 19 french, or more preferably no more than 17 french. Upon deployment the anchor and replacement valve capture the native valve leaflets and positively lock to maintain configuration and position.

[0077] A deployment tool is used to actuate, reposition, lock and/or retrieve anchor 30. In order to avoid delivery of anchor 30 on a balloon for balloon expansion, a non-hydraulic or non-pneumatic anchor actuator is used. In this embodiment, the actuator is a deployment tool that includes distal region control actuators 50, control actuators 60 (embodied here as rods or tubes) and proximal region control actuators 62. Locks 40 include posts or

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arms 38 preferably with male interlocking elements 44 extending from skirt region 34 and mating female interlocking elements 42 in lip region 32. Male interlocking elements 44 have eyelets 45. Control actuators 50 pass from a delivery system for apparatus 10 through female interlocking elements 42, through eyelets 45 of male interlocking elements 44, and back through female interlocking elements 42, such that a double strand of wire 50 passes through each female interlocking element 42 for manipulation by a medical practitioner external to the patient to actuate and control the anchor by changing the anchor's shape. Control actuators 50 may comprise, for example, strands of suture or wire.

[0078] Actuators 60 are reversibly coupled to apparatus 10 and may be used in conjunction with actuators 50 to actuate anchor 30, e.g., to foreshorten and lock apparatus 10 in the fully deployed configuration. Actuators 60 also facilitate repositioning and retrieval of apparatus 10, as described hereinafter. For example, anchor 30 may be foreshortened and radially expanded by applying a distally directed force on actuators 60 while proximally retracting actuators 50. As seen in Figures 3, control actuators 62 pass through interior lumens 61 of actuators 60. This ensures that actuators 60 are aligned properly with apparatus 10 during deployment and foreshortening. Control actuators 62 can also actuate anchor 60; proximally directed forces on control actuators 62 contacts the proximal lip region 32 of anchor 30. Actuators 62 also act to couple and decouple actuators 60 from apparatus 10. Actuators 62 may comprise, for example, strands of suture or wire.

[0079] Figures 1A and 2A illustrate anchor 30 in a delivery configuration or in a partially deployed configuration (e.g., after dynamic self-expansion expansion from a constrained delivery configuration within a delivery sheath). Anchor 30 has a relatively long length and a relatively small width in the delivery or partially deployed configuration, as compared to the foreshortened and fully deployed configuration of Figures IB and 2B.

[0080] In Figures 1A and 2A, replacement valve 20 is collapsed within lumen 31 of anchor 30. Retraction of actuators 50 relative to actuators 60 foreshortens anchor 30, which increases the anchor's width while decreasing its length. Such foreshortening also properly seats replacement valve 20 within lumen 31 of anchor 30. Imposed foreshortening will enhance radial force applied by apparatus 10 to surrounding tissue over at least a portion of anchor 30. In some embodiments, the anchor exerts an outward force on surrounding tissue to engage the tissue in such way to prevent migration of anchor caused by force of blood against closed leaflet during diastole. This anchoring force is preferably 1 to 2 lbs, more preferably 2 to 4 lbs, or more preferably 4 to 10 lbs. In some embodiments, the anchoring force is preferably greater than 1 pound, more preferably greater than 2 pounds, or more preferably greater than 4 pounds. Enhanced radial force of the anchor is also important for enhanced crush resistance of the anchor against the surrounding tissue due to the healing response (fibrosis and contraction of annulus over a longer period of time) or to dynamic changes of pressure and flow at each heart beat In an alternative embodiment, the anchor pattern or braid is designed to have gaps or areas where the native tissue is allowed to protrude through the anchor slightly (not shown) and as the foreshortening is applied, the tissue is trapped in the anchor. This feature would provide additional means to prevent anchor migration and enhance long term stability of the device.

[0081] Deployment of apparatus 10 is fully reversible until lock 40 has been locked via mating of male interlocking elements 44 with female interlocking elements 42. Deployment is then completed by decoupling actuators 60 from lip section 32 of anchor 30 by retracting one end of each actuator 62 relative to the other end of the actuator, and by retracting one end of each actuator 50 relative to the other end of the actuator until each actuator has been removed from eyelet 45 of its corresponding male interlocking element 44.

[0082] As best seen in Figure 2B, body region 36 of anchor 30 optionally may comprise barb elements 37 that protrude from anchor 30 in the fully deployed configuration, for example, for engagement of a patient's native valve leaflets and to preclude migration of the apparatus.

[0083] With reference now to Figures 3, a delivery and deployment system for a self-expanding embodiment of apparatus 10 including a sheath 110 having a lumen 112. Self-expanding anchor 30 is collapsible to a delivery configuration within lumen 112 of sheath 110, such that apparatus 10 may be delivered via delivery system 100. As seen in Figure 3A, apparatus 10 may be deployed from lumen 112 by retracting sheath 110 relative to apparatus 10, control actuators 50 and actuators 60, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. Control actuators 50 then are retracted relative to apparatus 10 and actuators 60 to impose foreshortening upon anchor 30, as seen in Figure 3B.

[0084] During foreshortening, actuators 60 push against lip region 32 of anchor 30, while actuators 50 pull on posts 3 8 of the anchor. Actuators 62 may be retracted along with actuators 50 to enhance the distally-directed pushing force applied by actuators 60 to lip region 32. Continued retraction of actuators 50 relative to actuators 60 would lock locks 40 and fully deploy apparatus 10 with replacement valve 20 properly seated within anchor 30, as in Figures IB and 2B. Apparatus 10 comprises enhanced radial strength in the fully deployed configuration as compared to the partially deployed configuration of Figure 3A. Once apparatus 10 has been fully deployed, actuators 50 and 62 may be removed from apparatus 10, thereby separating delivery system 100 including actuators 60 from the apparatus.

[0085] Deployment of apparatus 10 is fully reversible until locks 40 have been actuated. For example, just prior to locking the position of the anchor and valve and the operation of the valve may be observed under fluoros-

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copy. If the position needs to be changed, by alternately relaxing and reapplying the proximally directed forces exerted by control actuators 50 and/or control actuators 62 and the distally directed forces exerted by actuators 60, expansion and contraction of the lip and skirt regions of anchor 30 may be independently controlled so that the anchor and valve can be moved to, e.g., avoid blocking the coronary ostia or impinging on the mitral valve. Apparatus 10 may also be completely retrieved within lumen 112 of sheath 110 by simultaneously proximally retracting actuators 50 and actuators 60/actuators 62 relative to sheath 110. Apparatus 10 then may be removed from the patient or repositioned for subsequent redeployment.

[0086] Referring now to Figures 4, step-by-step deployment of apparatus 10 via delivery system 100 is described. In Figure 4A, sheath 110 is retracted relative to apparatus 10, actuators 50 and actuators 60, thereby causing self-expandable anchor 30 to dynamically self-expand apparatus 10 from the collapsed delivery configuration within lumen 112 of sheath 110 to the partially deployed configuration. Apparatus 10 may then be dynamically repositioned via actuators 60 to properly orient the apparatus, e.g. relative to a patient's native valve leaflets.

[0087] In Figure 4B, control actuators 50 are retracted while actuators 60 are advanced, thereby urging lip region 32 of anchor 30 in a distal direction while urging posts 38 of the anchor in a proximal direction. This foreshortens apparatus 10, as seen in Figure 4C. Deployment of apparatus 10 is fully reversible even after foreshortening has been initiated and has advanced to the point illustrated in Figure 4C.

[0088] In Figure 4D, continued foreshortening causes male interlocking elements 44 of locks 40 to engage female interlocking elements 42. The male elements mate with the female elements, thereby locking apparatus 10 in the foreshortened configuration, as seen in Figure 4E. Actuators 50 are then pulled through eyelets 45 of male elements 44 to remove the actuators from apparatus 10, and actuators 62 are pulled through the proximal end of anchor 30 to uncouple actuators 60 from the apparatus, thereby separating delivery system 100 from apparatus 10. Fully deployed apparatus 10 is shown in Figure 4F.

[0089] Referring to Figures 5, a method of percutaneously replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described. As seen in Figure 5A, sheath 110 of delivery system 100, having apparatus 10 disposed therein, is percutaneously advanced over guide wire G, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta A to the patient's diseased aortic valve AV. A nosecone 102 precedes sheath 110 in a known manner. In Figure 5B, sheath 110 is positioned such that its distal region is disposed within left ventricle LV of the patient's heart H.

[0090] Apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration, as in Figure 5C. Advantageously, apparatus 10 may be retracted within lumen 112 of sheath 110 via actuators 50 - even after anchor 30 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, e.g. via sheath 110 and/or actuators 60, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets L. When properly aligned, skirt region 34 of anchor 30 preferably is disposed distal of the leaflets, while body region 36 is disposed across the leaflets and lip region 32 is disposed proximal of the leaflets.

[0091] Once properly aligned, actuators 50 are retracted relative to actuators 60 to impose foreshortening upon anchor 30 and expand apparatus 10 to the fully deployed configuration, as in Figure 5D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus An, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. As seen in Figure 5E, locks 40 maintain imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle LV and aorta A is thereafter regulated by apparatus 10. Deployment of apparatus 10 advantageously is fully reversible until locks 40 have been actuated.

[0092] As seen in Figure 5F, actuators 50 have been pulled from eyelets 45 of male elements 44 of locks 40, actuators 60 are decoupled from anchor 30, e.g. via actuators 62, and delivery system 100 is removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to further preclude migration of the apparatus and/or reduce paravalvular regurgitation.

[0093] Figures 5G and 5H show further details of deployment using a deployment apparatus. Apparatus 10 is deployed from lumen Lu of sheath 110, for example, under fluoroscopic guidance by proximally retracting proximal handle 111 of sheath 110 relative to shaft 108, such that anchor 30 of apparatus 10 dynamically self-expands to the partially deployed configuration of Figure 5C. Advantageously, apparatus 10 may be retracted within lumen Lu of sheath 110 by retracting shaft 108 relative to the sheath, and thereby retracting actuators 106a coupled to anchor 30 relative to sheath 110. In this manner, anchor 30 may be retrieved even after the anchor has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets L. When properly aligned, a distal region of anchor 30 preferably is disposed distal of the leaflets, while a central region of the anchor is disposed across the leaflets and a proximal

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region is disposed proximal of the leaflets.

[0094] Once properly aligned, actuators 106b are proximally retracted relative to actuators 106a, e.g., via knob 126 of handle 120, to impose foreshortening upon anchor 30 and further expand apparatus 10 to the fully deployed configuration, as in Figure 5D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus An, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. Lock 40 formed by engaging post lock elements 44 of posts 32 with anchor lock elements 34 of anchor 30 maintains imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle LV and aorta A is thereafter completely regulated by apparatus 10, although valve 20 is functional during deployment as well. Deployment of apparatus 10 advantageously is fully reversible until the locks have been actuated. Releasable lock prevention mechanisms may be provided to ensure that the locks are not actuated prematurely. Furthermore, the locks may be reversible, such that apparatus 10 may be retrieved or repositioned even after actuation of the locks.

[0095] Once apparatus 10 is fully expanded and locked in the expanded configuration, actuators 106a are decoupled from anchor 30 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106a via knob 122 of handle 120. Likewise, actuators 106b are decoupled from posts 32 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106b via knob 124 of handle 120. As seen in Figure 5E, delivery system 100 then may be removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to preclude migration of the apparatus and/or to reduce paravalvular regurgitation.

[0096] With reference now to Figures 6, a method of percutaneously replacing a patient's diseased aortic valve with apparatus 10 is provided, wherein proper positioning of the apparatus is ensured via positive registration of a modified delivery system to the patient's native valve leaflets. In Figure 6A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve AV within sheath 110. As seen in Figures 6B and 6C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

[0097] Delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. Engagement element 120 is disposed between actuators 60 of delivery system 100' and lip region 32 of anchor 30. Element 120 releasably engages the anchor. As seen in Figure 6C, the element is initially deployed proximal of the patient's native valve leaflets L. Apparatus 10 arid element 120 then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. Also delivery system 100' includes filter structure 61 A (e.g., filter membrane or braid) as part of push actuators 60 to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage.

[0098] Arrows 6 IB in Figure 6E show blood flow through filter structure 61 A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[0099] Alternatively, foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as in Figure 6D. Upon positive registration of element 120 against leaflets L, element 120 precludes further distal migration of apparatus 10 during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 6E details engagement of element 120 against the native leaflets. As seen in Figure 6F, once apparatus 10 is fully deployed, element 120, actuators 50 and actuators 60 are decoupled from the apparatus, and delivery system 100' is removed from the patient, thereby completing the procedure.

[0100] With reference to Figure 7, an alternative embodiment of the apparatus of Figures 6 is described, wherein leaflet engagement element 120 is coupled to anchor 30 of apparatus 10', rather than to delivery system 100. Engagement element 120 remains implanted in the patient post-deployment of apparatus 10'. Leaflets L are sandwiched between lip region 32 of anchor 30 and element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets and precludes distal migration of the apparatus over time.

[0101] Referring now to Figures 8, an alternative delivery system adapted for use with a balloon expandable embodiment of the present invention is described. In Figure 8A, apparatus 10" comprises anchor 30' that maybe fabricated from balloon-expandable materials. Delivery system 100" comprises inflatable member 130 disposed in a deflated configuration within lumen 31 of anchor 30'. In Figure 8B, optional outer sheath 110 is retracted, and inflatable member 130 is inflated to expand anchor 30' to the fully deployed configuration. As inflatable member 130 is being deflated, as in earlier embodiments, actuators 50 and 62 and actuators 60 maybe used to assist deployment of anchor 30' and actuation of locks 40, as well as to provide reversibility and retrievability of apparatus 10" prior to actuation of locks 40. Next, actuators 50 and 62 and actuators 60 are removed from apparatus 10", and delivery system 100" is removed, as seen in Figure 8C.

[0102] As an alternative delivery method, anchor 30' may be partially deployed via partial expansion of inflatable member 130. The inflatable member would then be

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advanced within replacement valve 20 prior to inflation of inflatable member 130 and full deployment of apparatus 10". Inflation pressures used will range from about 3 to 6 arm, or more preferably from about 4 to 5 arm, though higher and lower atm pressures may also be used (e.g., greater than 3 atm, more preferably greater than 4 atm, more preferably greater than 5 atm, or more preferably greater than 6 atm). Advantageously, separation of inflatable member 130 from replacement valve 20, until partial deployment of apparatus 10" at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This profile reduction may facilitate retrograde delivery and deployment of apparatus 10", even when anchor 30' is balloon-expandable.

[0103] Although anchor 30' has illustratively been described as fabricated from balloon-expandable materials, it should be understood that anchor 30' alternatively may be fabricated from self-expanding materials whose expansion optionally may be balloon-assisted. In such a configuration, anchor 30' would expand to a partially deployed configuration upon removal of outer sheath 110. If required, inflatable member 130 then would be advanced within replacement valve 20 prior to inflation. Inflatable member 130 would assist full deployment of apparatus 10", for example, when the radial force required to overcome resistance from impinging tissue were too great to be overcome simply by manipulation of actuators 50 and actuators 60. Advantageously, optional placement of inflatable member 130 within replacement valve 20, only after dynamic self-expansion of apparatus 10" to the partially deployed configuration at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This reduction may facilitate retrograde delivery and deployment of apparatus 10".

[0104] With reference to Figures 9 and 10, methods and apparatus for a balloon-assisted embodiment of the present invention are described in greater detail. Figures 9 and 10 illustratively show apparatus 10' of Figures 7 used in combination with delivery system 100" of Figures 8. Figure 10 illustrates a sectional view of delivery system 100". Inner shaft 132 of inflatable member 130 preferably is about 4 Fr in diameter, and comprises lumen 133 configured for passage of guidewire G, having a diameter of about 0.035", therethrough. Push actuators 60 and pull actuators 50 pass through guidetube 140, which preferably has a diameter of about 15 Fr or smaller. Guide tube 140 is disposed within lumen 112 of outer sheath 110, which preferably has a diameter of about 17 Fr or smaller.

[0105] In Figure 9A, apparatus 10' is delivered to diseased aortic valve AV within lumen 112 of sheath 110. In Figure 9B, sheath 110 is retracted relative to apparatus 10' to dynamically self-expand the apparatus to the partially deployed configuration. Also retracted and removed is nosecone 102 which is attached to a pre-slit lumen (not shown) that facilitates its removal prior to loading and advancing of a regular angioplasty balloon catheter over guidewire and inside delivery system 110.

[0106] In Figure 9C, pull actuators 50 and push actuators 60 are manipulated from external to the patient to foreshorten anchor 30 and sufficiently expand lumen 31 of the anchor to facilitate advancement of inflatable member 130 within replacement valve 20. Also shown is the tip of an angioplasty catheter 130 being advanced through delivery system 110.

[0107] The angioplasty balloon catheter or inflatable member 130 then is advanced within the replacement valve, as in Figure 9D, and additional foreshortening is imposed upon anchor 30 to actuate locks 40, as in Figure 9E. The inflatable member is inflated to further displace the patient's native valve leaflets L and ensure adequate blood flow through, and long-term patency of, replacement valve 20, as in Figure 9F. Inflatable member 130 then is deflated and removed from the patient, as in Figure 9G. A different size angioplasty balloon catheter could be used repeat the same step if deemed necessary by the user. Push actuators 60 optionally may be used to further set leaflet engagement element 120, or optional barbs B along posts 38, more deeply within leaflets L, as in Figure 9H. Then, delivery system 100" is removed from the patient, thereby completing percutaneous heart valve replacement.

[0108] As will be apparent to those of skill in the art, the order of imposed foreshortening and balloon expansion described in Figures 9 and 10 is only provided for the sake of illustration. The actual order may vary according to the needs of a given patient and/or the preferences of a given medical practitioner. Furthermore, balloon-assist may not be required in all instances, and the inflatable member may act merely as a safety precaution employed selectively in challenging clinical cases.

[0109] Referring now to Figures 11, alternative locks for use with apparatus of the present invention are described. In Figure 11A, lock 40' comprises male interlocking element 44 as described previously. However, female interlocking element 42' illustratively comprises a triangular shape, as compared to the round shape of interlocking element 42 described previously. The triangular shape of female interlocking element 42' may facilitate mating of male interlocking element 44 with the female interlocking element without necessitating deformation of the male interlocking element.

[0110] In Figure 11B, lock 40" comprises alternative male interlocking element 44' having multiple in-line arrowheads 46 along posts 38. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female interlocking element 42. Appendages 48 optionally comprise eyelets 49, such that control actuator 50 or a secondary wire may pass therethrough to constrain the appendages in the deformed configuration. To actuate lock 40", one or more arrowheads 46 of male interlocking element 44' are drawn through female interlocking element 42, and the wire is removed from eyelets 49, thereby causing appendages 48 to resiliently expand and actuate lock 40".

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[0111] Advantageously, providing multiple arrowheads 46 along posts 38 yields a ratchet that facilitates in-vivo determination of a degree of foreshortening imposed upon apparatus of the present invention. Furthermore, optionally constraining appendages 48 of arrowheads 46 via eyelets 49 prevents actuation of lock 40" (and thus deployment of apparatus of the present invention) even after male element 44' has been advanced through female element 42. Only after a medical practitioner has removed the wire constraining appendages 48 is lock 40" fully engaged and deployment no longer reversible.

[0112] Lock 40"' of Figure 11C is similar to lock 40" of Figure 11B, except that optional eyelets 49 on appendages 48 have been replaced by optional overtube 47. Overtube 47 serves a similar function to eyelets 49 by constraining appendages 48 to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Overtube 47 is then removed, which causes the appendages to resiliently expand, thereby fully actuating lock 40"'.

[0113] With reference to Figures 12, an alternative locking mechanism is described that is configured to engage the patient's aorta. Male interlocking elements 44" of locks 40"" comprise arrowheads 46' having sharpened appendages 48'. Upon expansion from the delivery configuration of Figure 12A to the foreshortened configuration of Figure 12B, apparatus 10 positions sharpened appendages 48' adjacent the patient's aorta A. Appendages 48' engage the aortic wall and reduce a risk of device migration over time.

[0114] With reference now to Figure 13, a risk of paravalvular leakage or regurgitation around apparatus of the present invention is described. In Figure 13, apparatus 10 has been implanted at the site of diseased aortic valve AV, for example, using techniques described hereinabove. The surface of native valve leaflets L is irregular, and interface I between leaflets L and anchor 30 may comprise gaps where blood B may seep through. Such leakage poses a risk of blood clot formation or insufficient blood flow.

[0115] Referring to Figure 14, optional elements for reducing regurgitation or leakage are described. Compliant sacs 200 may be disposed about the exterior of anchor 30 to provide a more efficient seal along irregular interface **I.** Sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel. Alternative fill materials will be apparent.

[0116] With reference to Figures 15, illustrative arrangements for sacs 200 are provided. In Figure 15A, sacs 200 are provided as discrete sacs at different positions along the height of anchor 30. In Figure 15B, the sacs are provided as continuous cylinders at various heights. In Figure 15C, a single sac is provided with a cylindrical shape that spans multiple heights. The sacs of Figure 15D are discrete, smaller and provided in larger quantities. Figure 15E provides a spiral sac. Alternative sac configurations will be apparent to those of skill in the art.

[0117] With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 20 comprise 'fish-scale' slots 202 that may be back-filled, for example, with ambient blood passing through replacement valve 20. hi Figure 16B, the sacs comprise pores 204 that may be used to fill the sacs. In Figure 16C, the sacs open to lumen 31 of anchor 30 and are filled by blood washing past the sacs as the blood moves through apparatus 10.

[0118] Figures 17 and 18 show yet another alternative embodiment of the anchor lock. Anchor 300 has a plurality of male interlocking elements 302 having eyelets 304 formed therein. Male interlocking elements are connected to braided structure 300 by inter-weaving elements 302 (and 308) or alternatively suturing, soldering, welding, or connecting with adhesive. Valve commissures 24 are connected to male interlocking elements 302 along their length. Replacement valve 20 annular base 22 is connected to the distal end 34 of anchor 300 (or 30) as is illustrated in figures 1A and IB. Male interlocking elements 302 also include holes 306 that mate with tabs 310 extending into holes 312 in female interlocking elements 308. To lock, control actuators 314 passing through eyelets 304 and holes 312 are pulled proximally with respect to the proximal end of braided anchor 300 to draw the male interlocking elements through holes 312 so that tabs 310 engage holes 306 in male interlocking elements 302. Also shown is release actuators 314B that passes through eylet 304B in female interlocking element 308. If needed, during the procedure, the user may pull on release actuators 314B reversing orientation of tabs 310 releasing the anchor and allowing for repositioning of the device or it's removal from the patient. After the desired final position has been attained, release actuator 314B and control actuator 314 be removed from the patient with the delivery system.

[0119] Figures 19-21 show an alternative way of releasing the connection between the anchor and its actuating actuators and control actuators. Control actuators 62 (i.e., release actuators) extend through actuators 60 from outside the patient, loop through the proximal region of anchor 30 and extend partially back into tube 60 (i.e., an anchor actuator). The doubled up portion of control actuator 62 creates a force fit within tube 60 that maintains the control actuators's position with respect to tube 60 when all confrol actuators 62 are pulled proximally to place a proximally directed force on anchor 30. When a single half of control actuator 62 is pulled proximally, however, the frictional fit between that control wire and the tube in which it is disposed is overcome, enabling the end 63 of control actuator 62 to pull free of the tube, as shown in Figure 21, thereby releasing anchor 30.

[0120] Figures 22-24 show an alternative embodiment of the anchor. Anchor 350 is made of a metal braid, such as Nitinol or stainless steel. A replacement valve 354 is disposed within anchor 350. Anchor 350 is actuated in

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substantially the same way as anchor 30 of Figures 1-4 through the application of proximally and distally directed forces from confrol actuators (not shown) and actuators 352.

[0121] Figures 25 and 26 show yet another embodiment of the delivery and deployment apparatus of the invention. As an alternative to the balloon expansion method described with respect to Figures 8, in this embodiment the nosecone (e.g., element 102 of Figures 5) is replaced by an angioplasty balloon catheter 360. Thus, expandable balloon cathether 360 precedes sheath 110 on guidewire G. When anchor 30 and valve 20 are expanded through the operation of actuators 60 and the control actuators (not shown) as described above, balloon cathether 360 is retracted proximally within the expanded anchor and valve and expanded further as described above with respect to Figures 8.

[0122] Figures 27-31 show seals 370 that expand over time to seal the interface between the anchor and valve and the patient's tissue. Seals 370 are preferably formed from Nitinol wire surrounded by an expandable foam. As shown in cross-section in Figures 28 and 29, at the time of deployment, the foam 372 is compressed about the wire 374 and held in the compressed form by a time-released coating 376. After deployment, coating 376 dissolves in vivo to allow foam 372 to expand, as shown in Figures 30 and 31.

[0123] Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 3 80 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

[0124] Figures 35A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus 450 comprises replacement valve 460 (see Figures 37B and 38C) disposed within and coupled to anchor 470. Replacement valve 460 is preferably biologic, e.g. porcine, but alternatively may be synthetic. Anchor 470 preferably is fabricated from self-expanding materials, such as a stainless steel wire mesh or a nickel-titanium alloy ("Nitinol"), and comprises lip region 472, skirt region 474, and body regions 476a, 476b and 476c. Replacement valve 460 preferably is coupled to skirt region 474, but alternatively may be coupled to other regions of the anchor. As described herein below, lip region 472 and skirt region 474 are configured to expand and engage/capture a patient's native valve leaflets, thereby providing positive registration, reducing paravalvular regurgitation, reducing device migration, etc.

[0125] As seen in Figure 35A, apparatus 450 is collapsible to a delivery configuration, wherein the apparatus may be delivered via delivery system 410. Delivery system 410 comprises sheath 420 having lumen 422, as well as actuators 424a and 424b seen in Figures 35D-35G. Actuators 424a are configured to expand skirt region 474 of anchor 470, as well as replacement valve 460 coupled thereto, while actuators 424b are configured to expand lip region 472.

[0126] As seen in Figure 35B, apparatus 450 may be delivered and deployed from lumen 422 of catheter 420 while the apparatus is disposed in the collapsed delivery configuration. As seen in Figures 35B-35D, catheter 420 is retracted relative to apparatus 450, which causes anchor 470 to dynamically self-expand to a partially deployed configuration. Actuators 424a are then retracted to expand skirt region 474, as seen in Figures 35E and 35F. Preferably, such expansion may be maintained via locking features described hereinafter.

[0127] In Figure 35G, actuators 424b are retracted to expand lip region 472 and fully deploy apparatus 450. As with skirt region 474, expansion of lip region 472 preferably may be maintained via locking features. After both lip region 472 and skirt region 474 have been expanded, actuators 424 may be removed from apparatus 450, thereby separating delivery system 410 from the apparatus. Delivery system 410 then may be removed, as seen in Figure 35H.

[0128] As will be apparent to those of skill in the art, lip region 472 optionally may be expanded prior to expansion of skirt region 474. As yet another alternative, lip region 472 and skirt region 474 optionally may be expanded simultaneously, in parallel, in a step-wise fashion or sequentially. Advantageously, delivery of apparatus 450 is fully reversible until lip region 472 or skirt region 474 has been locked in the expanded configuration.

[0129] With reference now to Figures 36A-E, individual cells of anchor 470 of apparatus 450 are described to detail deployment and expansion of the apparatus. In Figure 36A, individual cells of lip region 472, skirt region 474 and body regions 476a, 476b and 476c are shown in the collapsed delivery configuration, as they would appear while disposed within lumen 422 of sheath 420 of delivery system 410 of Figures 35. A portion of the cells forming body regions 476, for example, every 'nth' row of cells, comprises locking features.

[0130] Body region 476a comprises male interlocking element 482 of lip lock 480, while body region 476b comprises female interlocking element 484 of lip lock 480. Male element 482 comprises eyelet 483. Wire 424b passes from female interlocking element 484 through eyelet 483 and back through female interlocking element 484, such that there is a double strand of wire 424b that passes through lumen 422 of catheter 420 for manipulation by a medical practitioner external to the patient. Body region 476b further comprises male interlocking element 492 of skirt lock 490, while body region 476c comprises female interlocking element 494 of the skirt lock. Wire 424a passes from female interlocking element 494 through eyelet 493 of male interlocking element 492, and back through female interlocking element 494. Lip lock 480 is config-

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ured to maintain expansion of lip region 472, while skirt lock 490 is configured to maintain expansion of skirt region 474.

[0131] In Figure 36B, anchor 470 is shown in the partially deployed configuration, e.g., after deployment from lumen 422 of sheath 420. Body regions 476, as well as lip region 472 and skirt region 474, self-expand to the partially deployed configuration. Full deployment is then achieved by refracting actuators 424 relative to anchor 470, and expanding lip region 472 and skirt region 474 outward, as seen in Figures 36C and 36D. As seen in Figure 36E, expansion continues until the male elements engage the female interlocking elements of lip lock 480 and skirt lock 490, thereby maintaining such expansion (lip lock 480 shown in Figure 36E). Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated.

[0132] With reference to Figures 37A-B, isometric views, partially in section, further illustrate apparatus 450 in the fully deployed and expanded configuration. Figure 37A illustrates the wireframe structure of anchor 470, while Figure 37B illustrates an embodiment of anchor 470 covered in a biocompatible material B. Placement of replacement valve 460 within apparatus 450 may be seen in Figure 37B. The patient's native valve is captured between lip region 472 and skirt region 474 of anchor 470 in the fully deployed configuration (see Figure 38B).

[0133] Referring to Figures 38 A-C, in conjunction with Figures 35 and 36, a method for percutaneously replacing a patient's diseased aortic valve with apparatus 450 is described. Delivery system 410, having apparatus 450 disposed therein, is percutaneously advanced, preferably in a retrograde fashion, through a patient's aorta A to the patient's diseased aortic valve AV. Sheath 420 is positioned such that its distal end is disposed within left ventricle LV of the patient's heart H. As described with respect to Figures 35, apparatus 450 is deployed from lumen 422 of sheath 420, for example, under fluoroscopic guidance, such that skirt section 474 is disposed within left ventricle LV, body section 476b is disposed across the patient's native valve leaflets L, and lip section 472 is disposed within the patient's aorta A. Advantageously, apparatus 450 may be dynamically repositioned to obtain proper alignment with the anatomical landmarks. Furthermore, apparatus 450 may be refracted within lumen 422 of sheath 420 via actuators 424, even after anchor 470 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition sheath 420.

[0134] Once properly positioned, elements 424a are retracted to expand skirt region 474 of anchor 470 within left ventricle LV. Skirt region 474 is locked in the expanded configuration via skirt lock 490, as previously described with respect to Figures 36. In Figure 38A, skirt region 474 is maneuvered such that it engages the patient's valve annulus An and/or native valve leaflets L, thereby providing positive registration of apparatus 450 relative to the anatomical landmarks.

[0135] Elements 424b are then actuated external to the patient in order to expand lip region 472, as previously described in Figures 35. Lip region 472 is locked in the expanded configuration via lip lock 480. Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated. Elements 424 are pulled from eyelets 483 and 493, and delivery system 410 is removed from the patient. As will be apparent, the order of expansion of lip region 472 and skirt region 474 may be reversed, concurrent, etc.

[0136] As seen in Figure 38B, lip region 472 engages the patient's native valve leaflets L, thereby providing additional positive registration and reducing a risk of lip region 472 blocking the patient's coronary ostia O. Figure 38C illustrates the same in cross-sectional view, while also showing the position of replacement valve 460. The patient's native leaflets are engaged and/or captured between lip region 472 and skirt region 474. Advantageously, lip region 472 precludes distal migration of apparatus 450, while skirt region 474 precludes proximal migration. It is expected that lip region 472 and skirt region 474 also will reduce paravalvular regurgitation.

[0137] With reference to Figures 39-41, a first embodiment of two-piece apparatus of the present invention adapted for percutaneous replacement of a patient's heart valve is described. As seen in Figures 41, apparatus 510 comprises a two-piece device having custom-designed expandable anchor piece 550 of Figures 39 and expandable replacement valve piece 600 of Figures 40. Both anchor piece 550 and valve piece 600 have reduced delivery configurations and expanded deployed configurations. Both may be either balloon expandable (e.g. fabricated from a stainless steel) or self-expanding (e.g. fabricated from a nickel-titanium alloy ("Nitinol") or from a wire mesh) from the delivery to the deployed configurations.

[0138] When replacing a patient's aortic valve, apparatus 510 preferably may be delivered through the patient's aorta without requiring a transseptal approach, thereby reducing patient trauma, complications and recovery time. Furthermore, apparatus 510 enables dynamic repositioning of anchor piece 550 during delivery and facilitates positive registration of apparatus 510 relative to the native position of the patient's valve, thereby reducing a risk of device migration and reducing a risk of blocking or impeding flow to the patient's coronary ostia. Furthermore, the expanded deployed configuration of apparatus 510, as seen in Figure 41D, is adapted to reduce paravalvular regurgitation, as well as to facilitate proper seating of valve piece 600 within anchor piece 550.

[0139] As seen in Figures 39, anchor piece 550 preferably comprises three sections. Lip section 560 is adapted to engage the patient's native valve leaflets to provide positive registration and ensure accurate placement of the anchor relative to the patient's valve annulus during deployment, while allowing for dynamic repositioning of the anchor during deployment. Lip section 560 also main-

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tains proper positioning of composite anchor/valve apparatus 510 post-deployment to preclude distal migration. Lip section 560 optionally may be covered or coated with biocompatible film B (see Figures 41) to ensure engagement of the native valve leaflets. It is expected that covering lip section 560 with film B especially would be indicated when the native leaflets are stenosed and/or fused together

[0140] Groove section 570 of anchor piece 550 is adapted to engage an expandable frame portion, described hereinbelow, of valve piece 600 to couple anchor piece 550 to valve piece 600. As compared to previously known apparatus, groove section 570 comprises additional material and reduced openings or gaps G, which is expected to reduce tissue protrusion through the gaps upon deployment, thereby facilitating proper seating of the valve within the anchor. Groove section 570 optionally may be covered or coated with biocompatible film B (see Figures 41) to further reduce native valve tissue protrusion through gaps G.

[0141] Finally, skirt section 580 of anchor piece 550 maintains proper positioning of composite anchor/valve apparatus 510 post-deployment by precluding proximal migration. When replacing a patient's aortic valve, skirt section 580 is deployed within the patient's left ventricle. As with lip section 560 and groove section 570, skirt section 580 optionally may be covered or coated with biocompatible film B (see Figures 41) to reduce paravalvular regurgitation. As will be apparent to those of skill in the art, all, a portion of, or none of anchor piece 50 may be covered or coated with biocompatible film B.

[0142] In Figure 39A, a portion of anchor piece 550 has been flattened out to illustrate the basic anchor cell structure, as well as to illustrate techniques for manufacturing anchor piece 550. hi order to form the entire anchor, anchor 550 would be bent at the locations indicated in Figure 39A, and the basic anchor cell structure would be revolved to form a joined 360° structure. Lip section 560 would be bent back into the page to form a lip that doubles over the groove section, groove section 570 would be bent out of the page into a 'C- or 'U'-shaped groove, while skirt section 580 would be bent back into the page. Figure 39B shows the anchor portion after bending and in an expanded deployed configuration.

[0143] The basic anchor cell structure seen in Figure 39A is preferably formed through laser cutting of a flat sheet or of a hollow tube placed on a mandrel. When formed from a flat sheet, the sheet would be cut to the required number of anchor cells, bent to the proper shape, and revolved to form a cylinder. The ends of the cylinder would then be joined together, for example, by welding.

[0144] If balloon expandable, anchor piece 550 would be formed from an appropriate material, such as stainless steel, and then crimped onto a balloon delivery catheter in a collapsed delivery configuration. If self-expanding and formed from a shape-memory material, such as a nickel-titanium alloy ("Nitinol"), the anchor piece would be heat-set such that it could be constrained within a sheath in the collapsed delivery configuration, and then would dynamically self-expand to the expanded deployed configuration upon removal of the sheath. Likewise, if anchor piece 550 were formed from a wire mesh or braid, such as a spring steel braid, the anchor would be constrained within a sheath in the delivery configuration and dynamically expanded to the deployed configuration upon removal of the sheath.

[0145] In Figures 40, valve piece 600 is described in greater detail. Figure 40A illustrates valve piece 600 in a collapsed delivery configuration, while Figure 40B illustrates the valve piece in an expanded deployed configuration. Valve piece 600 comprises replacement valve 610 coupled to expandable frame 620. Replacement valve 610 is preferably biologic, although synthetic valves may also be used. Replacement valve 610 preferably comprises three leaflets 611 coupled to three posts 621 of expandable frame 620. Expandable frame 620 is preferably formed from a continuous piece of material and may comprise tips 622 in the collapsed delivery configuration, which expand to form hoop 624 in the deployed configuration. Hoop 624 is adapted to engage groove section 570 of anchor piece 550 for coupling anchor piece 550 to valve piece 600. As with anchor piece 550, valve piece 600 may be balloon expandable and coupled to a balloon delivery catheter in the delivery configuration. Alternatively, anchor piece 550 may be self-expanding, e.g. Nitinol or wire mesh, and constrained within a sheath in the delivery configuration.

[0146] Referring again to Figures 41, a method for deploying valve piece 600 and coupling it to deployed anchor piece 550 to form two-piece apparatus 510 is described, hi Figure 41A, valve piece 600 is advanced within anchor piece 550 in an at least partially compressed delivery configuration. In Figure 41B, tips 622 of frame 620 are expanded such that they engage groove section 570 of anchor piece 550. In Figure 41C, frame 620 continues to expand and form hoop 624. Hoop 624 flares out from the remainder of valve piece 600 and acts to properly locate the hoop within groove section 570. Figure 41D shows valve piece 600 in a fully deployed configuration, properly seated and friction locked within groove section 570 to form composite anchor/valve apparatus 510.

[0147] Anchor piece 550 and valve piece 600 of apparatus 510 preferably are spaced apart and releasably coupled to a single delivery catheter while disposed in their reduced delivery configurations. Spacing the anchor and valve apart reduces a delivery profile of the device, thereby enabling delivery through a patient's aorta without requiring a transseptal approach. With reference to Figure 42, a first embodiment of single catheter delivery system 700 for use with apparatus 510 is described. Delivery system 700 is adapted for use with a preferred self-expanding embodiment of apparatus 510.

[0148] Delivery system 700 comprises delivery catheter 710 having inner tube 720, middle distal tube 730, and outer tube 740. Inner tube 720 comprises lumen 722

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adapted for advancement over a standard guide wire, per se known. Middle distal tube 730 is coaxially disposed about a distal region of inner tube 720 and is coupled to a distal end 724 of the inner tube, thereby forming proximally-oriented annular bore 732 between inner tube 720 and middle tube 730 at a distal region of delivery catheter 710. Outer tube 740 is coaxially disposed about inner tube 720 and extends from a proximal region of the inner tube to a position at least partially coaxially overlapping middle distal tube 730. Outer tube 740 preferably comprises distal step 742, wherein lumen 743 of outer tube 740 is of increased diameter. Distal step 742 may overlap middle distal tube 730 and may also facilitate deployment of valve piece 600, as described hereinbelow with respect to Figures 45.

[0149] Proximally-oriented annular bore 732 between inner tube 720 and middle distal tube 730 is adapted to receive skirt section 580 and groove section 570 of anchor piece 550 in the reduced delivery configuration. Annular space 744 formed at the overlap between middle distal tube 730 and outer tube 740 is adapted to receive lip section 560 of anchor piece 550 in the reduced delivery configuration. More proximal annular space 746 between inner tube 720 and outer tube 740 may be adapted to receive replacement valve 610 and expandable frame 620 of valve piece 600 in the reduced delivery configuration.

[0150] Inner tube 720 optionally may comprise retainer elements 726a and 726b to reduce migration of valve piece 600. Retainer elements 726 preferably are fabricated from a radiopaque material, such as platinum-iridium or gold, to facilitate deployment of valve piece 600, as well as coupling of the valve piece to anchor piece 550. Additional or alternative radiopaque elements may be disposed at other locations about delivery system 700 or apparatus 510, for example, in the vicinity of anchor piece 550.

[0151] With reference now to Figure 43, an alternative delivery system for use with apparatus of the present invention is described. Delivery system 750 comprises two distinct catheters adapted to deliver the anchor and valve pieces, respectively: anchor delivery catheter 710' and valve delivery catheter 760. hi use, catheters 710' and 760 may be advanced sequentially to a patient's diseased heart valve for sequential deployment and coupling of anchor piece 550 to valve piece 600 to form composite two-piece apparatus 510. Delivery catheter 710' is substantially equivalent to catheter 710 described hereinabove, except that catheter 710' does not comprise retainer elements 726, and annular space 746 does not receive valve piece 600. Rather, valve piece 600 is received within catheter 760 in the collapsed delivery configuration. Catheter 760 comprises inner tube 770 and outer tube 780. Inner tube 770 comprises lumen 772 for advancement of catheter 760 over a guide wire. The inner tube optionally may also comprise retainer elements 774a and 774b, e.g. radiopaque retainer elements 774, to reduce migration of valve piece 600. Outer tube 780 is coaxially disposed about inner tuber 770 and preferably comprises distal step 782 to facilitate deployment and coupling of valve piece 600 to anchor piece 550, as described hereinbelow. Valve piece 600 may be received in annular space 776 between inner tube 770 and outer tube 780, and more preferably may be received within annular space 776 between retainer elements 774.

[0152] Referring now to Figure 44, another alternative delivery system is described. As discussed previously, either anchor piece 550 or valve piece 600 (or portions thereof or both) may be balloon expandable from the delivery configuration to the deployed configuration. Delivery system 800 is adapted for delivery of an embodiment of apparatus 510 wherein the valve piece is balloon expandable. Additional delivery systems - both single and multi-catheter - for deployment of alternative combinations of balloon and self-expandable elements of apparatus of the present invention will be apparent to those of skill in the art in view of the illustrative delivery systems provided in Figures 42-44.

[0153] In Figure 44, delivery system 800 comprises delivery catheter 710". Delivery catheter 710" is substantially equivalent to delivery catheter 710 of delivery system 700, except that catheter 710" does not comprise retainer elements 726, and annular space 746 does not receive the valve piece. Additionally, catheter 710" comprises inflatable balloon 802 coupled to the exterior of outer tube 740", as well as an inflation lumen (not shown) for reversibly delivering an inflation medium from a proximal region of catheter 710" into the interior of inflatable balloon 802 for expanding the balloon from a delivery configuration to a deployed configuration. Valve piece 600 may be crimped to the exterior of balloon 802 in the delivery configuration, then deployed and coupled to anchor piece 550 in vivo. Delivery catheter 710" preferably comprises radiopaque marker bands 804a and 804b disposed on either side of balloon 802 to facilitate proper positioning of valve piece 600 during deployment of the valve piece, for example, under fluoroscopic guidance.

[0154] With reference now to Figures 45, in conjunction with Figures 39-42, an illustrative method of percutaneously replacing a patient's diseased heart valve using apparatus of the present invention is described. In Figure 45A, a distal region of delivery system 700 of Figure 42 has been delivered through a patient's aorta A, e.g., over a guide wire and under fluoroscopic guidance using well-known percutaneous techniques, to a vicinity of diseased aortic valve AV of heart H. Apparatus 510 of Figures 39-41 is disposed in the collapsed delivery configuration within delivery catheter 710 with groove section 570 and skirt section 580 of anchor piece 550 collapsed within annular bore 732, and lip section 560 of anchor piece 550 collapsed within annular space 744. Valve piece 600 is disposed in the collapsed delivery configuration between retainer elements 726 within more proximal annular space 746. Separation of anchor piece 550 and valve piece 600 of apparatus 510 along the longitudinal axis of delivery catheter 710 enables percutaneous aortic de-

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livery of apparatus 510 without requiring a transseptal approach.

[0155] Aortic valve AV comprises native valve leaflets L attached to valve annulus An. Coronary ostia O are disposed just proximal of diseased aortic valve AV. Coronary ostia O connect the patient's coronary arteries to aorta A and are the conduits through which the patient's heart muscle receives oxygenated blood. As such, it is critical that the ostia remain unobstructed post-deployment of apparatus 510.

[0156] In Figure 45A, a distal end of delivery catheter 710 has been delivered across diseased aortic valve AV into the patient's left ventricle LV. As seen in Figure 45B, outer tube 740 is then retracted proximally relative to inner tube 720 and middle distal tube 730. Outer tube 740 no longer coaxially overlaps middle distal tube 730, and lip section 560 of anchor piece 550 is removed from annular space 744. Lip section 560 self-expands to the deployed configuration. As seen in Figure 45C, inner tube 720 and middle tube 730 (or all of delivery catheter 710) are then distally advanced until lip section 560 engages the patient's native valve leaflets L, thereby providing positive regisfration of anchor piece 550 to leaflets L. Registration may be confirmed, for example, via fluoroscopic imaging of radiopaque features coupled to apparatus 510 or delivery system 700 and/or via resistance encountered by the medical practitioner distally advancing anchor piece 550.

[0157] Lip section 560 may be dynamically repositioned until it properly engages the valve leaflets, thereby ensuring proper positioning of anchor piece 550 relative to the native coronary ostia O, as well as the valve annulus An, prior to deployment of groove section 570 and skirt section 580. Such multi-step deployment of anchor piece 550 enables positive registration and dynamic repositioning of the anchor piece. This is in contrast to previously known percutaneous valve replacement apparatus.

[0158] As seen in Figure 45D, once leaflets L have been engaged by lip section 560 of anchor piece 550, inner tube 720 and middle distal tube 730 are further distally advanced within left ventricle LV, while outer tube 740 remains substantially stationary. Lip section 560, engaged by leaflets L, precludes further distal advancement/migration of anchor piece 550. As such, groove section 570 and skirt section 580 are pulled out of proximally-oriented annular bore 732 between inner tube 720 and middle distal tube 730 when the tubes are distally advanced. The groove and skirt sections self-expand to the deployed configuration, as seen in Figure 45E. Groove section 570 pushes native valve leaflets L and lip section 560 against valve annulus An, while skirt section 580 seals against an interior wall of left ventricle LV, thereby reducing paravalvular regurgitation across aortic valve AV and precluding proximal migration of anchor piece 550.

[0159] With anchor piece 550 deployed and native aortic valve AV displaced, valve piece 600 may be deployed and coupled to the anchor piece to achieve percutaneous aortic valve replacement. Outer tube 740 is further proximally retracted relative to inner tube 720 such that valve piece 600 is partially deployed from annular space 746 between inner tube 720 and outer tube 740, as seen in Figure 45F. Expandable frame 620 coupled to replacement valve 610 partially self-expands such that tips 622 partially form hoop 624 for engagement of groove section 570 of anchor piece 550 (see Figure 41B). A proximal end of expandable frame 620 is engaged by distal step 742 of outer tube 740.

[0160] Subsequent re-advancement of outer tube 740 relative to inner tube 720 causes distal step 742 to distally advance valve piece 600 within anchor piece 550 until tips 622 of expandable frame 620 engage groove section 570 of anchor piece 550, as seen in Figure 45G. As discussed previously, groove section 570 comprises additional material and reduced openings or gaps G, as compared to previously known apparatus, which is expected to reduce native valve tissue protrusion through the gaps and facilitate engagement of tips 622 with the groove section. Outer tube 740 then is proximally retracted again relative to inner tube 720, and valve piece 600 is completely freed from annular space 746. Frame 620 of valve piece 600 fully expands to form hoop 624, as seen in Figure 45H.

[0161] Hoop 624 friction locks within groove section 570 of anchor piece 550, thereby coupling the anchor piece to the valve piece and forming composite two-piece apparatus 510, which provides a percutaneous valve replacement. As seen in Figure 45I, delivery catheter 710 may then be removed from the patient, completing the procedure. Blood may freely flow from left ventricle LV through replacement valve 610 into aorta A. Coronary ostia O are unobstructed, and paravalvular regurgitation is reduced by skirt section 580 of anchor piece 550.

[0162] Referring now to Figures 46, an alternative embodiment of two-piece apparatus 510 is described comprising an alignment/locking mechanism. Such a mechanism may be provided in order to ensure proper radial alignment of the expandable frame of the valve piece with the groove section of the anchor piece, as well as to ensure proper longitudinal positioning of the frame within the hoop. Additionally, the alignment/locking mechanism may provide a secondary lock to further reduce a risk of the anchor piece and the valve piece becoming separated post-deployment and coupling of the two pieces to achieve percutaneous valve replacement.

[0163] In Figures 46, apparatus 510' comprises valve piece 600' of Figure 46A and anchor piece 550' of Figure 46B. Anchor piece 550' and valve piece 600' are substantially the same as anchor piece 550 and valve piece 600 described hereinabove, except that anchor piece 550' comprises first portion 652 of illustrative alignment/locking mechanism 650, while valve piece 600' comprises second portion 654 of the alignment/locking mechanism for coupling to the first portion. First portion 652 illustratively comprises three guideposts 653 coupled to

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skirt section 580' of anchor piece 550' (only one guidepost shown in the partial view of Figure 46B), while second portion 654 comprises three sleeves 655 coupled to posts 621' of expandable frame 620' of valve piece 600'.

[0164] When anchor piece 550' is self-expanding and collapsed in the delivery configuration, guideposts 653 may be deployed with skirt section 580', in which case guideposts 653 would rotate upward with respect to anchor piece 550' into the deployed configuration of Figure 46B. Alternatively, when anchor piece 550' is either balloon or self-expanding and is collapsed in the delivery configuration, guideposts 653 may be collapsed against groove section 570' of the anchor piece and may be deployed with the groove section. Deploying guideposts 653 with skirt section 580' has the advantages of reduced delivery profile and ease of manufacturing, but has the disadvantage of significant dynamic motion during deployment. Conversely, deploying guideposts 653 with groove section 570' has the advantage of minimal dynamic motion during deployment, but has the disadvantage of increased delivery profile. Additional deployment configurations will be apparent to those of skill in the art. As will also be apparent, first portion 652 of alignment/locking mechanism 650 may be coupled to alternative sections of anchor piece 550' other than skirt section 580'.

[0165] Sleeves 655 of second portion 654 of alignment/locking mechanism 650 comprise lumens 656 sized for coaxial disposal of sleeves 655 about guideposts 653 of first portion 652. Upon deployment, sleeves 655 may friction lock to guideposts 653 to ensure proper radial and longitudinal alignment of anchor piece 550' with valve piece 600', as well as to provide a secondary lock of the anchor piece to the valve piece. The secondary lock enhances the primary friction lock formed by groove section 570' of the anchor piece with hoop 624' of expandable frame 620' of the valve piece.

[0166] To facilitate coupling of the anchor piece to the valve piece, suture or thread may pass from optional eyelets 651a of guideposts 653 through lumens 656 of sleeves 655 to a proximal end of the delivery catheter (see Figure 47). In this manner, second portion 654 of mechanism 650 may be urged into alignment with first portion 652, and optional suture knots (not shown), e.g. pre-tied suture knots, may be advanced on top of the mechanism post-coupling of the two portions to lock the two portions together. Alternatively, guideposts 653 may comprise optional one-way valves 651b to facilitate coupling of the first portion to the second portion. Specifically, sleeves 655 may be adapted for coaxial advancement over oneway valves 651b in a first direction that couples the sleeves to guideposts 653, but not in a reverse direction that would uncouple the sleeves from the guideposts.

[0167] Referring now to Figure 47, an alternative embodiment of apparatus 510' comprising an alternative alignment/locking mechanism is described. Apparatus 510" is illustratively shown in conjunction with delivery system 700 described hereinabove with respect to Figure 42. Valve piece 600" is shown partially deployed from outer tube 740 of catheter 710. For the sake of illustration, replacement valve 610" of valve piece 600", as well as inner tube 720 and middle distal tube 730 of delivery catheter 710, are not shown in Figure 47.

[0168] In Figure 47, anchor piece 550" of apparatus 510" comprises first portion 652' of alignment/locking mechanism 650', while valve piece 600" comprises second portion 654' of the alternative alignment/locking mechanism. First portion 652' comprises eyelets 660 coupled to groove section 570" of anchor piece 550". Second portion 654' comprises knotted loops of suture 662 coupled to tips 622" of expandable frame 620" of valve piece 600". Suture 661 extends from knotted loops of suture 662 through eyelets 660 and out through annular space 746 between outer tube 740 and inner tube 720 (see Figure 42) of catheter 710 to a proximal end of delivery system 700. In this manner, a medical practitioner may radially and longitudinally align valve piece 600'' with anchor piece 550" by proximally retracting sutures 661 (as shown by arrows in Figure 47) while distally advancing distal step 742 of outer tube 740 against valve piece 600" until tips 622" of the valve piece engage groove section 570" of anchor piece 550". Proximal retraction of outer tube 740 then causes expandable frame 620" to further expand and form hoop 624" that friction locks with groove section 570" of anchor piece 550", thereby forming apparatus 510" as described hereinabove with respect to apparatus 510. A secondary lock may be achieved by advancing optional suture knots (not shown) to the overlap of eyelets 660 and knotted loops of suture 662. Such optional suture knots preferably are pre-tied.

[0169] With reference now to Figure 48, yet another alternative embodiment of apparatus 510', comprising yet another alternative alignment/locking mechanism 650, is described. First portion 652" of alignment/locking mechanism 650" is coupled to anchor piece 550"' of apparatus 510"', while second portion 654" is coupled to valve piece 600"'. The first portion comprises male posts 670 having flared ends 671, while the second portion comprises female guides 672 coupled to tips 622"' of expandable frame 620"' of valve piece 600"'.

[0170] Female guides 672 are translatable about male posts 670, but are constrained by flared ends 671 of the male posts. In this manner, anchor piece 550"'; and valve piece 600"' remain coupled and in radial alignment with one another at all times - including delivery -but may be longitudinally separated from one another during delivery. This facilitates percutaneous delivery without requiring a transseptal approach, while mitigating a risk of inadvertent deployment of the anchor and valve pieces in an uncoupled configuration. Additional alignment/locking mechanisms will be apparent in view of the mechanisms described with respect to Figures 46-48.

[0171] Prior to implantation of one of the replacement valves described above, it may be desirable to perform a valvoplasty on the diseased valve by inserting a balloon

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into the valve and expanding it using saline mixed with a contrast agent, hi addition to preparing the valve site for implant, fluoroscopic viewing of the valvoplasty will help determine the appropriate size of replacement valve implant to use.

[0172] Figures 49A and 49B illustrate one embodiment of a delivery system/deployment tool and apparatus in accordance with the present invention. As seen in Figure 49A, apparatus 10 may be collapsed for delivery within delivery system/deployment tool 100. Delivery system 100 includes guidewire G, nosecone 102, anchor actuation elements 106, multi-lumen shaft or catheter 108 having optional central lumen 109 and a plurality of circumferentially disposed lumens Lu, external sheath 110 having optional proximal handle 111, and confrol handle 120. Nosecone 102 may, for example, be manipulated via a shaft extending through central lumen 109 of multi-lumen catheter 108.

[0173] Anchor actuation elements 106 preferably comprise both proximal anchor actuation elements and distal anchor actuation elements. The proximal anchor actuation elements may, for example, comprise actuators 106a that are releasably coupled to a proximal region of anchor 30 of apparatus 10 via releasable attachment mechanisms for manipulating a proximal region of apparatus 10. The distal anchor actuation elements may comprise actuators 106b that are releasably coupled to a distal region of anchor 30 via releasable attachment mechanisms for manipulating the distal region of apparatus 10. h some embodiments, the distal anchor actuation elements may comprise posts or anchor attachment elements 32 of anchor 30 and the releasable attachment mechanisms connecting actuators 106b to posts 32. In an alternative configuration, the proximal anchor actuation elements may be releasably coupled to a proximal region of apparatus 10 through posts and releasable attachment mechanisms for manipulation of a proximal region of the apparatus, while the distal anchor actuation elements may connect to a distal region of anchor 30 via releasable attachment mechanisms to manipulate a distal region of the apparatus. As another alternative, both proximal and distal anchor actuation element may connect to anchor 30 via releasable attachment mechanisms.

[0174] In the embodiment shown in Figures 49, actuators 106a may, for example, include stiff finger elements extending from a distal region of multi-lumen shaft 108, while actuators 106b may include control elements (e.g., stands of suture, or metal or polymer wires) which pass through one or more lumens Lu of shaft 108. Release actuators 112 for the releasable attachment mechanisms for both sets of actuators also may pass through one or more lumens Lu of shaft 108. The release actuators may comprise, for example, control elements (e.g., strands of suture, or metal or polymer wires), covers, mandrels, elongated elements, friction surfaces, wrap portions, interference shapes, etc. The release actuators preferably are movable relative to anchor actuation elements 106, e.g., via control handle 120.

[0175] Control handle 120 is coupled to multi-lumen shaft 108. Knob 122 disposed in slot 123 may actuate release actuators 112 that couple actuators 106a of anchor actuation elements 106 to apparatus 10. Likewise, knob 124 disposed in slot 125 may actuate release actuators 112 that couple actuators 106b of anchor actuation elements 106 to posts 32 of anchor 30 of apparatus 10. Handle 120 also comprises knob 126 for, e.g., manipulating the actuators 106b to control movement of the distal region of apparatus 10 relative to its proximal region. Conversely, controlled movement of the proximal region of apparatus 10 relative to its distal region may be achieved by holding knob 126 stationary while advancing or retracting handle 120. Knob 126 optionally may move actuators 106b in unison with their concomitant release actuators 112.

[0176] Apparatus 10 comprises anchor 30 and replacement valve 20. Anchor 30 preferably comprises a braid. Such braid can have closed ends at either or both its ends. Replacement valve 20 is preferably coupled to the anchor along posts 32, e.g., along a valve attachment structure, such as a tab and/or a plurality of holes. Posts 32, therefore, may function as valve supports and may be adapted to support the replacement valve within the anchor, h the embodiment shown, there are three posts, corresponding to the valve's three commissural attachment points. The posts can be attached to the braid portion of anchor 30. The posts can be attached to the braid's distal end, as shown in Figure 50A, central region, or proximal end. Replacement valve 20 can be composed of a synthetic material and/or may be derived from animal tissue. Replacement valve 20 is preferably configured to be secured within anchor 30.

[0177] Anchor 30 comprises a plurality of anchor lock elements 34, e.g., buckles 34, attached to its proximal region, one for each post 32. Posts 32 may comprise a lock element that forms a two-part locking mechanism with anchor lock elements 34 for maintaining anchor 30 in a deployed or expanded configuration (e.g., as illustrated in Figures 49B, 50B and 50C).

[0178] In this embodiment, anchor 30 is formed from a collapsible and expandable wire braid. Anchor braid 30 is preferably self-expanding and is preferably formed from a material such as Nitinol, cobalt-chromium steel or stainless steel wire using one or more strands of wire. Delivery and deployment of braided anchor 30 is similar to the delivery and deployment of the anchors described in U.S. Patent Appl. Ser. No. 10/746,120. Specifically, in one embodiment described below, during deployment braided anchor 30 is actively foreshortened by proximally retracting the actuators 106b relative to the actuators 106a to expand and lock the anchor in place. In some embodiments, foreshortening may expand anchor 30 to a radially symmetrical, bilaterally symmetrical, or asymmetrical expanded shape. The foreshortening step can include expanding a first region of the anchor to a first diameter and a second region of the anchor to a second

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diameter larger than the first diameter. A third region may also be expanded to a diameter larger than the first diameter. The expansion of various regions of the anchor (e.g., the distal region) can be especially useful in locating the aortic valve and centering the anchor within it. Preferably, the secured anchor does not interfere with the mitral valve or the ostia. In some embodiments, the anchor is allowed to self-expand prior to the foreshortening step.

[0179] As seen in Figures 49, after endovascular delivery through sheath 110 to the vicinity of the patient's native valve (such as the aortic valve), apparatus 10 may be expanded from the collapsed delivery configuration of Figure 49A to the expanded deployed configuration of Figure 49B using delivery system/deployment tool 100. To deploy apparatus 10, external sheath 110 may be retracted relative to apparatus 10 by proximally retracting sheath handle 111 relative to control handle 120. Sheath 110 is thereby removed from the exterior of apparatus 10, permitting the anchor 30 to self-expand. For example, if anchor braid 30 is composed of a shape memory material, it may self-expand to or toward its "at-rest" configuration. This at-rest configuration of the braid can be, for example its expanded configuration, a collapsed configuration, or a partially expanded configuration between the collapsed configuration and the expanded configuration, or some combination. In preferred embodiments, the anchor's at-rest configuration is between the collapsed configuration and the expanded configuration. Depending on the at-rest diameter of the braid and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

[0180] In its collapsed configuration, anchor 30 preferably has a collapsed delivery diameter between about 3 to 30 Fr, or more preferably 6 to 28 Fr, or more preferably 12 to 24 Fr. In some embodiments, anchor 30 in its collapsed configuration will have a length ranging from about 5 to about 170 mm, more preferably from about 10 to about 160 mm, more preferably from about 15 to about 150 mm, more preferably from about 20 to about 140 mm, or more preferably from about 25 mm to about 130 mm.

[0181] Similarly, in its expanded configuration, anchor 30 preferable has a diameter ranging between about 10 to about 36 mm, or more preferably from about 24 to about 33 mm, or more preferably from about 24 to about 30 mm. In some embodiments, anchor 30 in its expanded configuration will have a length ranging from about 1 to about 50 mm, more preferably from about 2 to about 40 mm, more preferably from about 5 to about 30 mm, or more preferably from about 7 to about 20 mm.

[0182] Overall, the ratio of deployed to collapsed/sheathed lengths is preferably between about 0.05 and 0.5, more preferably about 0.1 to 0.35, or more preferably about 0.15 to 0.25. In any of the embodiments herein, anchor 30 in its expanded configuration preferably has a radial crush strength that maintains the anchor substantially un-deformed in response to a pressure of up to about 0.5 atm directed substantially radially inward toward the central axis, or more preferably up to about 2 atm directed substantially radially inward toward the central axis, hi addition, in any of the embodiments herein, the anchor preferably has an axial spring constant of between about 10 to 250 g/cm, more preferably between about 20 to 200 g/cm, or more preferably between about 40 to 160 g/cm. In addition, in any of the embodiments herein, the anchor is preferably adapted to support the replacement valve at the anchor site in response to a differential pressure of up to about 120 mm Hg, more preferably up to about 240 mm Hg, or more preferably up to about 320 mm Hg.

[0183] These parameters are not intended to be limiting. Additional parameters within the scope of the present invention will be apparent to those of skill in the art.

[0184] As seen in Figure 49B, anchor 30 may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor 30 during endovascular deployment. In some embodiments, foreshortening of the apparatus involves applying a distally directed force on the proximal end of the anchor by one or more anchor actuation elements to move the proximal end of the anchor distally while maintaining the position of the distal end of the anchor. For example, the proximal region of anchor 30 may be pushed distally by certain anchor actuation elements 106, e.g., actuators 106a. Alternatively, foreshortening of the apparatus involves applying a proximally directed force on the distal end of the anchor by one or more anchor actuation elements to move the distal end of the anchor proximally while maintaining the position of the proximal end of the anchor. For example, the distal region of anchor 30 may be pulled proximally via a proximally directed force applied by post actuation elements 106b, this force opposed by anchor actuators 106a.

[0185] Anchor actuation elements 106 preferably are adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

[0186] The distal anchor actuation elements may include, for example, actuators 106b and/or release actuators 112 that are controlled, e.g., by control knobs 124 and 126 of confrol handle 120. Similarly, the proximal regions of anchor 30 may be pushed distally via proximal anchor actuation elements, e.g., actuators 106a, at the

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proximal region of the anchor. The proximal anchor actuation elements facilitate application of a distally directed force to the proximal end of anchor 30 to move or constrain the proximal end of the anchor distally and are controlled through motion of shaft 108 relative to the distal anchor actuation elements. Control knob 122 of control handle 120 may control release actuators 112 for releasing the proximal anchor actuation elements from the braid. The proximal anchor actuation elements may be further adapted to expand as the proximal end of the anchor expands radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal anchor actuation elements apply a distally directed force on the proximal end of the anchor system through a plurality of actuators 106a in order to expand the braid of anchor 30. Such braid expansion optionally may be assisted via inflation of a balloon catheter (see Figures 25 and 26) reversibly disposed within apparatus 10, as described in U.S. Patent Appl. Ser. No. 10/746,120.

[0187] In the fully deployed configuration, lock elements of posts 32 and anchor lock elements or buckles 34 of anchor 30 may be used to lock and maintain the anchor in the deployed configuration. Apparatus 10 may be repositioned or retrieved from the patient until the lock elements of posts 32 have been interlocked with anchor lock elements 34 of anchor 30 to form lock 40. In one embodiment, actuators 106b and attendant release actuators 112 comprise control elements attached to posts 32 that are threaded through buckles 34 so that the proximally directed force exerted on posts 32 by the control elements during deployment pulls a lock element of posts 32 toward and through buckles 34 to form lock 40. In this manner, the control elements may act as both anchor actuators and lock actuators.

[0188] Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus 10 during or post-deployment. When the lock is selectively reversible, the apparatus may be repositioned and or retrieved as desired, i.e., even after actuation of lock 40.

[0189] Locks used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the anchor lock elements at the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion (see, e.g., Figure 50F). Such locking mechanisms may, for example, comprise ratchets having multiple lock locations. Furthermore, lock alignment features may be provided to facilitate alignment of the post and anchor lock elements, such as a hinge or an oversized width of the post or anchor lock elements. FurtherstiU, lock prevention mechanisms may be provided to preclude locking until desired by a medical practitioner.

[0190] When apparatus 10 is placed across a patient's diseased heart valve, anchor 30 may be used to displace the patient's native valve leaflets, and replacement valve 20 will thereafter serve in place of the native valve. After final positioning and expansion, apparatus 10 may be decoupled from delivery system 100 by decoupling the proximal and distal anchor actuation elements 106 from the apparatus via releasable attachment mechanisms, e.g., by decoupling proximal actuators 106a from braided anchor 30 and distal actuators 106b from posts 32 of the anchor via the releasable attachment mechanisms. Moving release actuators 112, e.g., using knobs 122 and 124 of handle 120, may, for example, actuate the releasable attachment mechanisms. Preferably, the releasable attachment mechanisms may be actuated by moving the release actuator(s) less than about 1 inch. After decoupling, delivery system/deployment tool 100 may be removed from the patient, thereby completing endovascular replacement of a patient' s heart valve.

[0191] Prior to implantation of replacement valve apparatus described herein, it may be desirable to perform a valvuloplasty on the patient's diseased valve by inserting a balloon into the valve and expanding it using, e.g., saline mixed with a contrast agent, hi addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

[0192] Figures 50A-50C show further details of anchor 30 of apparatus 10. Figure 50A shows the apparatus in a collapsed configuration, such as for delivery within a sheath or other lumen or for retrieval and recapture into a sheath or other lumen. Figures 50B and 50C show the anchor and valve in an expanded and locked configuration.

[0193] As shown in Figure 50B, anchor 30 illustratively has three posts and three buckles. As seen in Figure 50C, the three leaflets of replacement valve 20 may be, coupled to the three posts 32 along valve support structures. Thus, posts 32 act as valve supports. The posts, unlike the braid, do not collapse or expand. In some embodiments, a post 32 has one or more proximal slots 33, at least one proximal hole 36a and at least one distal hole 36b. Leaflet tissue may, for example, be passed through slot 33 and sutured in place via suture routed through one or more proximal holes 36a. In this manner, slot(s) 33 and hole(s) 36a may form a valve support structure. Alternative valve support structures known in the art for fixing valve leaflets to posts may also be employed.

[0194] Posts 32 may be coupled to anchor braid 30 via one or more distal holes 36b. For example, anchor braid 30 may be woven through holes 36b, or a suture or wire may be routed through holes 36b and tied to the braid. Yet another proximal hole (not shown) in post 32 serves as an anchor lock element that interfaces with the anchor lock element provided by buckle 34 to form lock 40. Buckles 34 may likewise be attached to anchor braid 30 via weaving or suturing.

[0195] Alternative locks may be used to lock the anchor of the present invention in the foreshortened configuration, as shown, e.g., in Figures 50D-50F. Preferably, a lock of the present invention can have multiple locking

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options such that locking can confer a plurality of amounts of expansion. Furthermore, the locking option can be employed asymmetrically to confer non-cylindrical shapes to the anchor. In Figure 50D, lock 40' comprises male lock element 44 disposed on post 32 and anchor lock element 34 disposed on braided anchor 30. Anchor lock element 34 illustratively comprises triangular protrusion or eyelet 42 of anchor 30. The triangular shape of female lock element 42 may facilitate mating of male lock element 44 with the female lock element without necessitating deformation of the male lock element. One or more holes 45 may be provided through post 32, e.g., for releasably attaching an actuator 106b to the post.

[0196] In Figure 50E, lock 40" comprises alternative male lock element 44' having multiple in-line arrowheads 46 along posts 32. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female lock element 42', which illustratively comprises a rounded eyelet. Appendages 48 optionally comprise holes 49, such that releasable lock prevention mechanism 47, illustratively a control wire, may pass through the holes to constrain the appendages in the deformed configuration. To actuate lock 40", one or more arrowheads 46 of male lock element 44' are drawn through female lock element 42', e.g., via a post/lock actuator, and the lock prevention mechanism is removed from holes 49, thereby causing appendages 48 to resiliently expand and actuate lock 40".

[0197] Advantageously, providing multiple arrowheads 46 along posts 32 yields a ratchet that facilitates in-vivo determination of a degree of foreshortening and expansion imposed upon anchor 30. Furthermore, optionally constraining appendages 48 of arrowheads 46 via mechanism 47 prevents actuation of lock 40" (and thereby deployment of apparatus 10) even after male element 44' has been advanced through female element 42'. Only after a medical practitioner has removed lock prevention mechanism 47, which constrains appendages 48, is lock 40" fully engaged and is deployment no longer reversible.

[0198] Lock 40"' of Figure 50F is similar to lock 40" of Figure 50E, except that holes 49 on appendages 48 have been eliminated, and the lock prevention mechanism comprises overtube or cover 47. Overtube 47 constrains appendages 48 to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Lock 40"' may, for example, be actuated by applying a proximally-directed force to actuator 106b. Actuator 106b illustratively comprises a control wire releasably disposed through hole 45 in post 32. Lock prevention mechanism 47 then is withdrawn proximally relative to anchor 30, which causes the appendages to resiliently expand, thereby fully actuating lock 40"'.

[0199] Referring now to Figure 51, a detail view of a variation of post 32 is described, hi Figure 51, post 32 illustratively comprises actuator attachment element 250 for attaching the post to an actuator 106b; post lock element 252, illustratively a slot, for interlocking post 32 with an anchor lock element 34; valve attachment structure 254, comprising slot 255 and a plurality of holes 256, for attaching replacement valve 20 to the post (a tab of the valve may be passed through slot 255, then sewn to the back of the post through holes 256); and braid attachment element 258 for attaching the post to a distal region of anchor 30. The braid of anchor 30 may, for example, be interwoven through braid attachment element 258. Post 32 may be fabricated from a variety of materials, e.g., metallic materials such as stainless steel, and maybe laser cut, die cast, etc. In this variation of post 32, valve 20 is disposed distal of lock element 252. In alternative variations, the valve may be attached to the post proximal of the lock element or in-line with the lock element (i.e., neither proximal nor distal to the lock).

[0200] Figures 52 provide an alternative variation of post 32. In Figures 52, post 32 comprises lock element 260 having lock alignment feature 262, illustratively hinge 263. Hinge 263 allows lock element 260 to rotate from a position in line with post 32, as in Figure 52A, to a position out of alignment with the post, as in Figure 52B, thereby facilitating alignment with an anchor lock element 34. As shown, post 32 further comprises actuator attachment element 264, illustratively an eyelet, valve support structure 266 having slot 267 and a plurality of holes 268, and braid attachment element 269.

[0201] Figures 53 illustrate an alternative variation of lock alignment feature 262 comprising spring 270. As with hinge 263, spring 270 facilitates alignment of post lock element 260 with an anchor lock element 34 by allowing the post lock element to rotate from a position in line with post 32, as in Figure 53A, to a position out of alignment with the post, as in Figure 53B. Spring 270 also applies a restoring force that urges post lock element 260 back into alignment with post 32. Furthermore, spring 270 may facilitate dynamic elongation of post 32 in response to axial tension. This elongation may facilitate axial lengthening of anchor 30 in response to radially inward compression applied to the anchor.

[0202] With reference to Figure 54, another variation of post 32 is provided comprising expansion zone 280, which may, for example, comprise a laser cut feature along post 32. Expansion zone 280 facilitates dynamic elongation of post 32 in response to axial tension applied to the post, which facilitates axial lengthening of anchor 30 in response to radially inward compression applied to the anchor. Figure 55 illustrates an alternative expansile element 290 comprising a curved wire or rod that may be elongated and straightened through application of axial tension to facilitate axial lengthening of the anchor in response to radially inward compression applied to the anchor (and thereby axial tension applied to post 32 via interaction between post lock element 260 and an anchor lock element 34).

[0203] Element 290 additionally or alternatively may serve as a lock alignment feature. In such a configuration,

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element 290 optionally may not be expansile. More generally, post 32 may comprise proximal and distal ends connected by a tensile member.

[0204] Figures 56 illustrate another variation of post 32 having another alternative lock alignment feature 262. In Figures 56, actuator 106b applies a proximally-directed force which brings post lock element 260 and anchor lock element 34 proximate to one another allowing the system to lock. Anchor lock element 34 defines a lock width Wi. In this embodiment, lock alignment feature 262 comprises post lock element lock area or width W2 that is substantially wider than the lock width Wi, for example, at least about twice as wide. This increased width enhances the probability of interlocking the post and anchor lock elements, even at sharply misaligned angles. In Figures 56, post 32 and anchor lock element 34 are disposed at an illustrative misalignment angle of about 10°.

[0205] Referring now to Figure 57, the variation of post 32 of Figure 51 is shown in combination with an illustrative actuator 106b and release actuator 112. In Figure 57, actuator 106b illustratively comprises rod 300 having post attachment element 302 that mates with actuator attachment element 250 of post 32. Angled camming surfaces 304 and 305 of post attachment element 302 and actuator attachment element 250, respectively, form an interface between post attachment element 302 and actuator attachment element 250. Proximal movement of actuator 106b with respect to post 32 is translated by the camming surfaces into a lateral force between the two elements that acts to separate and release post 32 from actuator 106b,. Release actuator 112, illustratively tube 310, may be advanced over actuator 300 to cover the camming surface interface of the post and the actuator 106b, thereby forming a releasable attachment mechanism for securing the post to the actuator even during application of axial tension to the actuator. To separate post 32 from actuator 106b, e.g., after expansion and locking of anchor 30, release actuator 112 may be retracted relative to actuator 106b to the position shown in Figure 57, thereby removing a constraint from camming surfaces 304 and 305 and allowing the post and actuator to be pulled apart. Release actuator 112 preferably is retracted less than about 1 inch relative to the actuator 106b in order to actuate the releasable attachment mechanism, e.g., to remove constraint from camming surfaces 304 and 305.

[0206] Referring now to Figures 58, an alternative releasable attachment mechanism for attaching a variation of post 32 to a variation of actuator 106b is described, hi Figures 58A and 58B, post 32 having actuator attachment element 320, illustratively an enlarged proximal opening within the post, is interference fit with post attachment element 330 of actuator 106b, illustratively an enlarged bulb, knob or other distal protrusion of the actuator. The slope of element 330 provides a camming surface that interfaces with an inside surface of opening 320. The angle of the camming interface between element 330 and opening 320 translates proximal movement of actuator 106b with respect to post 32 into a lateral movement between actuator 106b and post 32, thereby separating these elements. Release actuator 112, illustratively tube 310, covers the interference fit releasable attachment mechanism to preclude lateral movement of the post attachment element relative to the actuator attachment element, thereby releasably attaching the post to the actuator 106b. In Figure 58C, tube 310 is retracted relative to the post and actuator, which permits lateral movement between the post and actuator attachment elements, thereby separating actuator 106b from post 32. If tube 310 has not been refracted, of course, proximal movement of actuator 106b moves post 32 and the distal portion of the anchor proximally.

[0207] Figures 59 illustrate a variation of the releasable attachment mechanism of Figures 58. In the variation of Figures 59, actuator attachment element 320 of post 32 is deformable from a substantially round profile to an oval or "figure eight" profile by advancement of release actuator 112 over the attachment element. This forms a releasable attachment mechanism, hi the deformed profile of Figures 59A and 59B, post attachment element 330 of actuator 106b is interference fit with the deformed actuator attachment element of post 32. In Figure 59C, retraction of release actuator 112 relative to the post and actuator allows actuator attachment element 320 to resiliently resume its un-deformed or at-rest configuration, thereby permitting separation of post 32 from actuator 106b. Actuator attachment element 320 may, for example, be fabricated from a shape memory material, such as Nitinol. A camming surface 331 on post attachment element 330 and a corresponding surface on the inner portion of element 320 translate proximal movement of actuator 106b with respect to post 32 into lateral movement of element 330 with respect to element 320 when release actuator 112 has been retracted.

[0208] In the variation of Figures 60, post attachment element 330 is deformable (as in Figures 60A and 60B), and anchor attachment element 320 may be interference fit with the post attachment element. Figure 60C shows the post attachment element 330 in its at-rest configuration after tube 310 has been retracted, thereby releasing anchor attachment element 320. As will be apparent, for many or all of the two-part locking or attachment element elements described herein, the position of the elements may be reversed.

[0209] In Figures 61, post attachment element 330 comprises wrap portion 332 that may be inserted through anchor attachment element 320, illustratively an eyelet, wrapped backwards, then covered with release actuator tube 310 to constrain the wrap portion 332 in the wrapped configuration, as in Figure 61A. Release actuator tube 310 may be retracted relative to the wrap portion to resiliently or dynamically (e.g., by retracting actuator 106b relative to post 32) reshape the wrap portion to a substantially straight configuration for releasing the attachment between the post and the actuator, as in Figure 61B. Wrap portion 332 preferably is fabricated from a

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shape memory material, such as Nitinol, or a resilient material, such as spring steel.

[0210] Figure 62 shows another variation of the post, actuator and anchor lock element. In Figure 62, post 32 comprises post lock element 260 and actuator attachment element 264, illustratively an eyelet, through which actuator 106b is reversibly disposed. Anchor lock element 34 illustratively comprises a buckle, which may, for example, be formed from a cut tube or a bent resilient material. Anchor lock element 34 comprises anchor or braid attachment element 340 for attaching the buckle to anchor 30, and tab 342 for interlocking the buckle with post lock element 260, which illustratively is a slot formed through post 32. Actuator 106b therefore actuates the post (and therefore the distal end of the anchor to which the post is attached) as well as the anchor lock. Actuator 106b may be released from the post (and therefore from the anchor) by pulling one end of the control wire proximally to draw the control wire through and out of opening 264.

[0211] Anchor lock element 34 also comprises optional unlock actuator attachment 344, illustratively a pair of eyelets, through which unlock actuator 350 is releasably coupled to anchor lock element 34. Unlock actuator 350 illustratively comprises a control wire. Upon locking of tab 342 of buckle 34 within slot 260 of post 32, a proximally-directed force applied to unlock actuator 350 may remove the tab from the slot, thereby unlocking buckle 34 and post 32 and permitting the anchor to contract and elongate. Unlocking may be utilized, for example, to reposition or retrieve the anchor and valve apparatus even after the apparatus has been locked in the fully deployed configuration, as described previously with respect to Figures 5.

[0212] Figures 63 show another variation of the actuator, the lock actuator and the release actuator. As with other anchor lock elements, anchor lock element 34 in this embodiment is attached to a proximal end of the anchor, and the distal end of post 32 is attached to a distal end of the anchor. The anchor is not shown in Figures 63 for ease of illustration. For the purposes of illustration, the unlock actuator also is not shown in Figures 63.

[0213] As shown, actuator 106b actuates both post 32 (and therefore the distal end of the anchor to which the post is attached) and the lock formed between post lock element 260 and anchor lock element 34. h Figure 63A, release actuator 112 passes through actuator 106b to actuate the releasable attachment mechanism between post 32 and actuator 106b. Figure 63B provides a detail view of the releasable attachment mechanism. Actuator 106b comprises wrap portion 360 that passes through actuator attachment element 264 and wraps around the end of post 32. Wrap portion 360 may comprise a shape memory material, such as Nitinol, or a deformable material, e.g., a resiliently deformable material.

[0214] Wrap portion 360 further comprises first opening 362 for engaging release actuator 112, illustratively a wire or rod that passes through lumen Lu of actuator 106b. The walls of the lumen act a linear bearing and/or motion guide during advancement and retraction of the release actuator relative to the actuator. Actuator 106b also comprises second opening 364, which may be aligned with first opening 362 to engage release actuator 112, as shown. As seen in the cross-sectional view of Figure 63C, wrap portion 360, and especially the curved portion 361 of the wrap portion, acts as a spring element that urges the first opening out of alignment with the second opening. In this manner, release actuator 112 may be interference or friction fit through first opening 362 and second opening 364. Retraction of the release actuator proximal of the first and second openings may actuate the releasable attachment mechanism to resiliently or dynamically unwrap portion 360 and release actuator 106b from post 32. Wrap and/or curved portion 360/361 of actuator 106b illustratively is disposed at a distal end of the actuator.

[0215] As will be apparent to those of skill in the art, the releasable attachment mechanism of Figures 63 may also be utilized to attach a actuator 106a to a braided anchor 30. More generally, wrap portion 360 provides an illustrative first shape on an anchor actuation element 106 that is adapted to mate with a second shape on a post or anchor actuator attachment element (such as element 264 in Figures 63, or a wire of the braid of anchor 30) to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor. The apparatus further comprises a release actuator adapted to actuate the releasable attachment mechanism. The release actuator is adapted to be moved to permit relative movement between the first shape and the second shape. This relative movement may change the first shape and/or the second shape to a third shape that permits relative distal or proximal movement between the anchor actuation element and the anchor or post. Furthermore, this relative movement may separate the anchor actuation element from the anchor or actuator attachment element.

[0216] Figure 64 illustrates a variation of the anchor lock element of Figures 63. In Figure 64, anchor lock element 34 comprises lock alignment feature 370. Feature 370 comprises engagement portion 372, illustratively a loop, that is adapted to engage post 32 before engagement of anchor lock element 34 (i.e., before engagement of tab 342 of the anchor lock element) with post lock element 260. Feature 370 ensures alignment of the post and buckle prior to locking. Furthermore, feature 370 adds additional strength to anchor lock element 34 and opposes inwardly-directed forces applied to element 34 when valve 20 of apparatus 10 closes during diastole.

[0217] Referring now to Figures 65, actuation of the apparatus of Figure 64 is described. As seen in Figure 65A, anchor lock element 34 is advanced distally relative to post 32, for example, by applying a distally-directed force to the anchor via anchor actuator 106a to move the proximal portion of the anchor distally while maintaining the position of post 32 via actuator 106b. Alternatively or

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additionally, a proximally-directed force may be applied to post 32 via actuator 106b while maintaining the position of the proximal end of the anchor to move the distal portion of the anchor proximally. Lock alignment feature 370 engages the proximal end of the post prior to interlocking of tab 342 of anchor lock element 34 with post lock element 260, thereby ensuring proper alignment. Continued retraction of post 32 relative to buckle 34 locks the post into the buckle, as shown in Figure 65B. This also expands apparatus 10 to the fully deployed configuration of, e.g., Figures 49B and 50C. Next, release actuator 112 is retracted proximally relative to actuator 106b, which causes wrap portion 360 of the actuator to resiliently or dynamically swing outwards, thereby bringing first opening 362 and second opening 364 out of alignment. Proximal retraction of actuator 106b relative to post 32 removes wrap portion 360 from actuator attachment element 264 of post 32.

[0218] Figure 66 shows a variation of the apparatus of Figures 64 and 65. In Figure 66, anchor lock element 34 comprises locking hoop 380, while post lock element 260 comprises a wrapped or curved proximal end of post 32. The curved proximal end also forms actuator attachment element 264. Wrap portion 360 of actuator 106b is wrapped about the curved end of post 32. Release actuator 112, passing through first opening 362 and second opening 364 of actuator 106b, releasably secures this attachment. The release actuator further comprises kink 390 that facilitates passage of the actuator through release actuator attachment elements 392 of post 32, illustratively eyelets. When disposed through elements 392, release actuator 112 further acts as a lock prevention mechanism that precludes locking of the curved proximal end of post 32 with hoop 380 of anchor lock element 34.

[0219] In use, the proximal end of post 32 may be retracted through hoop 380 of anchor lock element 34. Release actuator 112 then may be refracted relative to anchor actuator 106b and post 32, such that the release actuator is disposed proximal of attachment elements 392 of the post. Next, post 32 may be allowed to distally advance until its curved proximal end catches and locks against hoop 380 of element 34. Continued retraction of release actuator 112 relative to actuator 106b facilitates separation of the actuator from the post, as described previously.

[0220] Referring now to Figure 67, an embodiment of post 32 is described that is configured to lock against the braid of anchor 30, as opposed to a separate anchor lock element 34. Post lock element 260 illustratively comprises bent tab 400 that catches against the anchor braid to lock the anchor in a deployed configuration.

[0221] Figures 68 illustrate locking and unlocking of a variation of anchor lock element 34. Anchor lock element 34 of Figures 68 is similar to the buckle variation of element 34 described previously with respect to Figures 62 and 63. However, the variation of Figures 68 is fabricated from a strip of material that is bent to form a wrapped or curved portion. Figure 68A illustrates the apparatus prior to locking, Figure 68B illustrates the locked configuration, and Figure 68C illustrates unlocking through application of a proximally-directed unlocking force to unlock actuator 350.

[0222] Figures 69 show yet another embodiment of a releasable actuation mechanism. Anchor lock element 34 comprises lock alignment mechanism 410 disposed proximal of locking tab 412. As shown, lock alignment mechanism 410 engages the distal end of post 32 to align the post and the anchor lock element prior to locking of post lock element 260 with tab 412 of anchor lock element 34. Lock alignment mechanism 410 adds additional strength to anchor lock element 34 and opposes inwardly-directed forces applied to element 34 when valve 20 of apparatus 10 closes during diastole. Advantageously, the inwardly-directed forces act to maintain apparatus 10 in the locked configuration. Mechanism 410 optionally may be formed from a cut tube.

[0223] Figures 70 illustrate a variation of anchor lock element 34 that may be formed from a cut tube. As seen in Figures 70A and 70B, element 34 comprises tabs 420 for engaging the curved proximal end of post 32 that forms post locking element 260. In order to lock the post to element 34, the curved distal end of the post is retracted proximally of tabs 420 by the action of proximal tension on post 32 by actuator 106b while element 34 is held stationary, as described above. As it enters anchor lock element 34, the curved end of the post is cammed inward by the engagement of the distal edge of element 34 with the outer surface of the curved end. Once proximal of tabs 420, the curved end of the post moves outward, thereby locking the apparatus and preventing subsequent distal movement of post 32 with respect to element 34. To unlock the apparatus, the curved portion of the post is drawn further proximally by actuator 106b until the tip of the curved portion moves into an opening 422 formed in element 34. As seen in Figures 70C and 70D, resilient distal advancement of the post relative to element 34, e.g., via resilient expansion of the braid of anchor 30, deforms and straightens the curved proximal end of post 32 through a camming engagement of the underside of the curved portion of the post with the inner surface of opening 422, thereby allowing actuator 106b to slide off of post 32, unlocking apparatus 10. The curved portion of post 32 optionally may be formed from a shape memory material, such that the post resumes its curved profile for subsequent relocking after unlocking.

[0224] Figures 71 illustrate a variation of post 32 and anchor lock element 32. Anchor lock element 34 illustratively comprises a curved portion 35 that engages and enters the slot of post lock element 260 to lock the anchor as post 32 is drawn proximally into element 34 by actuator 106b. After locking, continued proximal retraction of post 32 by actuator 106b engages the distal end of the curved portion of element 34 with a camming surface 430 of post 32. Resilient distal advancement of post 32 (such as by the resilient contraction and elongation of the anchor to its at-rest configuration) then deforms and straightens

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the wrapped end of element 34, thereby permitting anchor lock element 34 to separate from post 32, unlocking the apparatus.

[0225] Figures 72 and 73 illustrate additional buckle variations of anchor lock element 34. Proximal movement of post 32 into anchor lock element 34 (by, e.g., actuator 106b) engages a bottom surface 702 of a curved portion 700 of element 34 with the proximal end of post 32. Further proximal movement of post 32 with respect to element 34 cams curved portion 700 forward until the curved end 704 of curved portion 700 meets and resiliently moves into opening 260 in post 32, locking the apparatus. The variation of Figures 73 illustrates attachment to the braid of anchor 30 via sutures or the like passed through openings 340 in element 34. The lock is unlockable via unlock actuator 350.

[0226] Referring now to Figure 74, an embodiment of a post 32 and anchor lock element 34 with a ratcheting lock is described. Post 32 comprises previously described actuator attachment element 250 that is releasably secured to post attachment element 302 of actuator 106b. (Other releasable attachment mechanisms may alternatively be used.) Post 32 also comprises braid attachment element 430 and valve attachment structure 432. In the variation of Figure 74, valve attachment structure 432 comprises tab 433 that extends from post 32, as well as a plurality of holes 434 through post 32 and a plurality of holes 435 through tab 433. Replacement valve 20 may be attached to post 32 by sewing the valve to the valve attachment structure through holes 434 and/or 435.

[0227] Post 32 further comprises ratcheting locking element 440 having a plurality of inclined planes with camming surfaces 442 and friction surfaces 443. The inclined planes are disposed along either side of tab 433 for ratcheting and locking against ratcheting anchor lock element 34. Anchor lock element 34 comprises ratchet teeth 450 on either side of the valve attachment elements that cam against surface 442 and lock against friction surfaces 443 of element 440 of post 32, as post 32 is proximally retracted through element 34. Advantageously, providing multiple rows of inclined plane ratchets along post 32 facilitates interlocking of the post and the element at multiple discrete locations.

[0228] Element 34 comprises proximal and distal slots 452 that receive post 32, as well as central longitudinal slot 453 that facilitate passage of tab 433 (and thereby valve 20) therethrough. Actuator 106b may be disposed through slots 452 prior to approximation and locking of the post to anchor lock element 34 in order to facilitate alignment of the post and the anchor lock element. Element 34 may be ratcheted to any position along ratchet lock element 440 to achieve any desired locking configuration and degree of expansion of apparatus 10. Valve attachment structure 432, and thereby replacement valve 20, may be positioned proximal of the ratchet lock post-deployment or in line with the ratchet lock (i.e., neither proximal nor distal to the ratchet lock). Element 34 further comprises unlock actuator attachment(s) 454 for coupling the element to an unlock actuator, e.g., previously described unlock actuator 350, to unlock element 34 by applying a proximally-directed unlocking force that displaces ratchet teeth 450 from friction surfaces 443.

[0229] Figures 75 illustrate variations of the apparatus of Figure 74. Ratchet lock elements 440 of posts 32 in Figures 75 comprise a plurality of ratchet slots 444 in which ratchet tooth 450 of anchor lock element 34 may be locked. Ratchet tooth 450 comprises proximal friction surface 456 and distal camming surface 457 to facilitate proximal retraction of a post 32 through slot 452 for ratcheting of camming surface 457 through ratchet slots 444, but to preclude distal advancement of the post once ratchet tooth 450 is engaged within ratchet slots 444 by locking a ratchet slot against friction surface 456. As with the variation of Figure 74, anchor lock element 34 is unlockable and comprises unlock actuator attachment 454. In contrast to the variation of Figure 74, the ratchet lock is disposed proximally of valve attachment structure 432, and thereby proximally of replacement valve 20. In Figure 75A, valve attachment structure 432 comprises slot 436 instead of tab 433.

[0230] Figures 76 illustrate another variation of the ratchet lock of Figure 74. hi Figures 76, ratchet lock elements 440 of post 32 extend along only one edge of the post. Thus, anchor lock element 34 comprises unitary ratchet tooth 450 for camming against surfaces 442 and locking against friction surfaces 443 of elements 440 of post 32, as post 32 is proximally refracted through element 34.

[0231] The apparatus of Figures 76 also comprises unlock or adjustment actuator 500 that is releasably attached to anchor lock element 34 along unlock actuator attachment 454. Actuator 500 comprises two independently or concurrently actuable elements: adjustment element 510 and release element 520. Adjustment element 510 comprises elongated member 512 having protrusion 514 with lumen 515, as well as distal extension 516 with notch 518 having optional camming surface 519. Release element 520 comprises elongated member 521, which may, for example, comprise a mandrel, that is configured for passage through lumen 515 of protrusion 514 of adjustment element 510. Elongated members 512 and 521 of actuator 500 preferably extend through delivery system 100 to the exterior of the patient for independent or concurrent advancement and/or retraction by a medical practitioner.

[0232] As seen in Figure 76A, notch 518 of adjustment element 510 of actuator 500 maybe positioned within unlock actuator attachment 454 of anchor lock element 34 during deployment of apparatus 10. As seen in Figure 76B, anchor lock element 34 is locked within ratcheting lock elements 440 of post 32 by proximally retracting actuator 106b relative to anchor lock element 34. Release element 520 then may be advanced relative to adjustment element 510 to position elongated member 521 within unlock actuator attachment 454 adjacent distal extension 516 of adjustment element 510. This serves to

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friction lock or interference fit actuator 500 within attachment 454 along notch 518 of adjustment element 510. Thus, concurrent advancement and/or retraction of the adjustment and release elements of actuator 500 by a medical practitioner causes anchor lock element 34 to move in unison with actuator 500. As will be apparent, actuator 500 alternatively may be friction locked with anchor lock element 34 prior to full deployment of apparatus 10. Furthermore, actuator(s) 500 may assist, or be used in place of, actuators 106a to deploy apparatus 10.

[0233] As seen in Figure 76C, the lock formed between anchor lock element 34 and post 32 may be unlocked or adjusted, as desired, by applying a lateral unlocking force to ratchet tooth 450 via actuator 500 that pulls the ratchet tooth away from a friction surface 443 of ratcheting lock elements 440. Actuator 500 then may be distally advanced or, as seen in Figure 76D, proximally retracted relative to ratcheting lock elements 440 and post 32 to further expand or partially collapse anchor 30, respectively (further expansion alternatively may be achieved by further ratcheting ratchet tooth 450 along camming surface 442 of ratcheting lock elements 440, e.g., by further proximally retracting actuator 106b, which is not shown in Figures 76C-76F for the sake of clarity). Anchor actuation elements 106 may assist such controlled expansion or collapse anchor 30.

[0234] When (re-)positioned at a desired location and/or when a desired degree of locking has been achieved, the lateral unlocking force may be removed from ratchet tooth 450 to again lock anchor lock element 34 to post 32 along ratcheting lock elements 440, as in Figure 76E. To complete deployment of apparatus 10, adjustment actuator 500 and actuator 106b, as well as actuator 106a (not shown), may be separated from the apparatus. In Figure 76F, release element 520 of actuator 500 is proximally refracted relative to adjustment element 510, thereby removing elongated member 521 of release element 520 from unlock actuator attachment 454 of anchor lock element 34. This removes the interference fit between notch 518 and attachment 454. Proximal retraction of actuator 500 relative to anchor lock element 34 detaches adjustment element 510 of actuator 500 from attachment 454 of anchor lock element 34, as in Figure 76G. Optional camming surface 519 along notch 518 may facilitate such detachment. In Figure 76H, actuator 106b is detached from post 32 by retracting release actuator 112 relative to the actuator, as described previously.

[0235] Referring now to Figures 77, another variation of an adjustable ratcheting lock element is described. As seen in Figure 77A, post 32 comprises tube 470 having lumen 471 and ratcheting lock element 472, illustratively a plurality of slots that communicate with lumen 471. Post 32 also comprises valve support structure or attachment element 474 and braid attachment element 476.

[0236] Anchor lock element 34, which may be fabricated from a cut tube, comprises a substantially cylindrical structure having braid attachment element 480, lumen 482 and tabs 484. As seen in the top view of Figure 77B, tabs 484 of anchor lock element 34 are configured for locking within the slots of ratcheting lock element 472 of post 32. As seen in the top view of Figure 77C, adjustment actuator 490, illustratively mandrel M having tapered distal end 494 that acts as a camming surface, may be advanced through lumen 481 of anchor lock element 34 and lumen 471 of tube 470 of post 32, to displace tabs 484 from the locking slots of post 32, thereby unlocking the post from the anchor lock element. This facilitates, for example, readjustment of a degree of locking/expansion of apparatus 10, repositioning of apparatus 10, retrieval of apparatus 10, etc.

[0237] Figures 78 illustrate a variation of anchor lock element 34 wherein tabs 484 are positioned along a different axis. This may provide a more secure lock between post 32 and anchor lock element 34. Figures 79 illustrate a variation of post 32 configured for use with the variation of anchor lock element 34. In Figures 69, post 32 comprises groove 478 that connects the slots of ratcheting lock element 472. Groove 478 does not communicate with lumen 471 of tube 470 of post 32. Rather, the groove may act as a lock alignment mechanism that guides tabs 484 of anchor lock element 34 along post 32 and ratcheting lock element 472, as seen in the top view of Figure 79B.

[0238] Referring now to Figures 80, a method of actuating the variation of Figures 78 is described. As seen in Figure 80A, adjustment actuator 490 is initially disposed through lumen 482 of anchor lock element 34 and within lumen 471 of post 32. Post 32 then may be proximally retracted relative to anchor lock element 34, e.g., via actuator 106b (not shown). In Figure 80B, actuator 490 serves as a lock prevention mechanism that precludes locking of tabs 484 within ratcheting lock element 472. In Figure 80C, actuator 490 is retracted relative to post 32 and anchor lock element 34, which opens up lumen 471 of tube 470 and allows tabs 484 to pass through the slots of ratcheting lock element 472, thereby locking the post to the anchor lock element. In Figure 80D, actuator 490 is re-advanced within lumen 471, such that tapered distal end 494 of mandrel M serves as a camming surface that urges tabs 484 out of lumen 471 as the actuator is advanced. This unlocks the post from the anchor lock element to facilitate adjustment, repositioning or retrieval of apparatus 10. In Figure 80E, a degree of locking/expansion of the apparatus is adjusted by repositioning anchor lock element 34 relative to post 32, and thereby tabs 484 relative to ratcheting lock element 472. When properly adjusted, actuator 490 may be removed from lumen 471 of tube 470 of post 32, as in Figure 80F. Tabs 484 resiliently return to the locked configuration within the slots of ratcheting lock element 472.

[0239] Referring now to Figures 81, an embodiment of anchor actuator 106a is described. Actuator 106a comprises elongated member 600 having proximal extension 602 that may be attached, for example, to previously described multi-lumen shaft or catheter 108 of delivery sys-

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tem/deployment tool 100 (see Figures 49), e.g., via epoxy, UV curing, etc. Lumen 601 extends through elongated member 600 from proximal extension 602 to releasable attachment mechanism 604. Releasable attachment mechanism 604 releasably attached actuator 106a to the braid of anchor 30. The mechanism comprises release actuator 112 and illustratively is similar to the previously described releasable attachment mechanism of Figures 63-65. Release actuator 112, illustratively a mandrel, passes through a lumen Lu of multi-lumen shaft 108 and then through lumen 601 of actuator 106a to mechanism 604.

[0240] Actuator 106a further comprises shaping features 606 that affect a shape of the anchor actuator when an anchor actuation force is applied to anchor 30. These features may comprise, for example, reduced diameter portions of the actuator, reduced wall thickness portions of the actuator and/or slits formed in the anchor actuator. Application of an anchor actuation force may, for example, provide actuator 106a with the profile seen in Figure 81A. This profile may facilitate expansion of anchor 30/apparatus 10. As will be apparent, shaping features may be provided with any anchor actuation elements 106, including any of the previously described variations of actuators 106b.

[0241] As seen in Figures 82, releasable attachment mechanism 604 comprises wrap portion 610 that may, for example, pass through the braid of anchor 30 and wrap around the proximal end of the anchor. Wrap portion 610 may comprise a shape memory material, such as Nitinol, or a deformable material, e.g., a resiliently deformable material. The wrap portion comprises first opening 612 for engaging release actuator 112. The walls of lumen 601 of elongated member 600 may act as a linear bearing and/or motion guide during advancement and refraction of the release actuator relative to the actuator. Actuator 106a also comprises second opening 614, which may be aligned with first opening 612 to engage release actuator 112, as shown. Wrap portion 610, and especially curved portion 611 of the wrap portion, acts as a spring element that urges the first opening out of alignment with the second opening to engage and hold release actuator 112 in place.

[0242] As seen in Figure 82C, when the release actuator is retracted proximally relative to the actuator, wrap portion 610 resiliently or dynamically swings outwards. Thereafter, proximal retraction of anchor actuator 106a relative to anchor 30 detaches wrap portion 610, and thereby actuator 106a, from the anchor. Surface 616 of wrap portion 610 may act as a camming surface as the inner surface of wrap portion 610 slides along the anchor braid 30 to facilitate such detachment.

[0243] In this manner, release actuator 112 may be interference or friction fit through first opening 612 and second opening 614. Retraction of the release actuator proximal of the first and second openings actuates releasable attachment mechanism 604 to resiliently or dynamically unwrap portion 610 and release actuator 106a from anchor 30. Wrap portion 610 of actuator 106a illustratively is disposed at a distal end of the actuator.

[0244] With reference to Figures 83, a variation of releasable attachment mechanism 604 is described. In Figures 83, wrap portion 610 illustratively comprises tabs 618 that act as an alignment mechanism for aligning the wrap portion of mechanism 604 with elongated member 600. This may facilitate advancement of release actuator 112 through mechanism 604. Figures 84 illustrate a variation of tabs 618 wherein the tabs are rounded. This may reduce friction, provide an afraumatic surface, etc. Additional shapes for tabs 618 will be apparent. Alternatively, tabs 618 may act as spring elements which are loaded when element 630 is seated, as shown in figure 84B. In this configuration tabs 618 apply a force directed towards element 630 such that 630 will be ejected when element 112 is refracted. In this way tabs 618 apply a restraining force on element 112 which reduces the risk of an early release.

[0245] Figures 85 illustrate a variation of wrap portion 610 that comprises a substantially straight distal region in an at-rest configuration, as seen in Figure 85C. It is expected that providing a substantially straight distal region along wrap portion 610 may facilitate detachment of actuator 106a from anchor 30, i.e., may reduce a risk of snagging the wrap portion along the braid of the anchor. The wrap portion may be resiliently deformed for passage of release actuator 112 through first opening 612, as in Figures 85A and 85B.

[0246] Referring now to Figures 86, variations of release actuator 112 for use with releasable attachment mechanism 604 are described. In Figure 86A, the release actuator comprises a simple mandrel. In Figures 86B and 86C, the release actuator comprises protrusion 620 having friction surface 621. In Figure 86D, actuator 112 comprises coil 622. In Figures 86E-86H, the actuator comprises kink 624, which may act as a camming surface, as shown. The kink may also provide tactile feedback to a medical practitioner. In Figures 86I and 86J, the release actuator comprises ball or knob 626 disposed proximal of the actuator's distal end. In Figures 86K and 86L, ball 626 is disposed at the distal end of actuator 112. The ball may act as a camming surface. In Figure 86M, actuator 112 comprises protrusion 628 having proximal camming surface 629. In Figure 86N, the actuator comprises oblong protrusion 430 having friction surface 431. Additional variations of actuator 112 will be apparent.

[0247] Referring now to Figures 87, an embodiment of delivery system/deployment tool 100 is described. Figure 87A provides a detail view of multi-lumen catheter 108 and sheath 110. As discussed previously catheter 108 comprises central lumen 109 and a plurality of circumferentially-disposed lumens Lu.

[0248] As seen in Figure 87B, actuator 106a is coupled to catheter 108 via proximal extension 602, such that lumen 601 is coaxially disposed within a lumen Lu of the catheter. Release actuator 112 extends through lumens Lu and 601. Actuator 106a is distally attached to the braid

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of anchor 30 along releasable attachment mechanism 604. For the sake of clarity, a single actuator 106a is shown in Figure 87B, but multiple such actuators preferably are provided, as in Figures 88 described hereinafter.

[0249] Figure 87B also illustrates actuator 106b. The actuator extends through a lumen Lu of catheter 108 and through anchor lock element 34 to post 32 (not shown). Unlock actuator 350 is also provided and extends through a lumen Lu to unlock actuator attachment 344 of anchor lock element 34. Anchor lock element 34 illustratively comprises the variation described previously with respect to Figures 68. The element is attached to the braid of anchor 30 along anchor, attachment elements 340. As with actuator 106a, a single anchor lock element 34 and actuator 106b are shown in Figure 87B. This is only for the sake of clarity, and multiple such actuators may be provided, e.g., three actuators.

[0250] Referring now to Figures 88, delivery system/deployment tool 100 is shown with a plurality of actuators 106a and actuators 106b for releasable attachment to anchor 30 of apparatus 10. In Figure 88A, anchor actuation elements 106a are coupled to the anchor. In Figure 88B, the elements are decoupled from the anchor.

[0251] With reference now to Figures 89, a variation of the delivery system/deployment tool of Figures 87 and 88 is described comprising a plurality of arms or actuators that extend from a unitary structure. Unitary structure 650, which may extend from a distal region of multi-lumen shaft 108, is preferably fabricated from a laser-cut tube. Structure 650 comprises a plurality of circumferentially disposed arms 652 that serve as actuators. Expansile elements 654 may be disposed between arms 652 and facilitate constraint of the arms radially outward or inward with respect to other arms as the anchor reshapes. Figure 89A shows the arms in a radially collapsed configuration, and Figures 89B shows the arms in a radially expanded configuration. Wrap portions 655 are adapted to wrap around the proximal portion of an anchor braid. Openings 656 and 657 are formed in wrap portions 655 to engage a release actuator, as described in embodiments above.

[0252] Referring now to Figures 90, various ways to connect elements to the braid of anchor 30 of replacement valve apparatus 10 are described. In Figure 90A, a post 32 having a single braid attachment hole 660 is attached to anchor 30 along three separate intersections of the braid via suture S. Figure 90B provides a detail view of one exemplary technique for routing the suture between hole 660 and anchor 30. Figure 90C illustrates a variation of the attachment, wherein post 32 comprises multiple braid attachment holes 660. As will be apparent, elements other than posts 32 may be attached to anchor 30 in the manner described, for example, anchor lock elements 34 may be attached in a similar manner.

[0253] As described in more detail in U.S. Patent Appl. Ser. No. 10/746,280, the distal region of anchor 30 may be pulled proximally via a proximally directed force applied to posts 32 via a distal deployment system interface. The distal deployment system interface is adapted to expand radially during application of a proximally directed force on the distal end of the anchor.

[0254] The distal deployment system interface may include confrol actuators that are controlled, e.g., by control knob 122 of confrol handle 120. Similarly, the proximal regions of anchor 30 may be pushed distally via a proximal deployment system interface at the proximal end of the anchor. The proximal deployment system interface is adapted to permit deployment system to apply a distally directed force to the proximal end of anchor 30 through, e.g., fingers 106, which are controlled by, e.g., Control knob 124 of control handle 120. The proximal deployment system interface may be further adapted to expand radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal deployment system interface is adapted to permit deployment system to apply a distally directed force on the proximal end of the anchor system through a plurality of deployment system fingers or actuators 160. Such expansion optionally may be assisted via inflation of a balloon catheter (not shown) reversibly disposed within apparatus 10, as described in U.S. Patent Appl. Ser. No. 10/746,280.

[0255] Once anchor 30 is fully deployed, posts 32 and buckles 34 of anchor 30 may be used to lock and maintain the anchor in the deployed configuration. In one embodiment, the control actuators attached to posts 32 are threaded through buckles 34 so that the proximally directed force exerted on posts 32 by the control actuators during deployment pulls the proximal locking end of posts 32 toward and through buckles 34. Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus 10 during or post-deployment. Apparatus 10 may be repositioned or retrieved from the patient until the two-part locking mechanism of posts 32 and buckles 34 of anchor 30 have been actuated. When the lock is selectively reversible, the apparatus may be repositioned and/or retrieved as desired, e.g., even after actuation of the two-part locking mechanism. Once again, further details of this and other anchor locking structures may be found in U.S. Patent Appl. Ser. No. 10/746,280. Locking mechanisms used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion.

[0256] Prior to implantation of replacement valve apparatus described herein, it may be desirable to perform a valvuloplasty on the patient's diseased valve by inserting a balloon into the valve and expanding it using, e.g., saline mixed with a contrast agent. In addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

[0257] Figures 50A-F show further details of anchor 30 of apparatus 10. Figure 50A shows the apparatus in a

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collapsed configuration, such as for delivery within a sheath or other lumen or for retrieval and recapture into a sheath or other lumen. Figures 50B and 50C show the anchor and valve in an expanded and locked configuration.

[0258] As shown in Figure 50C, anchor 30 has three posts and three buckles. As seen in Figure 50C, the three leaflets of replacement valve 20 may be coupled to the three posts 32 also known as valve supports. The posts, unlike the braid, do not collapse or expand, hi some embodiments a post 32 has one or more proximal slots 33, at least one proximal hole 36a and at least one distal hole 36b. Leaflet tissue may be passed through slot 33 and sutured in place via suture routed through one or more proximal holes 36a. Other means known in the art for fixing valve leaflets to posts may also be employed.

[0259] Figure 91 illustrates an exemplary apparatus for fabricating braided anchors. Such apparatus includes a cylindrical braiding fixture 200. The cylindrical braiding fixture 200 comprises proximal circumference of inner posts 202a separated by a distance x from distal circumference of inner posts 202b. x can be, for example, 10 to 60 mm, more preferably 20 to 50 mm, or more preferably 30 to 40 mm. Optionally, the fixture may also comprise proximal and distal circumferences of outer posts 204a and 204b, respectively. 204a and 204b can be situated about 2-10 mm from 202a and 202b, respectively. Posts 202a/b and 204a/b project from fixture 200 and may be used to route wire, e.g., for forming anchor braid 30. Inner posts 202a and 202b generally facilitate formation of a braid, while outer posts 204a and 204b generally facilitate formation of desired features at the ends of the braid, as described hereinafter with respect to Figures 93-96.

[0260] In some embodiments, fixture 200 comprises approximately 6-20 posts, more preferably 8-18 posts, or more preferably 10-16 posts around its circumference, though any alternative number of posts may be provided. Likewise, fixture 200 preferably has a diameter of about 2-40mm, more preferably 4-30 mm, or more preferably 6-20mm, though any alternative diameter may be provided. The diameter of fixture 200 preferably is the diameter of the braid in its "at rest" configuration.

[0261] Fixture 200 can optionally further comprise circumferential grooves 206 to facilitate interweaving of a first section of wire underneath an adjacent section of wire. The fixture optionally also may comprise localized depressions or holes 208 in addition, or as an alternative, to grooves 206. Depressions 208 may be provided at locations where wire segments cross to act as a visual guide for formation of anchor braid 30, as well as to facilitate the interweaving of a first section of wire beneath an adjacent section of wire.

[0262] Referring now to Figures 92A-D, an illustrative method of using fixture 200 to fabricate braided anchors in accordance with the present invention is described. Figure 92A provides a detail view of a proximal front side region of fixture 200 during formation of a braided anchor. Figure 92B shows a detail backside view of a central section of the fixture. Figure 92C shows a full-length front-side view of the fixture and Figure 92D shows the completed braid, hi Figures 92, anchor braid 30 is formed from a single strand of wrapped and interwoven wire W. However, it should be understood that anchor braid 30 alternatively may be formed from multiple strands of wire.

[0263] As seen in Figure 92A, formation of anchor braid 30 begins with wire W being routed from starting position P near the proximal end of fixture 200 past outer proximal posts 204a and inner proximal posts 202a. Wire W preferably is formed from a superelastic and/or shape-memory material, such as Nitinol. However, alternative wire materials may be utilized, including Cobalt-Chromium, Steel and combinations thereof, as well as additional materials that will be apparent to those of skill in the art.

[0264] After passing inner proximal posts 202a, wire W encircles fixture 200 in a helical spiral while extending towards the distal posts, as seen in Figures 92B and 92C. The wire illustratively encircles fixture 200 a full 360° revolution plus one additional post. However, any alternative degree of winding may be provided (e.g., a full 360° plus 2 additional posts, a full 360° plus 3 additional posts, o a number of posts less than a full 360°) . As will be apparent to those of skill in the art, altering the degree of winding will alter the expansion characteristics of the resultant braid in ways per se known.

[0265] At distal inner posts 202b, wire W forms turn Tu and is rerouted back towards proximal imier posts 202a. It should be noted that wire W can form turn Tu in either inner posts 202 or outer posts 204. Turn Tu forms a closed end of the braid. Additional sets of inner and outer posts are also contemplated. The wire once again encircles fixture 200 in a full 360° helical revolution plus one additional post before reaching the proximal inner posts and being rerouted back towards the distal inner posts. This process is repeated with the wire repetitively interwoven at crossing locations between the proximal and distal posts, e.g., via grooves 206 and/or depressions 208, to define the cells of the braid that will provide anchor 30 with desired characteristics. As seen in Figure 92D, wire W turns both proximally and distally in order to complete formation of the braid, hi this embodiment, wire W terminates in the central portion of the braid at T. Termination T may be formed, for example, by welding the wires together, applying a shrink tube about the overlap, using a crimp, braising the wires, etc. Additional techniques will be apparent to those of skill in the art.

[0266] When anchor braid 30 is formed from a shape-memory material, the braid may be heat set such that it maintains a desired degree of expansion in an at-rest configuration. The heat set at-rest configuration may comprise, for example, the delivery configuration (e.g., collapsed configuration) of Figure 50A, the deployed configuration (e.g., expanded configuration) of Figures 50B and 50C, or any desired configuration therebetween. In preferred embodiments, the anchor is heat-set in a configuration between the delivery configuration and the de-

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ployed configuration. Anchor braid 30 may be heat set while still disposed on fixture 200 to maintain an at-rest configuration as formed on the fixture, which preferably is a configuration between the delivery and deployed configurations. Alternatively, the braid may be heat set after complete or partial removal from the fixture. As yet another alternative, the braid may be initially heat set while still disposed on the fixture, but thereafter may be additionally heat set in a different shape, for example, a more expanded configuration. It is expected that heat setting anchor braid 30 will provide the braid with desired delivery and/or deployment characteristics.

[0267] Referring now to Figures 93A-93O, in conjunction with Figures 50C and 92, an anchor braid 30 may be defined by a set of cells that is different than other cells. Such cells may be formed to provide anchor braid 30 with one or more edge features (for either or both the distal and proximal ends). These edge features can, for example, reduce or relieve sfress within the braid during delivery and deployment, which in turn may reduce the incidence of anchor material fatigue caused by the pulsatile anchor motion of the anchor site. As will be apparent to those of skill in the art, forming braid 31 from a single strand of wire W (or from multiple strands of wire W that form turns or that are joined together) may lead to sfress concentration at turns Tu in the wire where the wire changes direction and extends back towards the opposite end of the braid. Such stress concentration may be most pronounced while the braid is disposed in its extreme configurations, i.e. when the braid is disposed in the collapsed delivery configuration of Figure 50A or the expanded deployed configuration of Figures 50B and 50C.

[0268] Stress concentration may increase the rigidity of an anchor braid and/or may impede delivery and deployment, as well as sheathing, of the braid. Thus, in preferred embodiments, a group of cells can be configured to reduce the sheathing force as described herein. Furthermore, to enhance deliverability, sfress concentration may require that anchor braid 30 be fabricated from a relatively thin wire W. However, thin wire may not provide anchor braid 30 with adequate radial strength to displace a patient's diseased native heart valve leaflets and/or to anchor apparatus 10 against a patient's anatomy. Conversely, use of a relatively thick wire W may increase stiffness, thereby precluding retrograde delivery of apparatus 10, as well as a risk of kinking at turns in the braid. Thus, in some embodiments, wires varying in thickness may be used, or multiple wires having different thickness may be woven together. Also, wires made from different materials may be used to form an anchor braid.

[0269] It may be desirable to reduce sfress concentration at the edges of anchor 30 where wire W changes direction and/or to reduce the circumferential stiffness of the anchor braid. The edge characteristics of the anchor may be altered by altering the shape of substantially all anchor braid cells at the anchor's edge (e.g., distal edge and/or proximal edge). Wire turns that confrol the shape of the edge cells may be formed within anchor braid 30 by routing wire W around optional outer posts 204 of fixture 200 during formation of the braid. Figure 93A illusfrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape. Figure 93B illustrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts 204 of fixture 200, and then heat setting the wire.

[0270] Figure 93C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn has been bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within fixture 200 and heat setting. The out-of-plane bend of turn Tu in the anchor edge cells in Figure 93C may reduce stress in some configurations, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus 10 during deployment.

[0271] In Figure 93D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post 202 and two flanking outer posts 204 of fixture 200. As with the elongated braid cells of Figures 93B and 93C, the W-shape may better distribute sfress about turn Tu. The anchor edge cell configuration in Figure 93E includes a loop formed in braid 31 at the turn, which may be formed by looping wire W around an inner or outer post of fixture 200. Figure 93F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post 202 and an aligned outer post 204 in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0272] In Figure 93G, the edge cells of braid 31 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post of fixture 200 in the desired manner. In Figure 93H, the edge cells of braid 31 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 31 during expansion and collapse of the braid, in addition to affecting stress concentration, hi Figure 93I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts of fixture 200. Additional loops may also be employed. The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 93I, or may be heat set with a more discontinuous shape, as in Figure 93J.

[0273] Figure 93K illusfrates that the edge cells of braid 31 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 93K have extended length cells as

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in Figure 93B disposed adjacent to standard size edge cells, as in Figure 93A. The anchor edge cells of Figure 93L have an extended turn configuration having an extended loop. The anchor edge cells shown in Figure 93M have an alternative extended configuration with a specified heat set profile. Finally, the anchor edge cells shown in Figure 93N that overlap or are interwoven to be coupled to one another.

[0274] In preferred embodiments, the edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 93O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0275] The edge cell configuration of Figure 93 may be heat set independently of the rest of the braid. The anchor edge cell configurations of Figures 93 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of Figures 93. Furthermore, combinations of any such turn features may be provided to achieve desired characteristics of anchor braid 30.

[0276] Referring now to Figures 94A-E, additional configurations for reducing sfress concentration and/or circumferential stiffness of anchor braid 30 are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 94A and 94B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 94C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

[0277] Localized reduction may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 94D-94E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

[0278] Referring now to Figures 95 A- J, instead of terminating the beginning and end of wire W of braid 31 at an overlap within the braid, as discussed previously, the two ends of the wire may be terminated at the anchor's edge. Likewise, when braid 31 is fabricated from multiple wires W, the wires (or a subset of the wires) optionally may be joined together or terminated at turn(s) of the braid. In Figure 95A, wire termination T at the ends of wire(s) W comprises a hinged termination with hinge post 38. In Figure 95B termination T comprises a clipped or crimped termination with end cap 39. In Figure 95C, cap 39 is wrapped about the ends of wire W to form wrapped termination T.

[0279] In Figure 95D, cap 39 is placed over the wire ends, which are then bent to provide a swivel termination, hi Figure 95E, the wire ends are potted within cap 39 at termination T. In Figure 95F, cap 39 is swaged about the wire ends. In Figure 95G, the wire ends are welded or glued together, hi Figure 95G, the wire ends are spot welded together. Alternatively, the wire ends may be braised to form termination T, as in Figure 95H. As yet another alternative, cap 39 may be placed about the wire ends, and kinks K may be formed in wire W to provide the ends of the wire with an 'over-center' bias that maintains termination T, e.g., swivel termination T. Additional terminations will be apparent to those of skill in the art.

[0280] With reference now to Figures 96A-B, alternative anchors of the present invention are described having anchor edge features that facilitate sheathing of the apparatus and reduce the sheathing force. In Figure 96A, the edge cells of anchor 30 have inwardly canted configurations at the wire turns Tu about a proximal circumference of the anchor. These edge cell configurations provide the proximal circumference with a conical profile that facilitates sheathing of the apparatus within a delivery system, e.g., previously described delivery system 100, by allowing collapse of anchor 30 to proceed in a more gradual and/or continuous manner, and tunneling the anchor into the sheath.

[0281] Figure 96B illusfrates another alternative anchor 30 having edge cell configurations formed by wire turns Tu about its proximal circumference that first cant outward, and then cant inward. The inward cant provides the proximal circumference with a conical profile and may facilitate sheathing, while the outward cant may facilitate anchoring at a treatment site, e.g., may engage a patient's native valve leaflets. As will be apparent, the edge cell configurations of Figures 8, as well as those of Figures 93-95, optionally may be provided at either the proximal or distal ends of the anchor, or both. The edge cell configurations of Figures 96, as well as those of Figures 93 and 95, may, for example, be formed by heat setting braid 31 in the desired configuration.

[0282] Referring now to Figures 97, further alternative anchors are described having edge cell configurations adapted to lock the anchor in the deployed configuration to maintain expansion. In Figure 97A, anchor 30 comprises elongated, hooked edge cells formed from wire turns Tu that are configured to snag braid 31 and maintain the anchor in the deployed configuration, as shown, hi

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Figure 97B, the hooked turn features have been elongated, such that the hooks are configured to snag the opposing end of anchor 30 to maintain expansion.

[0283] In Figure 97C, anchor edge cells defined by wire turns TuP and distal turn features TuD are configured to interlock between the ends of anchor braid 30 in order to maintain the deployed configuration of anchor 30. The proximal edge cells form a hook adapted to engage elongated turns of the distal turn features. As will be apparent, the disposition of all or a portion of the proximal and distal edge cell configurations optionally may be reversed, i.e. the proximal edge cells may form hooks and the distal edge cells may be configured as elongated turns. Figure 97D illusfrates interlocking proximal and distal edge cell configurations of more complex geometry. Figure 97E illustrates interlocking proximal and distal edge cell configurations while anchor 30 is disposed in the collapsed delivery configuration. The locking turn features of Figures 97 may, for example, be formed by heat setting anchor braid 30 (or locking features only) in the desired configuration. Additional locking turn features will be apparent to those of skill in the art. In preferred embodiments, the anchor locking mechanism can be set to have alternative locking options that allow for various amounts of expansion.

[0284] Figures 98A-98D illustrate various embodiments of anchor braids. An anchor braid can be made of one or more wire and can be used to form various density braids. The density of the braid can be assessed by the size of cells formed by the weave. In some embodiments, two or more different density braids may be woven together. For example, Figure 98A illusfrates two groups of cells or two braids interwoven in the center. The top group of cells forms a more open weave than the bottom group of cells, which forms a denser weave. Figure 98B illusfrates another embodiment of an anchor braid having three groups of cells. The top and bottom (proximal and distal) edges of the anchor braid have denser cells than the central portion of the anchor. Also, the edges of the anchor are woven from a thinner filament than the central portion. In another embodiment illustrated by Figure 98C, all three sections of an anchor valve are woven by more than one wire. The wires of each section are made of a different material and/or thickness. Wires at the sectional boundaries may or may not interconnect with wires from a different section. Each of the sections of the braid anchor may be composed of a different number of wires. Figure 98D illustrates another embodiment of a braided anchor having three sections, i this embodiment, all sections are composed of a single wire. The proximal and distal sections/edges of the braided anchor have the same pitch. The central region of the braided anchor has a different pitch than the edge sections.

[0285] Figures 99A-99E illustrate side views of braided anchor having more than one braid pitch. Varying pitch within the anchor allows localized variations in foreshortening across the anchor, as greater foreshortening is achieved by higher pitch of the braid. Moreover, the localized foreshortening features allow for the design of a braid which incorporates various diameters depending upon the amount of foreshortening. (The greater the foreshortening, the greater the diameter increase upon deployment.)

[0286] Figure 99A, for example, is a side view representation of braided anchor of Figure 98D. On the left side of the figure, the expanded anchor is illustrated having a denser weave (shorter pitch) at the distal and proximal ends; hence the dots are located closer to each other. The middle section of the anchor is composed of a looser weave that is generated by a higher pitch braid and is represented by dots that are farther away from each other. On the right side of the figure, the braided anchor is foreshortened and the dots are collapsed closer to each other. In this case, the central portion of the anchor foreshortened more than the proximal and distal edges. Figure 99B illustrates a side view of a foreshortened braided anchor that is created by low pitch at the edges and high pitch in the middle. Figure 99C illustrates a side view of a foreshortened braided anchor that is created by high pitch edges and low pitch middle section. Figure 99D illusfrates a side view of a foreshortened braided anchor that includes a sealing feature or space filling feature at both ends. This type of anchor can be created by a high pitch braid at edges, low pitch braid in the middle and heat setting the edges to curl upon unsheathing. This end feature is useful in facilitating anchoring by functioning as a locator and sealing. Figure 99E illustrates a side view of a foreshortened braided anchor that is associated with an everting valve or locational features.

[0287] In preferred embodiments, the middle section of the anchor may be composed of thicker wire(s) than edge section(s)

[0288] Figures 100A-100C illustrate an example of the process of deploying the anchor, such as the one illustrated in Figure 99B above. Figure 100A illusfrates a braided anchor 30 in its expanded configuration. The anchor is composed of three sections. The distal and proximal sections of the anchor are made of a fine weave (low pitch) braid. The middle section of the anchor is made of a higher pitch braid and are preferably heat set to roll upon unsheathing. Furthermore, in preferred embodiments, the filaments of the distal and proximal sections may be thinner (e.g..005 in thickness) than the filaments of the middle section (e.g., .010 in thickness). Posts 32 are coupled to the middle section of the anchor. For deployment, proximal actuators 106 are coupled to the anchor's middle section. Figure 100B illusfrates the process of deployment. As the anchor is pushed distally by the proximal actuators and pulled proximally by the distal actuators, it is unsheathed and begins foreshortening. The distal section rolls up and can act as a locator, assisting the operator in locating the aortic valve. It then functions as a seal preventing leakage. The proximal section may optionally also roll up. hi Figure 100C, the device may be configured such that the middle section of the

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valve may form an hour glass shape or a round shape. The actuators may subsequently be removed as described before. Figure 100D is another illustration of the braided anchor in its elongated configuration. Figure 100E is another illustration of the braided anchor in its foreshortened configuration.

[0289] Figures 101A-101B illustrate another embodiment of a braided anchor. In this embodiment, the anchor includes two sections - a distal section made of a fine weave and a higher pitch braid than the proximal section. In Figure 101A the device is deployed such that the distal section made of the fine weave is distal to the aortic valve. In Figure 101B, the distal section is foreshortened, either by heat set memory or actively. The foreshortening of the distal section allows the operator to locate the valve and situate the anchor prior to release.

[0290] The anchors described herein can be, for example, radially symmetrical, bilaterally symmetrical, or asymmetrical. A radially symmetrical anchor is one for which symmetry exists across any diameter. A bilaterally symmetrical anchor is one for which symmetry exists across a finite number if diameters). An asymmetrical anchor is one for which there exists no diameter across which a symmetry may be found. Figure 50B illustrates one embodiment of a radially symmetrical anchor. Figure 102A illustrates one embodiment of a bilaterally symmetrical anchor. Figure 102B illusfrates two embodiments (side and top views) of asymmetrical anchors. The benefits of bilaterally symmetrical an asymmetrical anchors is their ability to avoid interfering with anatomical features, such as, for example the coronary ostial and/or mitral valve. Thus, in preferred embodiments, a braided anchor includes a region adapted to prevent expansion of the anchor into the mitral valve, as is illustrated in Figure 102A.

[0291] In preferred embodiments, the anchor includes a leaflet engagement element and/or a seal inverting element situated on its proximal end. The leaflet engagement element is adapted for engaging the native leaflets of the patient's heart, or more preferably the proximal edge and/or the commissural attachments of the native leaflets. The leaflet engagement v element need not extend all the way into the pocket or the distal end of the native leaflet. Preferred embodiments of the apparatus herein are depicted in Figures 32-34, 49, 50, 93 and 98-109, which are discussed in more detail below.

[0292] Figure 103 provides a detail view of a front side region of anchor braid 30 with closed end turns Tu. Anchor braid 30 includes various cells, some having an end turn (Tu). End turns can serve various functions. For example, end turns can be configured to reduce the sheathing force, to reduce stress within the braid during delivery and deployment, to prevent distal migration during expansion of the anchor, and/or to positively register the anchor against the native valve during deployment. In preferred embodiments, an end turn feature functions to prevent distal migration and to register the anchor by engaging the native leaflets. In preferred embodiments, the proximal end of an anchor comprises embodiments (Tu).

[0293] Figures 93A-93N provide multiple examples of edge cells having end turn feature. The end turn features disclosed and others known in the art may be used as leaflet engagement elements to engage the native heart leaflets with the anchor. The leaflet engagement elements are preferably integral with the anchor, or more preferably part of a braided anchor. The end turn features can occur at the proximal end, the distal end, or both proximal and distal ends of the anchor.

[0294] For example, Figure 93 A illustrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape.

[0295] Figure 93B illusfrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts and then heat setting the wire.

[0296] Figure 93 C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn may be bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within a fixture and then heat setting. Such a turn Tu in the anchor edge cells in Figure 93 C may reduce stress in some configurations without increasing height, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus 10 during deployment.

[0297] In Figure 93D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post and two flanking outer posts. As with the elongated braid cells of Figures 93B and 93C, the W-shape may better distribute stress about turn Tu.

[0298] The anchor edge cell configuration in Figure 93E includes a loop formed in braid 30 at the turn, which may be formed by looping wire W around an inner or outer post.

[0299] Figure 93F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post and an aligned outer post in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0300] In Figure 93G, the edge cells of braid 30 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post in the desired mamier.

[0301] In Figure 93H, the edge cells of braid 30 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 30 during expansion and collapse of the braid, in addition to affecting stress concentration.

[0302] In Figure 93I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two

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adjacent inner or outer posts. Additional loops may also be employed.

[0303] The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 93I, or may be heat set with a more discontinuous shape, as in Figure 93J.

[0304] Figure 93K illustrates that the edge cells of braid 30 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 93K have extended length cells as in Figure 93B disposed adjacent to standard size edge cells, as in Figure 93A.

[0305] The anchor edge cells of Figure 93L have an extended turn configuration having an extended loop.

[0306] The anchor edge cells shown in Figure 93M have an alternative extended configuration with a specified heat set profile.

[0307] In Figure 93N, some or all anchor edge cells are interwoven. When interwoven, one or more edge cells may be shorter or longer than an adjacent edge cell. This permits one or more edge cells to extend into one or more leaflet pocket(s). For example, in Figure 93N the middle Tu may be taller than the two adjacent edge cells thus permitting the edge cell to be situated within a leaflet pocket.

[0308] In any of the embodiments herein, edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 93O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0309] The anchor and any of its features may be heat set at different configurations. For example, the anchor may be heat set ay its "at rest" configuration such that upon unsheathing it expands radially. The end turn features/leaflet engagement elements may be heat set at a different "at rest" configuration than the rest of the anchor. In preferred embodiment, end turn features are heat set to "flower" and then "evert" upon unsheathing.

[0310] The end turn features of Figures 93 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of Figures 93. Furthermore, combinations of any such end turn features may be provided to achieve the desired characteristics of anchor 30.

[0311] Referring now to Figures 104A-E, additional configurations for reducing and/or circumferential stiffness of an anchor braid and/or leaflet engagement elements are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 104A and 104B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 104C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

[0312] In any of the embodiments herein, localized reduction of an anchor wire may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 104D-104E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

[0313] With reference now to Figures 105A-F, a method of endovascularly replacing a patient's diseased aortic valve is provided. The method involves endovascularly delivering an anchor/valve apparatus and properly positioning such apparatus via positive registration with the patient's native valve leaflets. Regisfration with the native valve leaflet preferably occurs using the leaflet engagement elements.

[0314] In Figure 105 A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve AV within sheath 110. Apparatus 10 is delivered in a collapsed delivery configuration.

[0315] As seen in Figures 105B and 105C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance. Sheath 110 includes at its distal end leaflet engagement elements 120. Upon deployment, anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. This causes elements 60 to also dynamically expand, as well as membrane filter (or braid) 61 A and leaflet engagement elements 120. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

[0316] Thus, delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. hi preferred embodiments, the distal end of leaflet engagement elements 120 expands a greater radial distance than anchor 30. Moreover, engagement elements 120 maybe disposed between elements 60 of delivery system 100' and lip region 32 of anchor 30. However, leaflet engagement elements 120 may also be disposed on the proximal end of an anchor (as is illustrated in Figure 106). Leaflet engagement elements 120 releasably engage the anchor. As seen in

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Figure 105C, the leaflet engagement elements 120 are initially deployed proximal of the patient's native valve leaflets L. Apparatus 10 and element 120 then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. The leaflet engagement element engages with the proximal edges of the native valve leaflets and/or the commissural attachments. The leaflet engagement element need not extend all the way to the distal edge of the native leaflets (the leaflet pockets). In preferred embodiments, a leaflet engagement element length is less than about 20 mm, more preferably less than about 15 mm, or more preferably less than about 10 mm. Once leaflet engagement element 120 is registered against the native valve leaflets and/or commissural attachments, apparatus 10 deploys substantially distal to the coronary ostia of the heart.

[0317] In any of the embodiments herein, delivery system 100' can include filter structure 61A (e.g., filter membrane or braid) as part of push elements 60 to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor from either diseased native leaflet or surrounding aortic tissue and can cause blockage. Arrows 61B in Figure 105C show blood flow through filter structure 61A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[0318] Active foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as is illustrated in Figure 105D. Active foreshortening can be accomplished by actuating distal anchor actuation elements (e.g., elements 50) and/or proximal anchor actuation elements (e.g., elements 60). Upon positive registration of element 120 against leaflets L, element 120 precludes further distal migration of apparatus 10 during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 105E details engagement of element 120 against the native leaflets.

[0319] As seen in Figure 105F, once apparatus 10 is fully deployed, anchor 30 may be locked (reversibly or irreversibly). Subsequently, structure 61A leaflet engagement, elements 120, elements 50 and/or elements 60 may be decoupled from the apparatus, and delivery system 100' may be removed from the patient, thereby completing the procedure.

[0320] Figure 106 illustrates an alternative embodiment of the apparatus of Figures 105A-F described above, wherein leaflet engagement elements 120 are coupled to anchor 30 of apparatus 10' rather than to delivery system 100. In the embodiment illustrated in Figure 106, leaflet engagement elements 120 remain implanted near the patient's native heart valve after the deployment of apparatus 10' and removal of delivery system 100. Leaflets L may be sandwiched between the proximal region of anchor 30 and leaflet engagement element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets L and precludes distal migration of the apparatus over time.

[0321] Figures 107A-107C illustrate another embodiment for endovascularly delivering an apparatus of the present invention. In Figure 107A, a catheter 600 is delivered percutaneously in a retrograde fashion to the aortic valve. The catheter passes through the native aortic valve before an operator actuates the unseathing of the anchor/valve apparatus. As the sheathing catheter is pulled proximally out of the native valve, anchor 30 and replacement valve 20 become unsheathed. Immediately the portion of the unsheathed anchor 30 dynamically self-expands to its "at rest" position, and replacement valve 20 within the anchor regains an uncollapsed structure, allowing it to begin to function. In preferred embodiments in its "at rest" position, anchor 30 presses against the native leaflets limiting blood from flowing in between the anchor and leaflet. Also, in preferred embodiments, anchor 30 portions relatively adjacent to the valve is externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric. The seal can be attached by any means known in the art to the anchor and, in some embodiments, to the distal end of the valve. In preferred embodiments, a seal is attached to the anchor by suturing.

[0322] In Figure 107B, as the catheter is further pulled proximally, the proximal end of anchor 30 and fingers 50 are unsheathed. In this embodiment, it is possible to visualize that the seal covers the entire contour of the anchor including the external face of the leaflet engagement element 70. As soon as the proximal end of the anchor is exposed, it also dynamically expands. Furthermore, when fingers 50 become exposed, replacement valve 20 begins to function permitting blood to flow through replacement valve 20, between fingers 50, and around the catheter 600. This also permits blood to flow into the coronary ostias. In other embodiments where the seal does not cover the proximal end of the anchor, the replacement valve can begin to function as soon as the unsealed portion of the anchor is unsheathed. This causes the leaflet engagement elements 70 to radially expand to their heat set position and engage with the native heart leaflets.

[0323] Next, Figure 107C, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., elements 55), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal 60 to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned

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between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently'withdrawn, leaving behind valve 20, seal 60 and anchor 70. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

[0324] Figures 108A-108B illustrate an embodiment wherein only a distal portion anchor 30 is covered by seal 60 and wherein anchor 30 is only partially deployed since the blood can escape through the proximal end of the anchor braid. As anchor 30 in this embodiment is unsheathed, it presses against the native valve leaflets. At this point replacement valve 20 is functional even though anchor 30 is not fully deployed since blood can escape through the proximal end of the anchor braid. This allows blood to flow through replacement valve 20 and out of holes in the distal end of anchor 30 during systole (Figure 108A) while preventing backflow during diastole (Figure 108B).

[0325] Figures 109A-109B illustrate a similar embodiment wherein seal 60 around anchor 30 surrounds the entire contour of anchor 30. In this embodiment, valve 20 does not become functional until both anchor 30 and a portion of fingers 50 are unsheathed. As soon as a portion of fingers 50 is unsheathed, replacement valve 20 is fully functional. This allows blood to flow through replacement valve 20 and anchor 30, out of fingers 50, and around catheter 60 into the aorta and coronary ostias during systole. Similarly, during diastole, replacement valve 20 closes preventing blood backflow from entering the chamber.

[0326] In any of the embodiments herein the anchor is preferably a self-expanding anchor braid. Anchor braid of the present invention can be made from one or more wires, more preferably 2-20 wires, more preferably 3-15 wires, or more preferably 4-10 wires. Moreover, the density of the braid can be modified by various forms of weave used.

[0327] Figures 32-34 illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. Figure 32 illusfrates a fabric seal 380 prior to deployment and foreshortening of the anchor/valve apparatus. In Figure 32, the fabric seal 380 extends from the distal end of valve 20 proximally over anchor 30 during delivery. During deployment, as illustrated in Figure 33, anchor 30 foreshortens and the fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement valve. Figure 34 illustrates anchor 30, surrounded by fabric seal 380 in between native valve leaflets 382. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is fully deployed.

EMBODIMENTS

[0328] Although the present invention is defined in the attached claims, it should be understood that the present invention can also (alternatively) be defined in accordance with the following embodiments:

1. Apparatus for replacing a native aortic valve, the apparatus comprising: an anchor comprising an expandable braid with closed ends, the anchor being adapted to be endovascularly delivered and secured at an anchor site within the native aortic valve; and a replacement valve configured to be secured within the anchor.
2. The apparatus of embodiment 1 wherein the anchor comprises a central axis, the anchor being further adapted to remain substantially undeformed in response to a pressure up to 0.5 atm directed substantially radially inward toward the central axis.
3. The apparatus of embodiment 2 wherein the anchor is further adapted to remain substantially undeformed in response to a pressure up to 2 atm directed substantially radially inward toward the central axis.
4. The apparatus of embodiment 1 wherein the anchor is adapted to support the replacement valve at the anchor site in response to differential pressure across the replacement valve of up to about 200 mm Hg.
5. The apparatus of embodiment 4 wherein the anchor is adapted to support the replacement valve at the anchor site in response to differential pressure across the replacement valve of up to about 80 mm Hg.
6. The apparatus of embodiment 1 wherein the anchor comprises sfress reduction elements adapted to reduce the incidence of anchor material fatigue caused by pulsatile motion of the anchor site.
7. The apparatus of embodiment 6 wherein the braid comprises a plurality of cells, the stress reduction elements comprising a set of cells at a distal or proximal edge of the anchor.
8. The apparatus of embodiment 1 wherein the braid comprises sheathing features adapted to reduce sheathing force.
9. The apparatus of embodiment 8 wherein the braid comprises a plurality of cells, the sheathing features comprising a set of cells at a proximal edge of the anchor.
10. The apparatus of embodiment 1 wherein the braid comprises a first region and a second region having a diameter larger than a diameter of the first region when the anchor is expanded.
11. The apparatus of embodiment 10 wherein the braid defines a plurality of cells, at least a first set of the cells in the first region each being of a substan-

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tially different configuration than a second set of the cells in the second region.

12. The apparatus of embodiment 11 wherein the braid further comprises a third region having a diameter larger than the first region diameter when the anchor is expanded.

13. The apparatus of embodiment 12 wherein the first, second and third regions are adapted to center the anchor within the native aortic valve.

14. The apparatus of embodiment 12 wherein the braid defines a plurality of cells, at least a first set of the cells in the first region each being of a substantially different configuration than a second set of the cells in the second region and a third set of cells in the third region.

15. The apparatus of embodiment 1 wherein the anchor is further adapted to avoid interference with coronary ostia.

16. The apparatus of embodiment 1 wherein the anchor is further adapted to avoid interference with a mitral valve.

17. The apparatus of embodiment 16 wherein the braid comprises a region adapted to prevent expansion of the anchor into the mitral valve.

18. The apparatus of embodiment 1 wherein the braid is configured to have an expanded shape that is radially symmetrical.

19. The apparatus of embodiment 1 wherein the braid is configured to have an expanded shape that is bilaterally symmetrical.

20. The apparatus of embodiment 1 wherein the braid is configured to have an expanded shape that is asymmetrical.

21. The apparatus of embodiment 1 wherein the braid is configured to have distal fine mesh section with a higher pitch than the proximal section.

22. The apparatus of embodiment 1 wherein the braid defines a plurality of cells, at least a first set of the cells each being of a substantially different configuration than a second set of the cells.

23. The apparatus of embodiment 22 wherein the anchor comprises distal and proximal edges, the first set of cells being disposed at at least the distal edge or the proximal edge.

24. The apparatus of embodiment 23 wherein each cell in the first set of cells is longer in a first direction than the cells in the second set of cells.

25. The apparatus of embodiment 24 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

26. The apparatus of embodiment 23 wherein each cell in the first set of cells has a portion bent out of a cylindrical shape defined by the braid and each cell in the second set of cells does not have a portion bent out of the cylindrical shape defined by the braid.

27. The apparatus of embodiment 26 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

28. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises an inward bend to form a W shape along one side of the cell and each cell in the second set of cells does not.

29. The apparatus of embodiment 28 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

30. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises a loop and each cell in the second set of cells does not.

31. The apparatus of embodiment 30 wherein the loop is disposed asymmetrically within each cell of the first set of cells.

32. The apparatus of embodiment 30 each cell in the first set of cells comprises a plurality of loops and each cell in the second set of cells does not.

33. The apparatus of embodiment 30 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

34. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises a figure 8 shaped loop and each cell in the second set of cells does not.

35. The apparatus of embodiment 34 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

36. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises a heart shaped loop and each cell in the second set of cells does not.

37. The apparatus of embodiment 36 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

38. The apparatus of embodiment 23 wherein a wire section of each cell of the first set of cells comprises a reduced cross-sectional diameter in at least one location and each cell in the second set of cells does not.

39. The apparatus of embodiment 38 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

40. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises an inward cant with respect to the second set of cells.

41. The apparatus of embodiment 40 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

42. The apparatus of embodiment 23 wherein each cell in the first set of cells comprises an inward cant and an outward cant with respect to the second set of cells.

43. The apparatus of embodiment 42 wherein the first set of cells comprises substantially all cells at at least the proximal edge or the distal edge.

44. The apparatus of embodiment 23 wherein each cell of the first set of cells comprises a lock adapted to lock the anchor in an expanded configuration.

45. The apparatus of embodiment 44 wherein the braid further comprises a third set of cells each being of a substantially different configuration than the sec-

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ond set of cells, each of the third set of cells being adapted to interact with the first set of cells to lock the anchor in the expanded configuration.

46. The apparatus of embodiment 22 further comprising a third set of cells having a substantially different configuration than a second set of the cells.

47. The apparatus of embodiment 46 wherein the first set of cells is disposed at a distal end of the anchor and the third set of cells is disposed at a proximal end of the anchor.

48. The apparatus of embodiment 1 wherein the anchor comprises first and second wires, the first wire having a diameter smaller than a diameter of the second wire.

49. The apparatus of embodiment 1 wherein the anchor comprises first and second wires formed from different materials.

50. The apparatus of embodiment 1 wherein the anchor has a collapsed delivery configuration, an at-rest configuration and an expanded deployed configuration.

51. The apparatus of embodiment 50 wherein the braid comprises a shape memory material that is heat set in the at-rest configuration.

52. The apparatus of embodiment 50 wherein the at-rest configuration is between the collapsed delivery configuration and expanded deployed configuration.

53. The apparatus of embodiment 1 wherein the braid is configured for active foreshortening during endovascular deployment.

54. The apparatus of embodiment 1 further comprising a lock configured to maintain expansion of the braid.

55. The apparatus of embodiment 1 further comprising a plurality of locks configured to maintain expansion of the braid.

56. The apparatus of embodiment 55 wherein the plurality of locks are further configured to maintain expansion of the braid at a plurality of amounts of expansion.

57. The apparatus of embodiment 1 further comprising a valve support adapted to support the replacement valve within the anchor.

58. The apparatus of embodiment 57 further comprising a lock configured to maintain expansion of the braid.

59. The apparatus of embodiment 58 wherein the lock comprises an extension of the valve support.

60. The apparatus of embodiment 1 wherein the anchor comprises a distal deployment system interface disposed at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor.

61. The apparatus of embodiment 60 wherein the distal deployment system interface is further adapted to expand radially during application of a proximally directed force on the distal end of the anchor.

62. The apparatus of embodiment 61 wherein the distal deployment system interface is further adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor without passing any portion of a deployment system through a center opening of the replacement valve.

63. The apparatus of embodiment 1 wherein the anchor comprises a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor.

64. The apparatus of embodiment 63 wherein the proximal deployment system interface is further adapted to expand radially during application of a distally directed force on the proximal end of the anchor.

65. The apparatus of embodiment 63 wherein the proximal deployment system interface is further adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor through a plurality of deployment system fingers.

66. The apparatus of embodiment 1 wherein the delivery length is between about 15 mm and about 150 mm and the deployed length is between 5 mm and about 40 mm.

67. Apparatus for replacing a native aortic valve, the apparatus comprising:

an expandable anchor adapted to be endovascularly delivered and secured at an anchor site within the native aortic valve, the expandable anchor having a delivery length in a delivery configuration substantially greater than a deployed length in a deployed configuration; and

a replacement valve configured to be secured within the anchor.

68. The apparatus of embodiment 67 wherein the delivery length is between about 15 mm and about 150 mm and the deployed length is between about 2 mm and about 40 mm.

69. The apparatus of embodiment 68 wherein the delivery length is between about 20 mm and about 140 mm and the deployed length is between about 5 mm and about 30 mm.

70. The apparatus of embodiment 68 wherein the delivery length is between about 25 mm and about 130 mm and the deployed length is between about 7 mm and about 20 mm.

71. The apparatus of embodiment 67 wherein ratio of delivery length to deployed length is between about 0.05 and about 0.5.

72. The apparatus of embodiment 71 wherein ratio of delivery length to deployed length is between about 0.1 and about 0.35.

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73. The apparatus of embodiment 72 wherein ratio of delivery length to deployed length is between about 0.15 and about 0.25.

74. The apparatus of embodiment 67 wherein the anchor has an at-rest configuration and wherein the anchor comprises a shape memory material that is heat set in the at-rest configuration.

75. The apparatus of embodiment 74 wherein the at-rest configuration has a length between the delivery length and the deployed length.

76. The apparatus of embodiment 67 wherein the anchor is configured for active foreshortening during endovascular deployment.

77. The apparatus of embodiment 67 further comprising a lock configured to maintain expansion of the anchor.

78. The apparatus of embodiment 67 further comprising a plurality of locks configured to maintain expansion of the anchor.

79. The apparatus of embodiment 78 wherein the plurality of locks are further configured to maintain expansion of the anchor at a plurality of amounts of expansion.

80. The apparatus of embodiment 67 further comprising a valve support adapted to support the replacement valve within the anchor.

81. The apparatus of embodiment 80 further comprising a lock configured to maintain expansion of the anchor.

82. The apparatus of embodiment 81 wherein the lock comprises an extension of the valve support.

83. The apparatus of embodiment 67 wherein the anchor comprises a distal deployment system interface disposed at a distal end of the anchor, the distal deployment system interface being adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor.

84. The apparatus of embodiment 83 wherein the distal deployment system interface is further adapted to expand radially during application of a proximally directed force on the distal end of the anchor.

85. The apparatus of embodiment 84 wherein the distal deployment system interface is further adapted to permit a deployment system to apply a proximally directed force on the distal end of the anchor without passing any portion of a deployment system through a center opening of the replacement valve.

86. The apparatus of embodiment 67 wherein the anchor comprises a proximal deployment system interface at a proximal end of the anchor, the proximal deployment system interface being adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor.

87. The apparatus of embodiment 86 wherein the proximal deployment system interface is further adapted to expand radially during application of a distally directed force on the proximal end of the anchor.

88. The apparatus of embodiment 86 wherein the proximal deployment system interface is further adapted to permit a deployment system to apply a distally directed force on the proximal end of the anchor through a plurality of deployment system fingers.

89. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an expandable anchor comprising a lip region and a skirt region; and
a replacement valve,
wherein the lip region and skirt region are configured for percutaneous expansion to engage leaflets of the heart valve.

90. The apparatus of embodiment 89 wherein the lip region and skirt region are configured for independent expansion.

91. The apparatus of embodiment 89 wherein the lip region and skirt region are configured for concurrent expansion.

92. The apparatus of embodiment 89 wherein the lip region is adapted to preclude distal migration of the apparatus post-deployment and expansion.

93. The apparatus of embodiment 89 wherein the skirt section is adapted to preclude proximal migration of the apparatus post-deployment and expansion.

94. The apparatus of embodiment 89 wherein the anchor is at least partially covered by a biocompatible film.

95. The apparatus of embodiment 89 wherein the replacement valve is configured to be coupled to the anchor during percutaneous delivery.

96. The apparatus of embodiment 89 wherein the anchor and the replacement valve are adapted for expansion from the delivery to the deployed configurations via a mechanism chosen from the group consisting of balloon-expansion, self-expansion, and combinations thereof.

97. The apparatus of embodiment 89 further comprising a delivery system configured for percutaneous advancement of the apparatus to a vicinity of the patient's diseased valve while the anchor is disposed in a collapsed delivery configuration.

98. The apparatus of embodiment 97 wherein the delivery system facilitates deployment and expansion of the apparatus to endovascularly replace the heart valve.

99. The apparatus of embodiment 98 wherein the delivery system is configured to retrieve the apparatus.

100. The apparatus of embodiment 89 further comprising at least one locking element configured to maintain expansion of the lip region and the skirt region.

101. Apparatus for endovascularly replacing a pa-

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tient' s heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage leaflets of the patient's heart valve.

102. The apparatus of embodiment 101 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

103. The apparatus of embodiment 101 wherein the anchor is further adapted to be actively foreshortened during deployment.

104. The apparatus of embodiment 103 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

105. The apparatus of embodiment 103 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

106. The apparatus of embodiment 103 further comprising a lock adapted to lock the anchor in a deployed shape.

107. The apparatus of embodiment 101 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

108. The apparatus of embodiment 101 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

109. The apparatus of embodiment 101 wherein the leaflet engagement elements are integral with the anchor.

110. The apparatus of embodiment 109 wherein the anchor comprises a braid, the leaflet engagement elements being part of the braid.

111. The apparatus of embodiment 101 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow to the chamber of the heart through the replacement valve during deployment of the anchor and replacement valve.

112. The apparatus of embodiment 101 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

113. The apparatus of embodiment 112 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter but before the anchor completely exits the catheter.

114. The apparatus of embodiment 112 wherein the anchor comprises a self-expanding anchor.

115. The apparatus of embodiment 112 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

116. The apparatus of embodiment 112 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

117. The apparatus of embodiment 112 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

118. The apparatus of embodiment 112 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

119. The apparatus of embodiment 101 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

120. The apparatus of embodiment 119 wherein the seal comprises a pleated seal.

121. The apparatus of embodiment 119 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

122. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising a braid, the braid comprising leaflet engagement elements adapted to engage leaflets of the patient's heart valve.

123. The apparatus of embodiment 122 wherein the leaflet engagement elements extend from a proximal end of the anchor.

124. The apparatus of embodiment 122 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is

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fully deployed.

125. The apparatus of embodiment 122 wherein the anchor is further adapted to be actively foreshortened during deployment.

126. The apparatus of embodiment 125 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

127. The apparatus of embodiment 125 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

128. The apparatus of embodiment 125 further comprising a lock adapted to lock the anchor in a deployed shape.

129. The apparatus of embodiment 123 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

130. The apparatus of embodiment 123 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

131. The apparatus of embodiment 123 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow through the replacement valve during deployment of the anchor and replacement valve.

132. The apparatus of embodiment 123 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

133. The apparatus of embodiment 132 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before the anchor completely exits the catheter.

134. The apparatus of embodiment 132 wherein the anchor comprises a self-expanding anchor.

135. The apparatus of embodiment 132 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

136. The apparatus of embodiment 132 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

137. The apparatus of embodiment 132 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

138. The apparatus of embodiment 132 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

139. The apparatus of embodiment 123 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

140. The apparatus of embodiment 139 wherein the seal comprises a pleated seal.

141. The apparatus of embodiment 139 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

142. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve and a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor and the replacement valve being further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

143. The apparatus of embodiment 142 wherein the anchor comprises a self-expanding anchor.

144. The apparatus of embodiment 142 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

145. The apparatus of embodiment 142 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

146. The apparatus of embodiment 142 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment

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of the anchor.

147. The apparatus of embodiment 142 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

148. The apparatus of embodiment 142 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

149. The apparatus of embodiment 148 wherein the seal comprises a pleated seal.

150. The apparatus of embodiment 148 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

151. Apparatus for endovascularly replacing a patient's heart valve comprising:

a replacement valve;
an anchor; and
a deployment tool adapted to apply a non-hydraulic or non-pneumatic actuation force on the anchor to reshape the anchor.

152. The apparatus of embodiment 151 wherein the deployment tool is adapted to deliver a proximally directed actuation force on the anchor.

153. The apparatus of embodiment 152 wherein the deployment tool comprises a control member adapted to move a distal end of the anchor proximally.

154. The apparatus of embodiment 152 wherein at least a portion of the anchor is adapted to expand in response to application of the proximally directed actuation force.

155. The apparatus of embodiment 152 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor proximally.

156. The apparatus of embodiment 152 wherein at least a portion of the anchor is adapted to contract in response to application of the proximally directed actuation force.

157. The apparatus of embodiment 151 wherein the deployment tool is adapted to deliver a distally directed actuation force on the anchor.

158. The apparatus of embodiment 157 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor distally.

159. The apparatus of embodiment 157 wherein at least a portion of the anchor is adapted to contract in response to application of the distally directed actuation force.

160. The apparatus of embodiment 151 further comprising a releasable connection between the deployment tool and the anchor.

161. The apparatus of embodiment 151 wherein the anchor comprises self-expanding shape memory material.

162. The apparatus of embodiment 151 wherein further comprising an anchor lock adapted to lock the anchor in a deployed configuration.

163. The apparatus of embodiment 162 further comprising a lock prevention element actuatable from outside the patient.

164. The apparatus of embodiment 151 wherein the anchor comprises barbs adapted to penetrate tissue when the anchor is in an expanded configuration.

165. The apparatus of embodiment 151 further comprising a registration element adapted to determine a position of the replacement valve with respect to the heart valve.

166. The apparatus of embodiment 165 further comprising a catheter adapted to deliver the anchor and the replacement valve to a vicinity of the heart valve, the registration element being disposed on the catheter.

167. The apparatus of embodiment 165 wherein the registration element is disposed on the anchor.

168. The apparatus of embodiment 165 wherein the registration element is adapted to extend radially outward from the anchor to entrap at least part of the heart valve.

169. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a collapsed delivery configuration and an expanded deployed configuration; and
a replacement valve coupled to the anchor,
wherein the anchor comprises enhanced radial strength in the expanded deployed configuration as compared to the collapsed delivery configuration due to imposed foreshortening.

170. The apparatus of embodiment 169 further comprising a locking mechanism for maintaining imposed foreshortening.

171. The apparatus of embodiment 170, wherein the apparatus is configured for retrieval prior to actuation of the locking mechanism.

172. The apparatus of embodiment 170, wherein the locking mechanism is configured to maintain a degree of imposed foreshortening selected in vivo.

173. The apparatus of embodiment 169 further comprising a delivery system configured for percutaneous delivery, deployment and foreshortening of the anchor.

174. The apparatus of embodiment 173 further comprising a leaflet engagement element coupled to the delivery system to provide positive registration of the apparatus relative to an anatomical landmark.

175. The apparatus of embodiment 173, wherein the delivery system is releasably coupled to the anchor in a manner facilitating dynamic repositioning and

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retrieval of the anchor post-deployment.

176. The apparatus of embodiment 169, wherein the anchor is at least partially covered by a biocompatible film.

177. The apparatus of embodiment 169, wherein the replacement valve comprises a valve chosen from the group consisting of mechanical valves, biologic valves, and combinations thereof.

178. The apparatus of embodiment 169, wherein the anchor is fabricated from materials chosen from the group consisting of self-expanding materials, balloon-expandable materials, and combinations thereof.

179. The apparatus of embodiment 169, wherein the anchor further comprises barbs adapted to engage tissue at the heart valve when the anchor is disposed in the expanded deployed configuration.

180. The apparatus of embodiment 169 further comprising a leaflet engagement element coupled to the anchor to provide positive registration of the apparatus relative to anatomical landmarks.

181. The apparatus of embodiment 169, wherein the anchor further comprises an element configured to reduce paravalvular leakage or regurgitation.

182. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor;
a replacement valve coupled to the anchor; and
a delivery system,
wherein the delivery system is configured to retrieve the anchor and replacement valve post-deployment.

183. The apparatus of embodiment 182, wherein the delivery system is further configured for percutaneous delivery, deployment and foreshortening of the anchor.

184. Apparatus for endovascularly replacing a patient's heart valve comprising:

a replacement valve;
an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor.

185. The apparatus of embodiment 184 wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

186. The apparatus of embodiment 184 wherein the anchor actuation elements comprise a plurality of distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

187. The apparatus of embodiment 184 wherein the anchor actuation elements each comprise a first member attached to the anchor and a second member releasably attached to the first member.

188. The apparatus of embodiment 187 wherein the first members each comprise a post adapted to support the valve within the anchor.

189. The apparatus of embodiment 188 wherein at least one post comprises valve attachment structure, the replacement valve being attached to the post via the valve attachment structure.

190. The apparatus of embodiment 189 wherein the valve attachment structure comprises a plurality of holes formed in the post.

191. The apparatus of embodiment 190 wherein the valve attachment structure comprises a tab extending from the post.

192. The apparatus of embodiment 187 wherein the first members each comprise a lock element adapted to lock the anchor in a deployed shape.

193. The apparatus of embodiment 192 wherein the lock element is further adapted to engage an anchor element to lock the anchor in the deployed shape.

194. The apparatus of embodiment 192 wherein the apparatus further comprises anchor lock elements attached to the anchor and adapted to mate with the lock element of each first member to lock the anchor in the deployed shape.

195. The apparatus of embodiment 194 wherein the anchor lock elements each comprise a camming surface adapted to engage the first member and to move at least a portion of the anchor lock element in response to a lock actuation force.

196. The apparatus of embodiment 194 further comprising a lock actuator adapted to apply a locking force to move at least a portion of the anchor lock element.

197. The apparatus of embodiment 194 wherein at least one first member lock element and at least one anchor lock element are adapted to mate at a plurality of mating configurations.

198. The apparatus of embodiment 197 wherein the at least one first member lock element comprises a plurality of ratchets adapted to engage a tooth portion of the at least one anchor lock element.

199. The apparatus of embodiment 198 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed distal to the valve support structure.

200. The apparatus of embodiment 198 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed neither distal to nor proximal to the valve support structure.

201. The apparatus of embodiment 198 wherein the at least one first member further comprises valve support structure, substantially all of the plurality of ratchets being disposed proximal to the valve sup-

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port structure.

202. The apparatus of embodiment 194 wherein the anchor lock elements each comprise a buckle.

203. The apparatus of embodiment 202 wherein the buckle is formed from a cut tube.

204. The apparatus of embodiment 202 wherein the buckle is formed from bent resilient material.

205. The apparatus of embodiment 194 wherein the first member lock element further comprises a lock alignment feature adapted to align the first member lock element with the anchor lock element.

206. The apparatus of embodiment 205 wherein the lock alignment feature comprises a hinge.

207. The apparatus of embodiment 205 wherein the lock alignment feature comprises an engagement portion of the anchor lock element adapted to engage the first member before engagement of the anchor lock element with the first member lock element.

208. The apparatus of embodiment 205 wherein the first member lock element and the anchor lock element define a lock width, the lock alignment feature comprising a first member lock element lock area substantially wider than the lock width.

209. The apparatus of embodiment 192 further comprising a lock actuator adapted to apply a locking force to lock the anchor in the deployed shape.

210. The apparatus of embodiment 209 wherein the distal anchor actuation element comprises the lock actuator.

211. The apparatus of embodiment 209 further comprising an unlocking actuator adapted to unlock the anchor.

212. The apparatus of embodiment 211 wherein the lock actuator comprises the unlocking actuator.

213. The apparatus of embodiment 211 wherein the unlocking actuator comprises a proximal pull actuator.

214. The apparatus of embodiment 211 wherein the unlocking actuator comprises a distal push actuator.

215. The apparatus of embodiment 209 further comprising a lock prevention mechanism.

216. The apparatus of embodiment 192 wherein the first members each comprise a spring adapted to permit axial lengthening of the anchor in response to radially inward compression.

217. The apparatus of embodiment 184 wherein the anchor actuation elements are adapted to apply a distally directed force on the anchor.

218. The apparatus of embodiment 184 wherein the anchor actuation elements are adapted to apply a proximally directed force on the anchor.

219. The apparatus of embodiment 184 wherein the anchor actuation elements are adapted to apply distally directed and proximally directed forces on the anchor.

220. The apparatus of embodiment 184 further comprising a releasable attachment mechanism adapted to releasably attach at least one anchor actuation element to the anchor.

221. The apparatus of embodiment 220 further comprising a movable release actuator adapted to actuate the releasable attachment mechanism.

222. The apparatus of embodiment 221 wherein the movable release actuator is adapted to prevent a release movement of the anchor attachment mechanism in a first position and to permit a release movement of the anchor attachment mechanism in a second position.

223. The apparatus of embodiment 222 wherein the release actuator comprises a cover covering at least a portion of the releasable attachment mechanism.

224. The apparatus of embodiment 221 wherein the release actuator comprises an elongated element movable within at least part of the releasable attachment mechanism.

225. The apparatus of embodiment 224 wherein the release actuator further comprises a camming surface adapted to resist actuation of the releasable attachment mechanism.

226. The apparatus of embodiment 224 wherein a distal portion of the elongated element is adapted to engage the anchor.

227. The apparatus of embodiment 221 wherein the release actuator comprises a friction surface.

228. The apparatus of embodiment 221 wherein the release actuator is adapted to move less than one inch to release the attachment mechanism.

229. The apparatus of embodiment 220 wherein the releasable attachment mechanism comprises a wrap portion adapted to wrap at least part way around an anchor element.

230. The apparatus of embodiment 229 wherein at least the wrap portion comprises shape memory material.

231. The apparatus of embodiment 229 wherein the wrap portion comprises an opening adapted to engage a release actuator.

232. The apparatus of embodiment 231 wherein the opening comprises a first opening, the releasable attachment mechanisms each comprising a second opening adapted to be aligned with the first opening and to engage the release actuator.

233. The apparatus of embodiment 232 wherein the releasable attachment mechanisms each comprise a spring element adapted to urge the first opening out of alignment with the second opening.

234. The apparatus of embodiment 220 wherein the releasable attachment mechanism comprises a first shape on an anchor actuation element adapted to mate with a second shape on an anchor attachment element to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor.

235. The apparatus of embodiment 234 further comprising a release actuator adapted to actuate the releasable attachment mechanism.

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236. The apparatus of embodiment 235 wherein the release actuator is adapted to be moved to permit relative movement between the first shape and the second shape.
237. The apparatus of embodiment 235 wherein the release actuator is adapted to be moved to permit the first shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
238. The apparatus of embodiment 235 wherein the release actuator is adapted to be moved to permit the second shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
239. The apparatus of embodiment 234 wherein the anchor actuation element is adapted to separate from the anchor attachment element in response to relative movement between the anchor actuation element and the anchor attachment element.
240. The apparatus of embodiment 239 wherein the first shape comprises a camming surface.
241. The apparatus of embodiment 239 wherein the second shape comprises a camming surface.
242. The apparatus of embodiment 184 wherein the anchor actuation elements each comprise a curved portion.
243. The apparatus of embodiment 242 wherein the curved portion of each anchor actuation element is at a distal end of the anchor actuation element.
244. The apparatus of embodiment 184 wherein the anchor actuation elements comprise shaping features adapted to affect a shape of the anchor actuation elements when an anchor actuation force is applied.
245. The apparatus of embodiment 244 wherein the shaping features comprise reduced diameter portions of the anchor actuation elements.
246. The apparatus of embodiment 244 wherein the shaping features comprise reduced wall thickness portions of the anchor actuation elements.
247. The apparatus of embodiment 244 wherein the shaping features comprise slits formed in the anchor actuation elements.
248. The apparatus of embodiment 184 wherein the anchor actuation elements comprise a plurality of arms extending from a unitary structure.
249. The apparatus of embodiment 248 wherein each arm is adapted to move radially outward and radially inward with respect to other arms as the anchor reshapes.
250. The apparatus of embodiment 248 wherein the anchor actuation elements comprise a cut tube.
251. The apparatus of embodiment 184 wherein the deployment tool further comprises a catheter adapted to percutaneously communicate the anchor actuation elements with an operator exterior to the patient.
252. The apparatus of embodiment 251 wherein the catheter comprises a plurality of lumens, at least part of each anchor actuation element being disposed in one of the lumens.
253. The apparatus of embodiment 251 wherein the deployment tool further comprises a handle adapted to actuate the anchor actuation elements.
254. The apparatus of embodiment 184 wherein the deployment tool is further adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor without passing any portion of the deployment tool through a central opening in the replacement valve.
255. Apparatus for endovascularly replacing a heart valve comprising:

a catheter;
a replacement valve configured to be disposed within the catheter for delivery to a vicinity of the heart valve; and
an expandable anchor configured to be disposed within the catheter for delivery to a vicinity of the heart valve, to be deployed from the catheter, to be expanded to contact tissue at an anchor site and to be retrieved back into the catheter after having been expanded.

256. The apparatus of embodiment 255 further comprising a deployment tool configured to apply an actuation force to the anchor when the anchor is in the vicinity of the heart valve.
257. The apparatus of embodiment 256 wherein the deployment tool is adapted to deliver a proximally directed actuation force on the anchor.
258. The apparatus of embodiment 257 wherein the deployment tool comprises a control member adapted to move a distal end of the anchor proximally.
259. The apparatus of embodiment 257 wherein at least a portion of the anchor is adapted to expand in response to application of the proximally directed actuation force.
260. The apparatus of embodiment 257 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor proximally.
261. The apparatus of embodiment 257 wherein at least a portion of the anchor is adapted to contract in response to application of the proximally directed actuation force.
262. The apparatus of embodiment 256 wherein the deployment tool is adapted to deliver a distally directed actuation force on the anchor.
263. The apparatus of embodiment 262 wherein the deployment tool comprises a control member adapted to move a proximal end of the anchor distally.
264. The apparatus of embodiment 262 wherein at least a portion of the anchor is adapted to contract in response to application of the distally directed actuation force.
265. The apparatus of embodiment 256 further com-

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prising a releasable connection between the deployment tool and the anchor.

266. The apparatus of embodiment 255 wherein the replacement valve is coupled to the anchor.

267. The apparatus of embodiment 255 wherein the catheter comprises a catheter having a diameter no more than 21 french.

268. Apparatus for endovascularly replacing a patient's heart valve comprising:

a sheath;

a deployment tool comprising a plurality of anchor actuation elements;

a replacement valve configured to be disposed within the sheath for delivery to a vicinity of the heart valve; and

an expandable anchor configured to be disposed within the sheath for delivery to the vicinity of the heart valve, to be deployed from the sheath, to be expanded by the deployment tool to contact tissue at an anchor site and to be retrieved back into the sheath after having been expanded.

269. The apparatus of embodiment 268 wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

270. The apparatus of embodiment 268 wherein the anchor actuation elements comprise a plurality of distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

271. The apparatus of embodiment 270 wherein the distal anchor actuation elements each comprises a first member attached to the distal portion of the anchor and a second member releasably attached to the first member.

272. The apparatus of embodiment 271 wherein the first members each comprise a post adapted to support the valve within the anchor.

273. The apparatus of embodiment 272 wherein at least one post comprises valve attachment structure, the replacement valve being attached to the post via the valve attachment structure.

274. The apparatus of embodiment 273 wherein the valve attachment structure comprises a plurality of holes formed in the post.

275. The apparatus of embodiment 274 wherein the valve attachment structure comprises a tab extending from the post.

276. The apparatus of embodiment 271 wherein the first members each comprise a lock element adapted to lock the anchor in a deployed shape.

277. The apparatus of embodiment 276 wherein the lock element is further adapted to engage an anchor element to lock the anchor in the deployed shape.

278. The apparatus of embodiment 276 wherein the apparatus further comprises anchor lock elements attached to the anchor and adapted to mate with the lock element of each first member to lock the anchor in the deployed shape.

279. The apparatus of embodiment 278 wherein the anchor lock elements each comprise a camming surface adapted to engage the first member and to move at least a portion of the anchor lock element in response to a lock actuation force.

280. The apparatus of embodiment 278 further comprising a lock actuator adapted to apply a locking force to move at least a portion of the anchor lock element.

281. The apparatus of embodiment 278 wherein at least one first member lock element and at least one anchor lock element are adapted to mate at a plurality of mating configurations.

282. The apparatus of embodiment 281 wherein the at least one first member lock element comprises a plurality of ratchets adapted to engage a tooth portion of the at least one anchor lock element.

283. The apparatus of embodiment 282 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed distal to the valve support structure.

284. The apparatus of embodiment 282 wherein the at least one first member further comprises valve support structure, at least a portion of the plurality of ratchets being disposed neither distal to nor proximal to the valve support structure.

285. The apparatus of embodiment 282 wherein the at least one first member further comprises valve support structure, substantially all of the plurality of ratchets being disposed proximal to the valve support structure.

286. The apparatus of embodiment 278 wherein the anchor lock elements each comprise a buckle.

287. The apparatus of embodiment 286 wherein the buckle is formed from a cut tube.

288. The apparatus of embodiment 286 wherein the buckle is formed from bent resilient material.

289. The apparatus of embodiment 278 wherein the first member lock element further comprises a lock alignment feature adapted to align the first member lock element with the anchor lock element.

290. The apparatus of embodiment 289 wherein the lock alignment feature comprises a hinge.

291. The apparatus of embodiment 289 wherein the lock alignment feature comprises an engagement portion of the anchor lock element adapted to engage the first member before engagement of the anchor lock element with the first member lock element.

292. The apparatus of embodiment 289 wherein the first member lock element and the anchor lock element define a lock width, the lock alignment feature comprising a first member lock element lock area substantially wider than the lock width.

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293. The apparatus of embodiment 276 further comprising a lock actuator adapted to apply a locking force to lock the anchor in the deployed shape.
294. The apparatus of embodiment 293 wherein the distal anchor actuation element comprises the lock actuator.
295. The apparatus of embodiment 293 further comprising an unlocking actuator adapted to unlock the anchor.
296. The apparatus of embodiment 295 wherein the lock actuator comprises the unlocking actuator.
297. The apparatus of embodiment 295 wherein the unlocking actuator comprises a proximal pull actuator.
298. The apparatus of embodiment 295 wherein the unlocking actuator comprises a distal push actuator.
299. The apparatus of embodiment 293 further comprising a lock prevention mechanism.
300. The apparatus of embodiment 276 wherein the first members each comprise a spring adapted to permit axial lengthening of the anchor in response to radially inward compression.
301. The apparatus of embodiment 268 wherein the anchor actuation elements are adapted to apply a distally directed force on the anchor.
302. The apparatus of embodiment 268 wherein the anchor actuation elements are adapted to apply a proximally directed force on the anchor.
303. The apparatus of embodiment 302 wherein the anchor actuation elements are further adapted to retrieve the anchor into the sheath.
304. The apparatus of embodiment 268 wherein the anchor actuation elements are adapted to apply distally directed and proximally directed forces on the anchor.
305. The apparatus of embodiment 268 further comprising a releasable attachment mechanism adapted to releasably attach at least one anchor actuation element to the anchor.
306. The apparatus of embodiment 305 further comprising a movable release actuator adapted to actuate the releasable attachment mechanism.
307. The apparatus of embodiment 306 wherein the movable release actuator is adapted to prevent a release movement of the anchor attachment mechanism in a first position and to permit a release movement of the anchor attachment mechanism in a second position.
308. The apparatus of embodiment 306 wherein the release actuator comprises a cover covering at least a portion of the releasable attachment mechanism.
309. The apparatus of embodiment 306 wherein the release actuator comprises an elongated element movable within at least part of the attachment mechanism.
310. The apparatus of embodiment 309 wherein the release actuator further comprises a camming surface adapted to resist actuation of the attachment mechanism.
311. The apparatus of embodiment 309 wherein a distal portion of the elongated element is adapted to engage the anchor.
312. The apparatus of embodiment 306 wherein the release actuator comprises a friction surface.
313. The apparatus of embodiment 306 wherein the release actuator is adapted to move less than one inch to release the attachment mechanism.
314. The apparatus of embodiment 305 wherein the releasable attachment mechanism comprises a wrap portion adapted to wrap at least part way around an anchor element.
315. The apparatus of embodiment 314 wherein at least the wrap portion comprises shape memory material.
316. The apparatus of embodiment 314 wherein the wrap portion comprises an opening adapted to engage a release actuator.
317. The apparatus of embodiment 316 wherein the opening comprising a first opening, the releasable attachment mechanisms each comprising a second opening adapted to be aligned with the first opening and to engage the release actuator.
318. The apparatus of embodiment 317 wherein the releasable attachment mechanisms each comprise a spring element adapted to urge the first opening out of alignment with the second opening.
319. The apparatus of embodiment 305 wherein the releasable attachment mechanisms each comprise a first shape on an anchor actuation element adapted to mate with a second shape on an anchor attachment element to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor.
320. The apparatus of embodiment 319 further comprising a release actuator adapted to actuate the releasable attachment mechanism.
321. The apparatus of embodiment 320 wherein the release actuator is adapted to be moved to permit relative movement between first shape and second shape.
322. The apparatus of embodiment 320 wherein the release actuator is adapted to be moved to permit the first shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
323. The apparatus of embodiment 328 wherein the release actuator is adapted to be moved to permit the second shape to change to a third shape permitting relative distal or proximal movement between the anchor actuation element and the anchor.
324. The apparatus of embodiment 319 wherein the anchor actuation element is adapted to separate from the anchor attachment element in response to relative movement between the anchor actuation element and the anchor attachment element.
325. The apparatus of embodiment 324 wherein the

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first shape comprises a camming surface.
326. The apparatus of embodiment 324 wherein the second shape comprises a camming surface.
327. The apparatus of embodiment 268 wherein the anchor actuation elements each comprise a curved portion.
328. The apparatus of embodiment 327 wherein the curved portion of each anchor actuation element is at a distal end of the anchor actuation element.
329. The apparatus of embodiment 268 wherein the anchor actuation elements comprise shaping features adapted to affect a shape of the anchor actuation elements when an anchor actuation force is applied.
330. The apparatus of embodiment 329 wherein the shaping features comprise reduced diameter portions of the anchor actuation elements.
331. The apparatus of embodiment 329 wherein the shaping features comprise reduced wall thickness portions of the anchor actuation elements.
332. The apparatus of embodiment 329 wherein the shaping features comprise slits formed in the anchor actuation elements.
333. The apparatus of embodiment 268 wherein the anchor actuation elements comprise a plurality of arms extending from a unitary structure.
334. The apparatus of embodiment 333 wherein each arm is adapted to move radially outward and radially inward with respect to other arms as the anchor reshapes.
335. The apparatus of embodiment 333 wherein the anchor actuation elements comprise a cut tube.
336. The apparatus of embodiment 268 wherein the deployment tool further comprises a deployment tool catheter adapted to percutaneously communicate the anchor actuation elements with an operator exterior to the patient.
337. The apparatus of embodiment 336 wherein the deployment tool catheter comprises a plurality of lumens, at least part of each anchor actuation element being disposed in one of the lumens.
338. The apparatus of embodiment 336 wherein the deployment tool further comprises a handle adapted to actuate the anchor actuation elements.
339. The apparatus of embodiment 268 wherein the deployment tool is configured to expand the anchor without passing any portion of the deployment tool through a center opening of the replacement valve.
340. Apparatus for endovascularly replacing "a patient's heart valve comprising:

a delivery catheter having a diameter of 21 french or less;
an expandable anchor disposed within the delivery catheter; and
a replacement valve disposed within the delivery catheter.

341. The apparatus of embodiment 340 wherein the replacement valve is coupled to the anchor within the catheter.
342. The apparatus of embodiment 340 wherein the catheter is adapted to deliver the anchor and replacement valve to an aortic valve along a retrograde approach.
343. The apparatus of embodiment 340 further comprising a sheath covering the anchor and the replacement valve within the catheter.
344. The apparatus of embodiment 340 further comprising a deployment tool coupled to the anchor within the catheter.
345. The apparatus of embodiment 344 wherein the deployment tool comprises a plurality of flexible control elements.
346. The apparatus of embodiment 344 wherein the deployment tool comprises a plurality of stiff control rods.
347. The apparatus of embodiment 344 further comprising a releasable connection between the deployment tool and the anchor.
348. The apparatus of embodiment 340 further comprising an expandable balloon disposed within the delivery catheter, the balloon being adapted to expand the anchor.
349. The apparatus of embodiment 348 wherein the balloon is disposed within the catheter apart from the anchor and the replacement valve.
350. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve adapted to be delivered endovascularly to a vicinity of the heart valve;
an expandable anchor adapted to be delivered endovascularly to the vicinity of the heart valve; and
a lock mechanism configured to maintain a minimum amount of anchor expansion.

351. The apparatus of embodiment 350 wherein the lock mechanism comprises an arm extending from a first anchor region toward a second anchor region.
352. The apparatus of embodiment 351 wherein the arm comprises a first interlocking element.
353. The apparatus of embodiment 352 wherein the second anchor region comprises a second interlocking element adapted to mate with the first interlocking element.
354. The apparatus of embodiment 352 wherein the first interlocking element comprises a locking configuration and a lock prevention configuration.
355. The apparatus of embodiment 352 wherein the arm comprises a plurality of first interlocking elements having substantially the same shape, the plurality of first interlocking elements extending along the arm in a spaced-apart relationship.
356. The apparatus of embodiment 355 wherein the

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second anchor region comprises a second interlocking element adapted to mate with one of the plurality of first interlocking elements.

357. The apparatus of embodiment 350 wherein the lock mechanism comprises first and second interlocking elements adapted to mate with each other.

358. The apparatus of embodiment 357 wherein the first and second interlocking elements are associated with first and second anchor regions, respectively.

359. The apparatus of embodiment 350 further comprising an anchor actuator adapted to change the anchor's shape.

360. The apparatus of embodiment 359 wherein the actuator is further adapted to move a first anchor region toward a second anchor region.

361. The apparatus of embodiment 360 wherein the anchor is adapted to radially expand when the first anchor region moves toward the second anchor region.

362. The apparatus of embodiment 360 wherein the actuator is further adapted to move the first anchor region away from the second anchor region.

363. The apparatus of embodiment 362 wherein the anchor is adapted to radially contract when the first anchor region moves away from the second anchor region.

364. The apparatus of embodiment 359 wherein the lock mechanism comprises first and second interlocking elements adapted to mate with each other to prevent the first anchor region and second anchor region from moving away from each other.

365. The apparatus of embodiment 359 further comprises an actuator release mechanism.

366. The apparatus of embodiment 350 wherein the replacement valve is adapted to be coupled to the anchor during delivery of the anchor and replacement valve through a catheter to the vicinity of the heart valve.

367. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor comprising a lip region and a skirt region;
a replacement valve coupled to the anchor; and
a lock,
wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve, and
wherein the lock is configured to maintain such expansion.

368. A replacement heart valve system comprising:

an anchor having a collapsed endovascular delivery configuration and an expanded deployed configuration;
a replacement valve support secured to the anchor in the anchor's delivery and deployed configurations, the replacement valve support having a length that is substantially the same in the anchor's delivery and deployed configurations; and
a replacement valve supported by the replacement valve support.

369. The system of embodiment 368 wherein the replacement valve support comprises a base portion and a commissure support portion, the base portion being adapted to be radially expandable.

370. The system of embodiment 368 wherein the replacement valve support comprises a base portion and a commissure support portion axially separated from the base portion.

371. The system of embodiment 368 wherein the replacement valve support comprises a base portion and a commissure support portion, the replacement valve support being secured to the anchor solely at the base portion.

372. The system of embodiment 371 where the replacement valve support is secured to the anchor at the base portion and at the commissure support portion.

373. The system of embodiment 368 wherein the replacement valve support comprises an anchor actuator interface.

374. The system of embodiment 373 wherein the replacement valve support comprises a commissure support portion, the commissure support portion comprising the anchor actuator interface.

375. The system of embodiment 373 wherein the anchor actuator interface comprises a first anchor actuator interface, the anchor further comprising a second anchor actuator interface.

376. The system of embodiment 375 wherein the first anchor actuator interface is adapted to actuate a distal portion of the anchor and the second anchor actuator interface is adapted to actuate a proximal portion of the anchor.

377. The system of embodiment 373 wherein the replacement valve support comprises a plurality of anchor actuator interfaces.

378. The system of embodiment 377 wherein thp anchor actuator interfaces are adapted to actuator a distal portion of the anchor, the system further comprising a plurality of proximal anchor actuator interfaces adapted to actuate a proximal portion of the anchor.

379. The system of embodiment 368 further comprising an anchor lock adapted to lock the anchor in the deployed configuration.

380. The system of embodiment 379 wherein the replacement valve support comprises the anchor lock.

381. The system of embodiment 380 wherein the replacement valve support comprises a base portion and a commissure support portion, the commissure

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support portion comprising the anchor lock.

382. The system of embodiment 381 wherein the anchor lock comprises first and second locking elements, the commissure support comprising the first locking element, the anchor supporting the second locking element.

383. The system of embodiment 380 wherein the anchor lock is adapted to lock the anchor in a plurality of expanded configurations.

384. The system of embodiment 368 wherein the replacement valve support comprises a plurality of commissure supports.

385. The system of embodiment 368 wherein the replacement valve support is adapted to have the same configuration in the anchor's delivery and deployed configurations.

386. The system of embodiment 368 wherein the anchor comprises a braid.

387. A replacement heart valve system comprising:

an anchor having a collapsed delivery configuration and an expanded deployed configuration; and

a replacement valve having a valve height and being supported within the anchor such that the valve height is substantially the same in the anchor's delivery and

deployed configurations.

388. The system of embodiment 387 wherein the anchor comprises a braid.

389. The system of embodiment 387 further comprising a replacement valve support secured to the anchor, the replacement valve support being adapted to support the replacement valve within the anchor.

390. The system of embodiment 389 wherein the replacement valve support comprises a base portion and a commissure support portion, the base portion being adapted to be expandable.

391. The system of embodiment 389 wherein the replacement valve support comprises a base portion and a commissure support portion axially separated from the base portion.

392. The system of embodiment 389 wherein the replacement valve support comprises a base portion and a commissure support portion, the replacement valve support being secured to the anchor solely at the base portion.

393. The system of embodiment 389 wherein the replacement valve support comprises an anchor actuator interface.

394. The system of embodiment 393 wherein the replacement valve support comprises a commissure support portion, the commissure support portion comprising the anchor actuator interface.

395. The system of embodiment 393 wherein the anchor actuator interface comprises a first anchor actuator interface, the anchor further comprising a second anchor actuator interface.

396. The system of embodiment 395 further comprising an anchor lock adapted to lock the anchor in the deployed configuration.

397. The system of embodiment 389 wherein the replacement valve support is adapted to have the same configuration in the anchor's delivery and deployed configurations.

398. The system of embodiment 387 further comprising an anchor lock adapted to lock the anchor in the deployed configuration.

399. The system of embodiment 398 wherein the replacement valve support comprises the anchor lock.

400. The system of embodiment 399 wherein the replacement valve support comprises a base portion and a commissure support portion, the commissure support portion comprising the anchor lock.

401. The system of embodiment 400 wherein the anchor lock comprises first and second locking elements, the commissure support comprising the first locking element, the anchor supporting the second locking element.

402. The system of embodiment 399 wherein the anchor lock is adapted to lock the anchor in a plurality of expanded configurations.

403. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a custom-designed anchor; and

a replacement valve,

wherein the custom-designed anchor is adapted to engage native leaflets of the heart valve, and

wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the heart valve.

404. The apparatus of embodiment 403, wherein the anchor comprises a lip section adapted to engage valve leaflets of the heart valve and to preclude distal migration of the composite apparatus.

405. The apparatus of embodiment 404, wherein the anchor comprises a groove section adapted to couple the anchor to the replacement valve to form the composite apparatus.

406. The apparatus of embodiment 405, wherein the groove section is adapted to reduce impingement of tissue from the valve leaflets within the groove section, thereby facilitating formation of the composite apparatus.

407. The apparatus of embodiment 403, wherein the anchor comprises a skirt section adapted to preclude proximal migration of the composite apparatus.

408. The apparatus of embodiment 403, wherein the anchor is at least partially covered by a biocompatible film.

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409. The apparatus of embodiment 403, wherein the anchor comprises a lip section, a groove section and a skirt section.

410. The apparatus of embodiment 409, wherein the replacement valve comprises a valve and an expandable frame.

411. The apparatus of embodiment 410, wherein the expandable frame of the replacement valve is adapted to engage the groove section of the anchor to form the composite apparatus.

412. The apparatus of embodiment 403, wherein the replacement valve comprises a valve chosen from the group consisting of mechanical valves, biologic valves, and combinations thereof.

413. The apparatus of embodiment 412, wherein the replacement valve further comprises an expandable frame coupled to the valve.

414. The apparatus of embodiment 413, wherein the expandable frame is adapted to couple the replacement valve to the anchor to form the composite apparatus.

415. The apparatus of embodiment 403, wherein the apparatus is fabricated from a material chosen from the group consisting of stainless steel, spring steel, shape-memory polymers, shape-memory alloys, nickel-titanium alloys, and combinations thereof.

416. The apparatus of embodiment 403, wherein both the anchor and the replacement valve have collapsed delivery configurations and expanded deployed configurations.

417. The apparatus of embodiment 416, wherein the anchor and the replacement valve are adapted for expansion from the delivery to the deployed configurations via a mechanism chosen from the group consisting of balloon-expansion, self-expansion, and combinations thereof.

418. The apparatus of embodiment 416 further comprising a delivery system for endovascularly advancing the anchor and the replacement valve to a vicinity of the patient's valve while the anchor and the replacement valve are disposed in the collapsed delivery configuration.

419. The apparatus of embodiment 418, wherein the delivery system comprises a single catheter.

420. The apparatus of embodiment 418, wherein the delivery system comprises multiple catheters.

421. The apparatus of embodiment 418, wherein the delivery system is adapted to facilitate expansion of the anchor and the replacement valve to the deployed configuration and to facilitate coupling of the anchor to the replacement valve to form the composite apparatus.

422. The apparatus of embodiment 403, wherein the apparatus comprises at least one radiopaque feature adapted to facilitate deployment and in vivo coupling of the anchor to the replacement valve under fluoroscopic guidance.

423. The apparatus of embodiment 418, wherein the delivery system comprises at least one radiopaque feature adapted to facilitate deployment and in vivo coupling of the anchor to the replacement valve under fluoroscopic guidance.

424. The apparatus of embodiment 403, wherein the apparatus is adapted to facilitate dynamic repositioning of the apparatus during delivery.

425. The apparatus of embodiment 403, wherein engagement of the native leaflets is adapted to facilitate positive registration of the anchor relative to the patient's heart valve and the patient's coronary ostia.

426. The apparatus of embodiment 403, wherein the composite apparatus is adapted to reduce paravalvular regurgitation.

427. The apparatus of embodiment 403, wherein the apparatus is configured for percutaneous delivery through the patient's aorta without necessitating a transseptal puncture.

428. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a first portion of an alignment/locking mechanism; and

a replacement valve having a second portion of the alignment/locking mechanism, wherein the anchor and the valve are adapted for in vivo expansion and coupling to one another to form composite apparatus that endovascularly replaces the patient's heart valve.

429. The apparatus of embodiment 428, wherein the first and second portions of the alignment/locking mechanism are configured to lockingly form the composite apparatus.

430. The apparatus of embodiment 428, wherein the anchor comprises a lip section, a groove section and a skirt section.

431. The apparatus of embodiment 430, wherein the lip section is adapted to engage valve leaflets of the heart valve and preclude distal migration of the composite apparatus.

432. The apparatus of embodiment 430, wherein the groove section is adapted to couple the anchor to the replacement valve to form the composite apparatus.

433. The apparatus of embodiment 430, wherein the skirt section is adapted to preclude proximal migration of the composite apparatus.

434. The apparatus of embodiment 428, wherein the anchor is at least partially covered by a biocompatible film.

435. The apparatus of embodiment 428, wherein the replacement valve comprises a valve chosen from the group consisting of mechanical valves, biologic valves, and combinations thereof.

436. The apparatus of embodiment 428, wherein the replacement valve further comprises an expandable frame coupled to the valve.

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437. The apparatus of embodiment 428, wherein both the anchor and the replacement valve have collapsed delivery configurations and expanded deployed configurations.

438. The apparatus of embodiment 437, wherein the anchor and the replacement valve are adapted for expansion from the delivery to the deployed configurations via a mechanism chosen from the group consisting of balloon-expansion, self-expansion, and combinations thereof.

439. The apparatus of embodiment 437 further comprising a delivery system for endovascularly advancing the anchor and the replacement valve to a vicinity of the patient's valve while the anchor and the replacement valve are disposed in the collapsed delivery configuration.

440. The apparatus of embodiment 439, wherein the apparatus comprises at least one radiopaque feature adapted to facilitate deployment and in vivo coupling of the anchor to the replacement valve under fluoroscopic guidance.

441. The apparatus of embodiment 428, wherein the apparatus is at least partially fabricated from a material chosen from the group consisting of stainless steel, spring steel, shape-memory polymers, shape-memory alloys, nickel-titanium alloys, and combinations thereof.

Claims

1. Apparatus for endovascularly replacing a patient's heart valve comprising:

   a replacement valve;
   an anchor; and
   a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor,
   wherein the anchor actuation elements comprise a plurality of proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

2. The apparatus of claim 1, wherein the anchor actuation elements comprise a plurality of distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

3. The apparatus of claim 1 or 2, wherein the anchor actuation elements each comprise a first member attached to the anchor and a second member releasably attached to the first member.

4. The apparatus of one of the preceding claims, wherein the first members each comprise a post adapted to support the valve within the anchor.

5. The apparatus of claim 4, wherein at least one post comprises valve attachment structure, the replacement valve being attached to the post via the valve attachment structure.

6. The apparatus of one of claims 3 to 5, wherein the first members each comprise a lock element adapted to lock the anchor in a deployed shape.

7. The apparatus of claim 6, wherein the lock element is further adapted to engage an anchor element to lock the anchor in the deployed shape.

8. The apparatus of claims 6 or 7, wherein the apparatus further comprises anchor lock elements attached to the anchor and adapted to mate with the lock element of each first member to lock the anchor in the deployed shape.

9. The apparatus of one of claims 6 to 8, further comprising a lock actuator adapted to apply a locking force to lock the anchor in the deployed shape.

10. The apparatus of one of claims 6 to 9, further comprising an unlocking actuator adapted to unlock the anchor.

11. The apparatus of claim 10, wherein the lock actuator comprises the unlocking actuator.

12. The apparatus of claim 11, wherein the unlocking actuator comprises a proximal pull actuator.

13. The apparatus of one of claims 6 to 12, further comprising a lock prevention mechanism.

14. The apparatus of one of the preceding claims, further comprising a releasable attachment mechanism adapted to releasably attach at least one anchor actuation element to the anchor.

15. The apparatus of claim 14, wherein the releasable attachment mechanism comprises a first shape on an anchor actuation element adapted to mate with a second shape on an anchor attachment element to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor.

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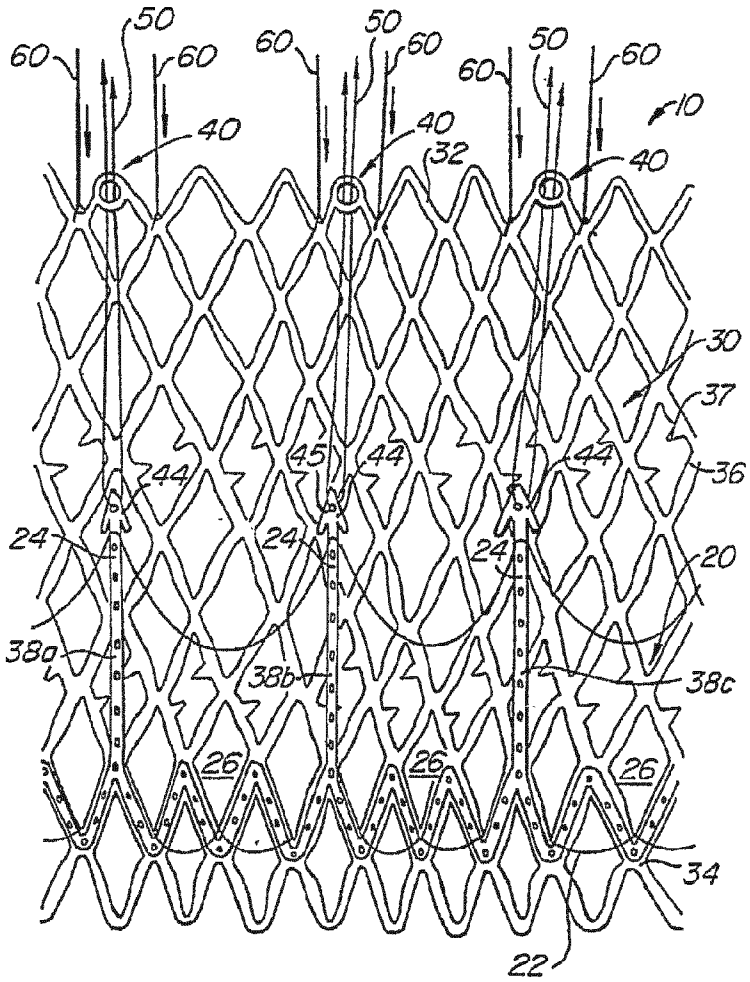


FIG. 1A

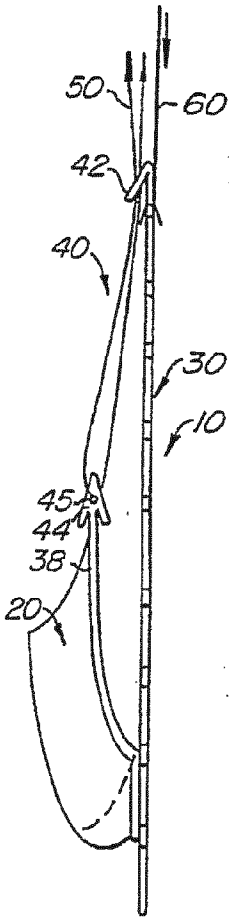


FIG. 2A

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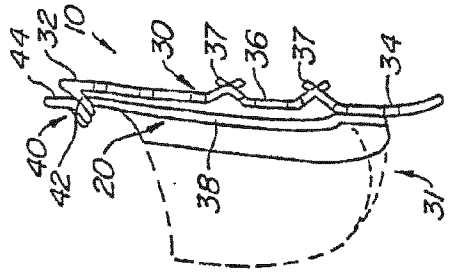


FIG. 2B

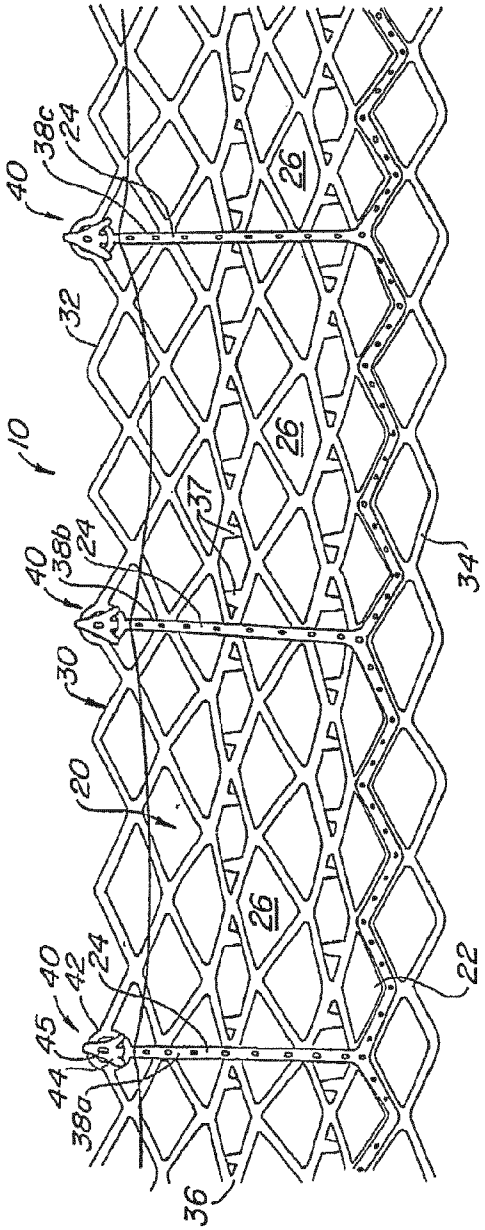


FIG. 1B

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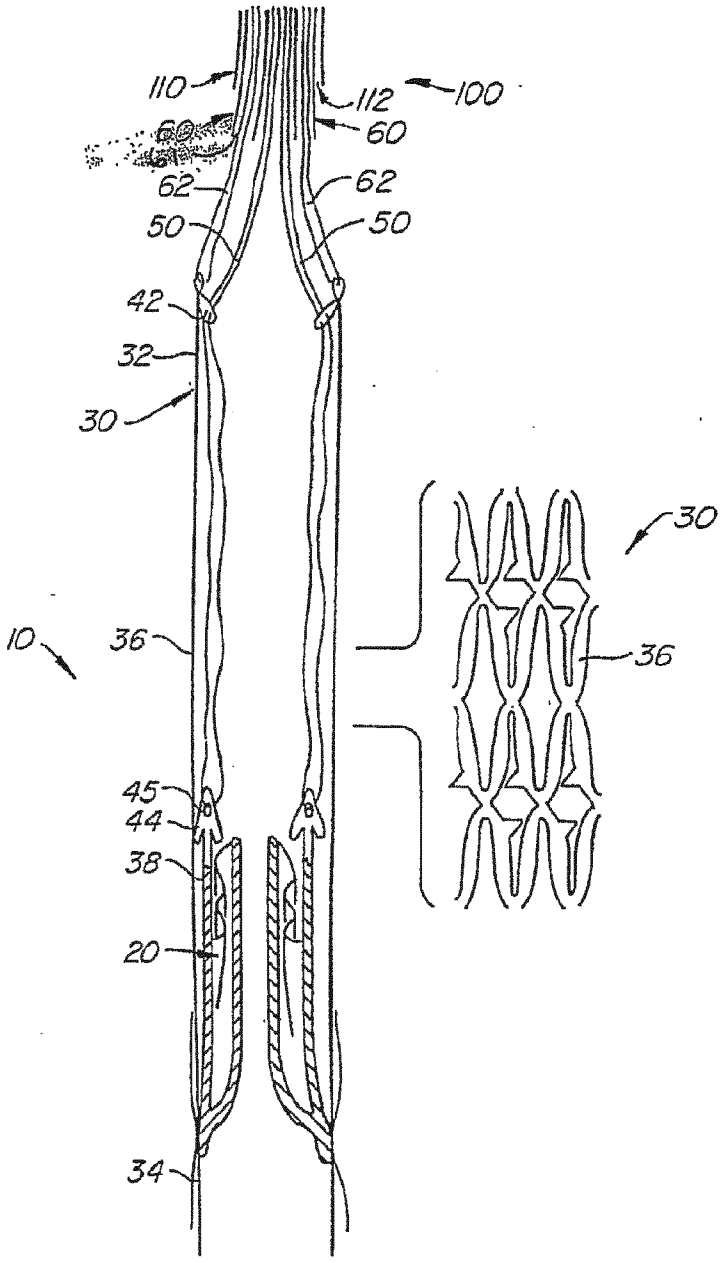


FIG. 3A

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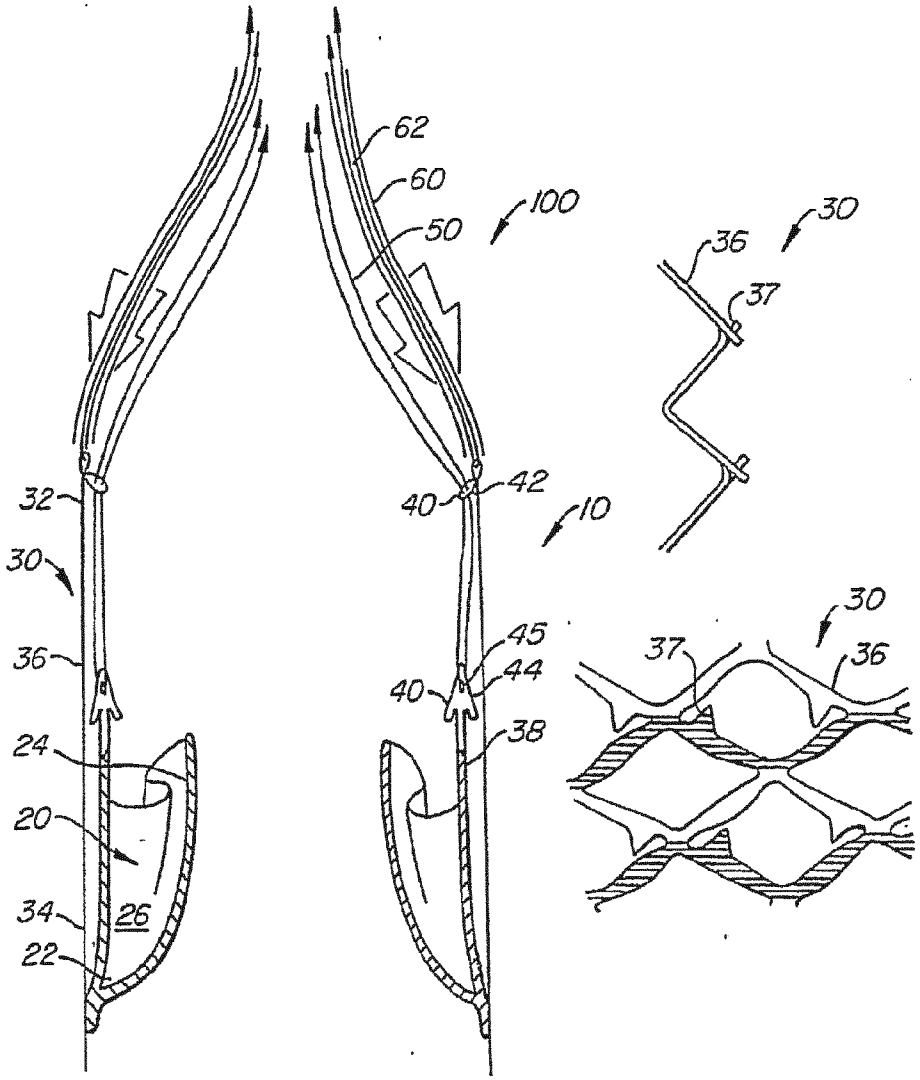


FIG. 3B

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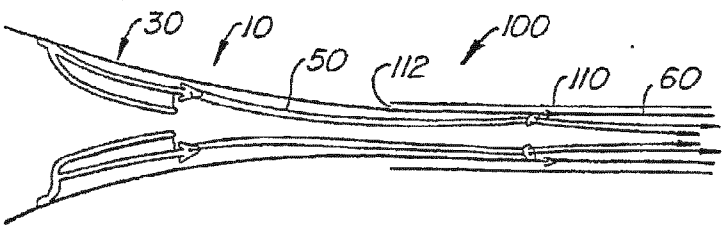


FIG. 4A

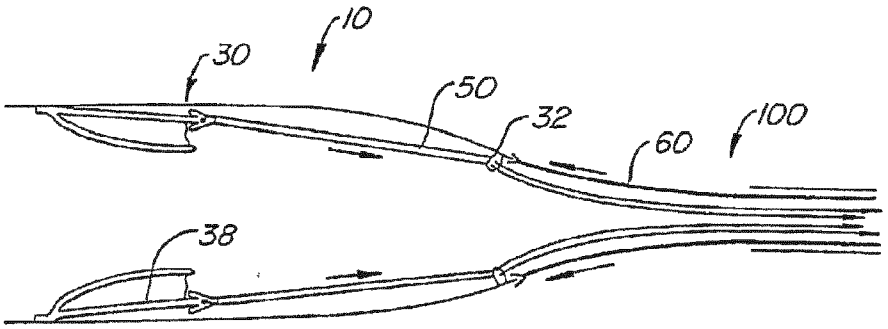


FIG. 4B

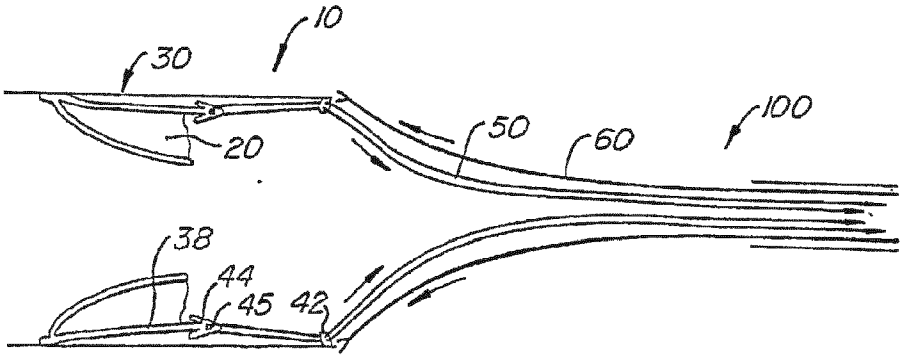


FIG. 4C

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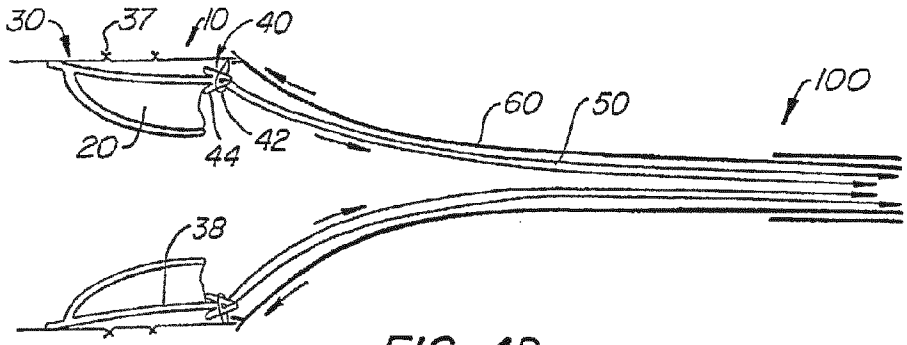


FIG. 4D

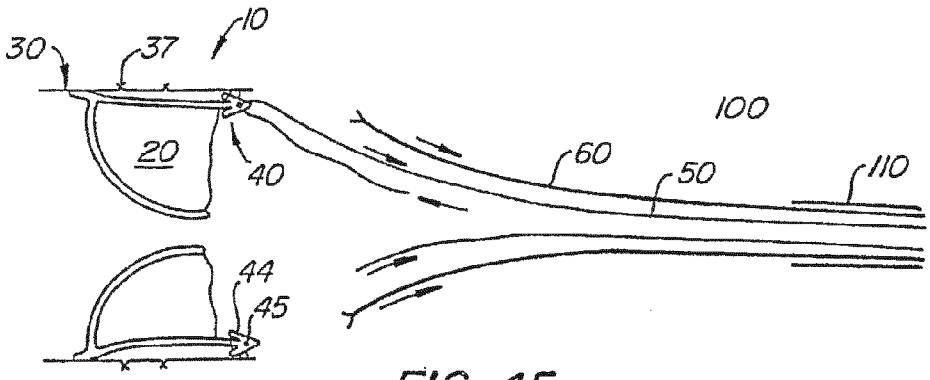


FIG. 4E

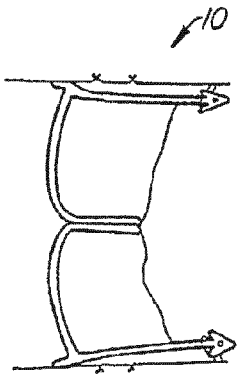


FIG. 4F

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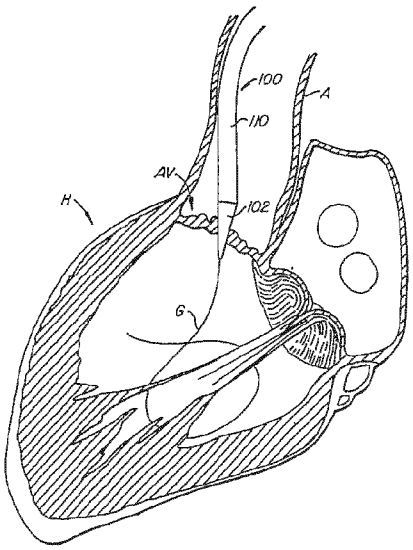


FIG. 5A

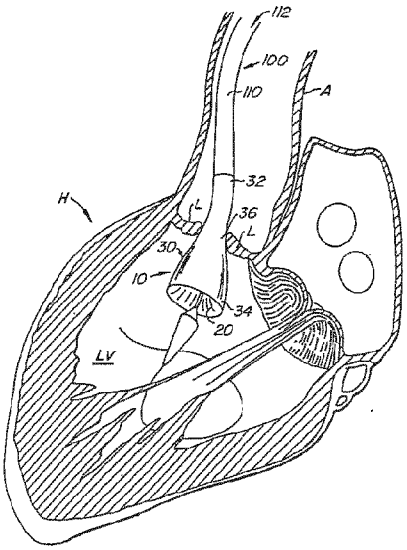


FIG. 5B

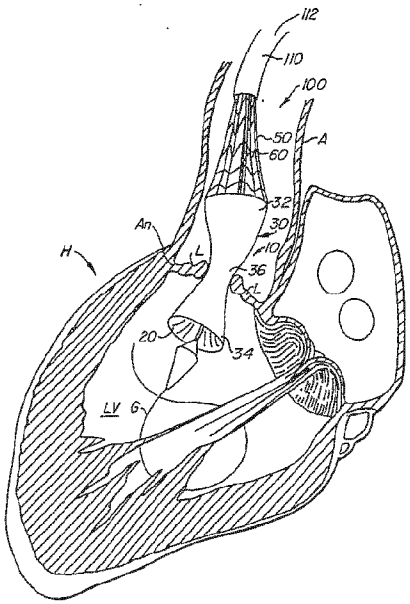


FIG. 5C

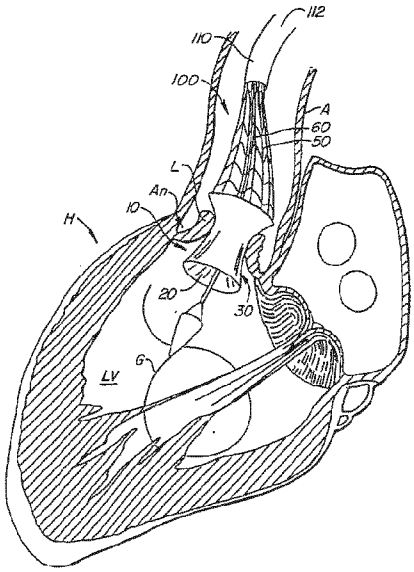


FIG. 5D

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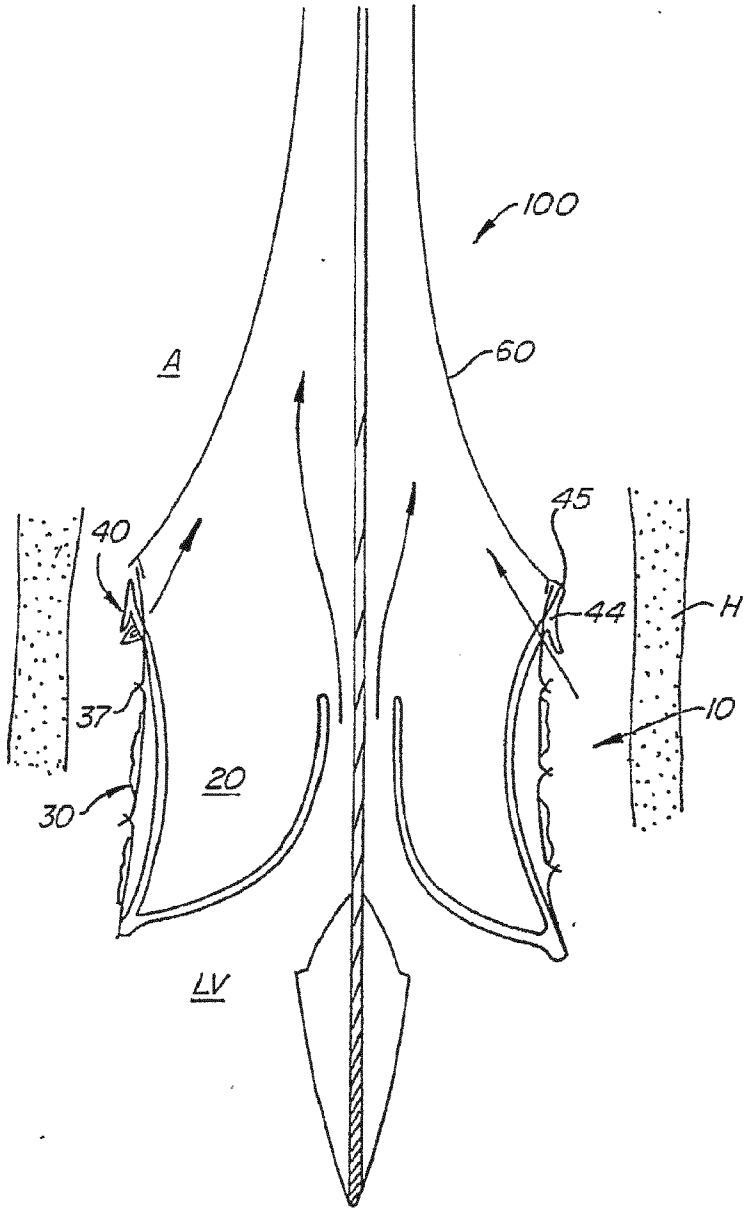


FIG. 5E

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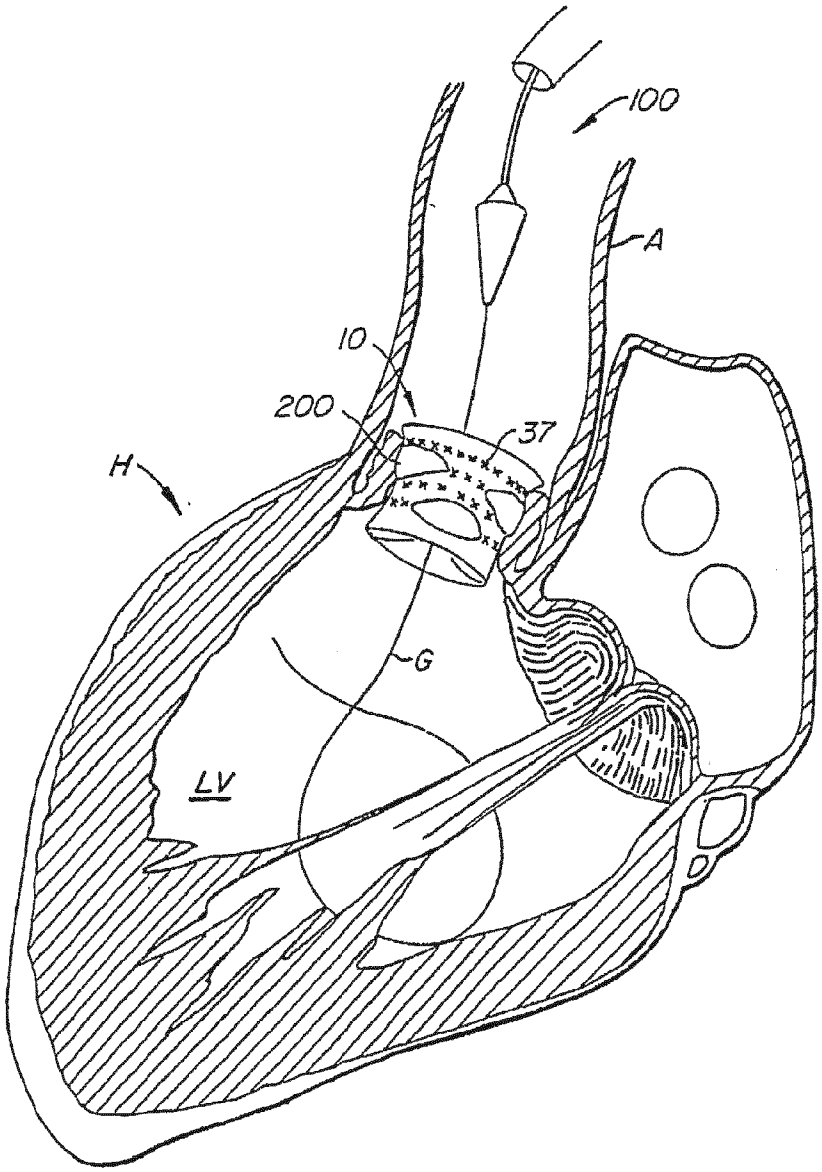


FIG. 5F

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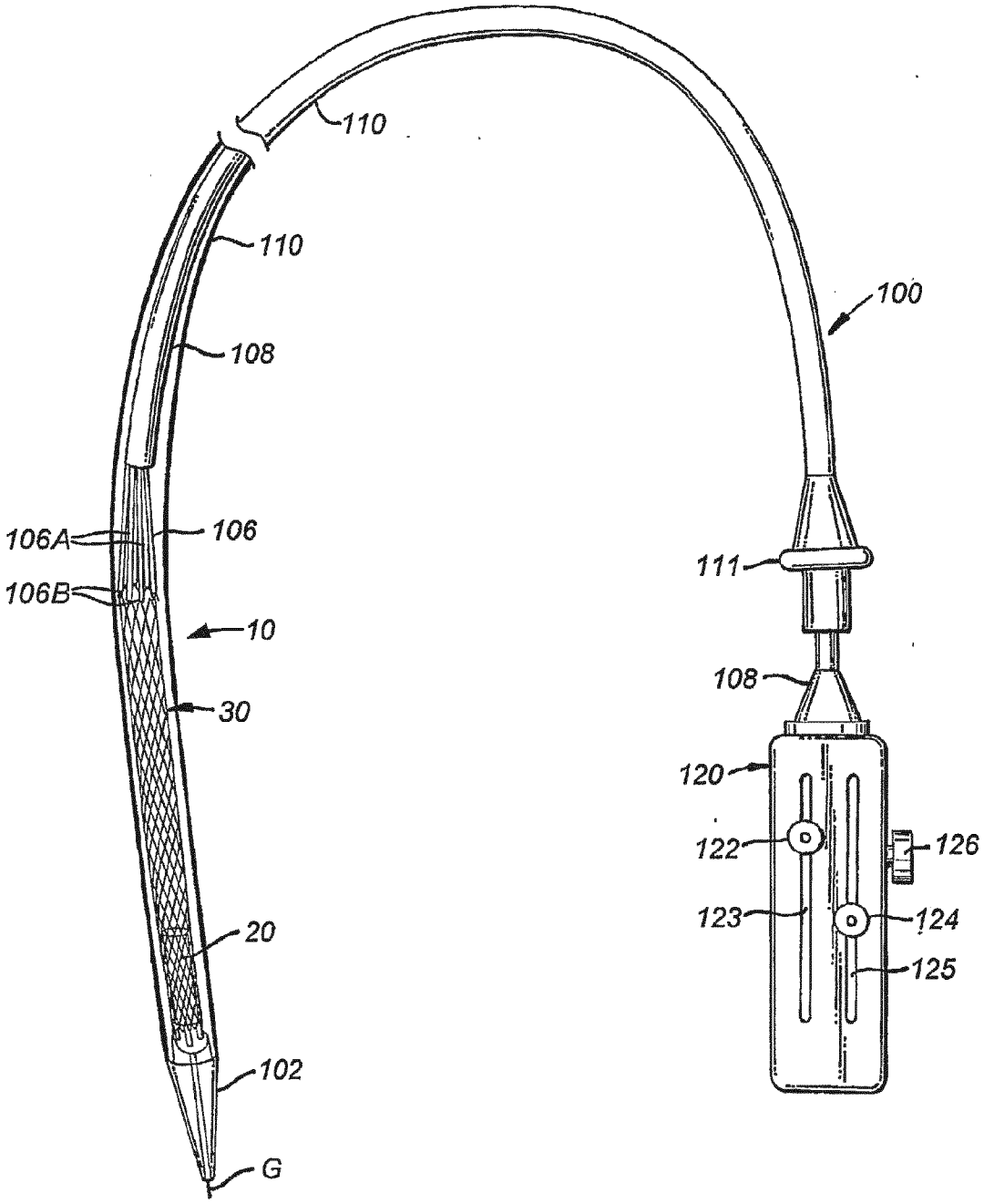


FIG. 5G

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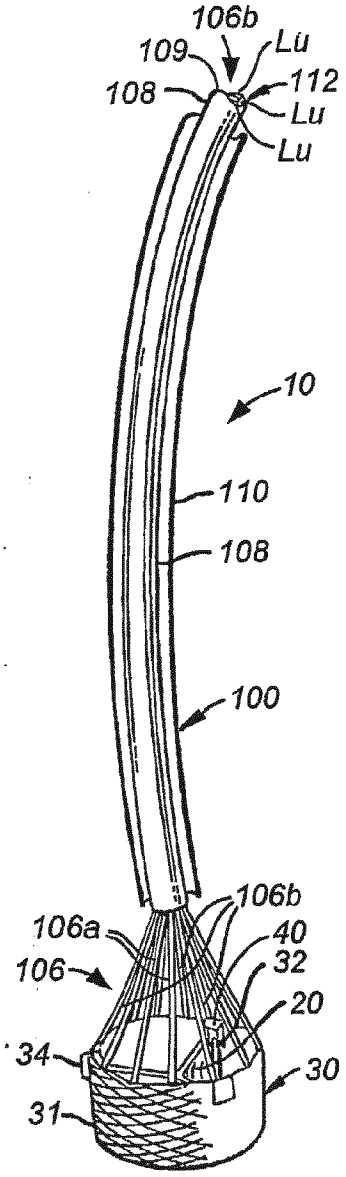


FIG. 5H

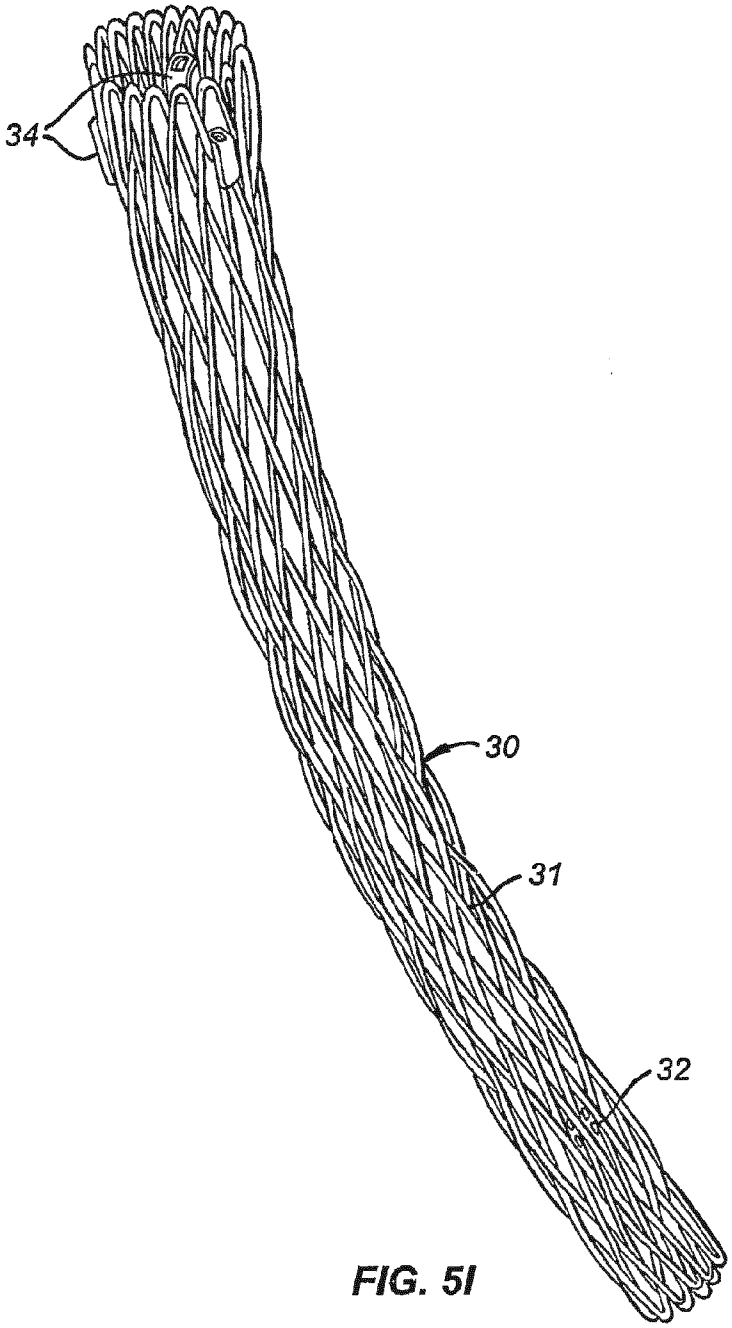


FIG. 5I

Aortic Innovations, LLC, Exhibit 2040
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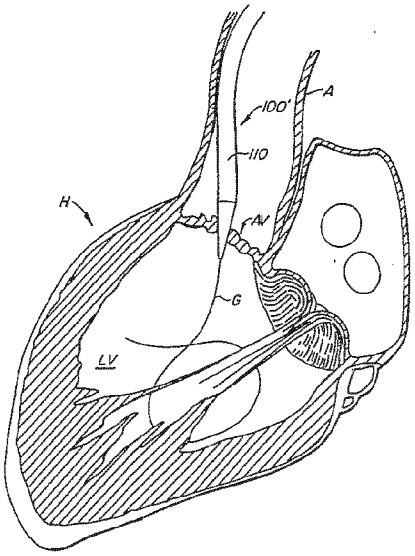


FIG. 6A

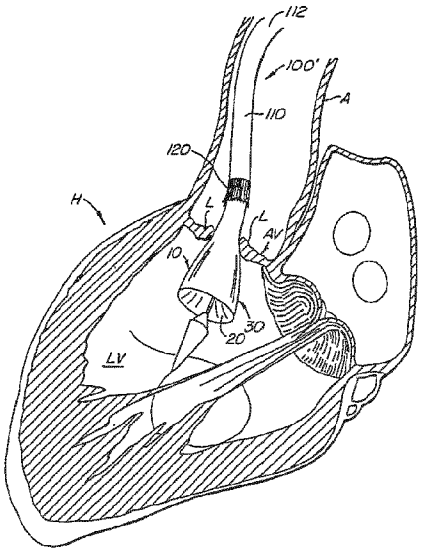


FIG. 6B

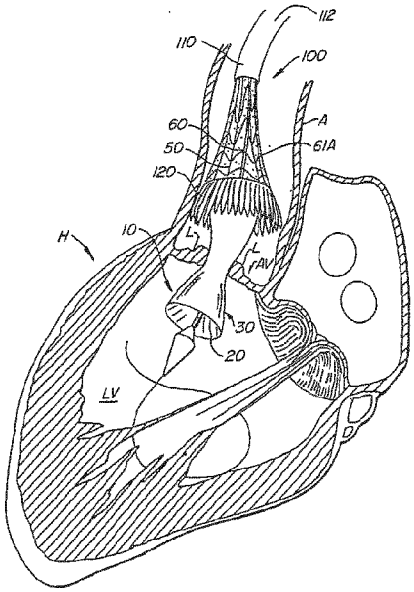


FIG. 6C

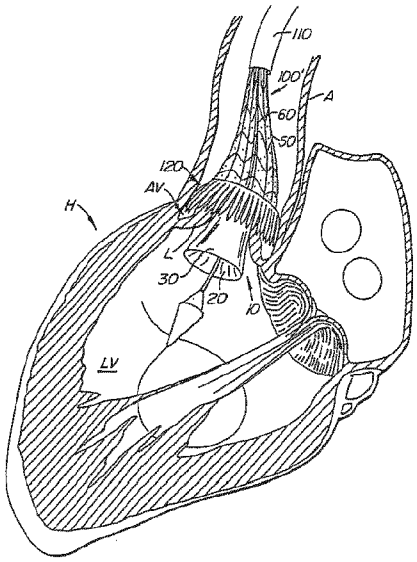


FIG. 6D

Aortic Innovations, LLC, Exhibit 2040
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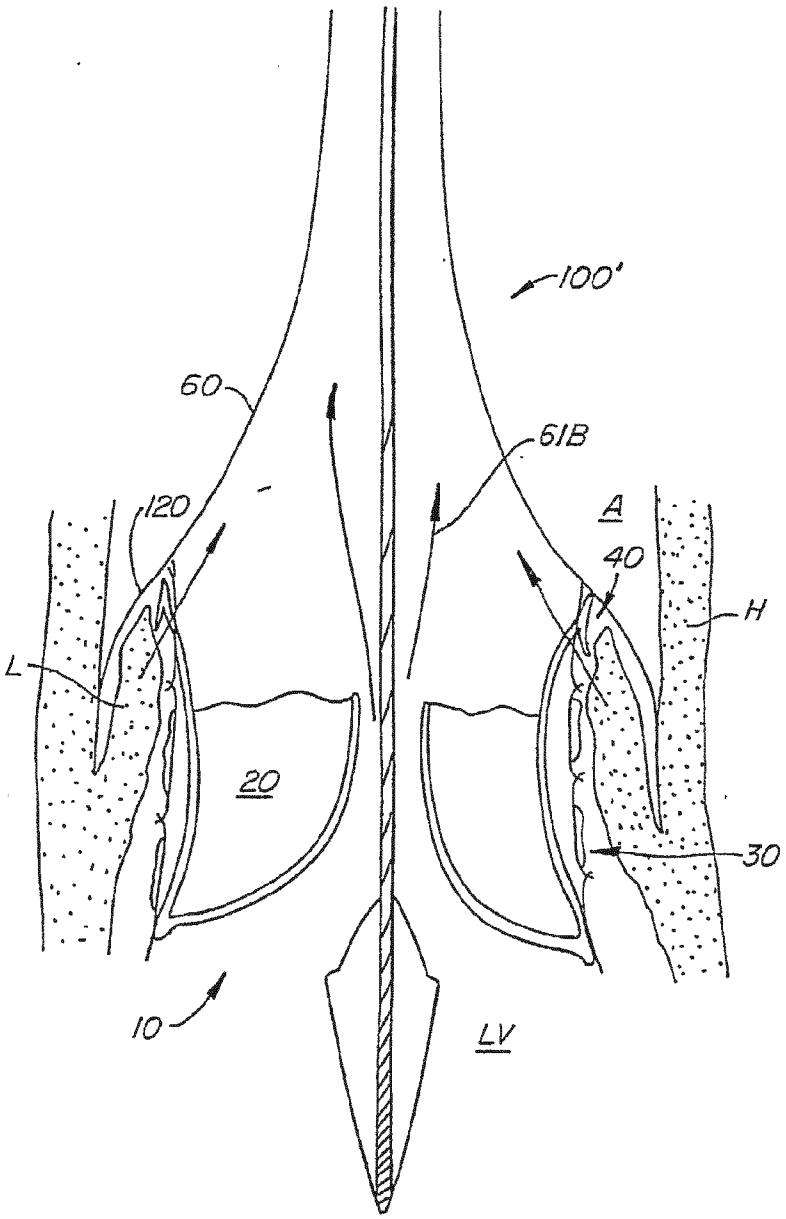


FIG. 6E

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

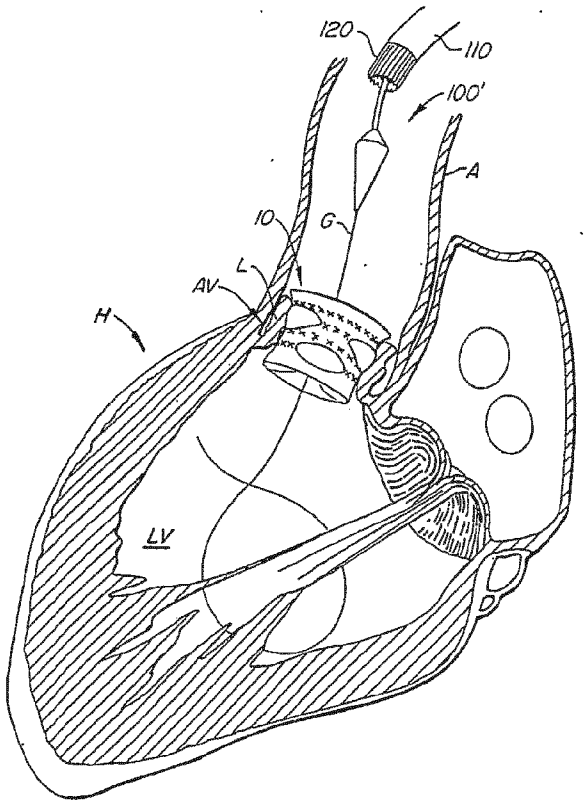


FIG. 6F

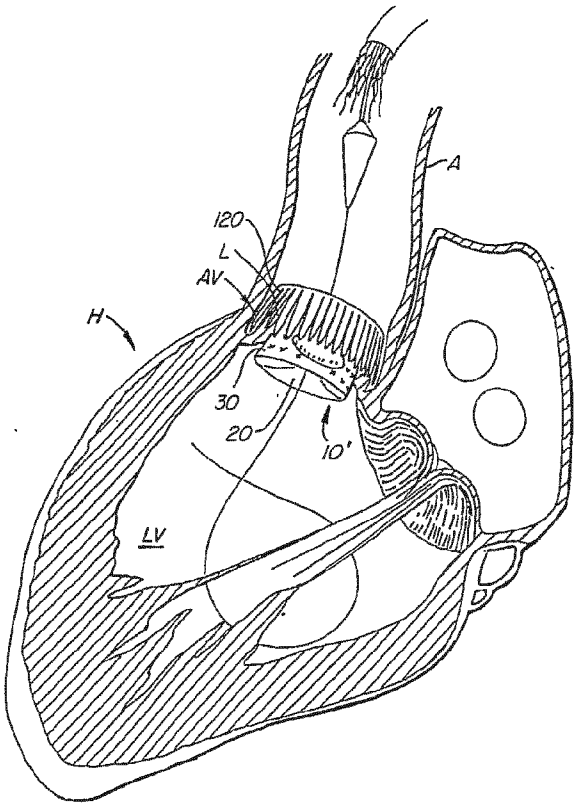


FIG. 7

Aortic Innovations, LLC, Exhibit 2040
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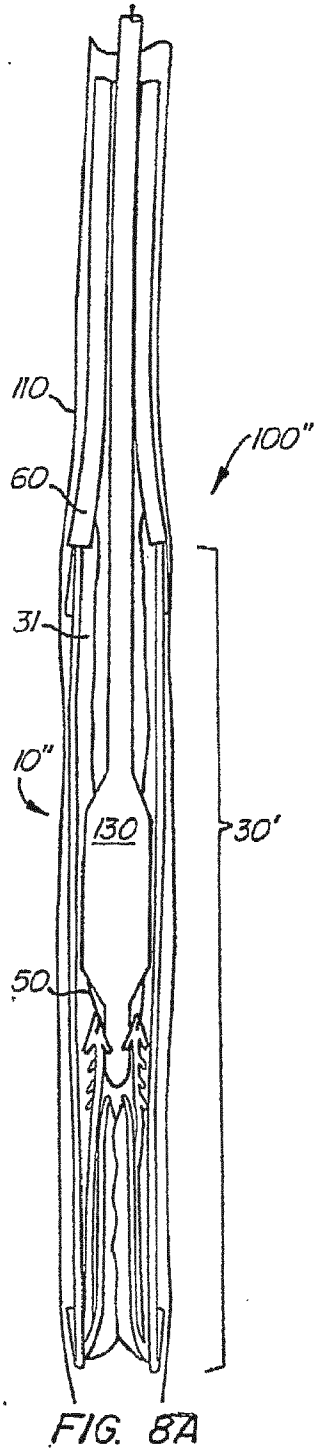


FIG. 8A

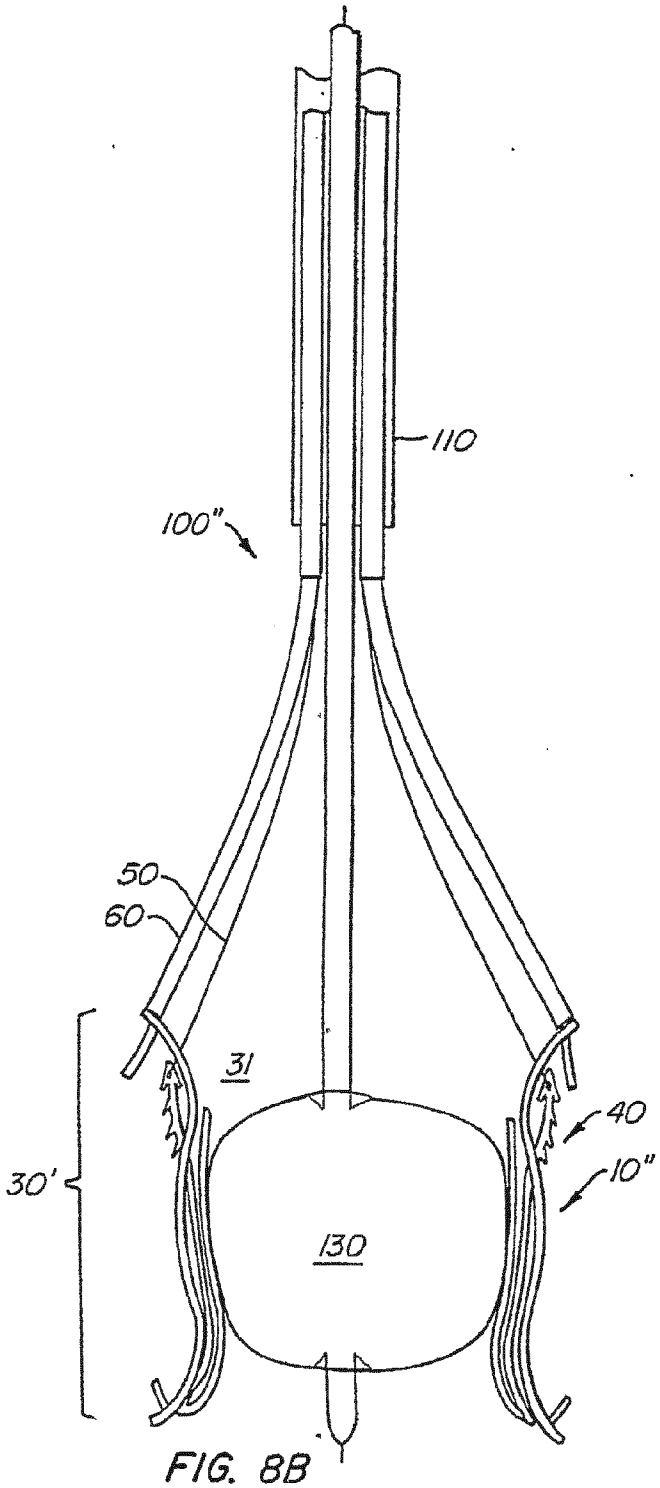


FIG. 8B

Aortic Innovations, LLC, Exhibit 2040
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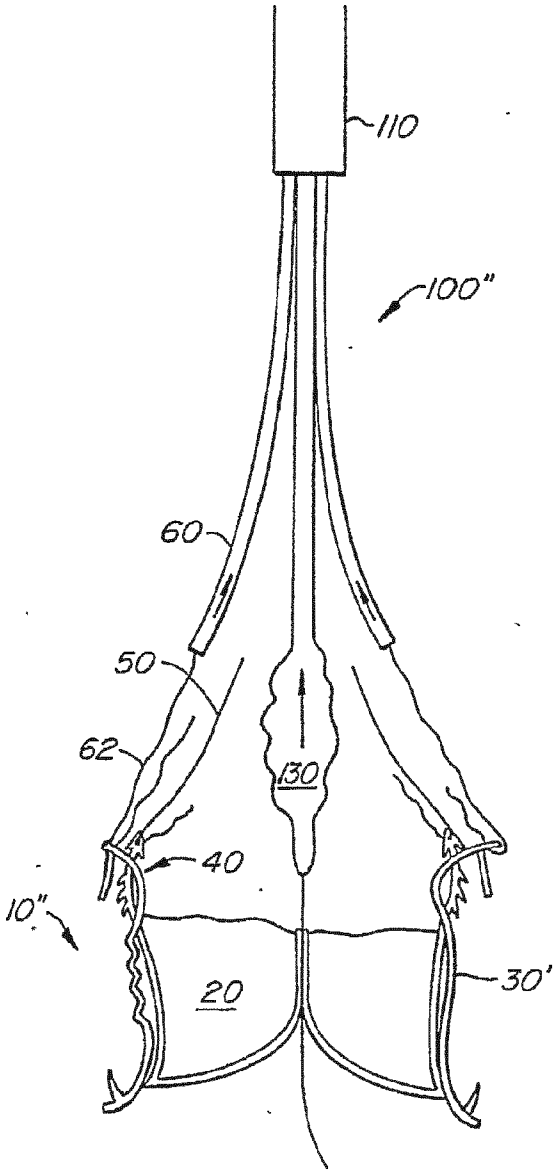


FIG. 8C

Aortic Innovations, LLC, Exhibit 2040
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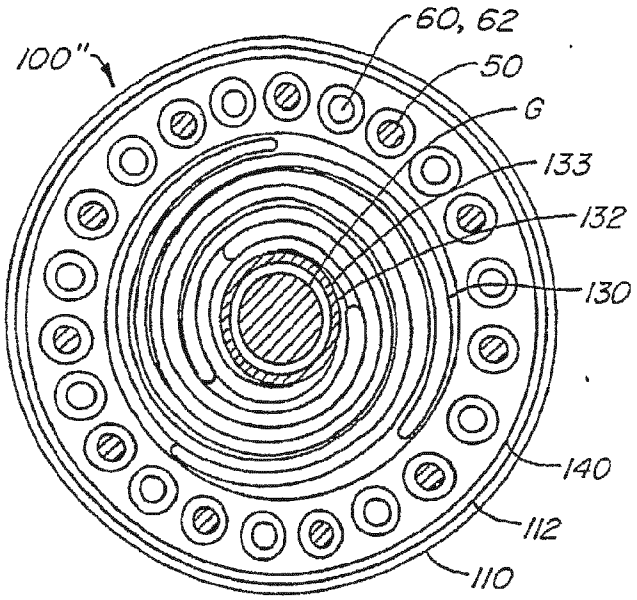


FIG. 10

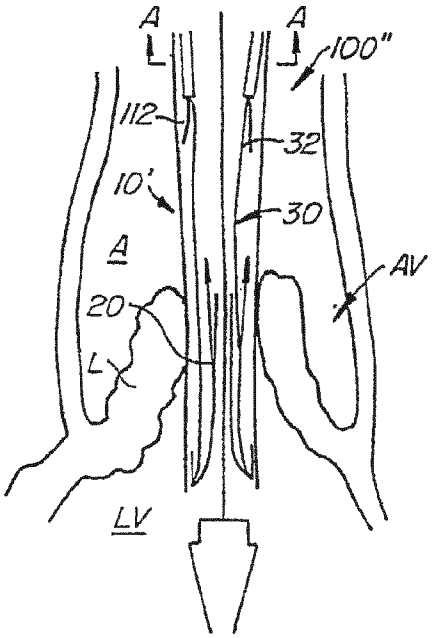


FIG. 9A

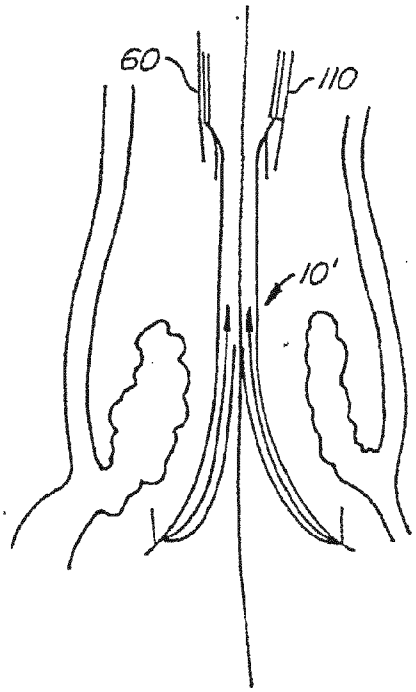


FIG. 9B

Aortic Innovations, LLC, Exhibit 2040
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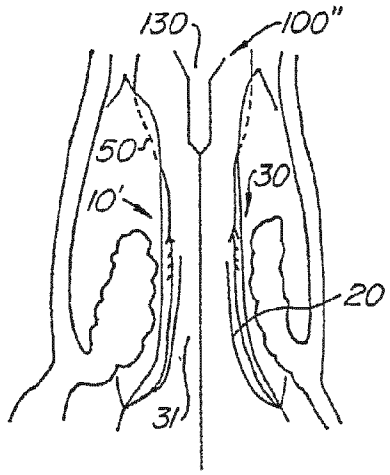


FIG. 9C

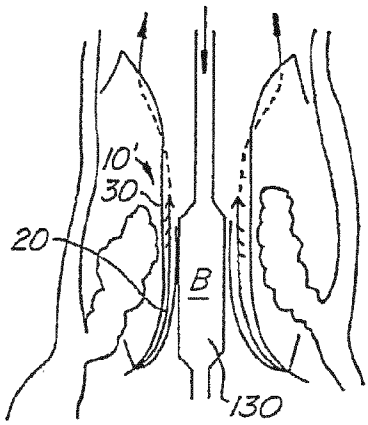


FIG. 9D

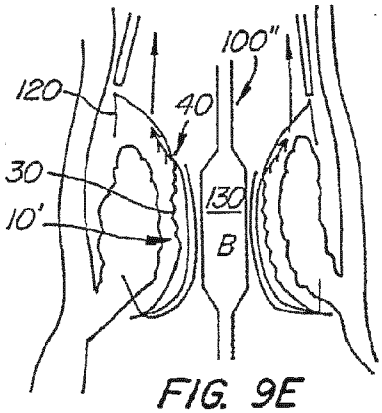


FIG. 9E

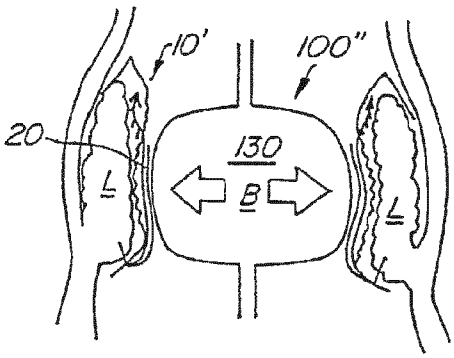


FIG. 9F

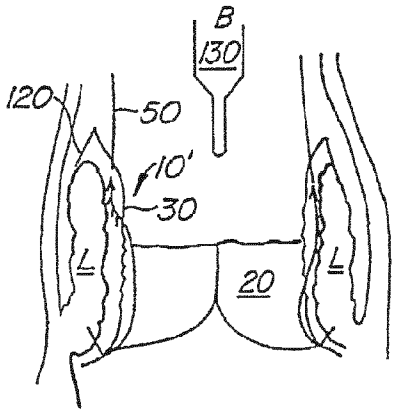


FIG. 9G

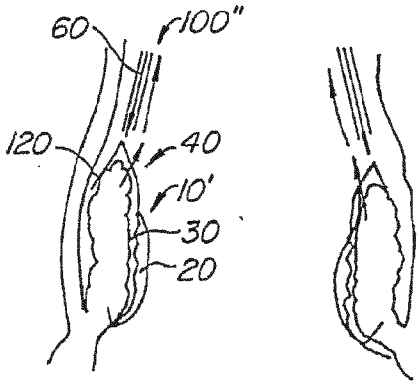


FIG. 9H

Aortic Innovations, LLC, Exhibit 2040
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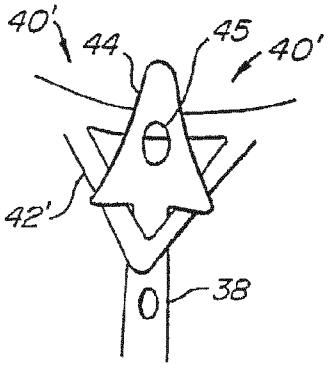


FIG. 11A

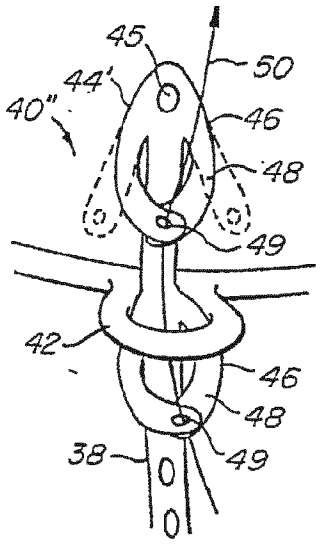


FIG. 11B

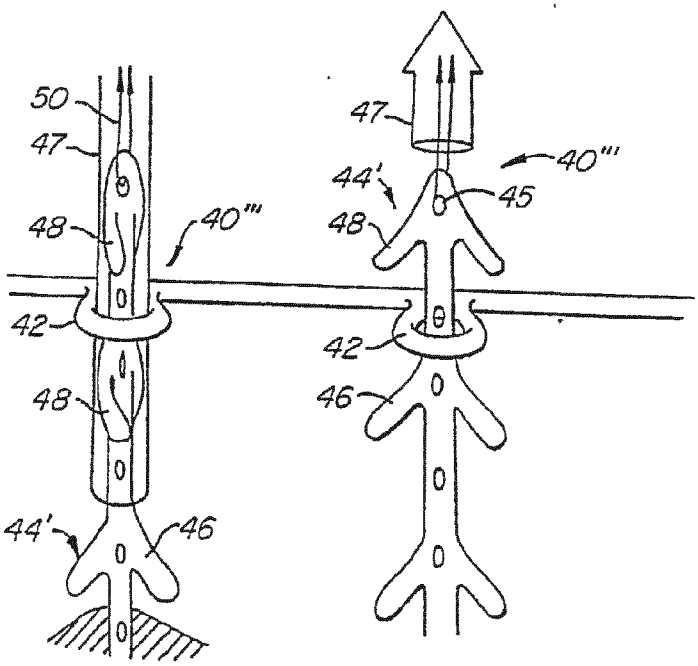


FIG. 11C

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

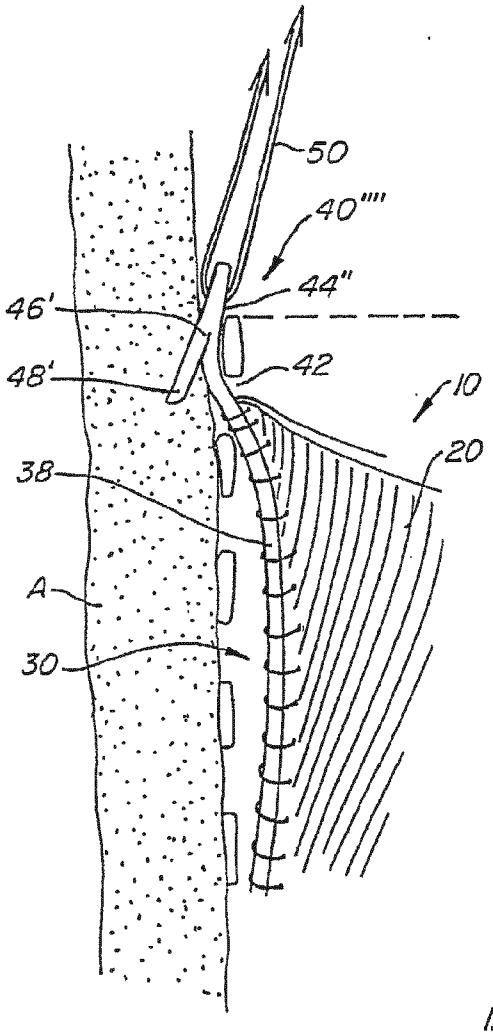


FIG. 12C

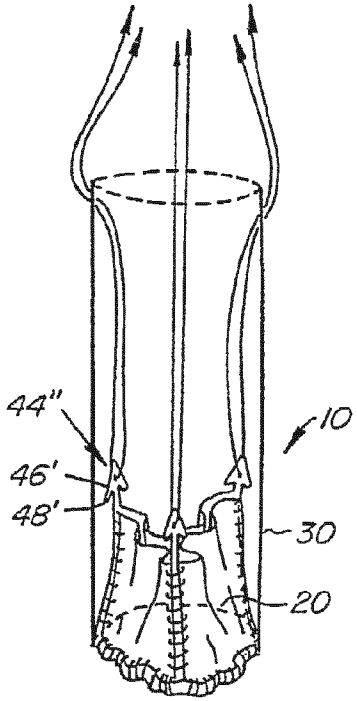


FIG. 12A

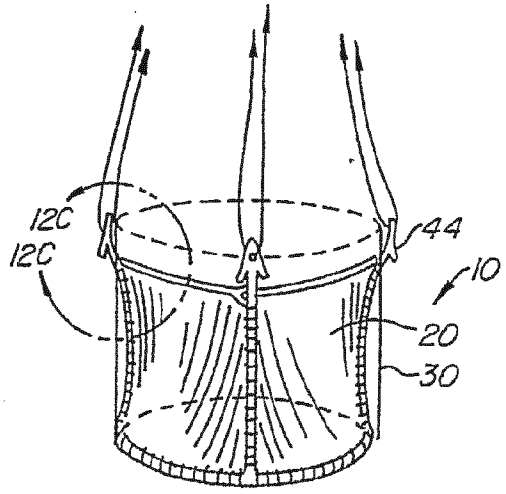


FIG. 12B

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

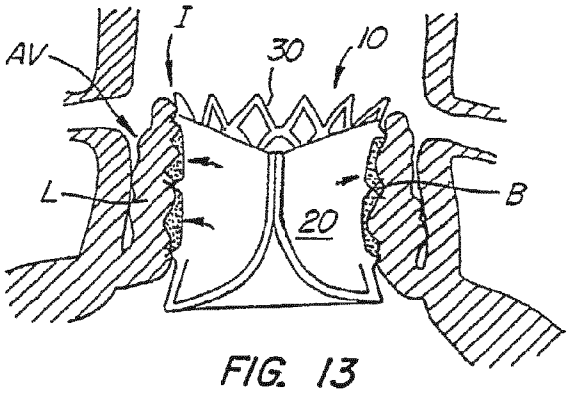


FIG. 13

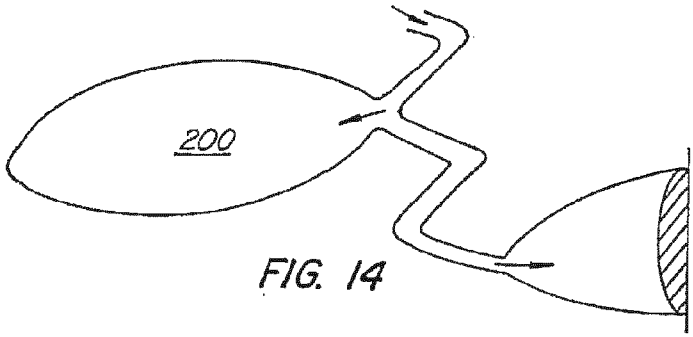


FIG. 14

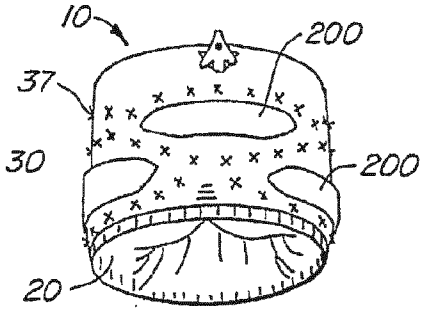


FIG. 15A

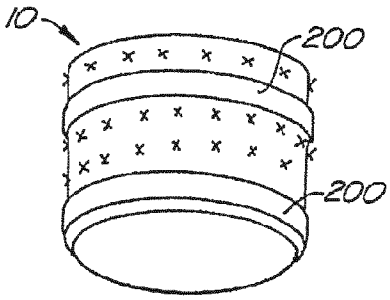


FIG. 15B

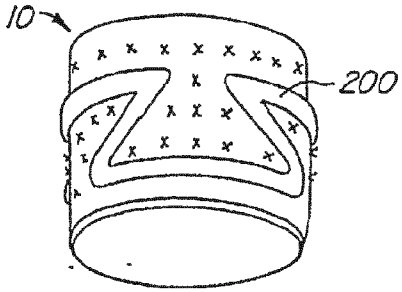


FIG. 15C

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

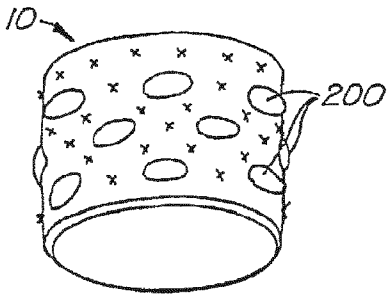


FIG. 15D

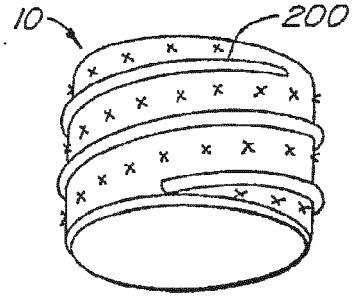


FIG. 15E

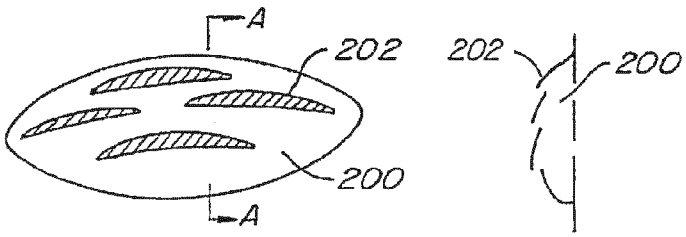


FIG. 16A

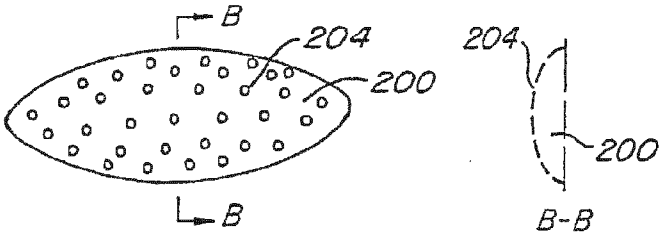


FIG. 16B

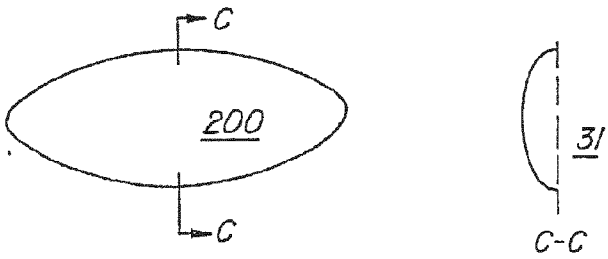


FIG. 16C

Aortic Innovations, LLC, Exhibit 2040
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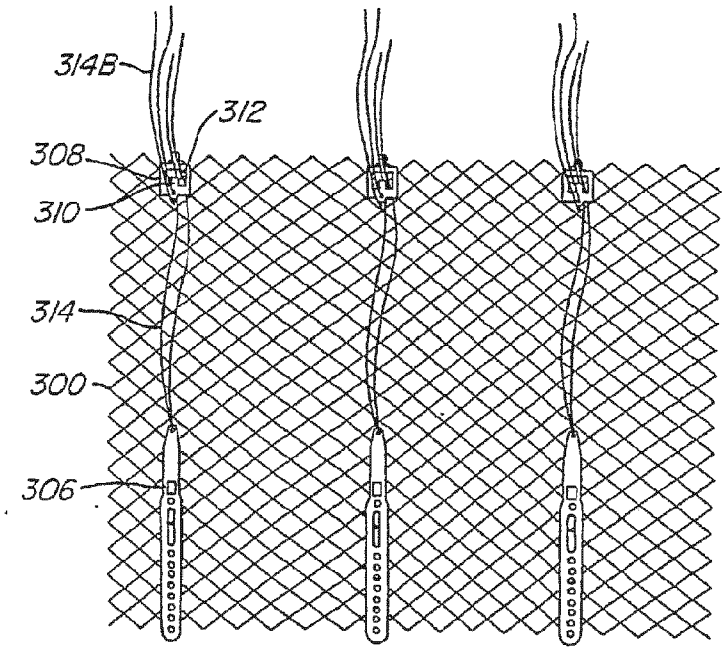


FIG. 17A

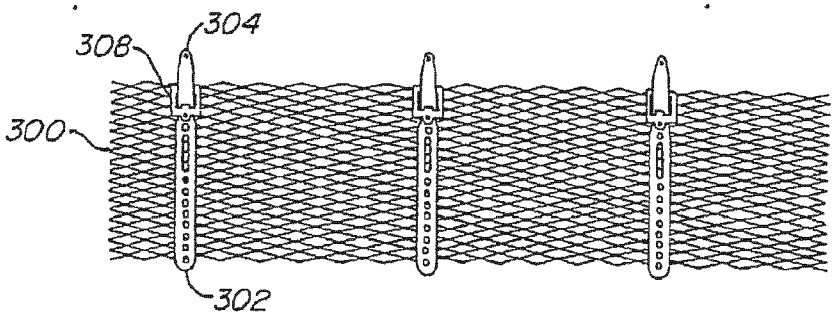


FIG. 18A

Aortic Innovations, LLC, Exhibit 2040
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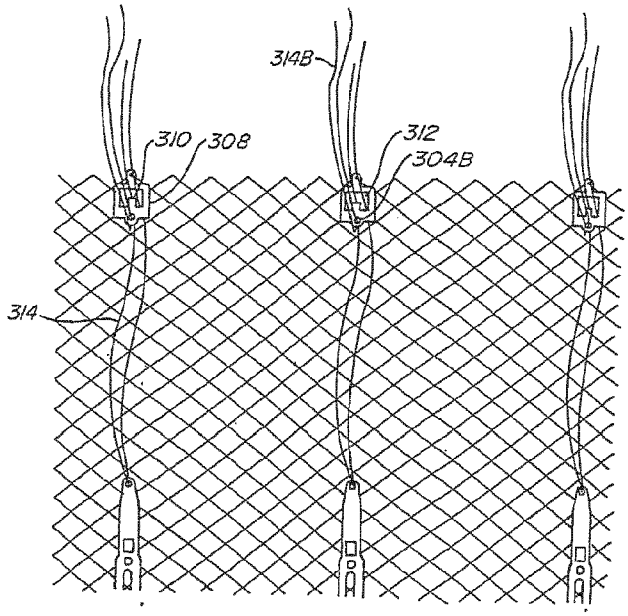


FIG. 17B

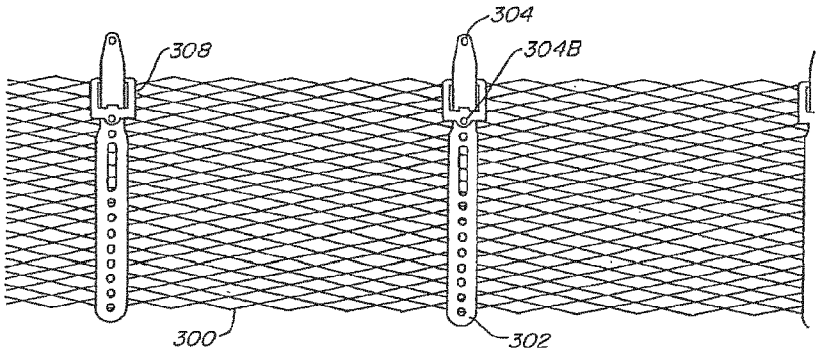


FIG. 18B

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

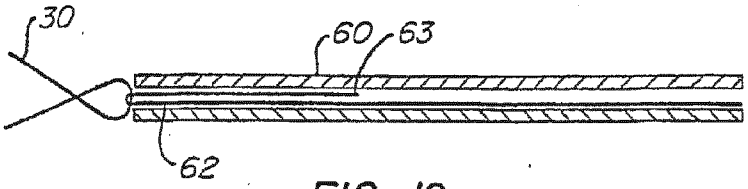


FIG. 19

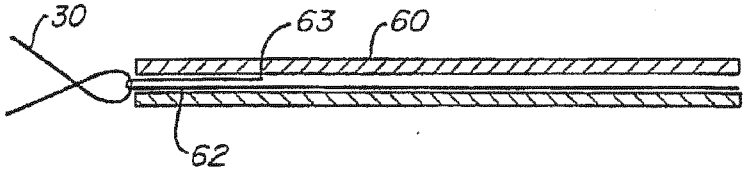


FIG. 20

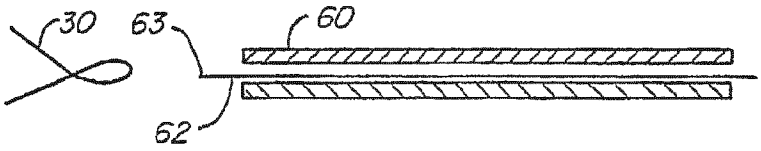


FIG. 21

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

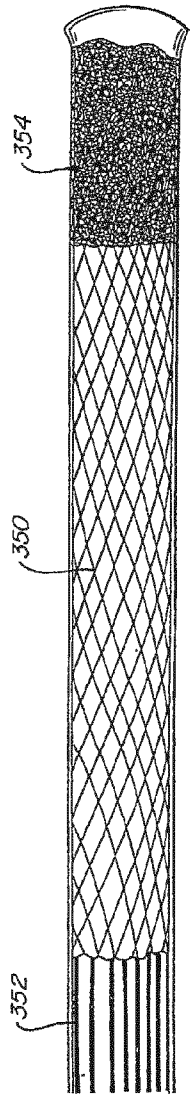


FIG. 22

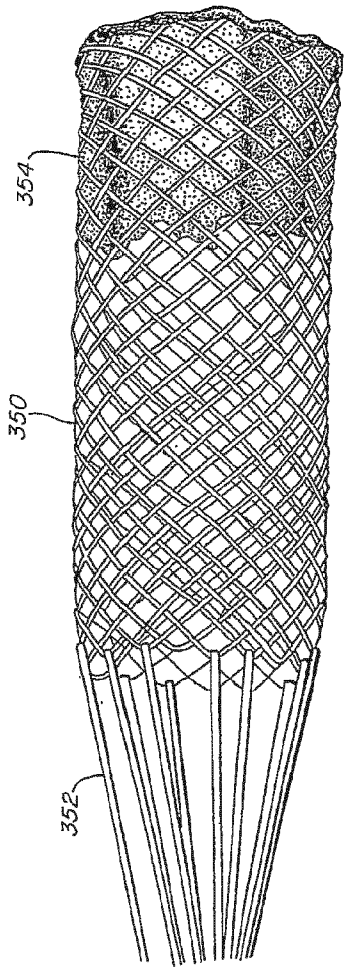


FIG. 23

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

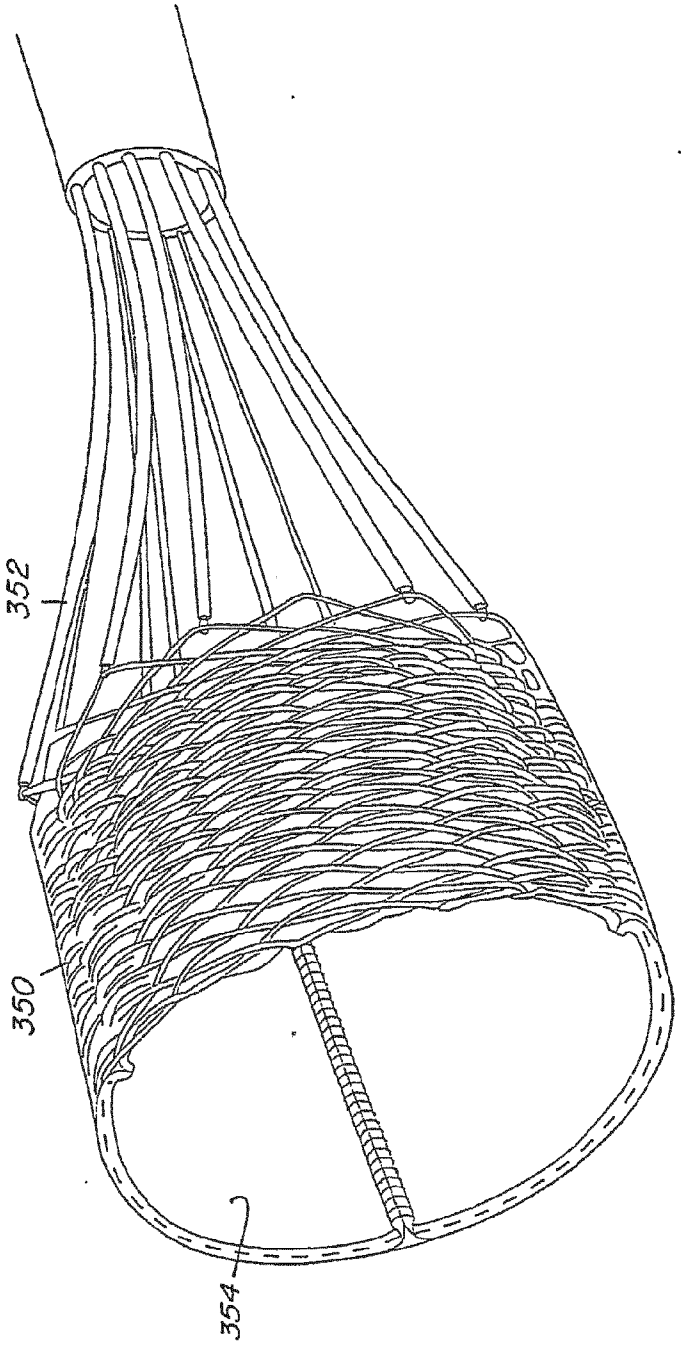


FIG. 24

Aortic Innovations, LLC, Exhibit 2040
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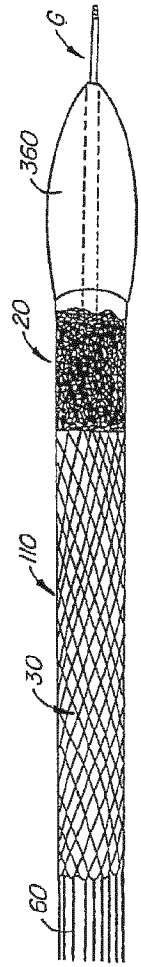


FIG. 25

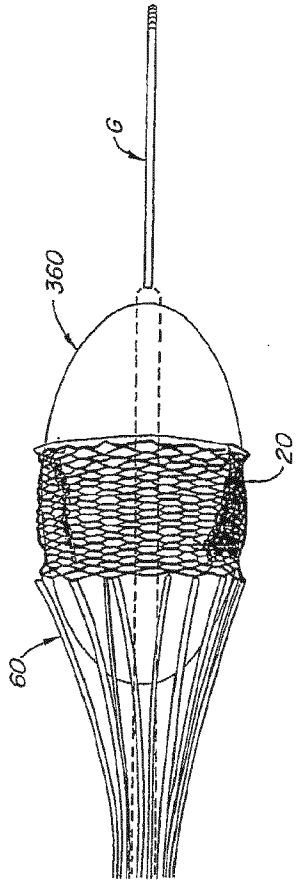


FIG. 26

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

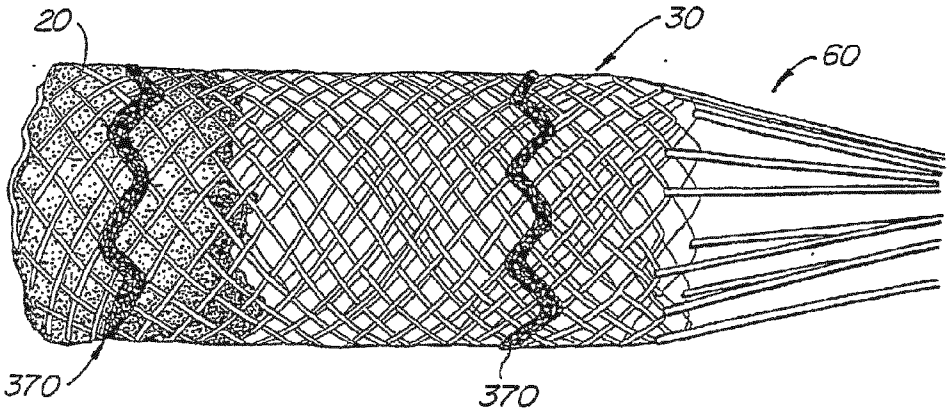


FIG. 27

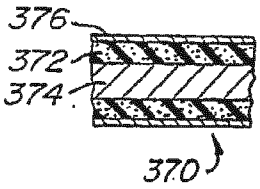


FIG. 28

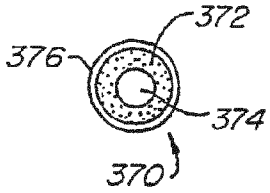


FIG. 29

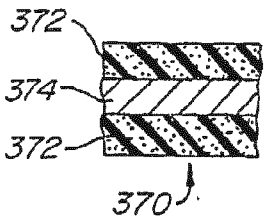


FIG. 30

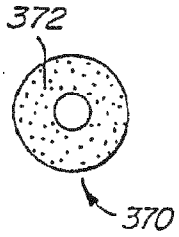


FIG. 31

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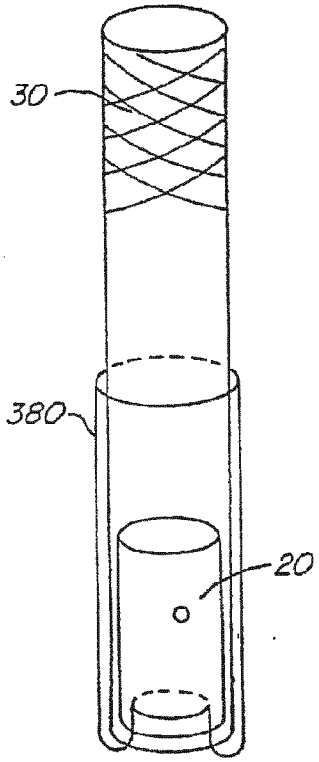


FIG. 32

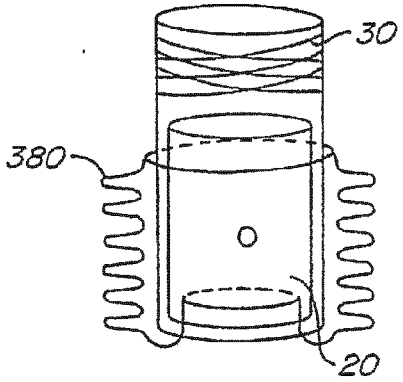


FIG. 33

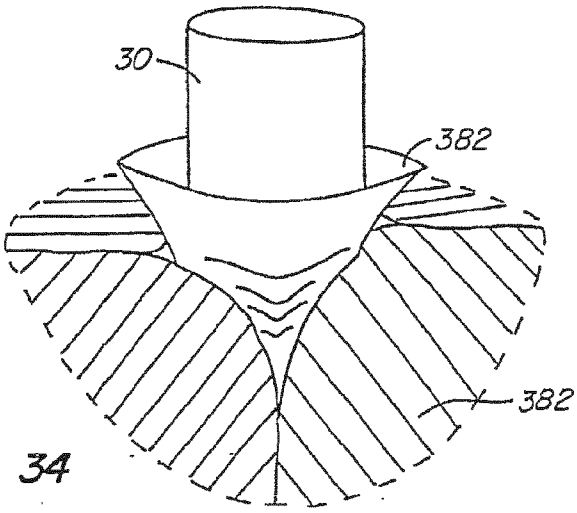


FIG. 34

Aortic Innovations, LLC, Exhibit 2040
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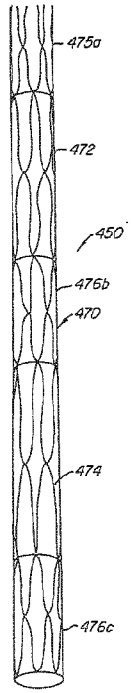


FIG. 35A

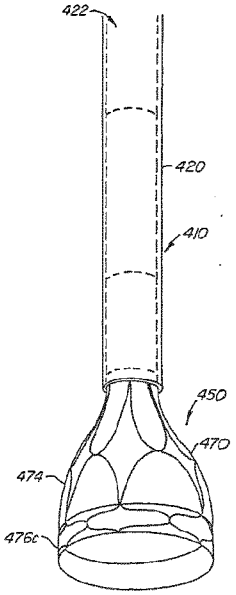


FIG. 35B

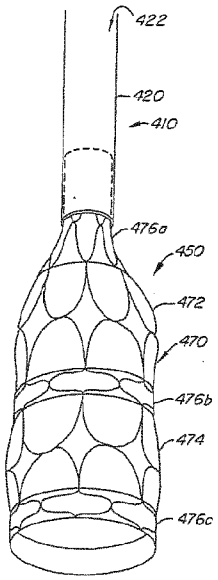


FIG. 35C

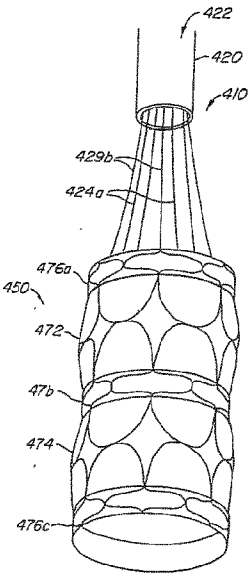


FIG. 35D

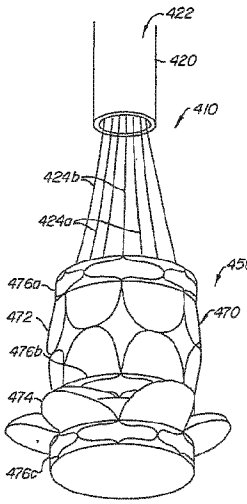


FIG. 35E

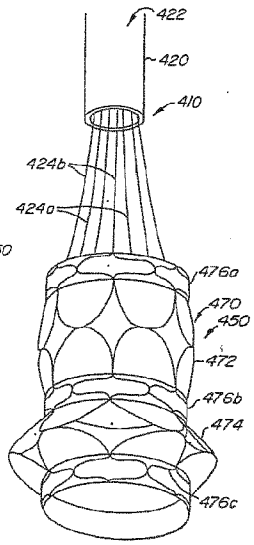


FIG. 35F

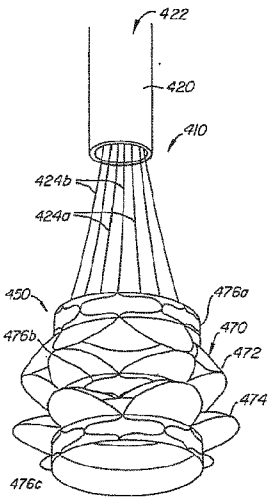


FIG. 35G

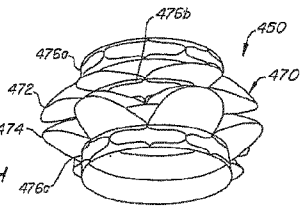


FIG. 35H

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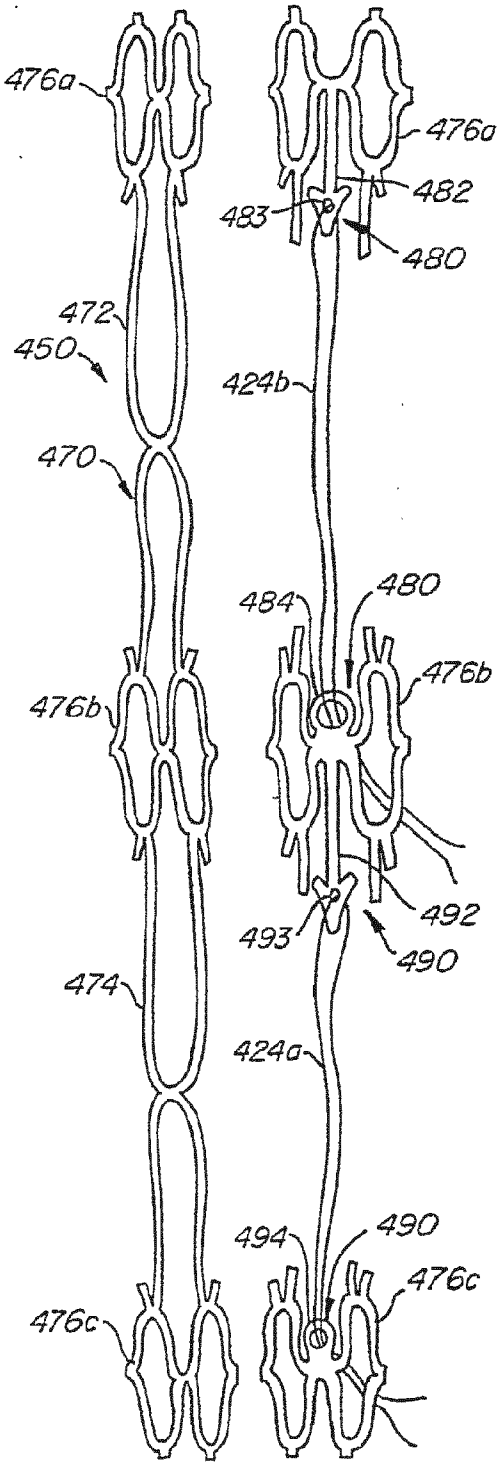


FIG. 36A

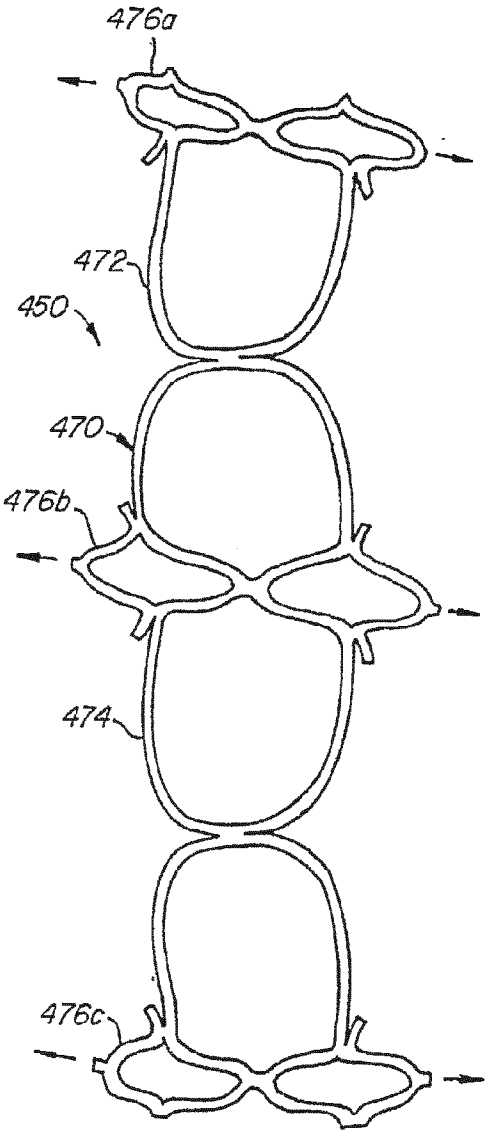


FIG. 36B

Aortic Innovations, LLC, Exhibit 2040
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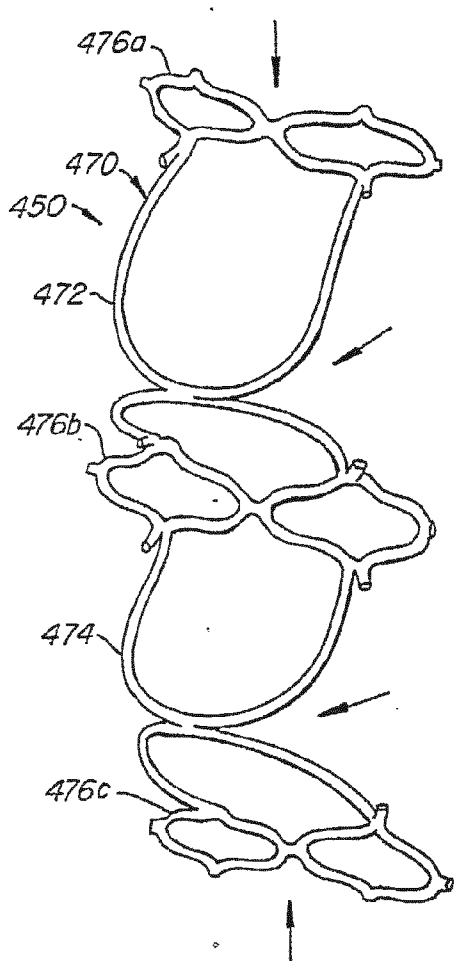


FIG. 36C

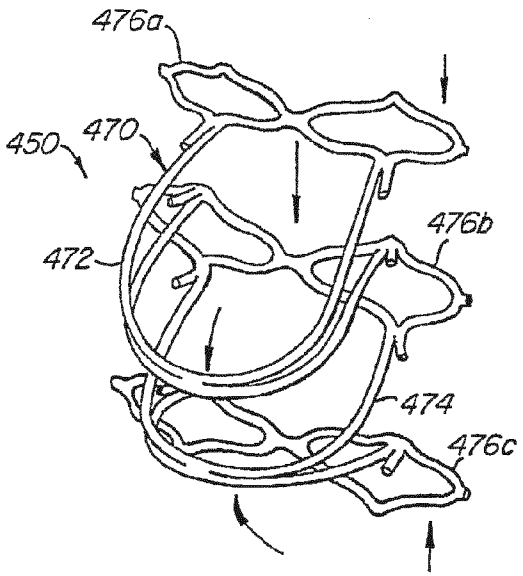


FIG. 36D

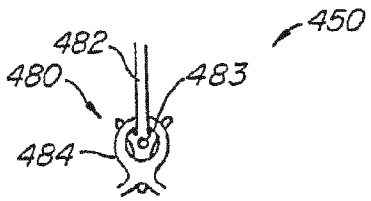


FIG. 36E

Aortic Innovations, LLC, Exhibit 2040
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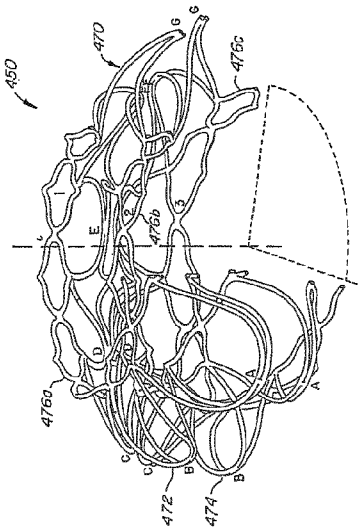


FIG. 37A

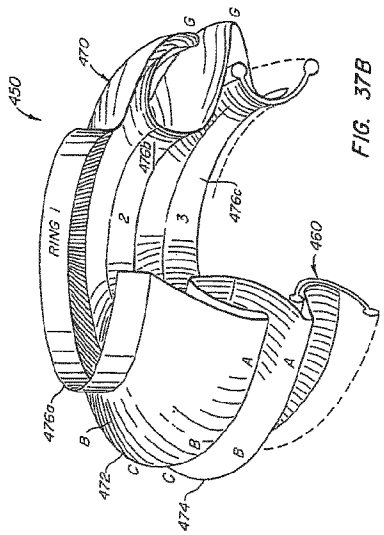


FIG. 37B

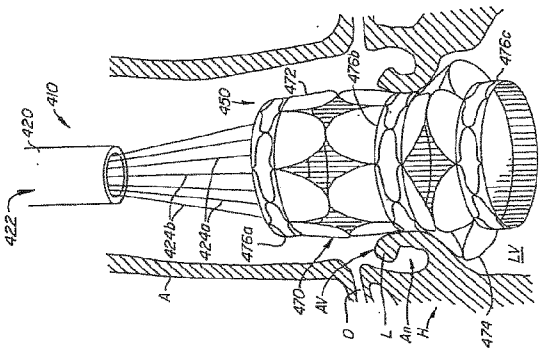


FIG. 38A

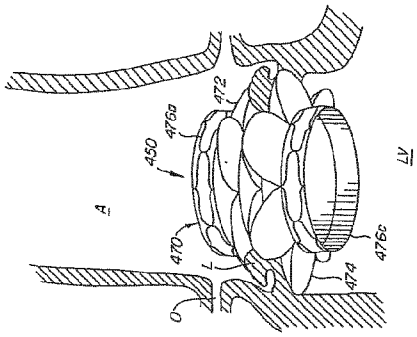


FIG. 38B

Aortic Innovations, LLC, Exhibit 2040
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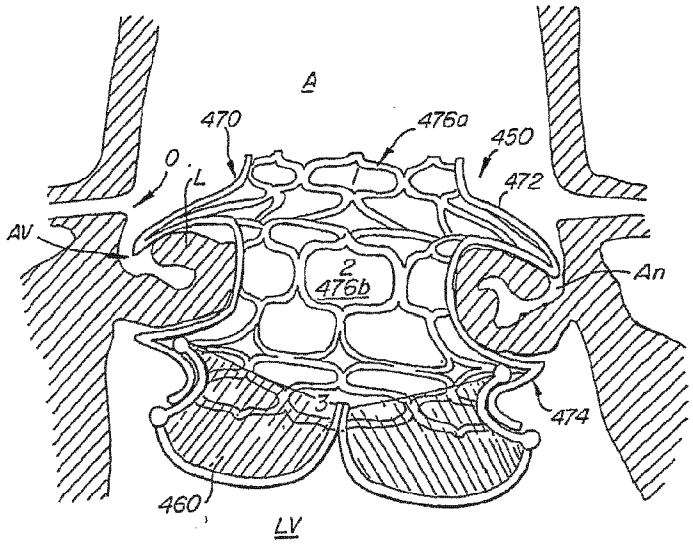


FIG. 38C

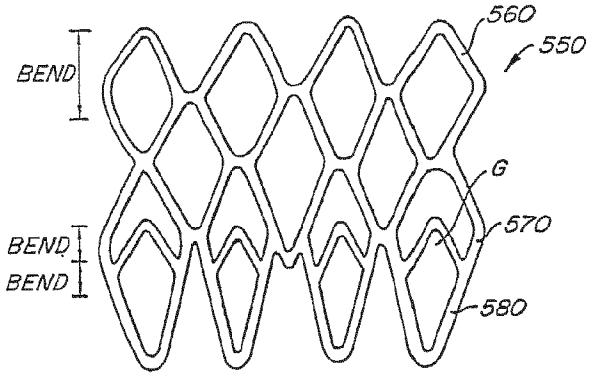


FIG. 39A

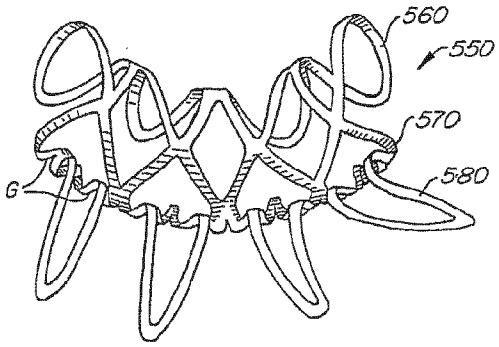


FIG. 39B

Aortic Innovations, LLC, Exhibit 2040
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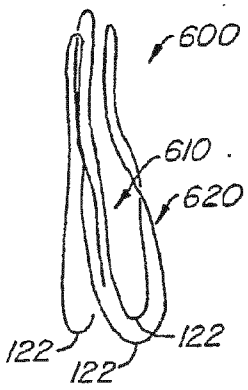


FIG. 40A

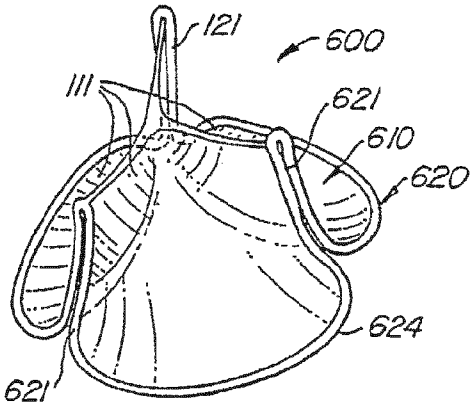


FIG. 40B

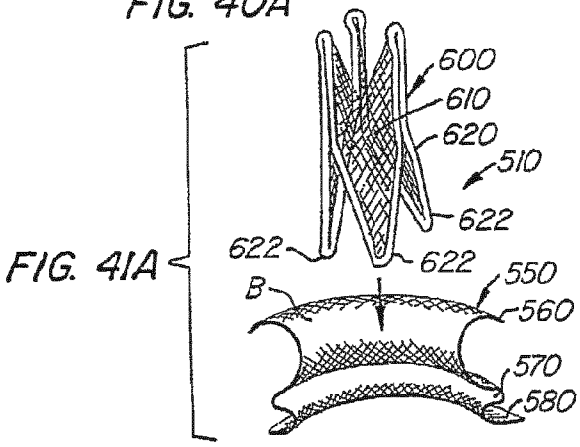


FIG. 41A

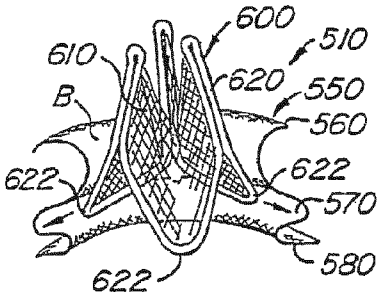


FIG. 41B

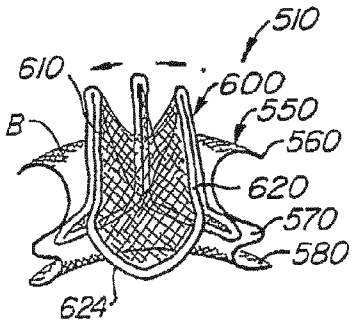


FIG. 41C

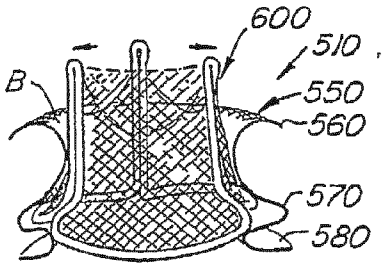


FIG. 41D

Aortic Innovations, LLC, Exhibit 2040
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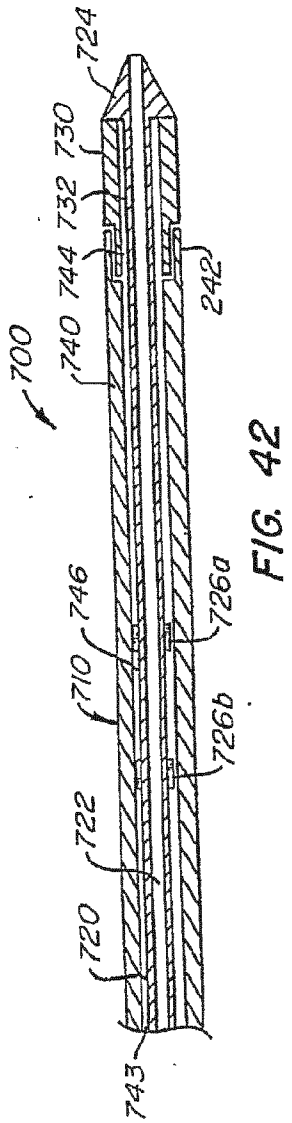


FIG. 42

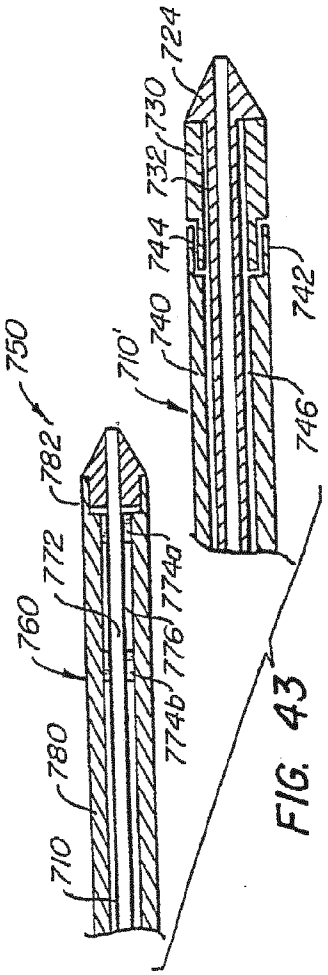


FIG. 43

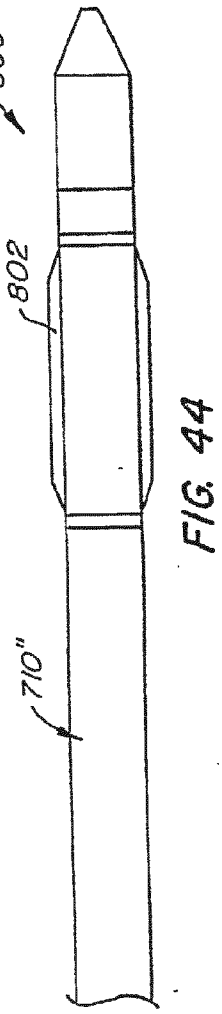


FIG. 44

Aortic Innovations, LLC, Exhibit 2040
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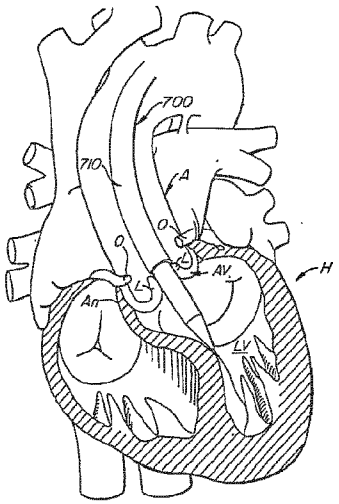


FIG. 45A

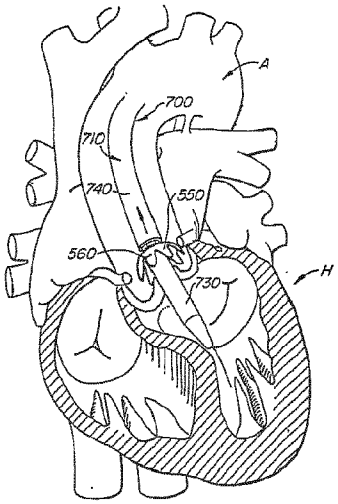


FIG. 45B

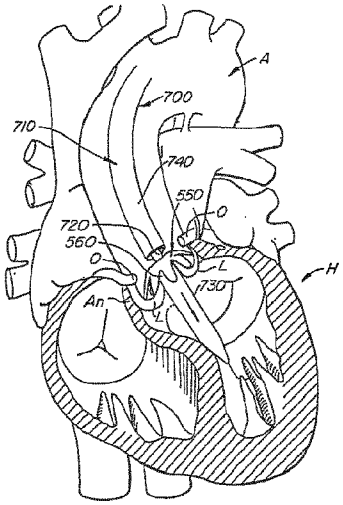


FIG. 45C

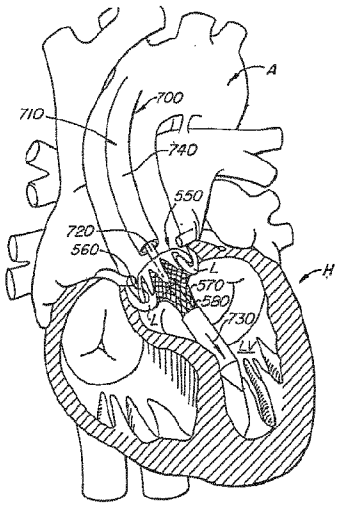


FIG. 45D

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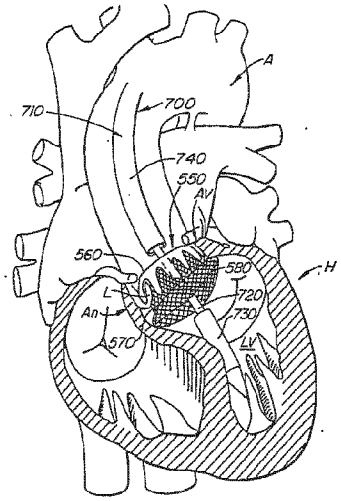


FIG. 45E

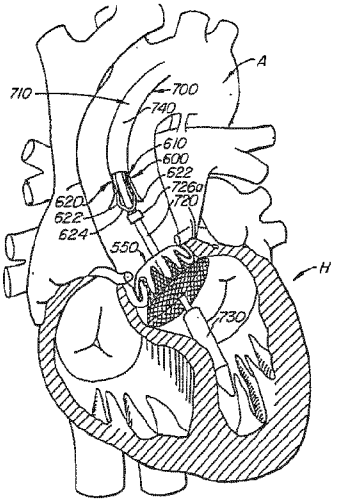


FIG. 45F

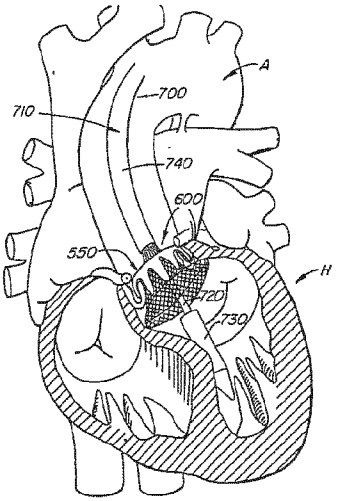


FIG. 45G

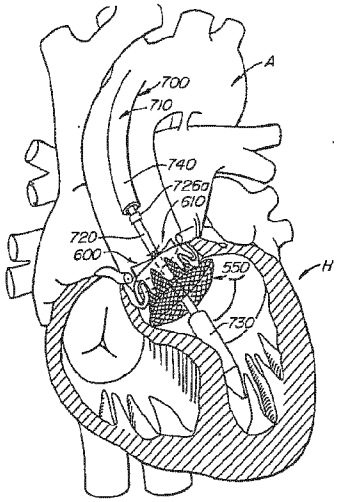


FIG. 45H

Aortic Innovations, LLC, Exhibit 2040
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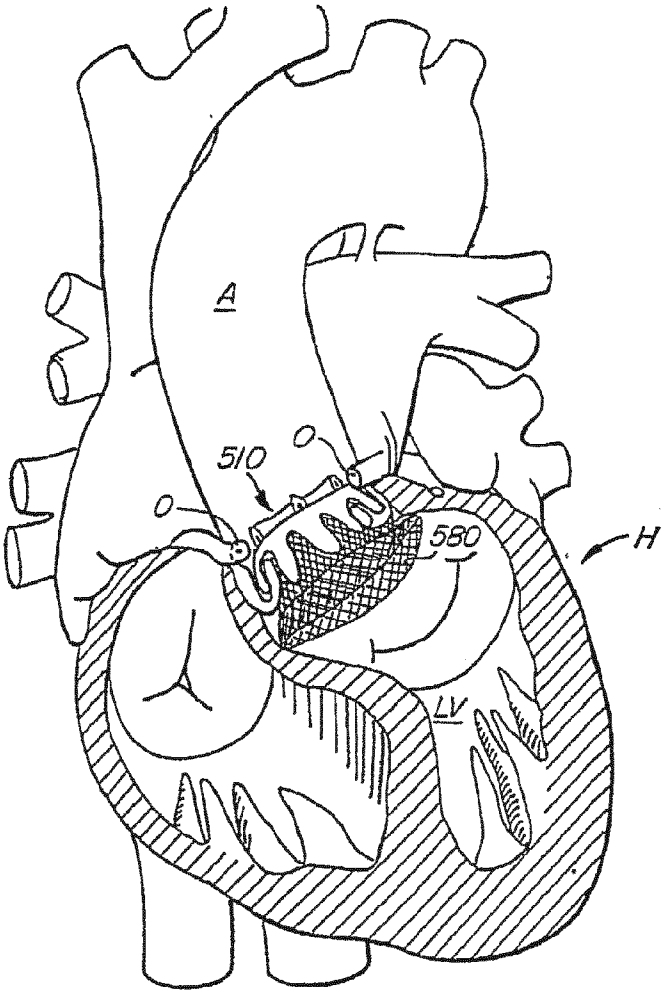


FIG. 45I

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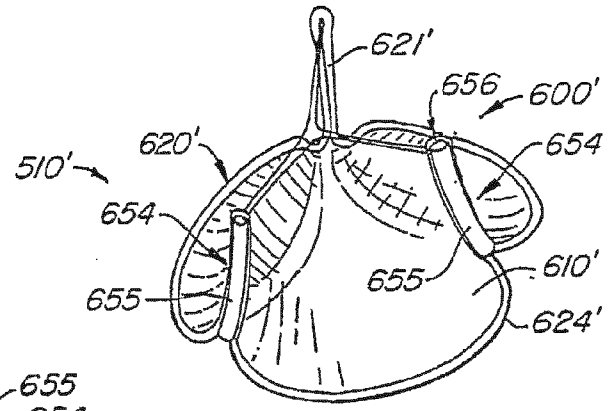


FIG. 46A

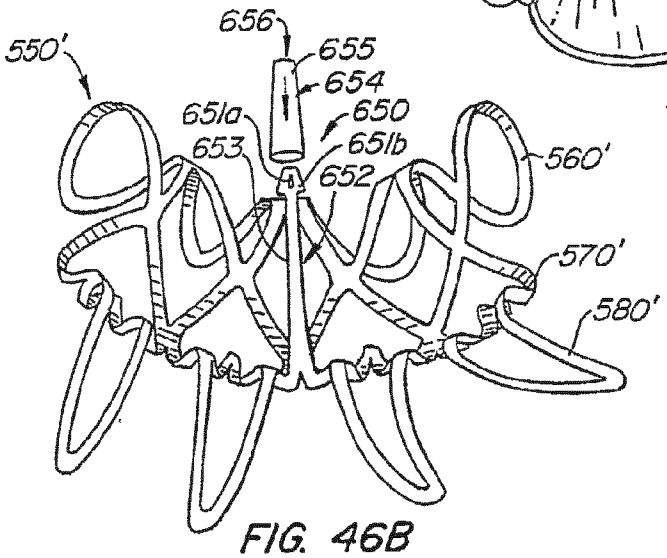


FIG. 46B

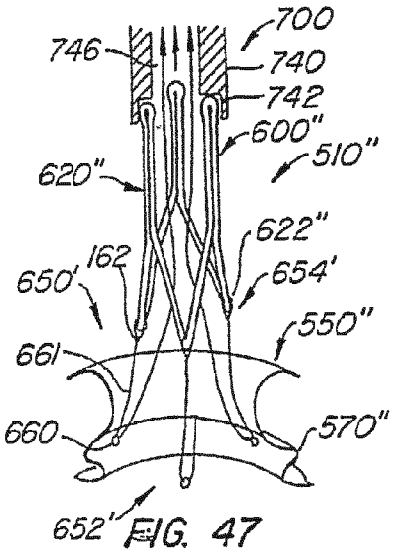


FIG. 47

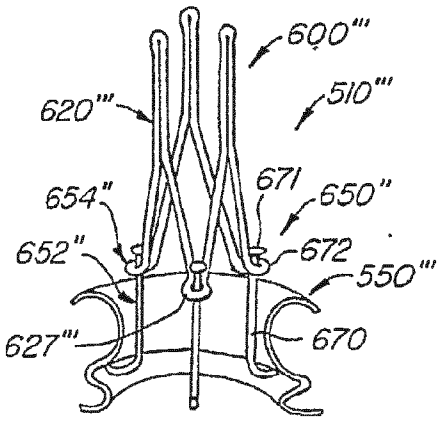


FIG. 48

Aortic Innovations, LLC, Exhibit 2040
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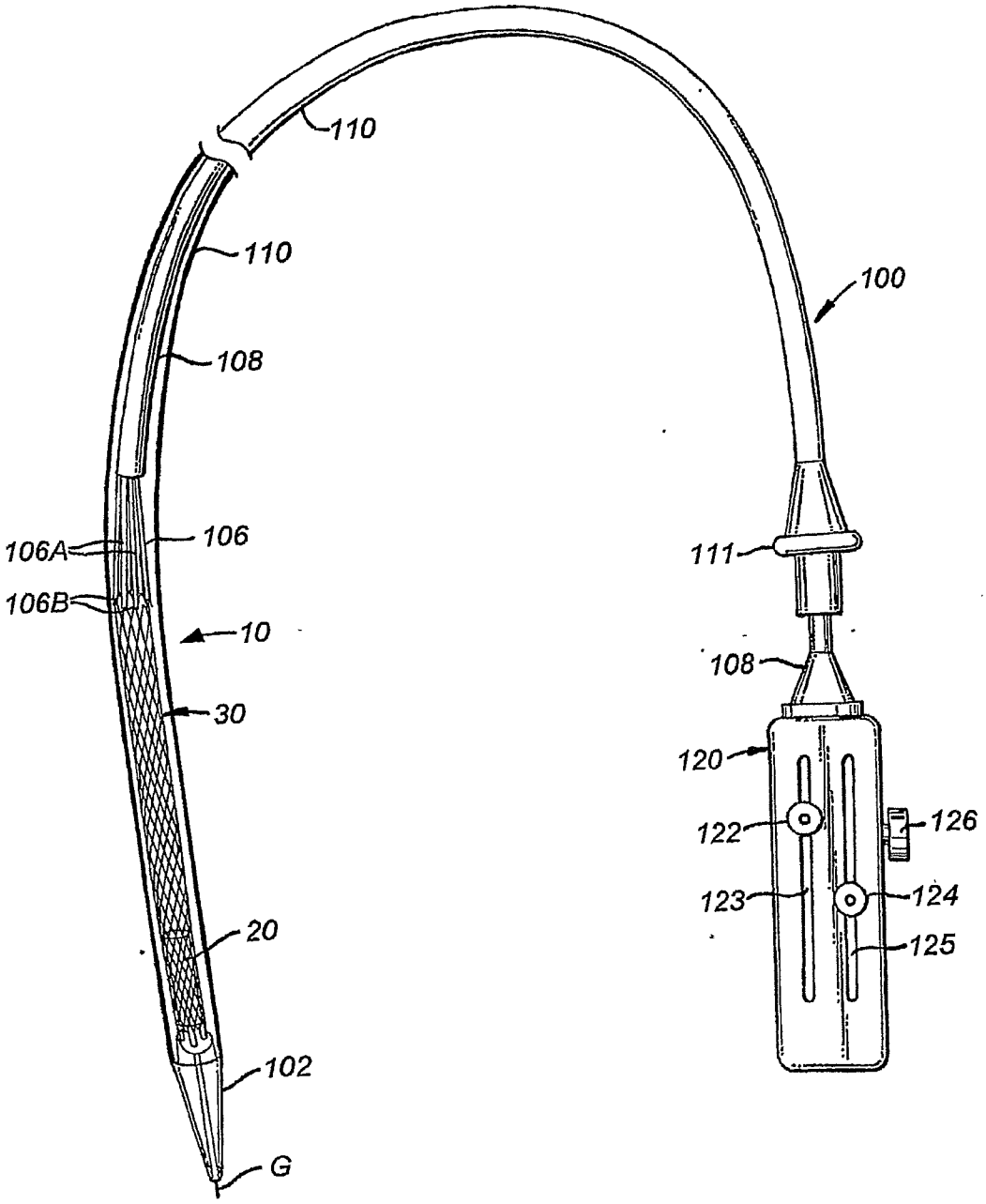


FIG. 49A

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 729
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

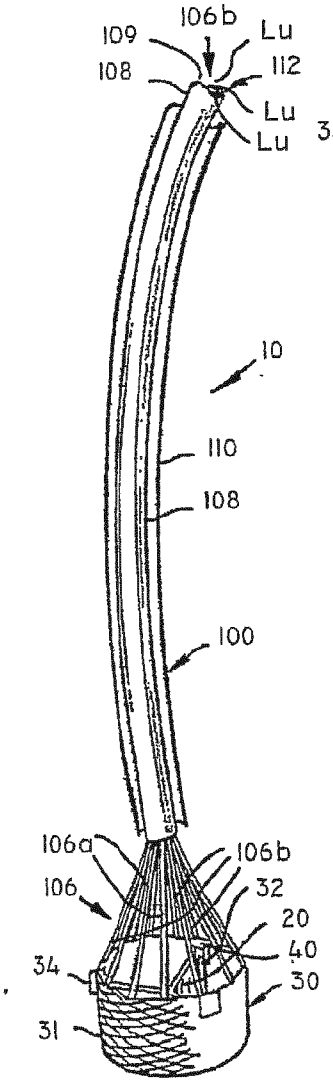


FIG. 49B

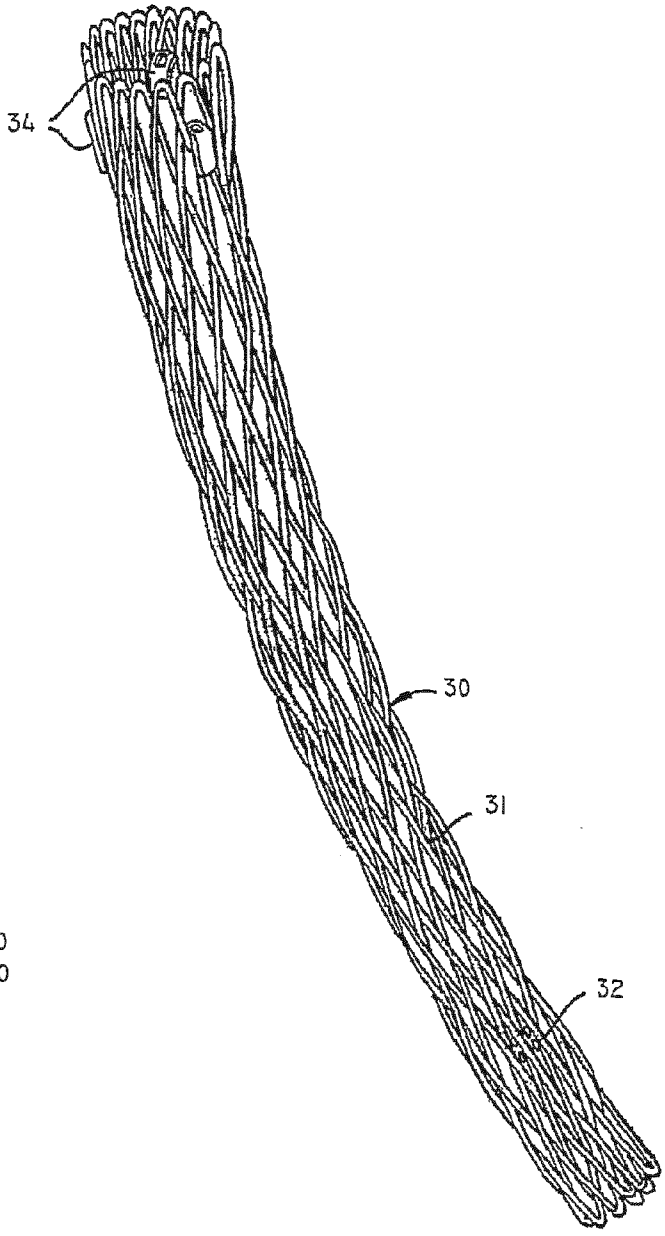


FIG. 50A

Aortic Innovations, LLC, Exhibit 2040
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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

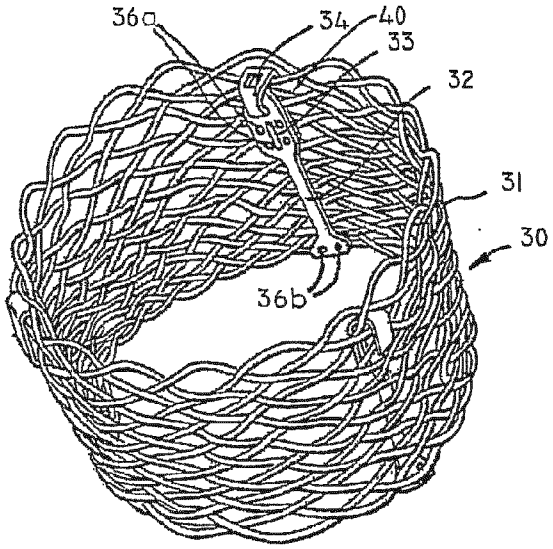


FIG. 50B

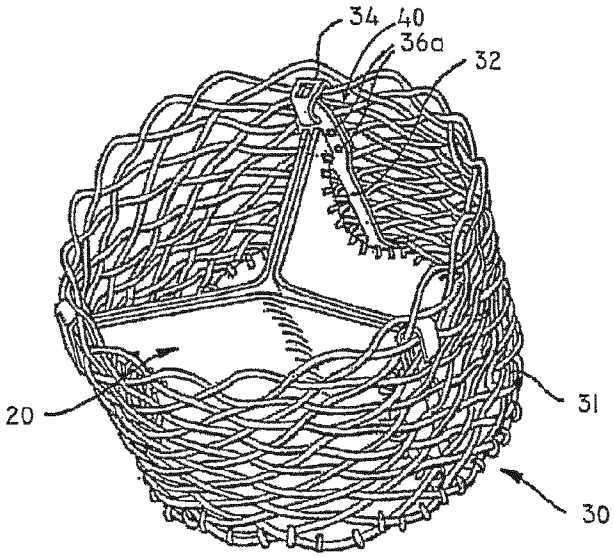


FIG. 50C

Aortic Innovations, LLC, Exhibit 2040
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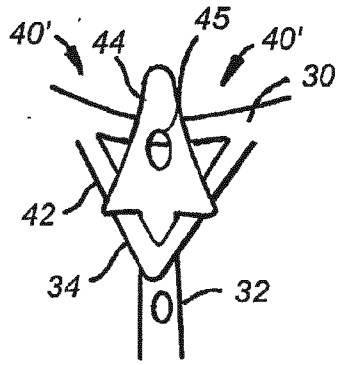


FIG. 50D

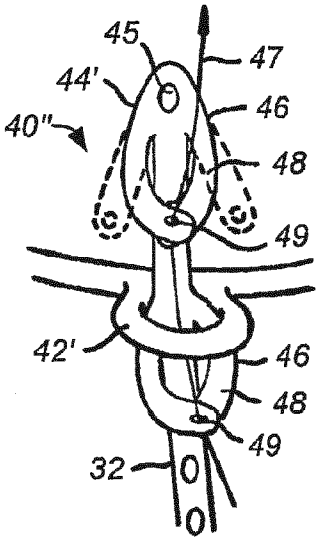


FIG. 50E

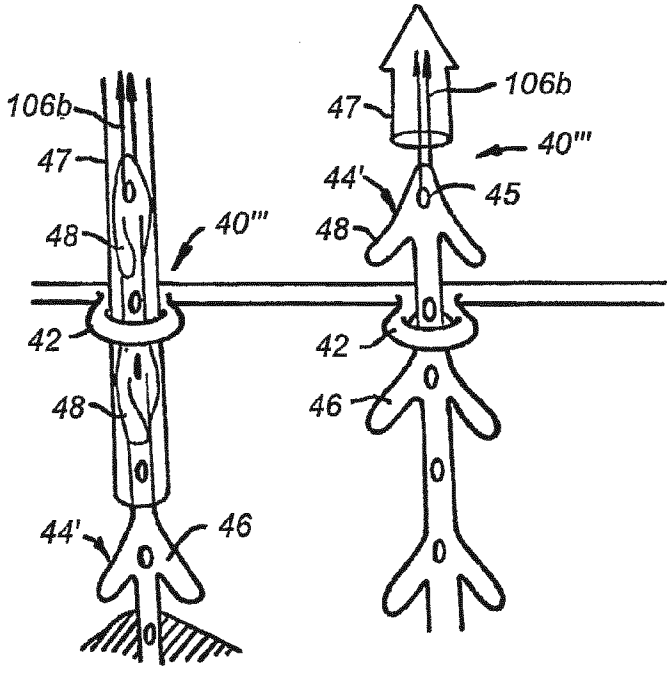


FIG. 50F

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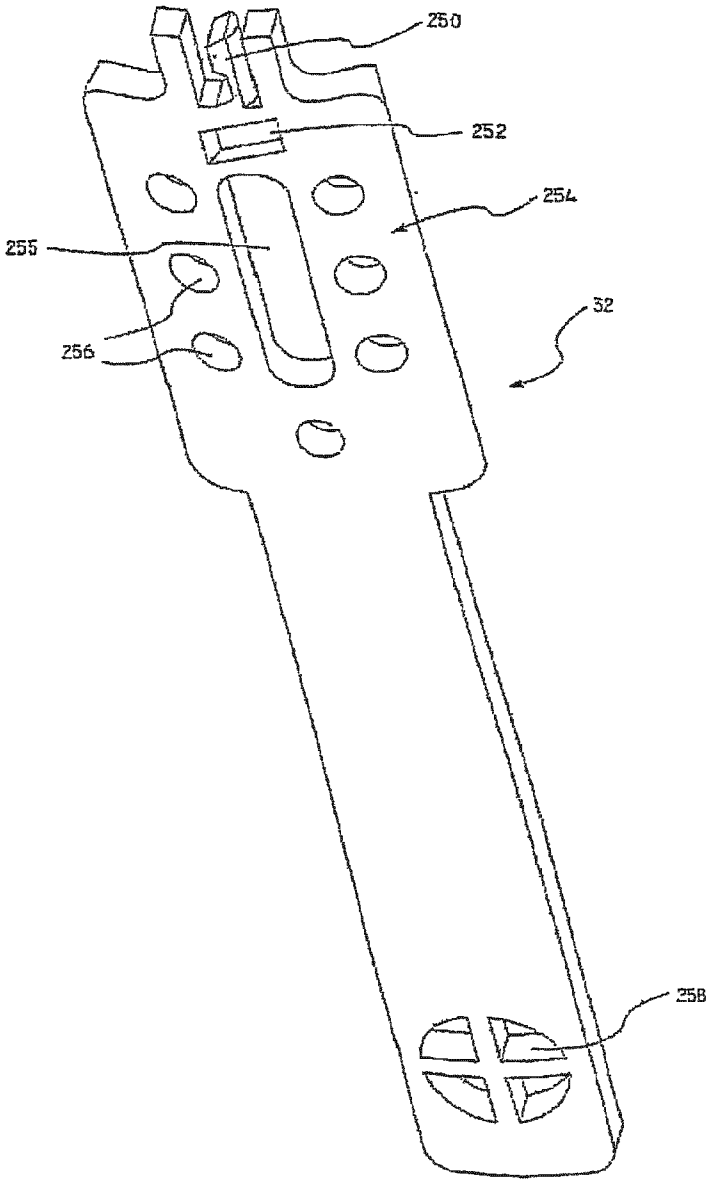


FIG. 51

Aortic Innovations, LLC, Exhibit 2040
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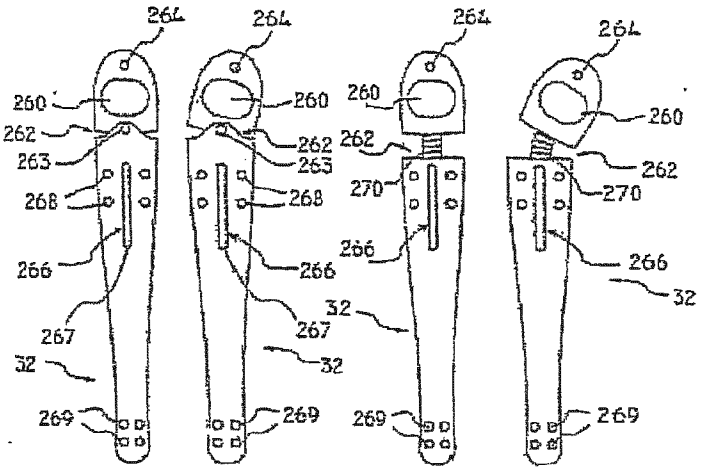


FIG. 52A FIG. 52B FIG. 53A FIG. 53B

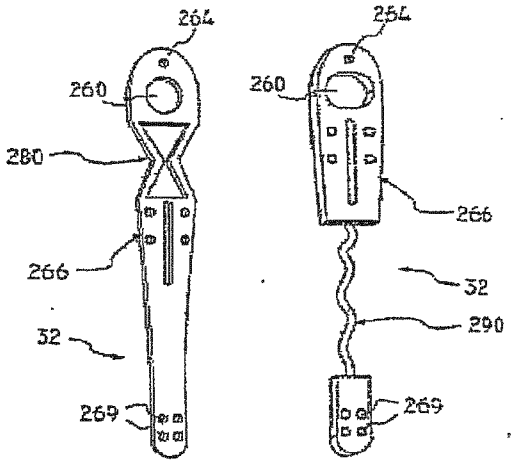


FIG. 54 FIG. 55

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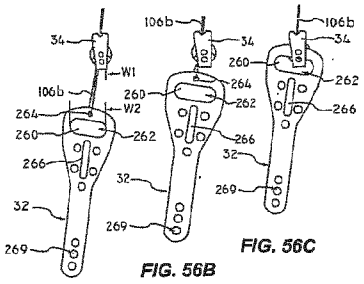


FIG. 56A

FIG. 56B

FIG. 56C

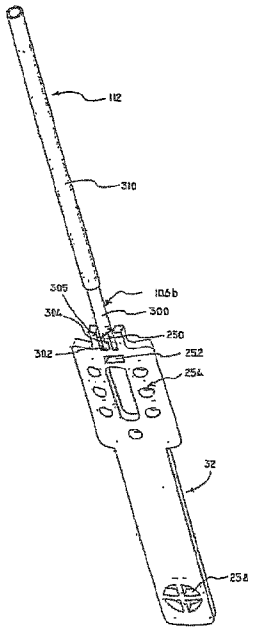


FIG. 57

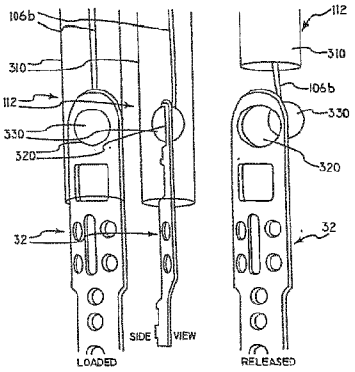


FIG. 58A

FIG. 58B

FIG. 58C

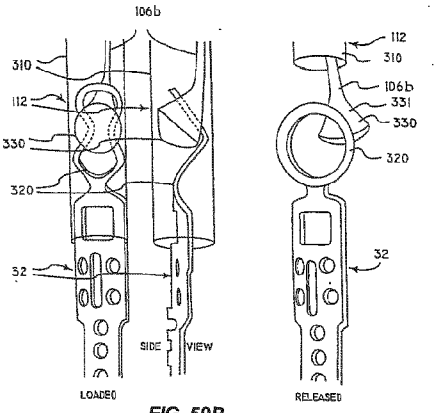


FIG. 59A

FIG. 59B

FIG. 59C

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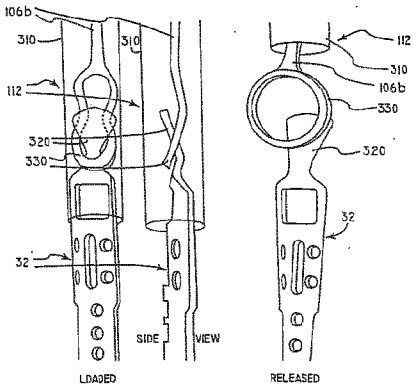


FIG. 60A FIG. 60B FIG. 60C

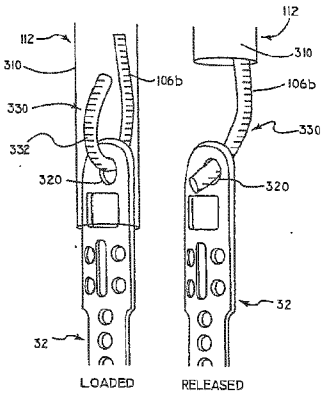


FIG. 61A FIG. 61B

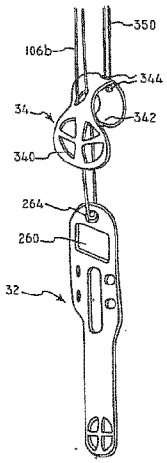


FIG. 62

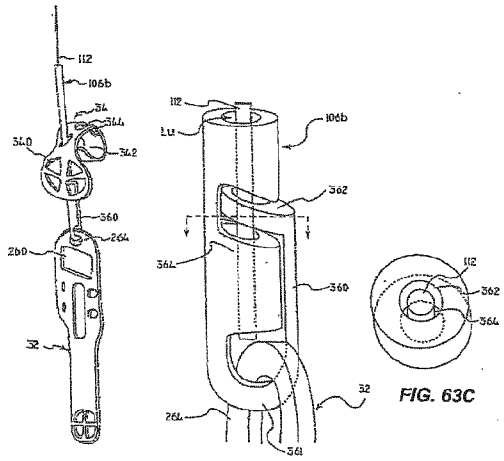


FIG. 63A FIG. 63B FIG. 63C

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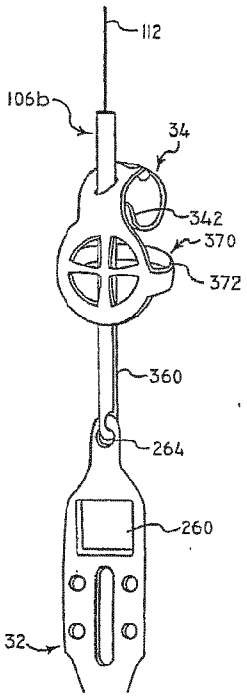


FIG. 64

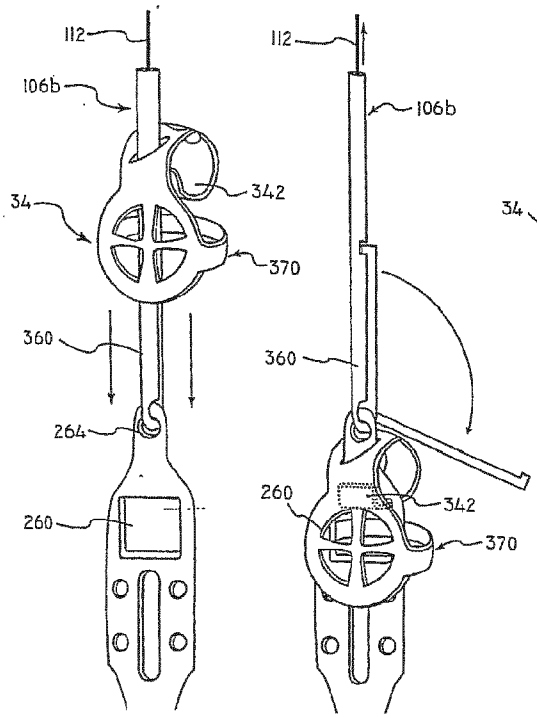


FIG. 65A FIG. 65B FIG. 66

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IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

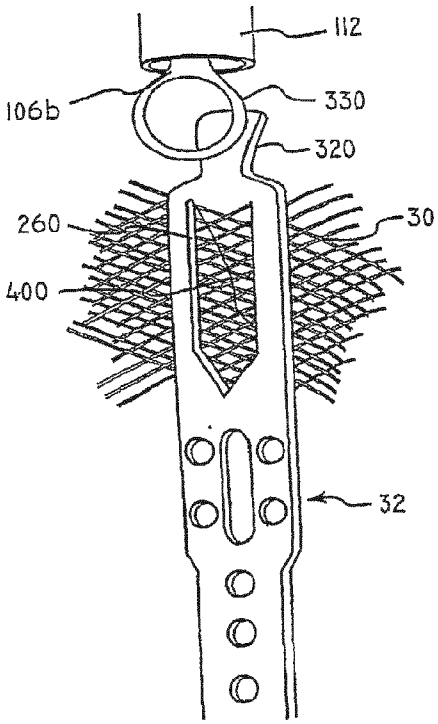


FIG. 67A

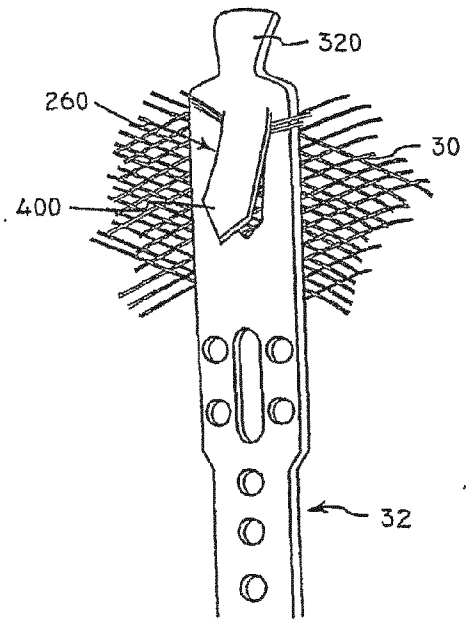


FIG. 67B

Aortic Innovations, LLC, Exhibit 2040
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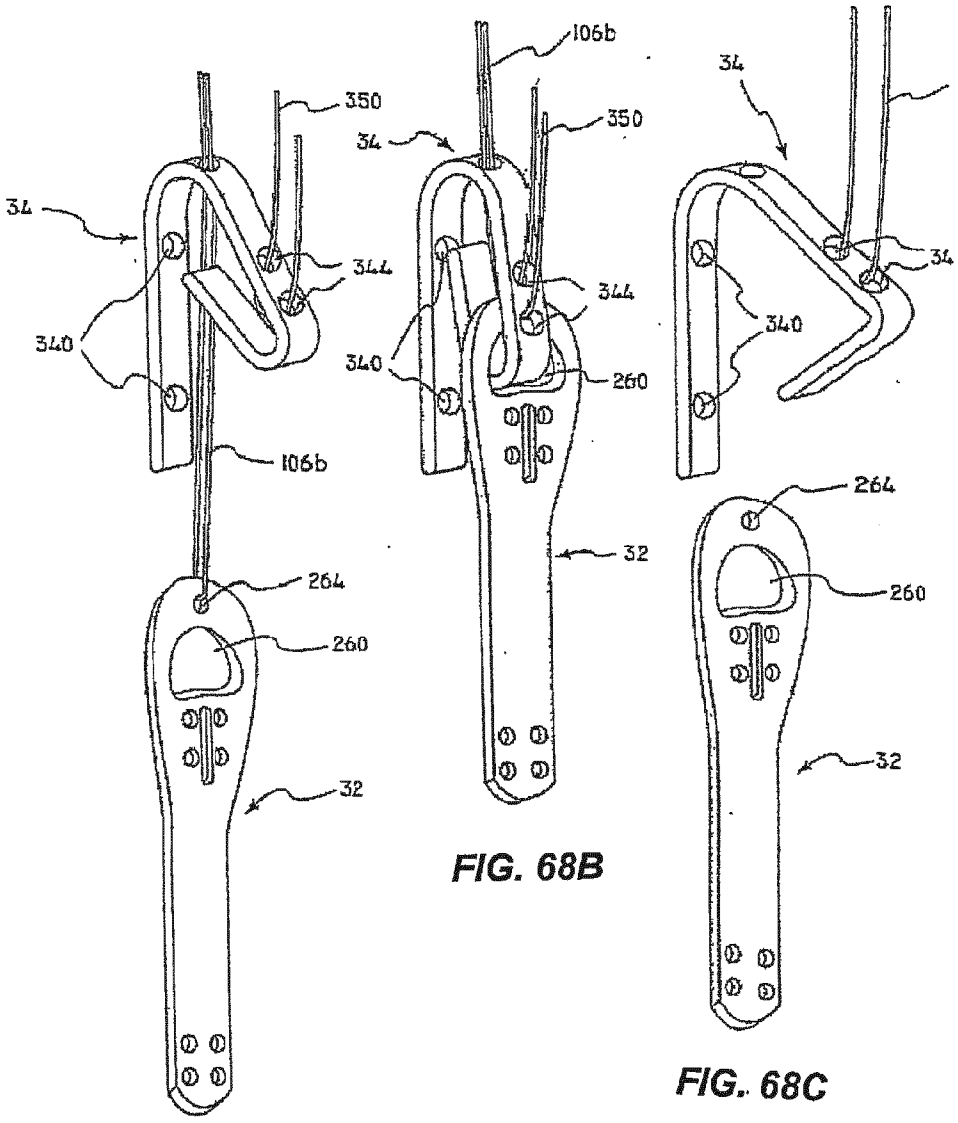


FIG. 68A

FIG. 68B

FIG. 68C

Aortic Innovations, LLC, Exhibit 2040
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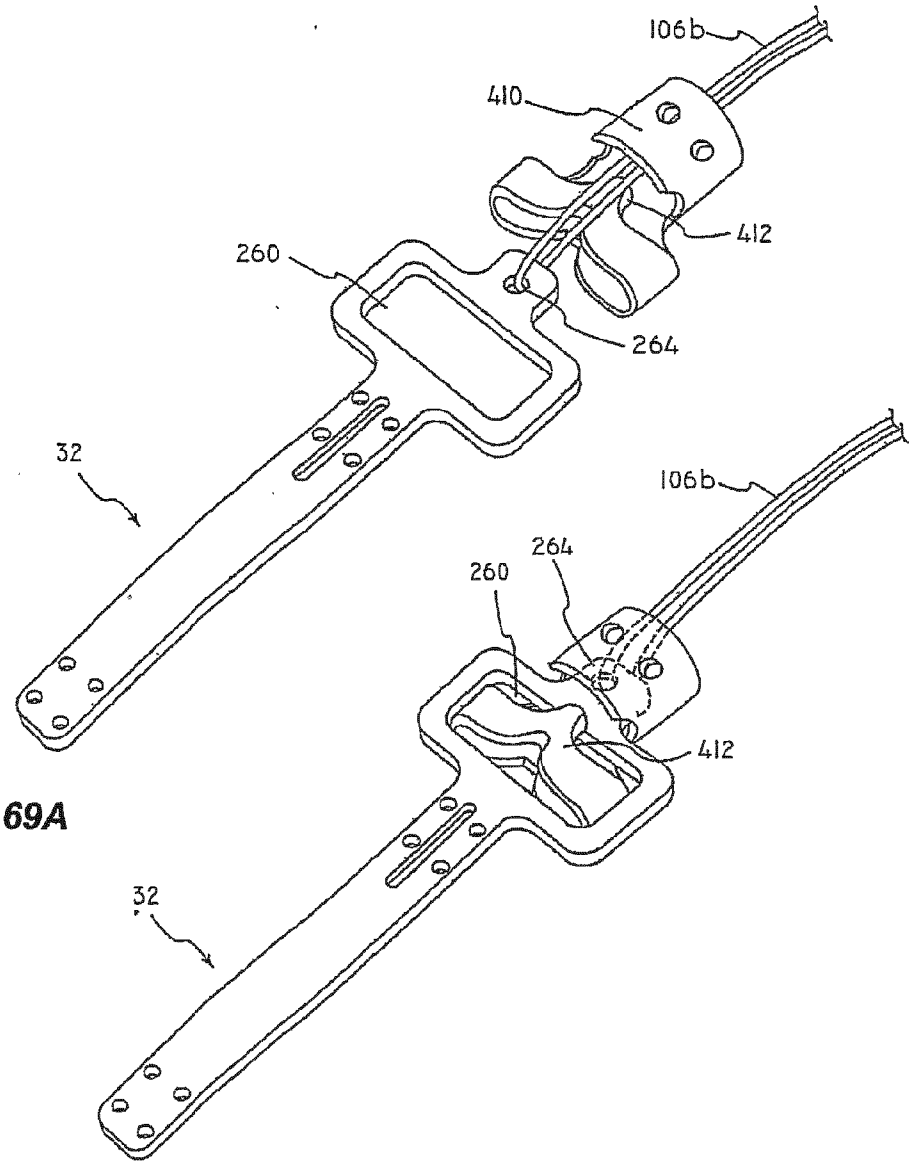


FIG. 69A

FIG. 69B

Aortic Innovations, LLC, Exhibit 2040
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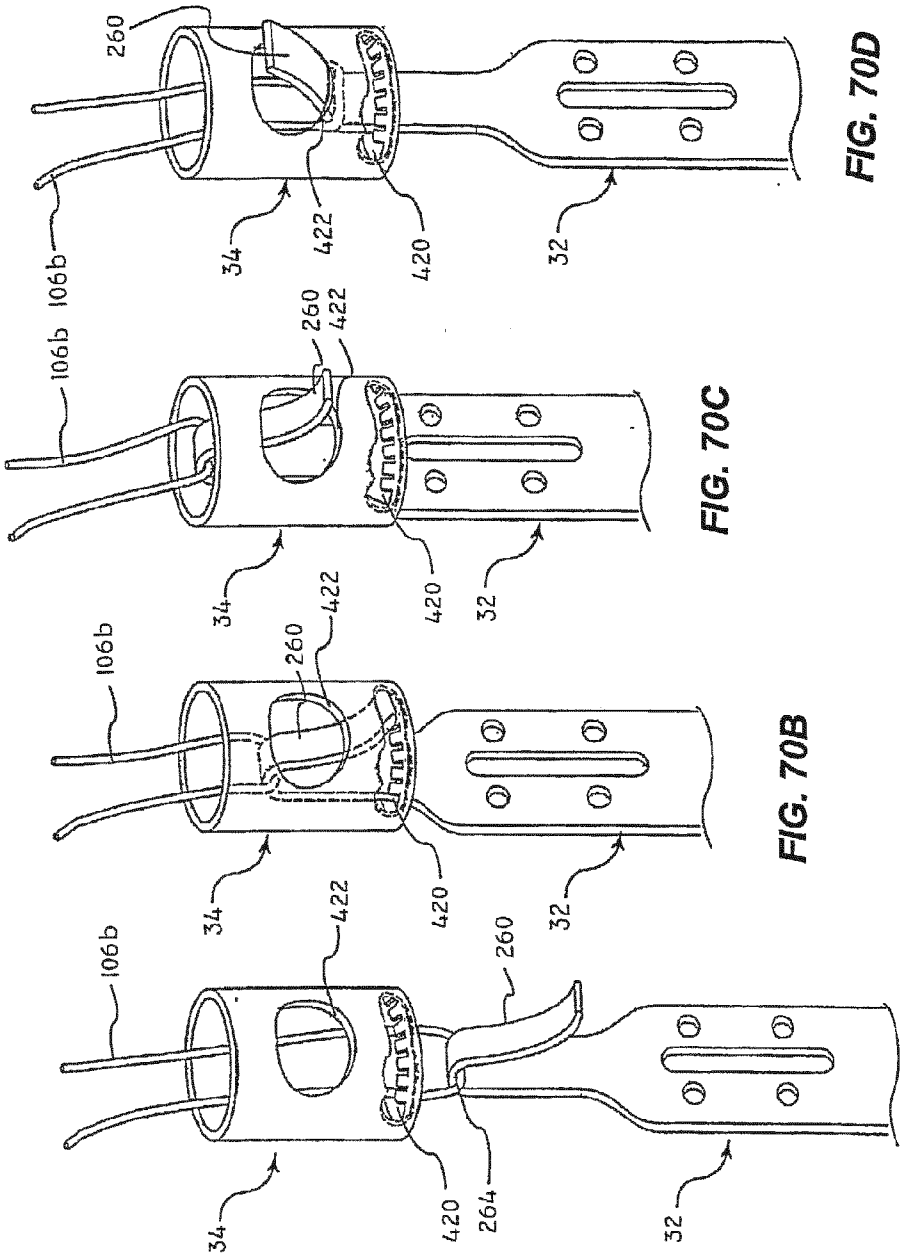


FIG. 70D

FIG. 70C

FIG. 70B

FIG. 70A

Aortic Innovations, LLC, Exhibit 2040
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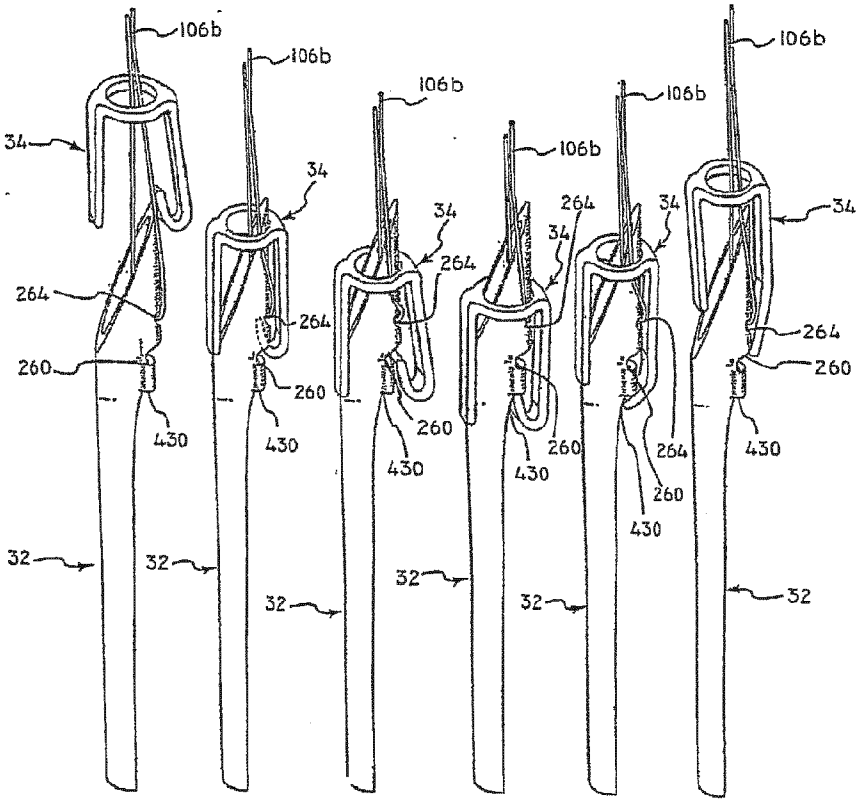


FIG. 71A FIG. 71B FIG. 71C FIG. 71D FIG. 71E FIG. 71F

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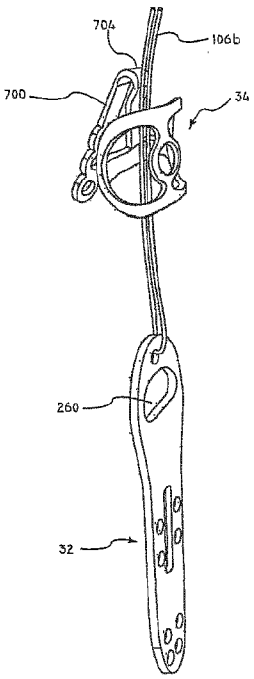


FIG. 72A

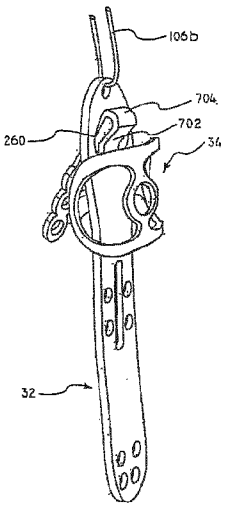


FIG. 72B

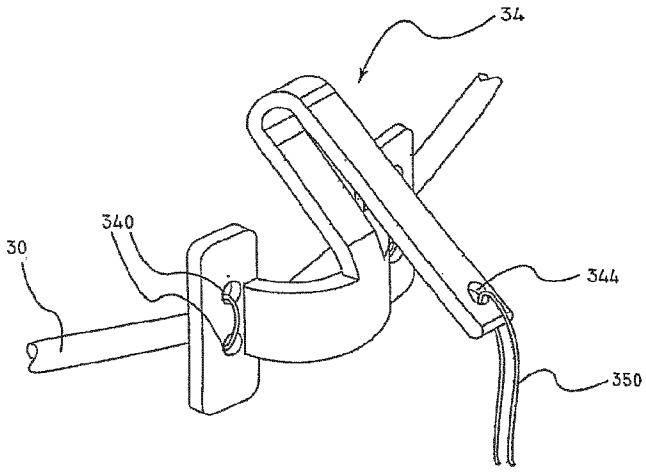


FIG. 73

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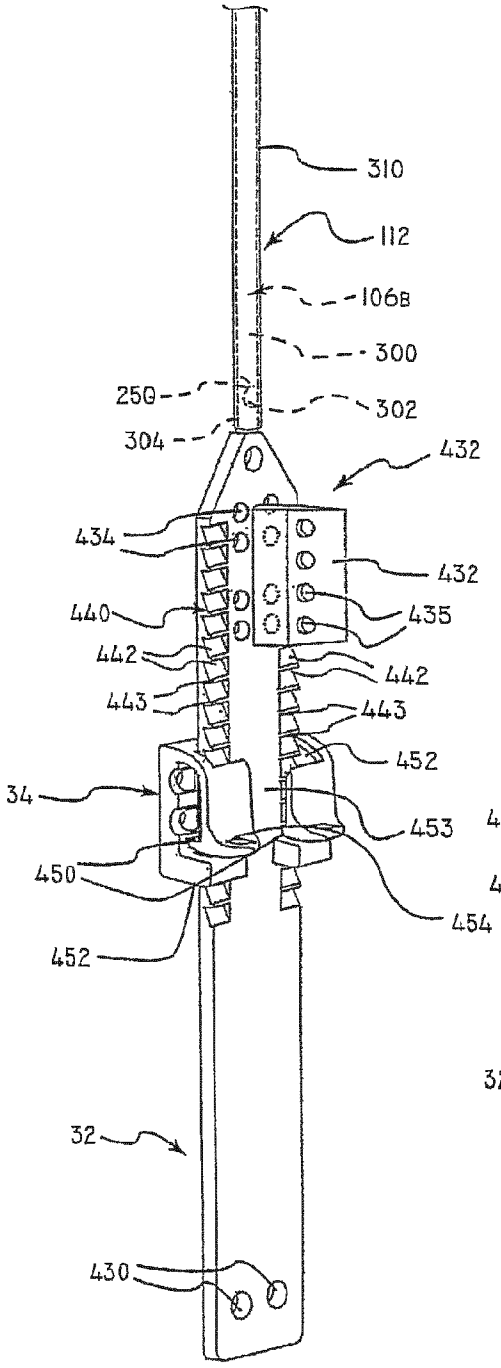


FIG. 74

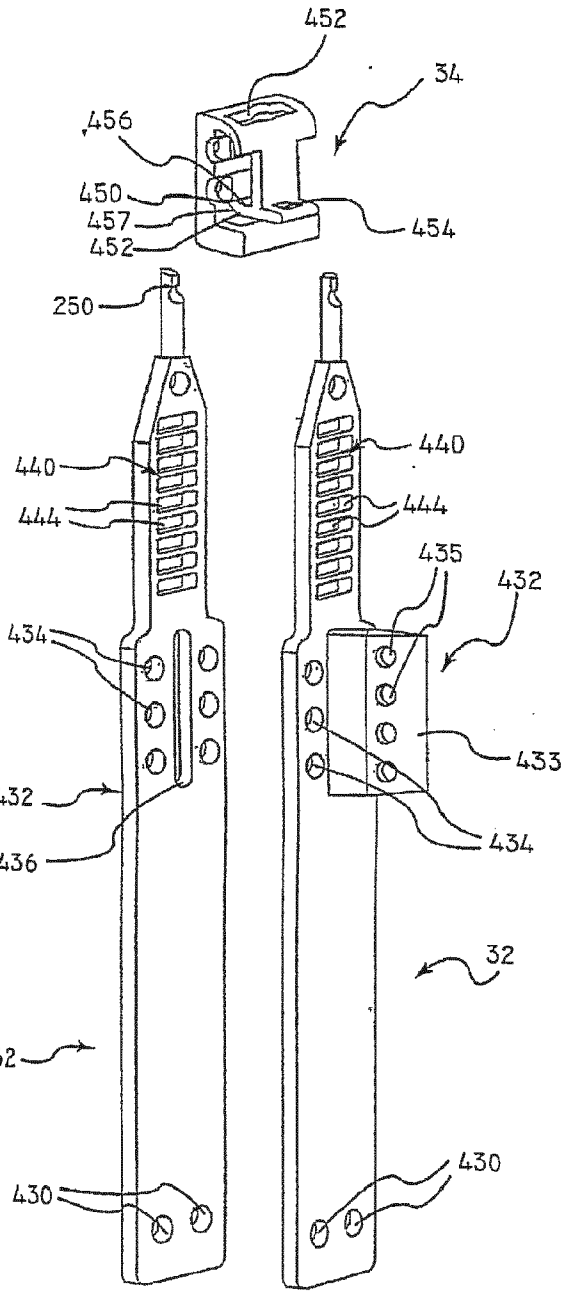


FIG. 75A FIG. 75B

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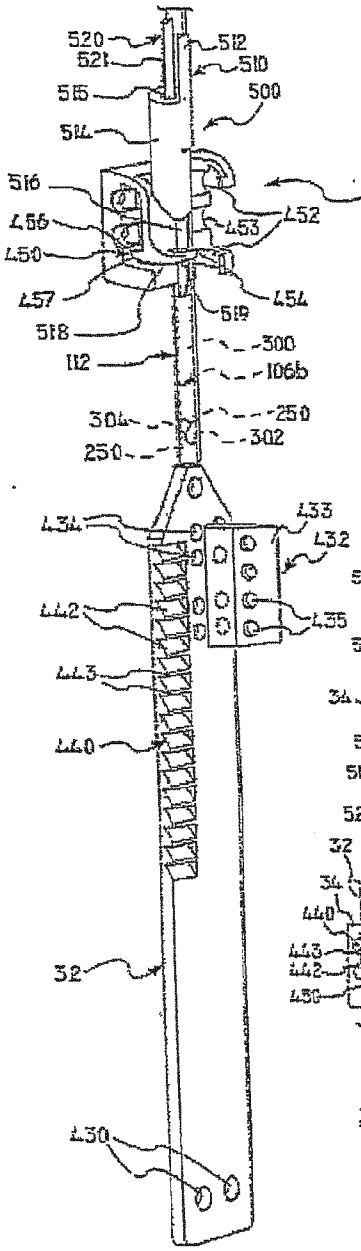


FIG. 76A

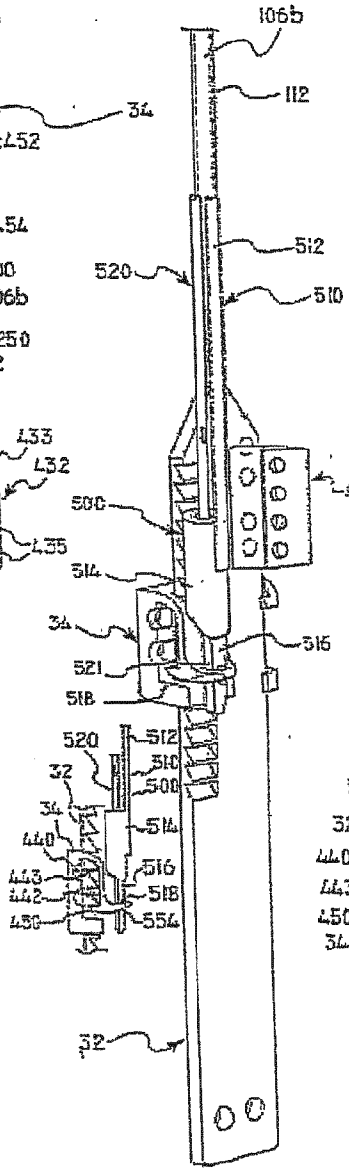


FIG. 76B

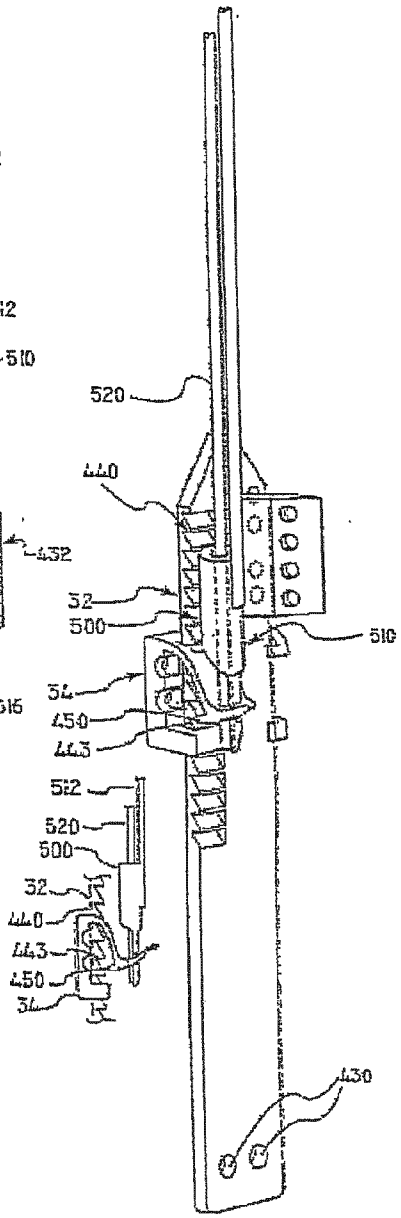


FIG. 76C

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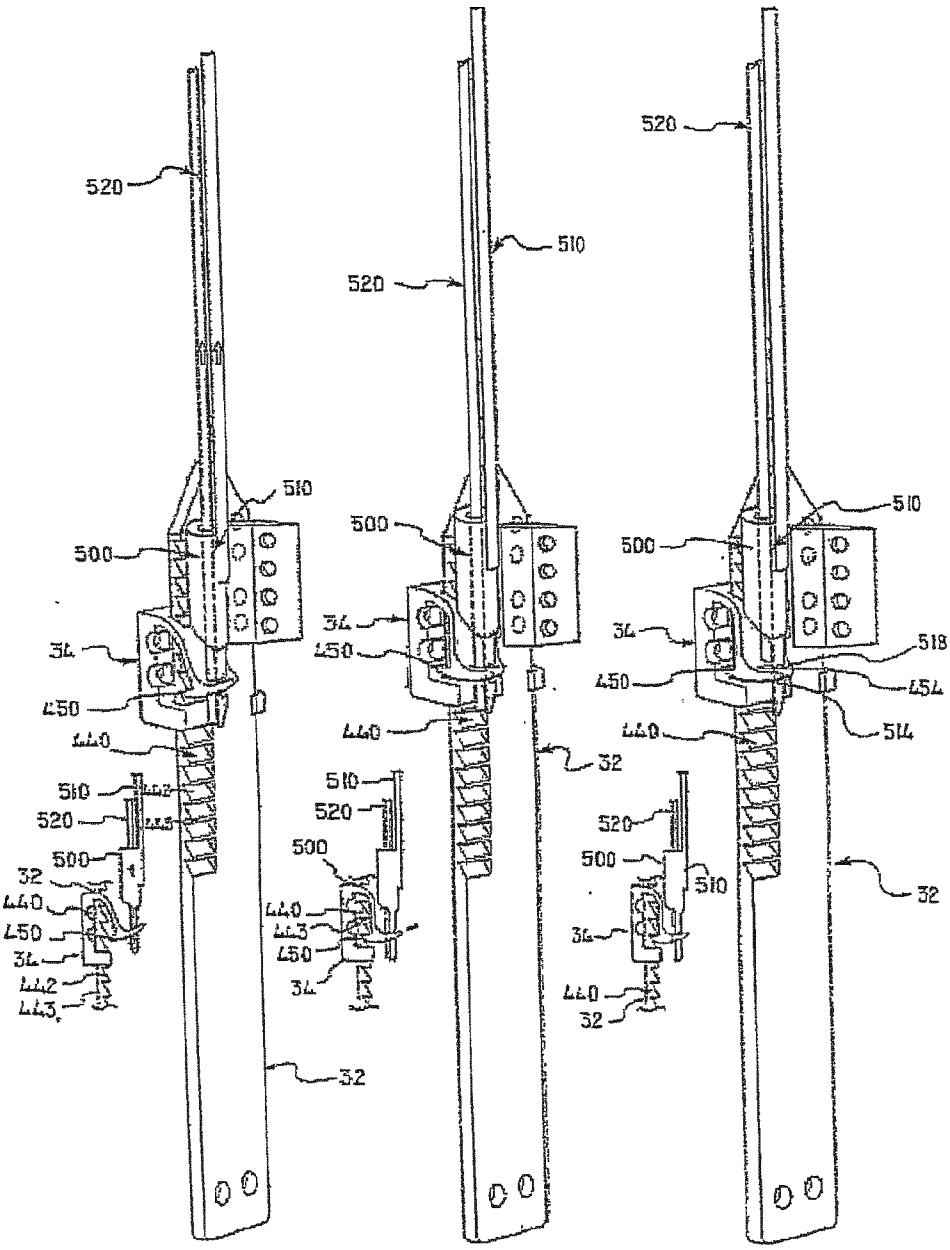


FIG. 76D FIG. 76E FIG. 76F

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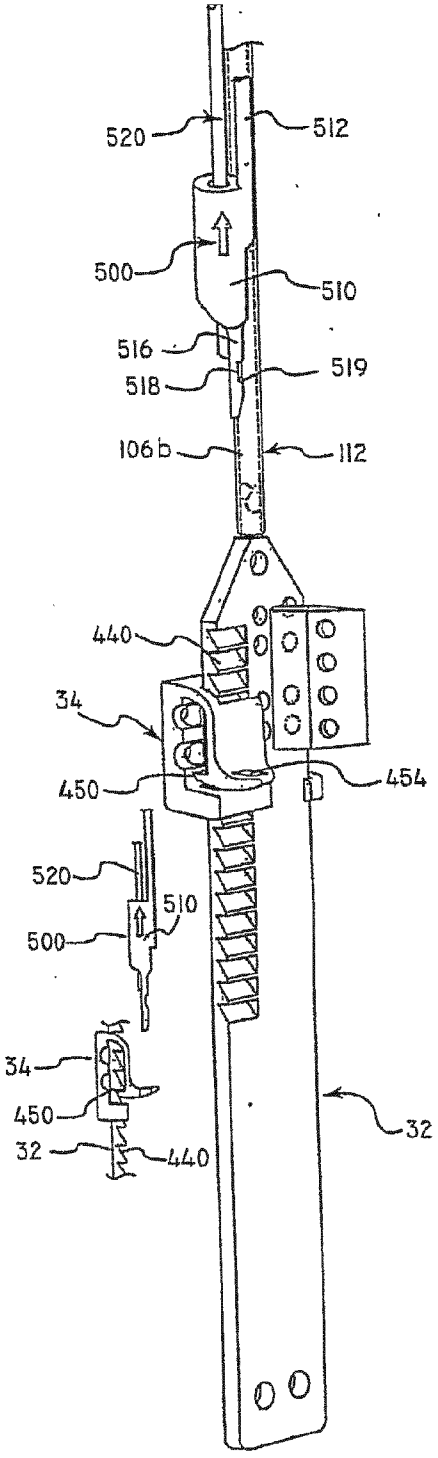


FIG. 76G

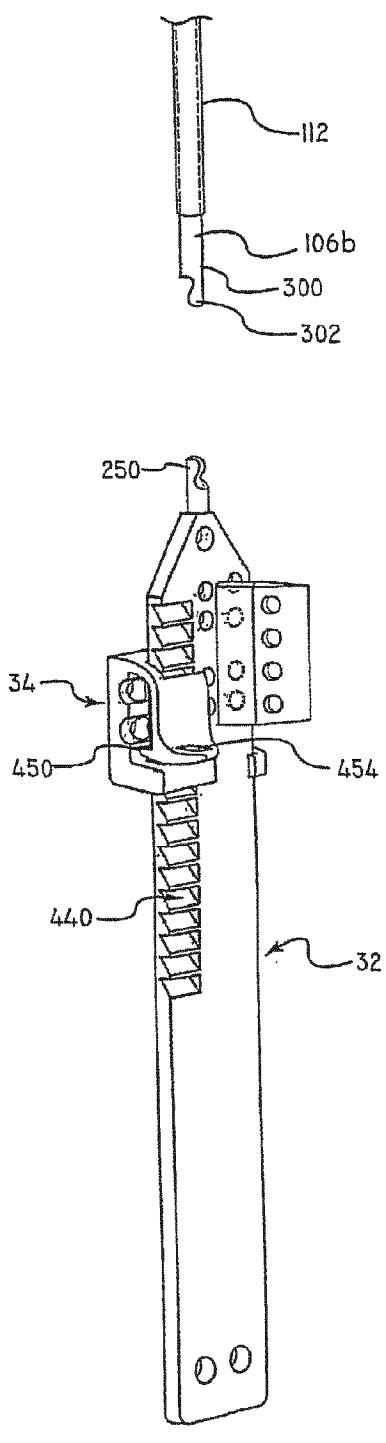
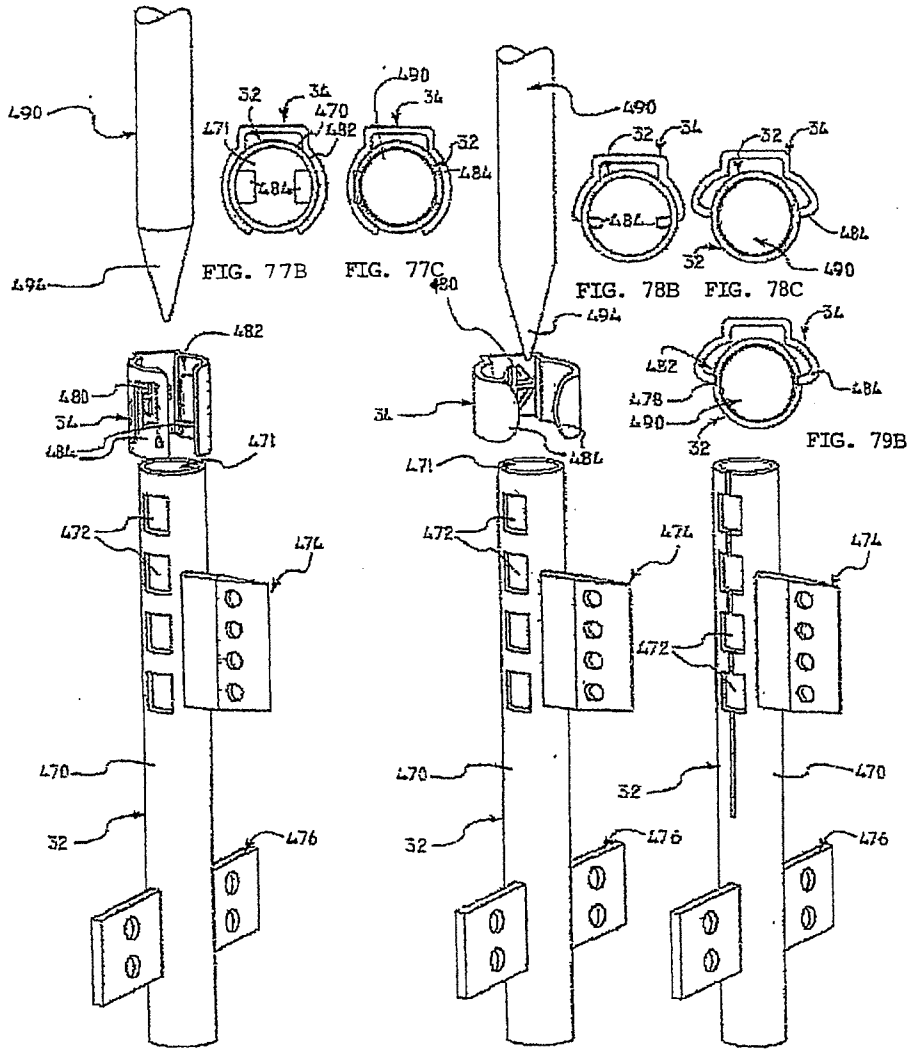
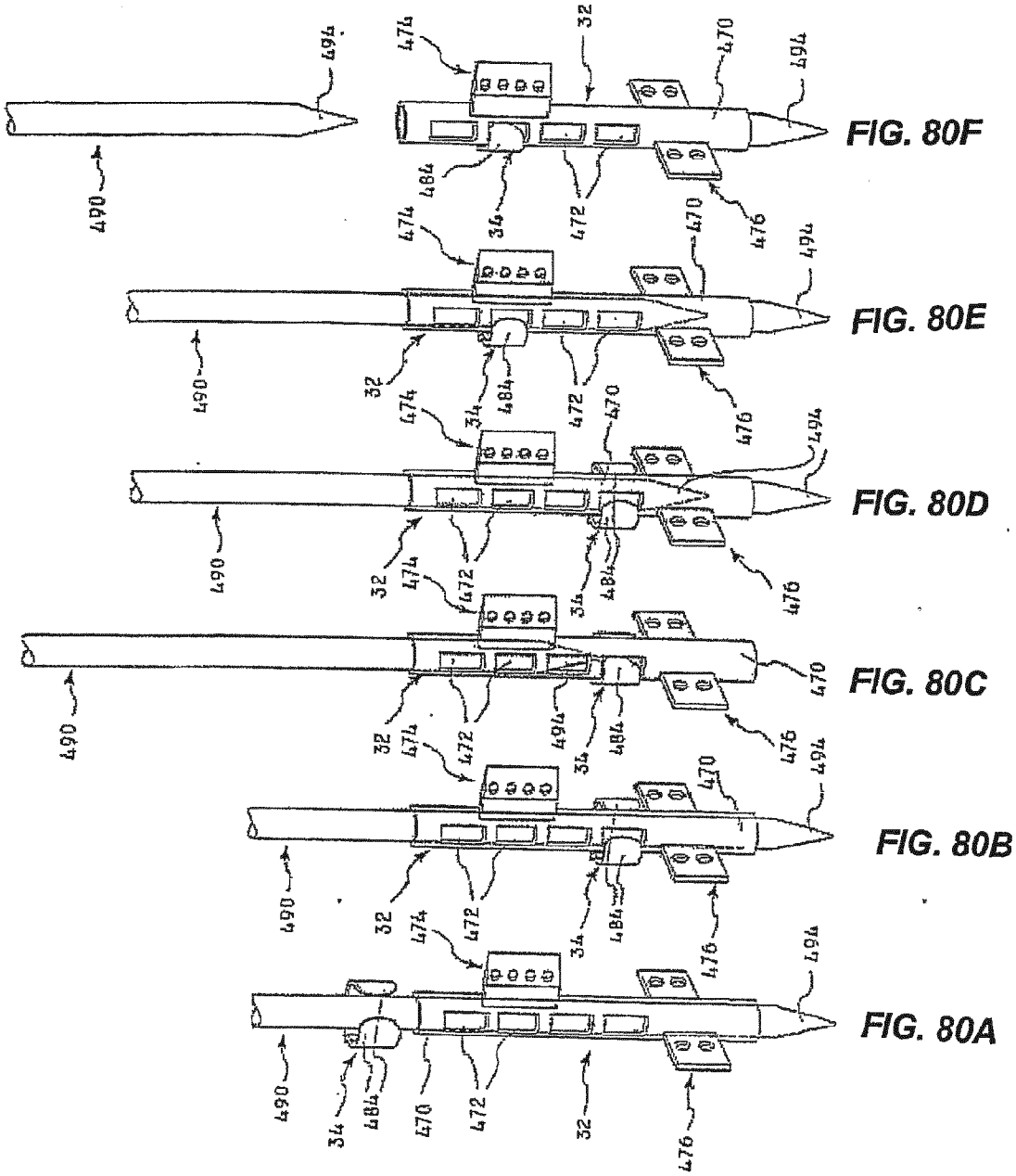


FIG. 76H

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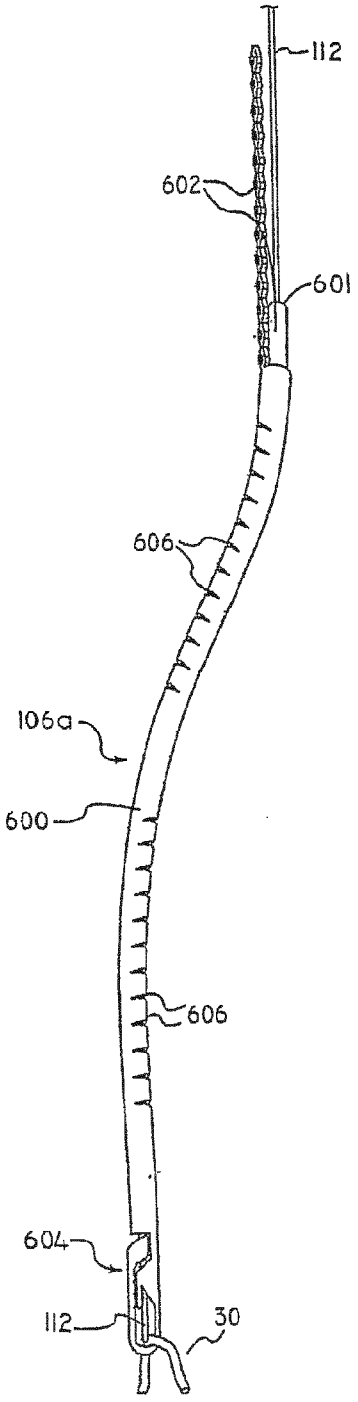


FIG. 81A

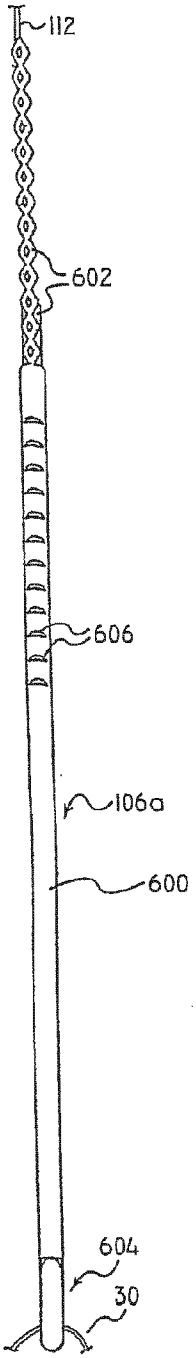


FIG. 81B

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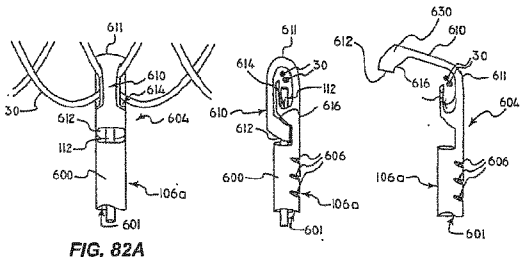


FIG. 82A FIG. 82B FIG. 82C

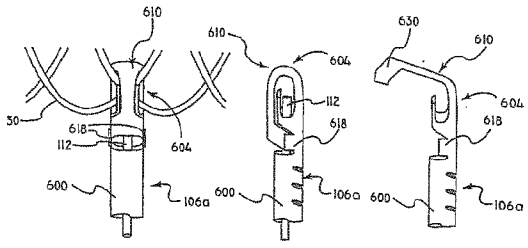


FIG. 83A FIG. 83B FIG. 83C

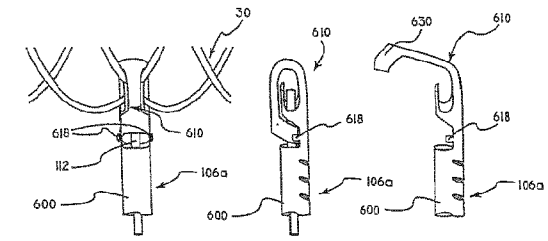


FIG. 84A FIG. 84B FIG. 84C

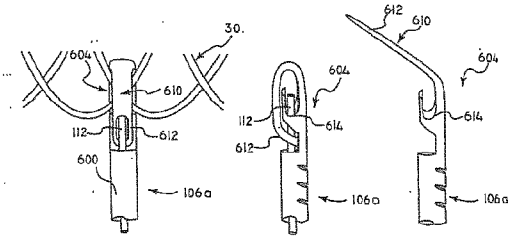
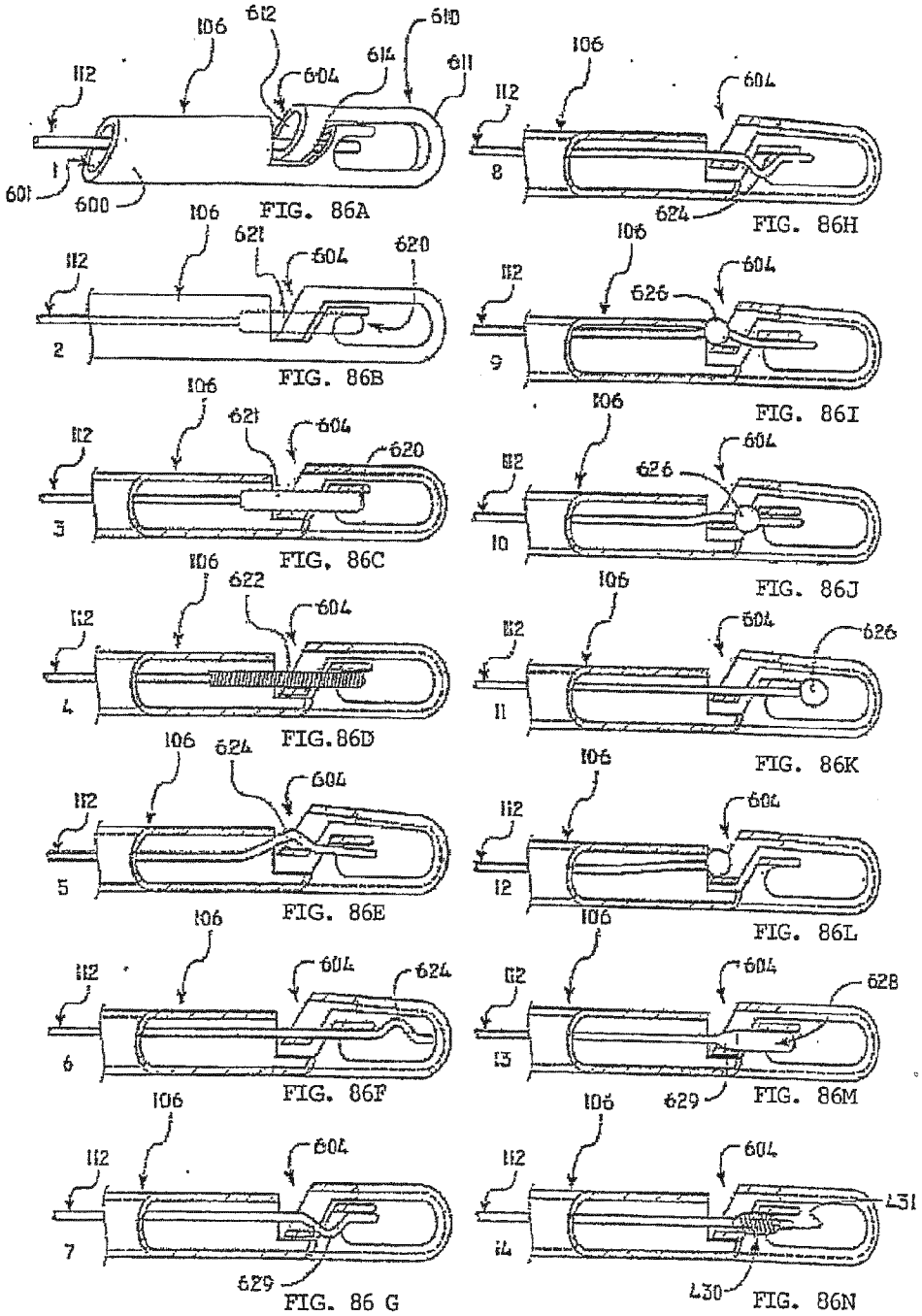


FIG. 85A FIG. 85B FIG. 85C

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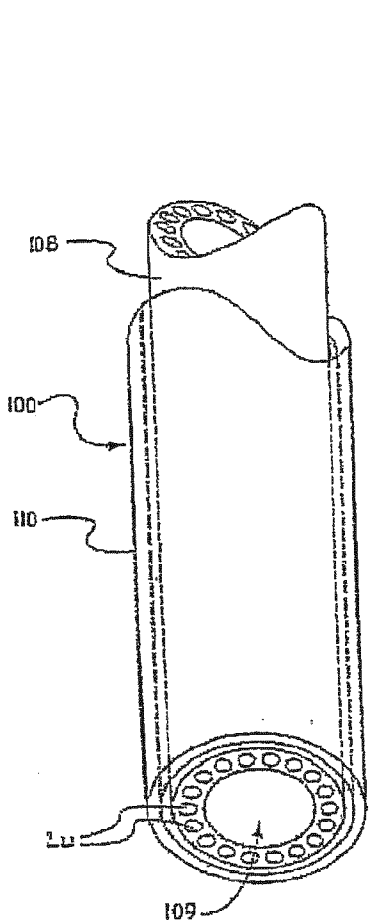


FIG. 87A

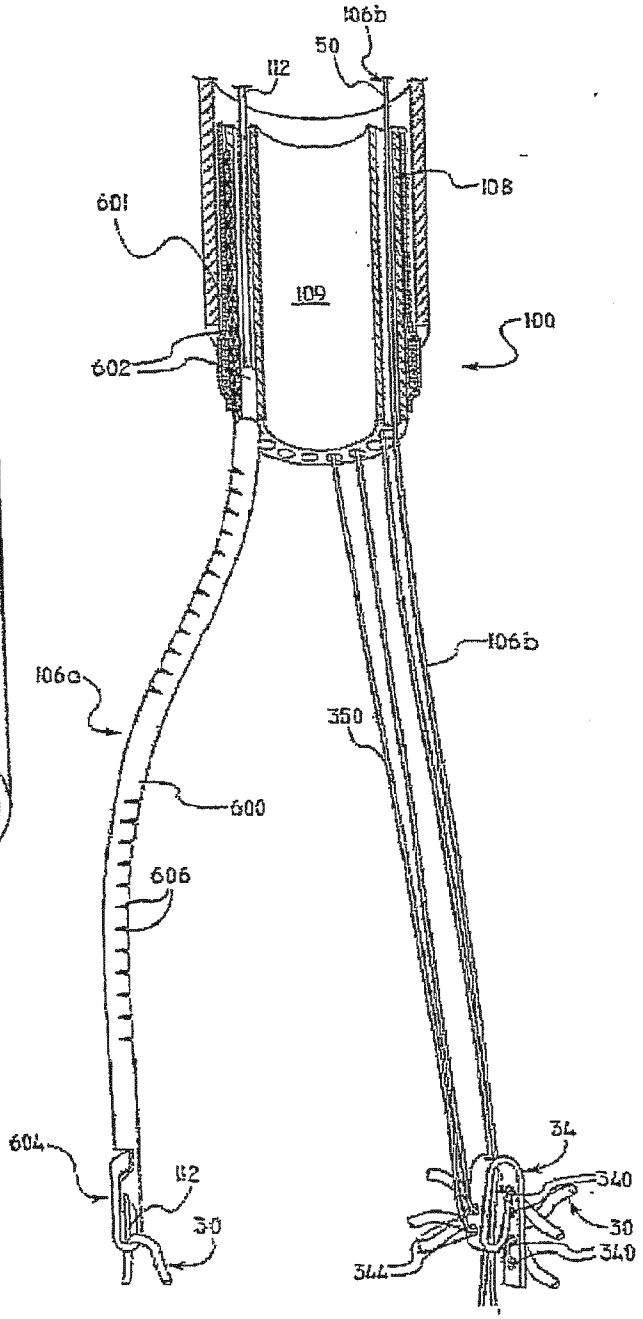


FIG. 87B

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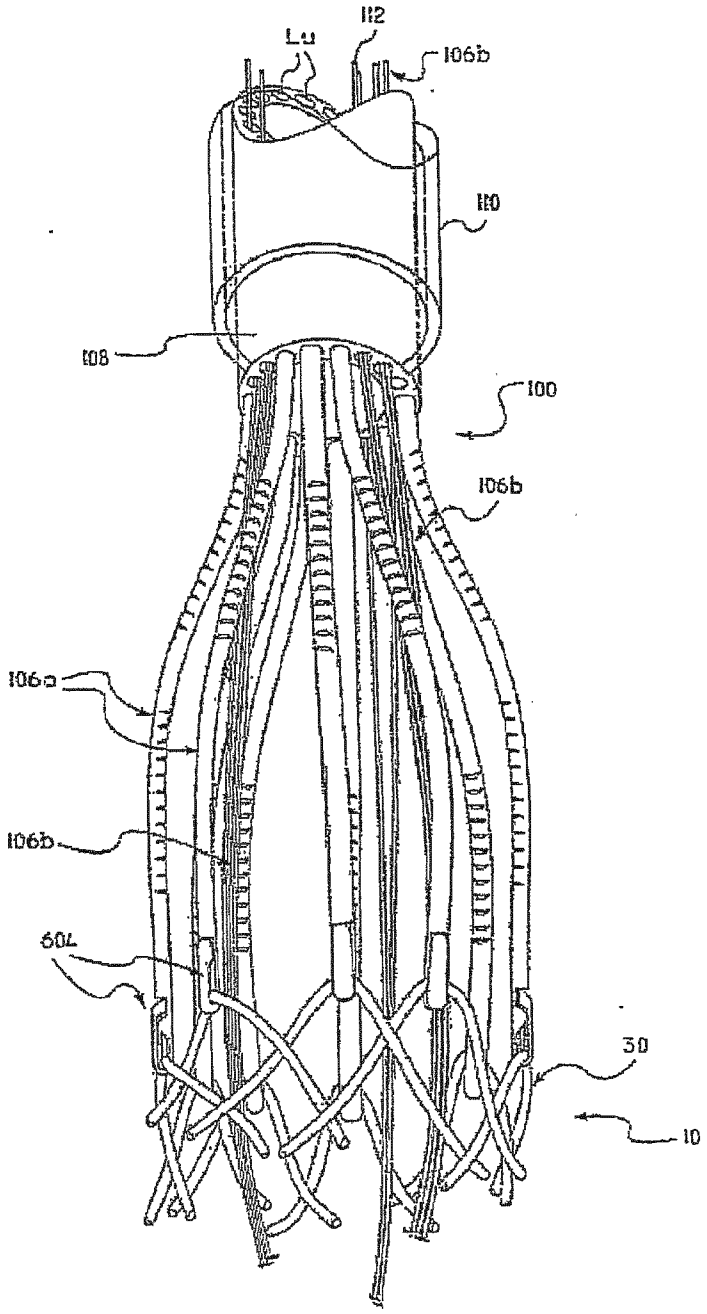


FIG. 88A

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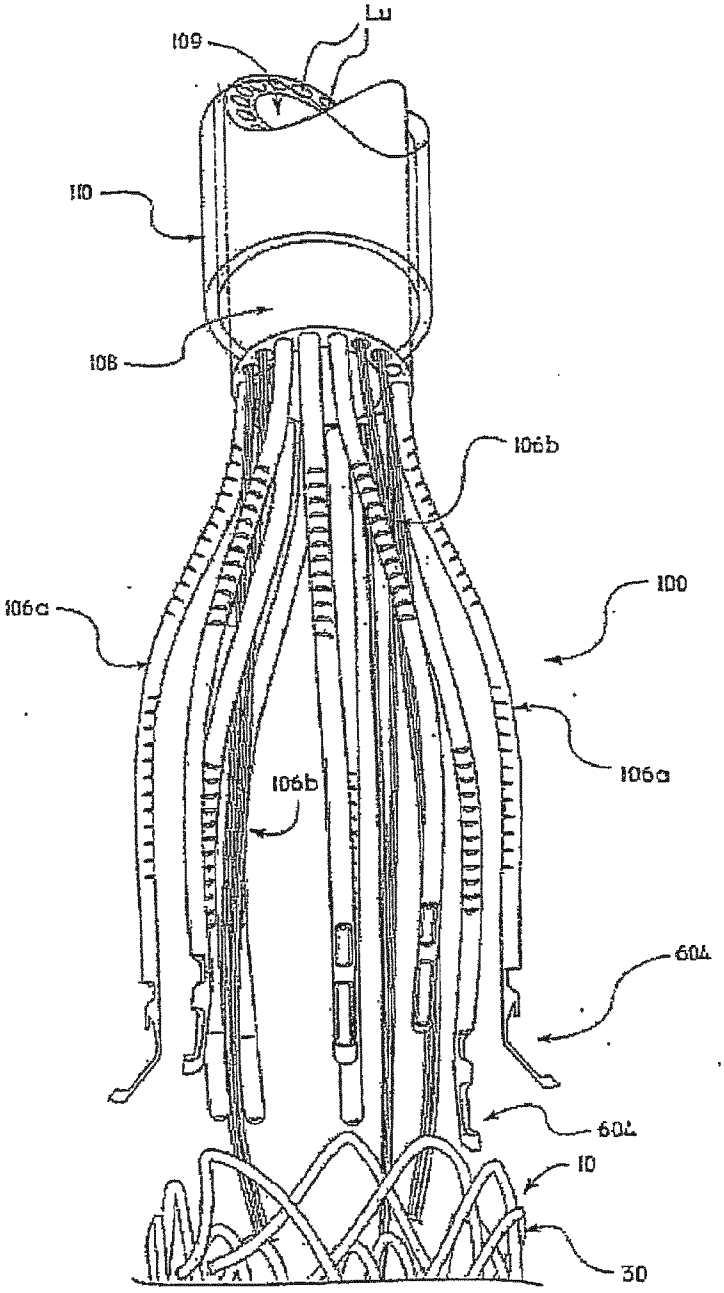


FIG. 88B

Aortic Innovations, LLC, Exhibit 2040
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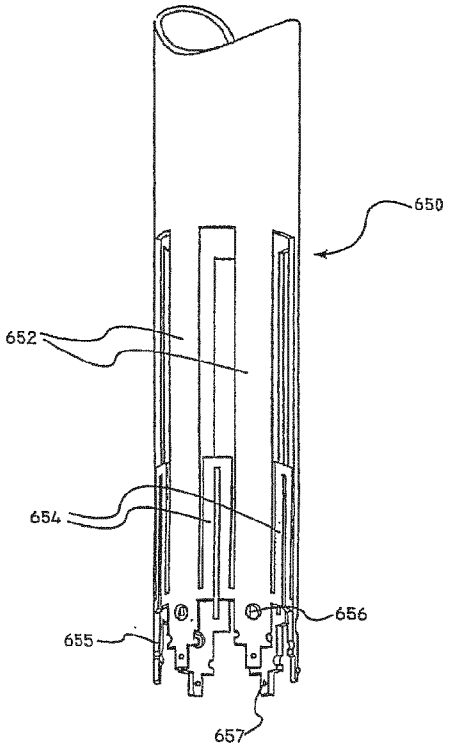


FIG. 89A

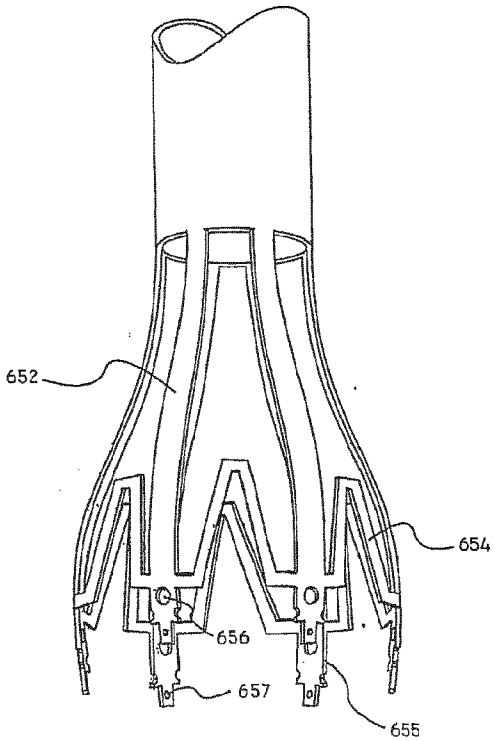


FIG. 89B

Aortic Innovations, LLC, Exhibit 2040
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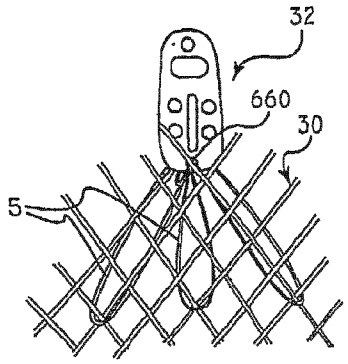


FIG. 90A

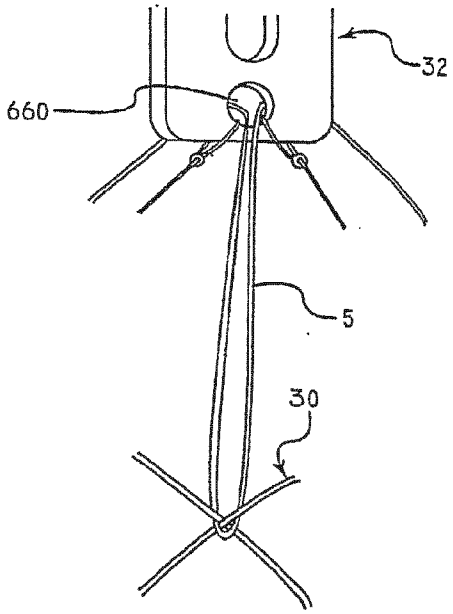


FIG. 90B

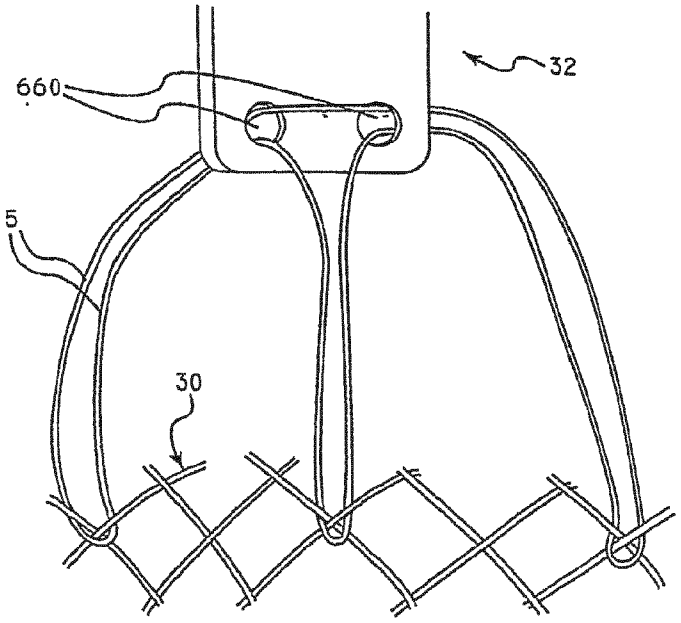


FIG. 90C

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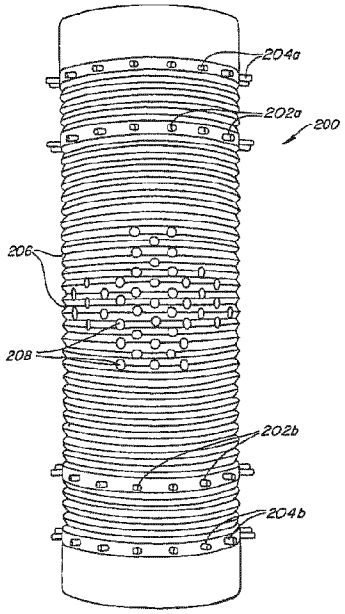


FIG. 91

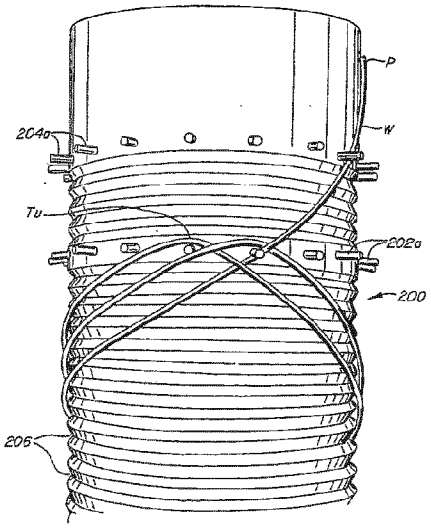


FIG. 92A

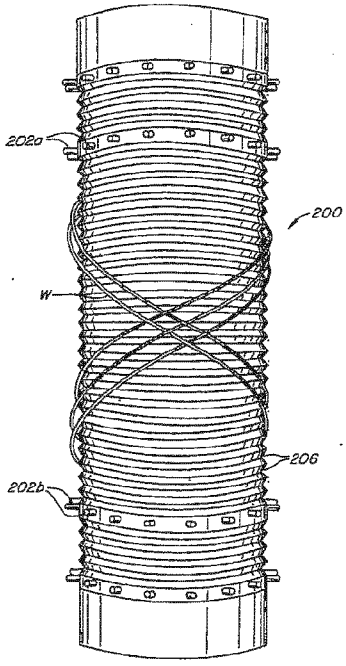


FIG. 92B

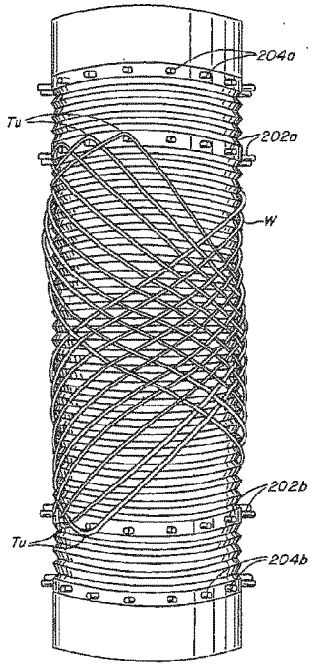


FIG. 92C

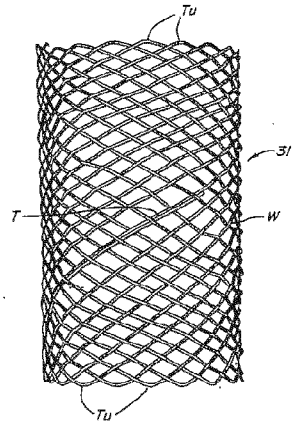


FIG. 92D

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FIG. 93A



FIG. 93D

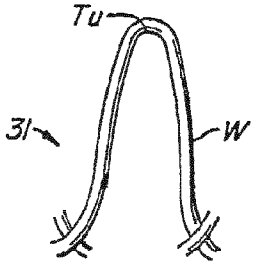


FIG. 93B

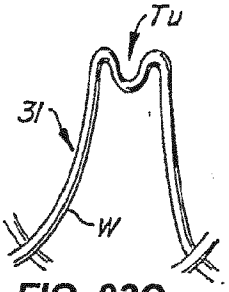


FIG. 93C

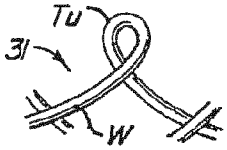


FIG. 93E

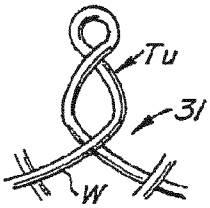


FIG. 93F

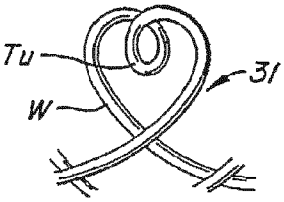


FIG. 93G

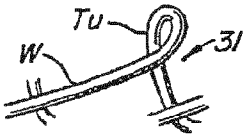


FIG. 93H

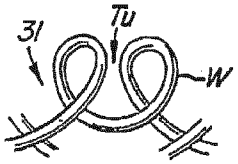


FIG. 93I

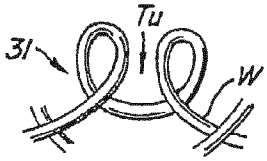


FIG. 93J

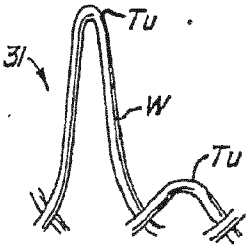


FIG. 93K

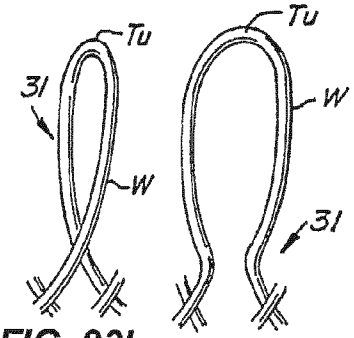


FIG. 93L FIG. 93M

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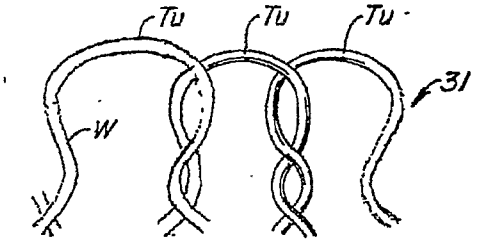


FIG. 93N

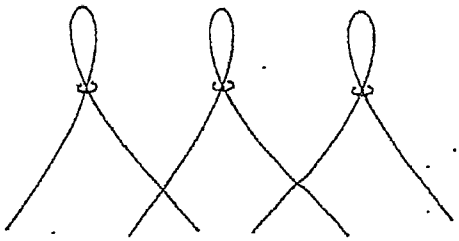


FIG. 93O

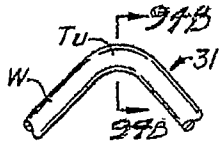


FIG. 94A

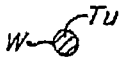


FIG. 94B

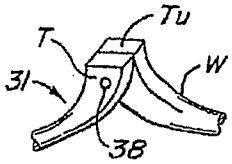


FIG. 95A

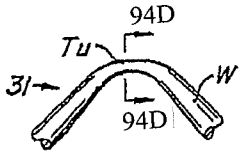


FIG. 94C

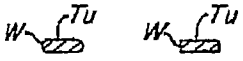


FIG. 94D FIG. 94E

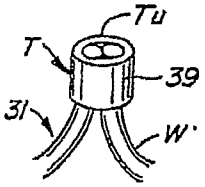


FIG. 95B

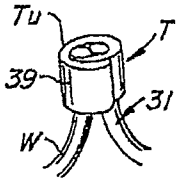


FIG. 95C

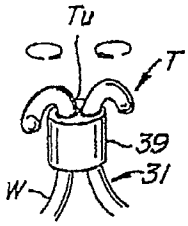


FIG. 95D

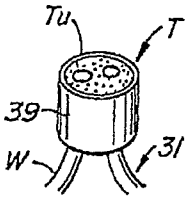


FIG. 95E

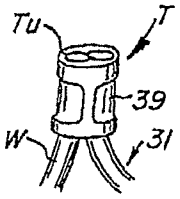


FIG. 95F

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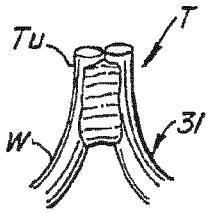


FIG. 95G

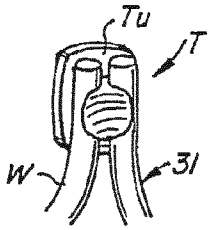


FIG. 95H

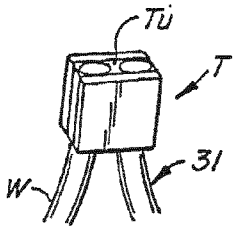


FIG. 95I

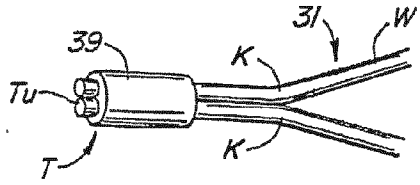


FIG. 95J

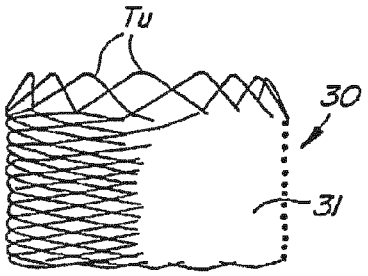


FIG. 96A

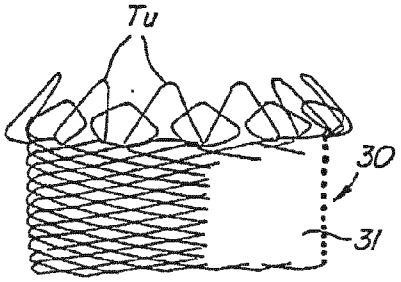


FIG. 96B

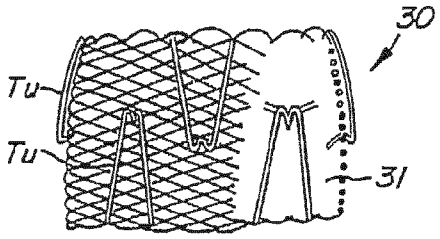


FIG. 97A

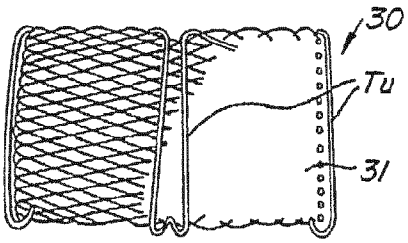


FIG. 97B

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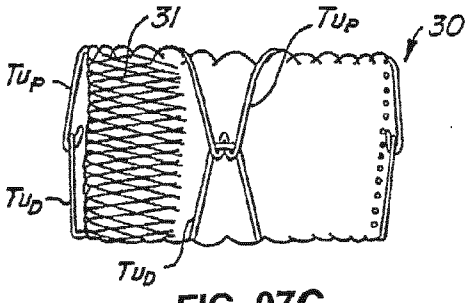


FIG. 97C

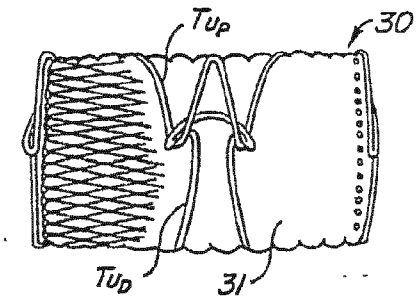


FIG. 97D

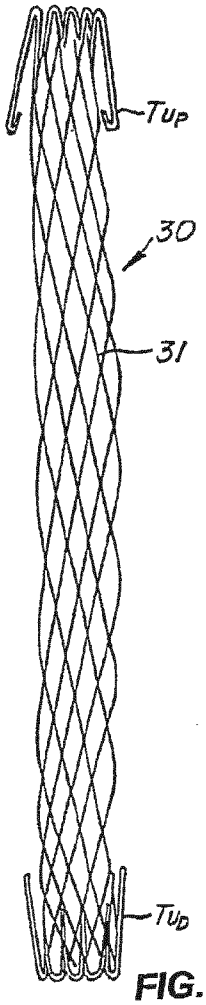


FIG. 97E

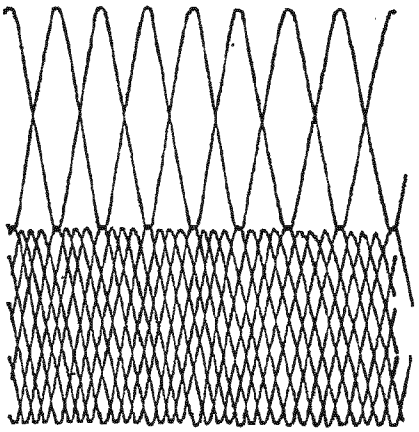


FIG. 98A

Aortic Innovations, LLC, Exhibit 2040
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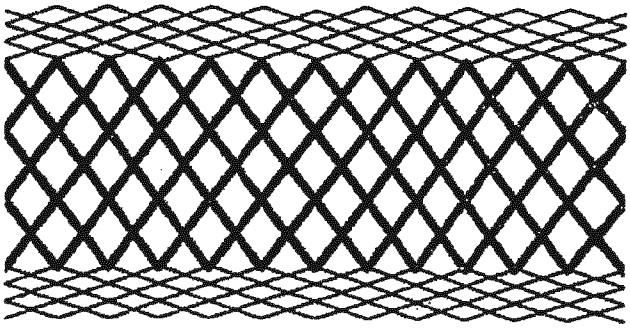


FIG. 98B

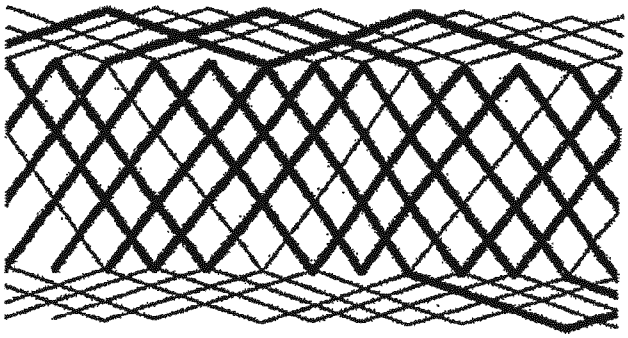


FIG. 98C

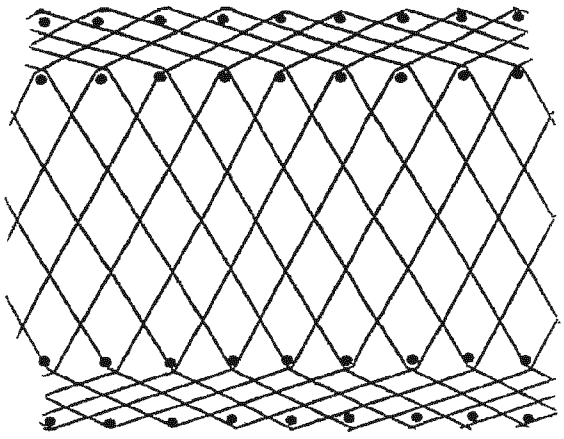


FIG. 98D

Aortic Innovations, LLC, Exhibit 2040
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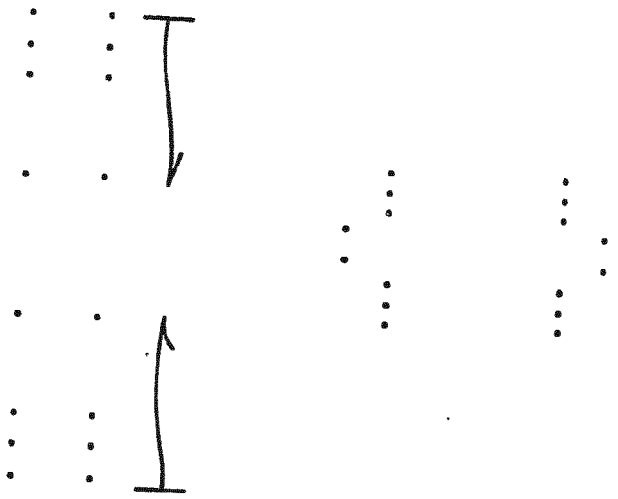


FIG. 99A



FIG. 99B



FIG. 99C



FIG. 99D



FIG. 99E

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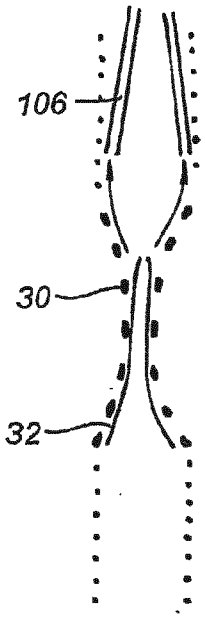


FIG. 100A

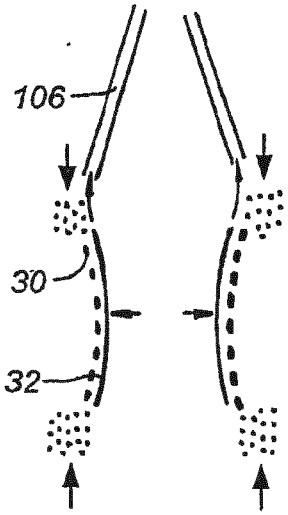


FIG. 100B

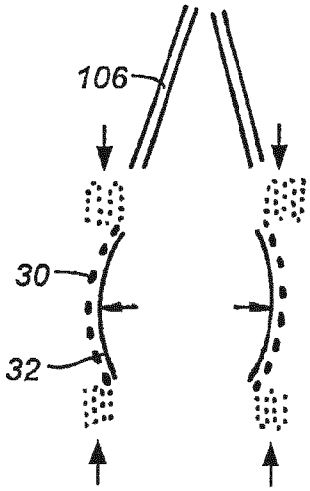


FIG. 100C

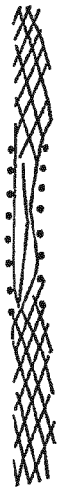


FIG. 100D

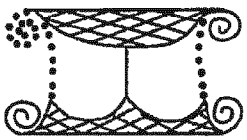


FIG. 100E

Aortic Innovations, LLC, Exhibit 2040
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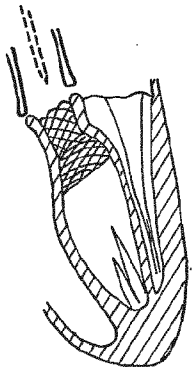


FIG. 101A

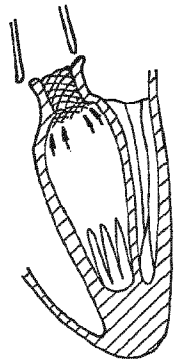


FIG. 101B

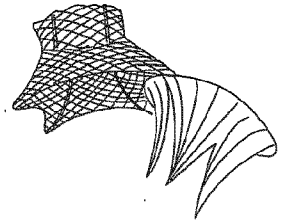


FIG. 102A

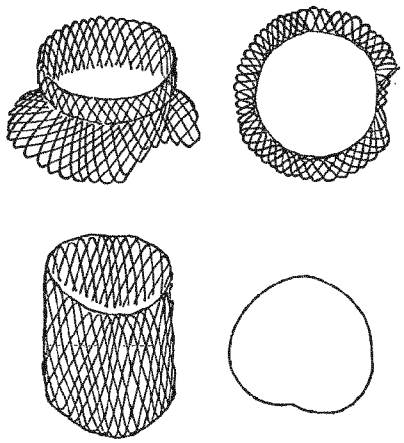


FIG. 102B

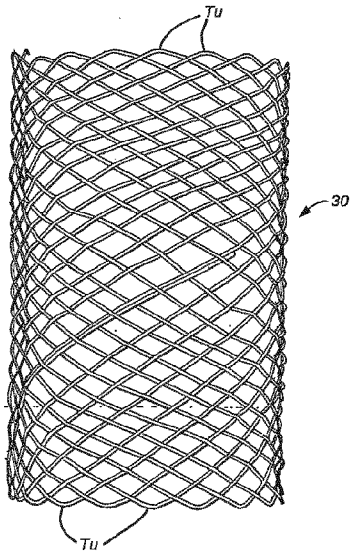


FIG. 103

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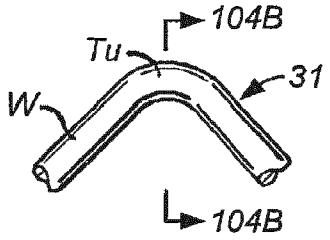


FIG. 104A



FIG. 104B

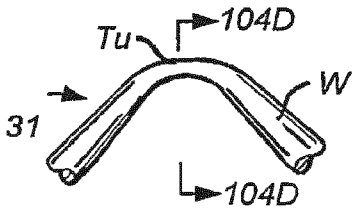


FIG. 104C



FIG. 104D

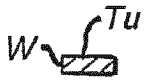


FIG. 104E

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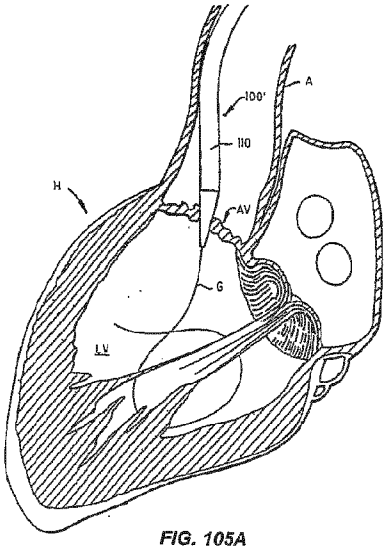


FIG. 105A

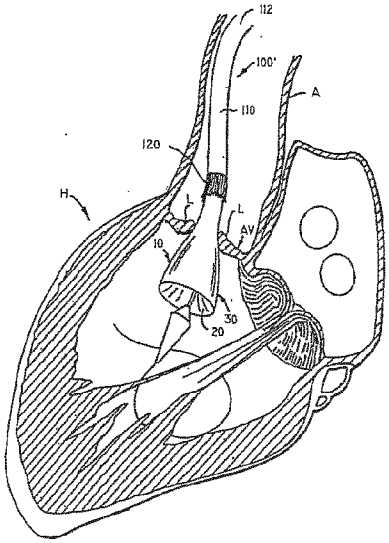


FIG. 105B

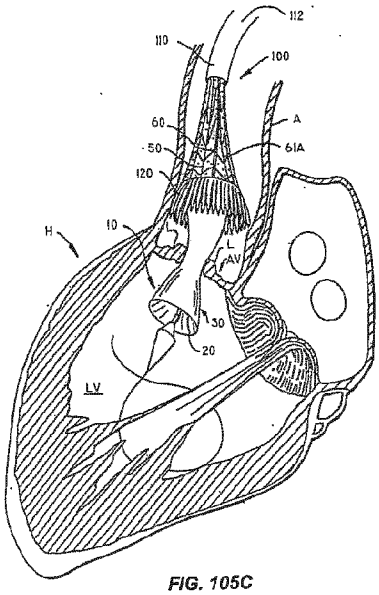


FIG. 105C

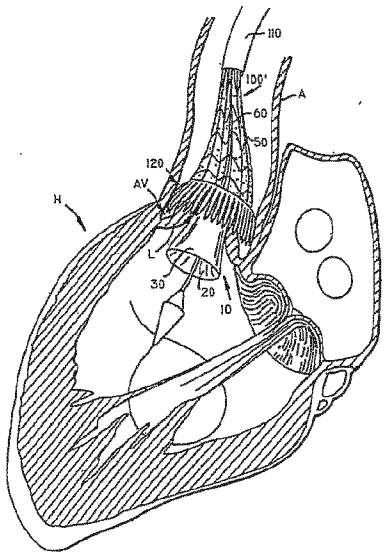


FIG. 105D

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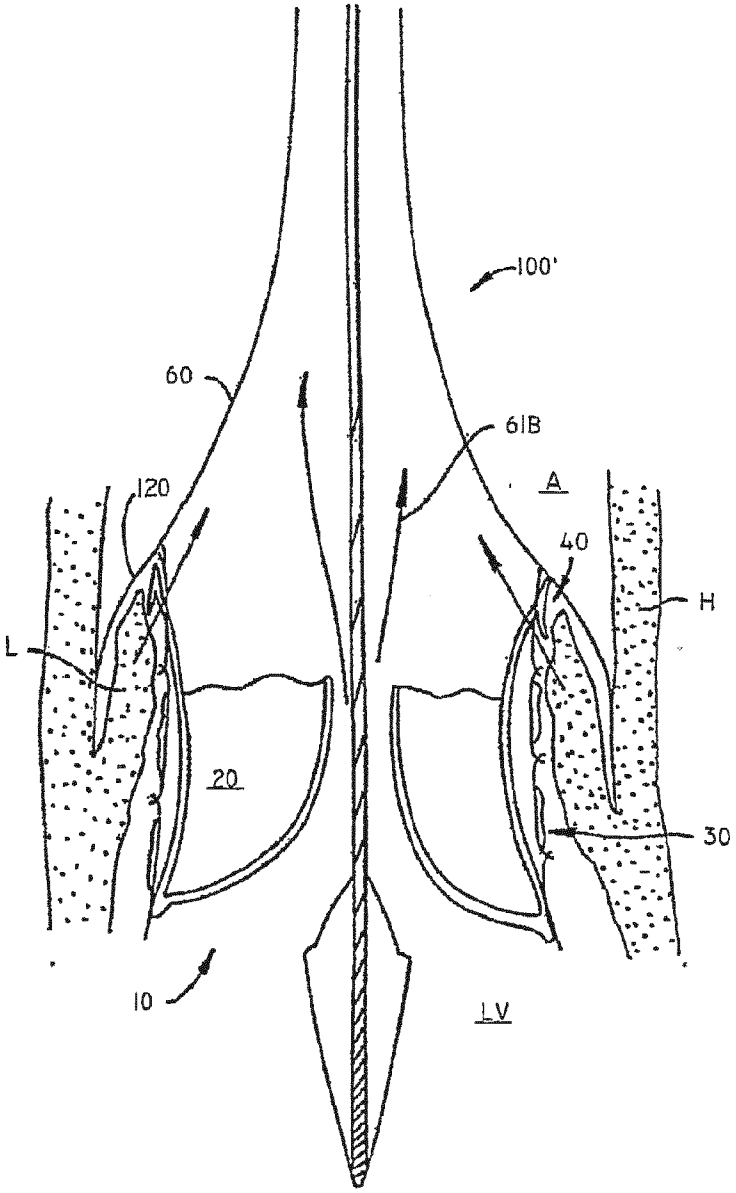


FIG. 105E

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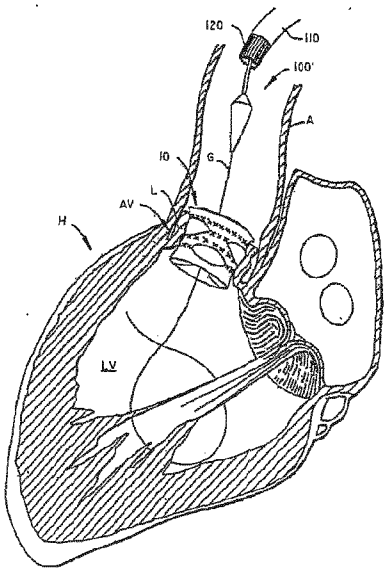


FIG. 105F

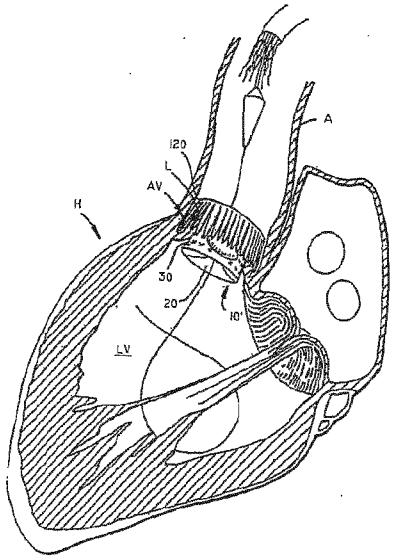


FIG. 106

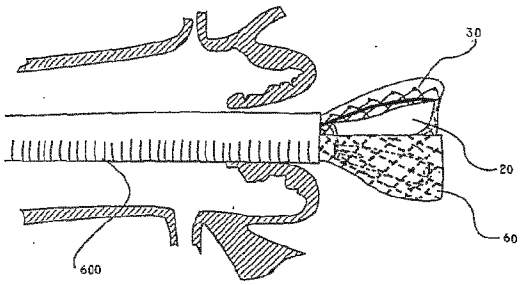


FIG. 107A

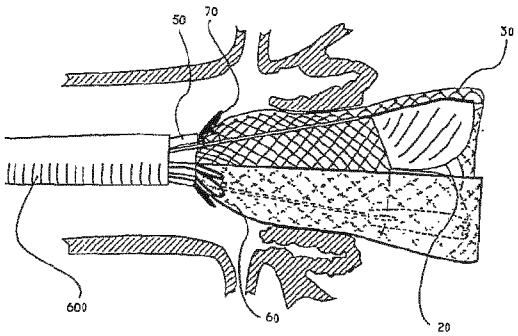


FIG. 107B

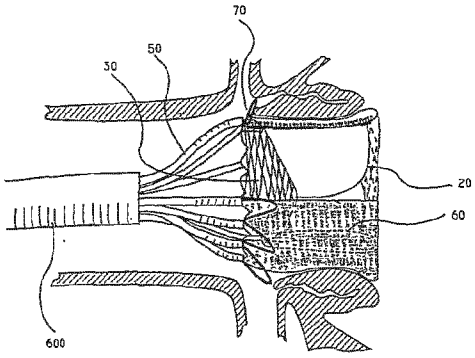


FIG. 107C

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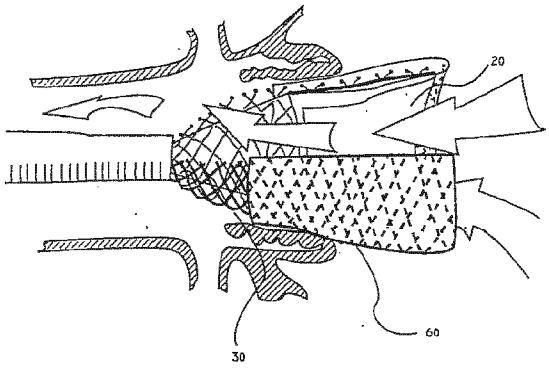


FIG. 108A

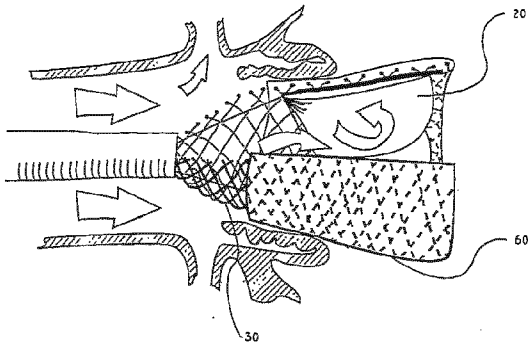


FIG. 108B

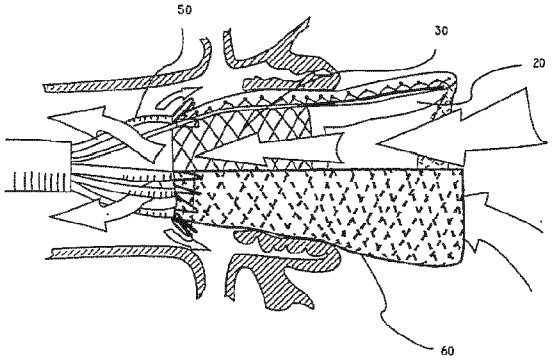


FIG. 109A

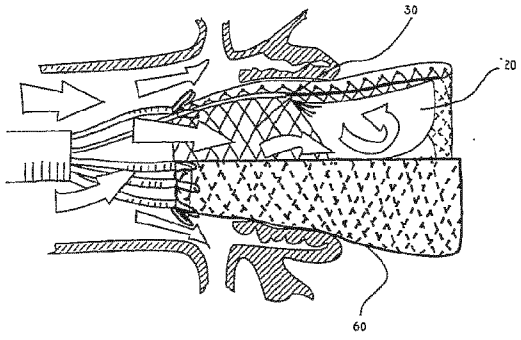


FIG. 109B

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EUROPEAN SEARCH REPORT

Application Number
EP 12 17 9330

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	US 2002/123802 A1 (SNYDERS ROBERT V [US]) 5 September 2002 (2002-09-05) * paragraphs [0056] - [0064]; figures 8,9,16-18 *	1-15	INV. A61F2/01 A61F2/24
A	US 5 957 949 A (LEONHARDT HOWARD J [US] ET AL) 28 September 1999 (1999-09-28) * column 9, line 6 - line 24 * * figures 7A,B *	1-15	
A,D	WO 00/47139 A1 (HEARTPORT INC [US]) 17 August 2000 (2000-08-17) * page 7, line 18 - line 25 * * figures 9,10 *	1-15	

TECHNICAL FIELDS SEARCHED (IPC)

A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	29 October 2012	Geuer, Melanie

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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EPO FORM 1503 03.82 (P04C01)

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 12 17 9330

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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29-10-2012

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US005554184A

United States Patent [19]

Machiraju

[11] Patent Number: 5,554,184

[45] Date of Patent: Sep. 10, 1996

[54] **HEART VALVE**

[76] Inventor: **Venkat R. Machiraju**, 534 Squaw Run E., Pittsburgh, Pa. 15238

[21] Appl. No.: **281,305**

[22] Filed: **Jul. 27, 1994**

[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/901; 606/167

[58] **Field of Search** 606/167; 623/2, 623/11, 900, 901

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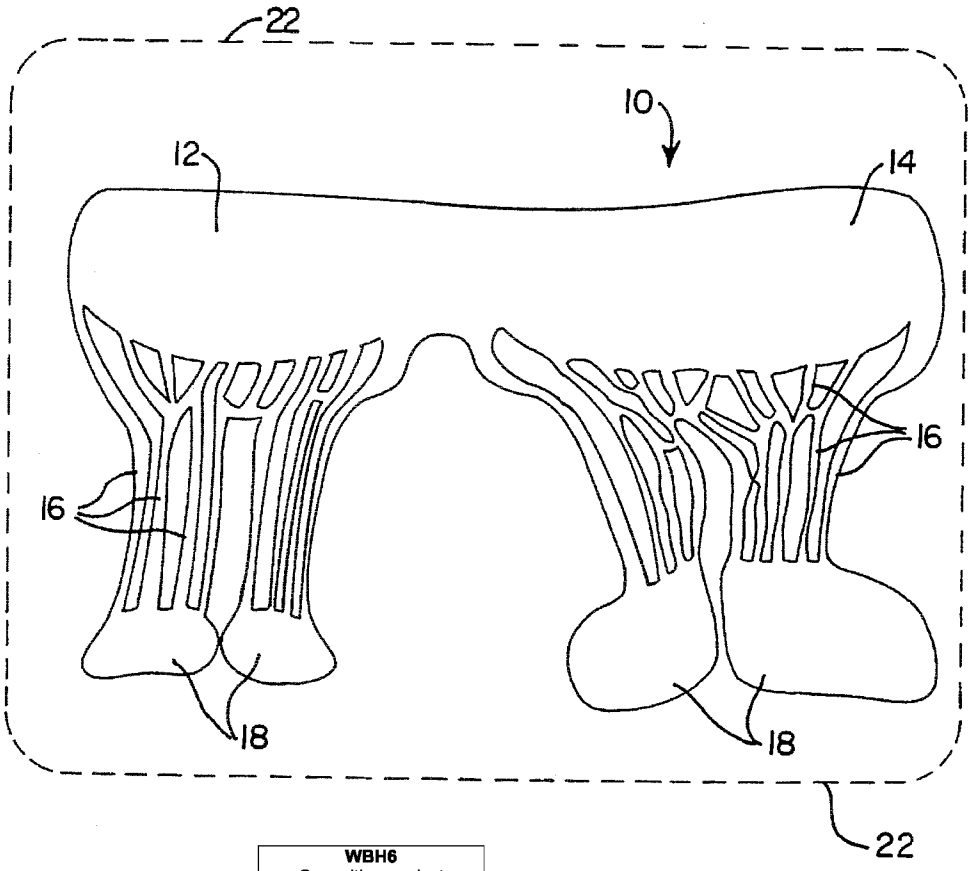
Primary Examiner—Michael A. Brown

Attorney, Agent, or Firm—Webb Ziesenheim Bruening Logsdon Orkin & Hanson, P.C.

[57] **ABSTRACT**

A heart valve, and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs.

16 Claims, 3 Drawing Sheets



WBH6
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

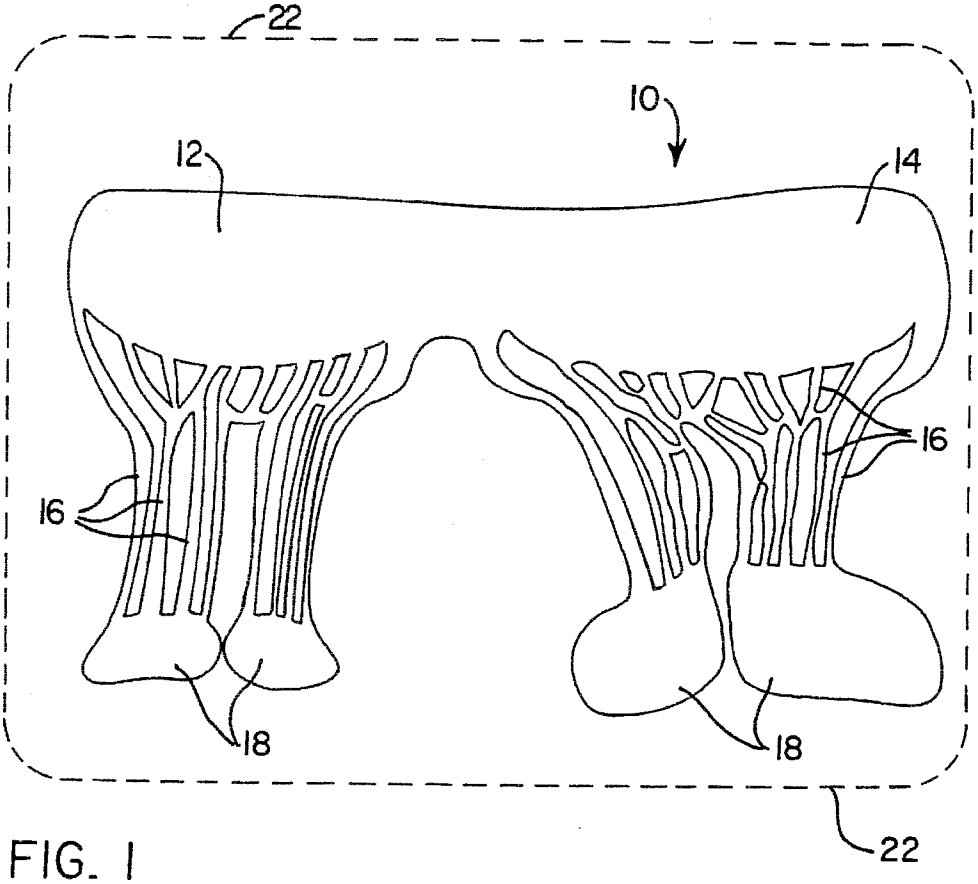


FIG. 1

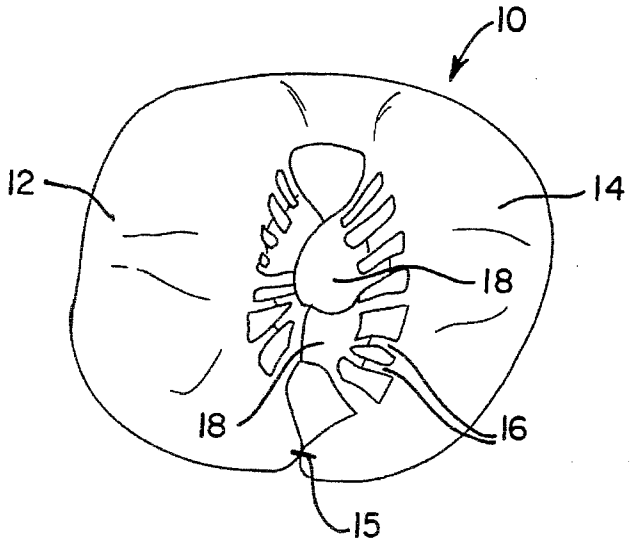


FIG. 2

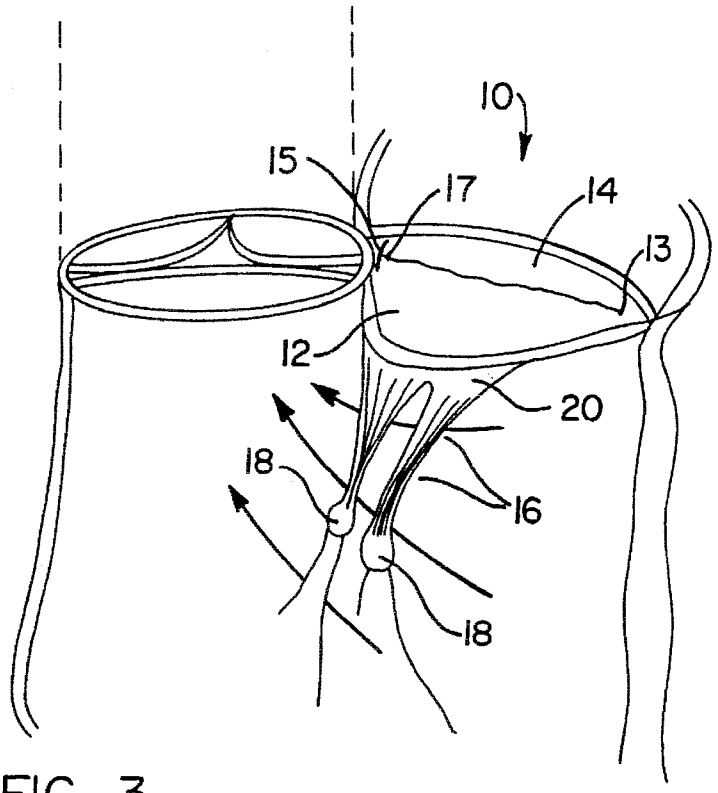


FIG. 3

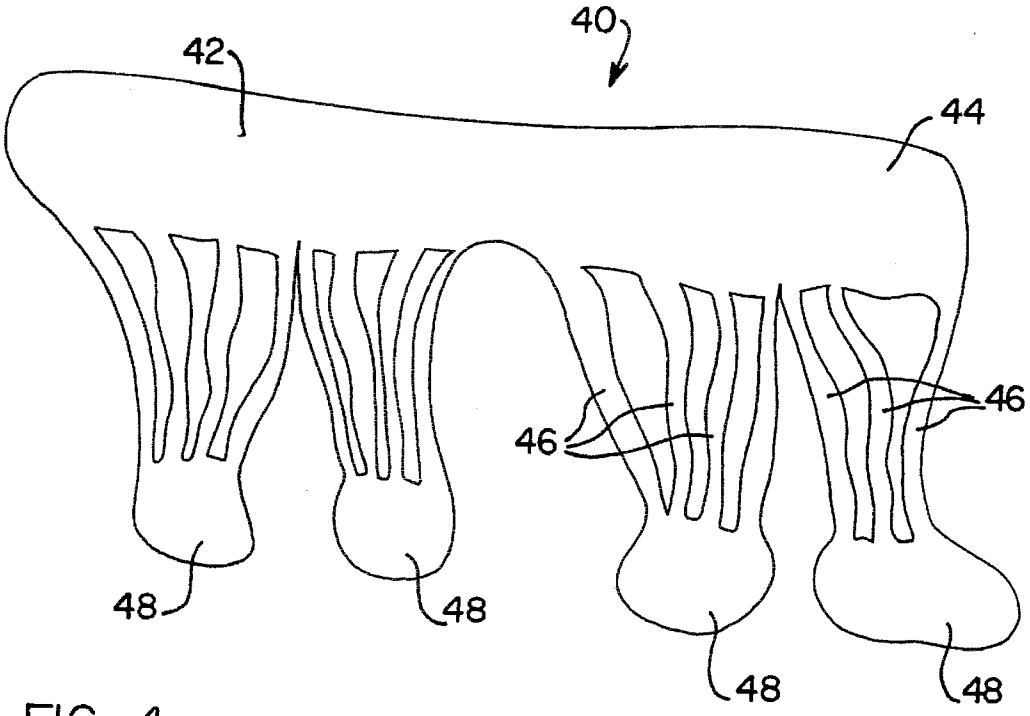


FIG. 4

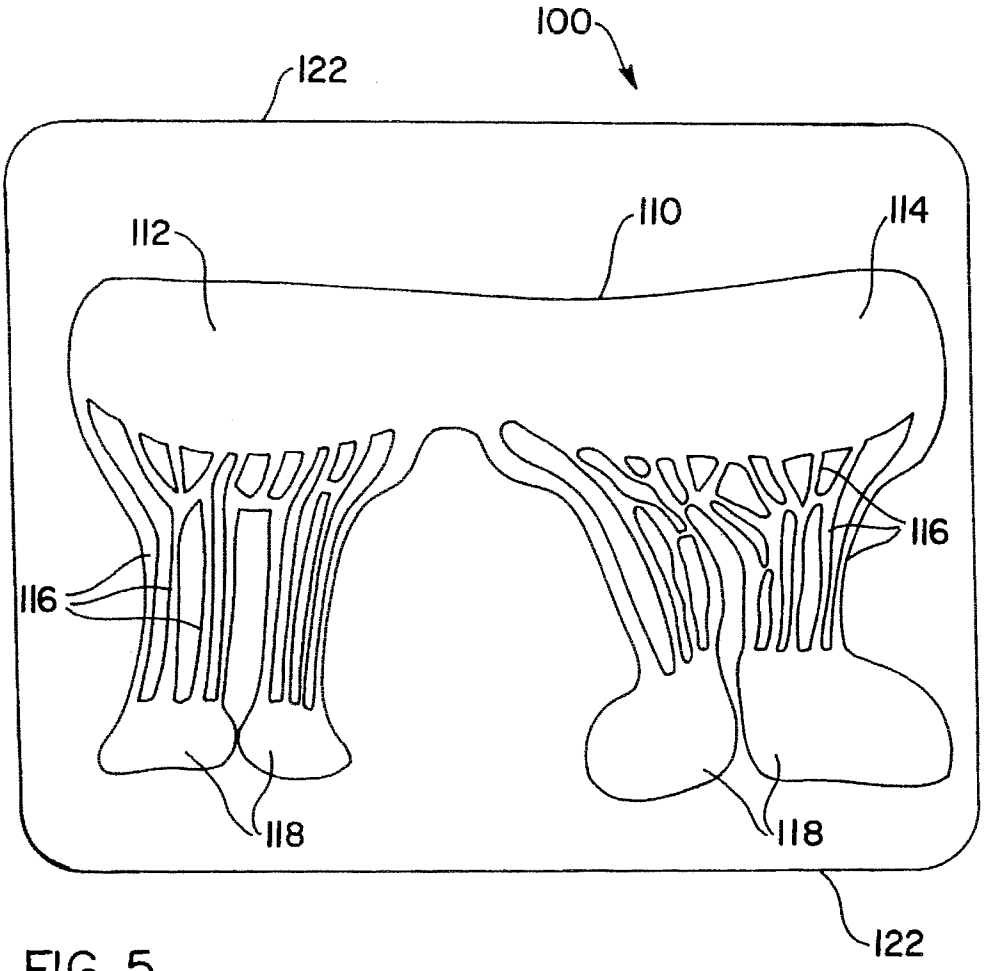


FIG. 5

HEART VALVE

FIELD OF THE INVENTION

The present invention relates to surgical techniques for correcting diseases of the mitral or tricuspid valve, as well as a replacement mitral valve or tricuspid valve structure, which improve upon the valves and techniques of the prior art.

BACKGROUND OF THE INVENTION

Natural heart valves are thin membranes which can seem to the uninitiated to be too fragile to open and close constantly hour after hour to keep a human heart pumping for a lifetime. Despite their apparent fragility, however, human heart valves are generally tough and reliable. Surgeons who repair or replace heart valves thus face a daunting challenge: to reproduce the performance and longevity of natural heart valves using tissue or synthetic materials and surgical techniques. Not surprisingly, many if not all prior art valve replacement and repair techniques have been acknowledged as only partially meeting this challenge, inasmuch as they provide only a temporary correction (10–20 years or so, and sometimes significantly less) and do not reproduce the original valve's function or efficiency.

As if the above challenges in heart valve technology were not enough, existing techniques and prostheses are also plagued by enormous costs. Understandably, synthetic structures and xenografts must be carefully engineered to create not only generally biocompatible structures but nonimmunogenic ones as well. Even seemingly safe materials such as surgical titanium and stainless steel, and polymers such as polyether polyurethane, have demonstrated troublesome biocompatibility or immunogenicity problems, and the useful life of a prosthesis incorporating them is thus unfortunately shortened. Alternative, expensive materials have been developed but even these synthetic materials and treated xenografts are imperfect.

Finally, one heart valve in particular—the mitral valve—has traditionally been less satisfactorily replaced than the other valves of the heart. (The same might be said of the mitral and tricuspid valves both, except that as a practical matter tricuspid valve replacement is not as important as mitral valve replacement—one tricuspid valve is replaced for every 1,000 mitral valves, in large part because repair can under certain circumstances succeed with annuloplasty alone.) The traditional difficulties in replacing or repairing mitral valves are due primarily to the challenge inherent in reproducing the natural valve structure including the chordae tendineae. The chordae tendineae connect the valve leaflets to the papillary muscles of the heart. Surgical replacement of the chordae tendineae in conjunction with mitral valve repair has previously been attempted, but with limited success. The area available for suturing one of the chordae directly to a papillary muscle is very small, due to the narrow width of a chord, and attempted attachment has invariably caused either the suture and/or the chord to pull free of the papillary muscle within a short time after surgery. Mitral valve replacement without reconstruction including chordae tendineae does not restore the original structure of the heart. It is helpful to note that standard trileaflet prosthetic valves for aortic or pulmonary valve replacement are not anatomically deficient with respect to their intended loci. Those same standard valves, however, cannot replace the mitral valve without anatomic compromise. A need therefore

remains for a mitral (tricuspid) heart valve which can claim the same distinction.

Accordingly, a new mitral valve, and a method for replacing or repairing the mitral valve, are needed in the cardiac surgery arts. An especial need persists for a mitral valve which is biocompatible and thoroughly nonimmunogenic, can be made and surgically implanted at substantially reduced cost (in comparison to prior art mitral valves), and which accurately reproduces and restores the original anatomy of the heart including chordae tendineae. Additionally, the mitral valve should be suitable for use in the tricuspid position, in those instances in which tricuspid valve replacement is indicated.

SUMMARY OF THE INVENTION

In order to meet these needs, the present invention is a heart valve, and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs. Prior to surgical implantation, the pericardial tissue is cured in an aqueous glutaraldehyde solution. The invention also embraces variations on this preferred embodiment including, but not limited to, the use of the above-identified substitute tissues other than pericardium as well as synthetic materials under certain circumstances, a reduced number of chordae and the use of alternative curing (or crosslinking) solutions.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** is a plan view of an excised and shaped pericardium according to the preferred embodiment of the present invention;

FIG. **2** is a plan view of the pericardium of FIG. **1** after the two leaflets are sutured into an annulus which is then laid flat, with the chordae in the center;

FIG. **3** is a section of the left ventricle of the heart, showing the heart valve of FIGS. **1** and **2** in place within the heart at the mitral valve position, and also showing its position relative to the aortic valve as well as the importance of preserving the cardiac anatomy with respect to the chordae tendineae and (pumping) blood flow therethrough;

FIG. **4** is a plan view of a heart valve according to an alternative embodiment of the invention; and

FIG. **5** is a plan view of a cutting tool according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a heart valve, and a technique for effecting heart valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or an equivalent bovine or porcine or other pericardial or synthetic sheet material. The autologous graft

material is preferably precut and shaped into a configuration which substantially restores the original anatomy of the heart, including the chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and then the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs. Prior to surgical implantation, and either before or after precutting and shaping, the pericardium graft is preferably cured in an aqueous glutaraldehyde solution. Apart from its preferred embodiment, the invention also embraces variations on this preferred embodiment including, but not limited to, the use of the dura mater or fascia lata instead of the pericardium as well as bovine or porcine pericardial or other synthetic materials under certain circumstances, a reduced number of chordae and alternative curing (or crosslinking) solutions. The synthetic materials can include any of the synthetic polymers accepted for use in cardiac repair and valve replacement, and recent developments in this field have yielded excellent sheet materials which will substitute for the pericardium or other tissue when autologous tissue is unavailable for some reason. It should be borne in mind, however, that the use of the patient's own pericardial or other tissue is essential to the preferred embodiment of this invention.

The pericardium is the protective sheath around the heart, and although ligaments anchor it and therefore also the heart itself within the chest cavity, it is not a structure necessary for good health or heart function. In other words, despite the protective and anchoring effect of the intact pericardium, the pericardium may be completely excised without any detriment to the patient. An important aspect of the preferred embodiment of the present invention, therefore, is the use of the patient's own pericardial tissue to construct a prosthetic mitral valve. The use of the patient's own tissue in a tissue heart valve greatly minimizes if not eliminates any biocompatibility, immunogenicity or general rejection problems which nonautologous materials may cause.

Although the untreated pericardium may be used to construct the present mitral valve, preferably the pericardial tissue is treated to cure or crosslink it, to stabilize it and to increase tensile strength with commensurate decrease in its elongation under load. Most preferably, the pericardium is cured in sterile 0.1–0.8% aqueous glutaraldehyde, although comparable crosslinking or curing agents may be determined without undue experimentation because they need merely stabilize the existing tissue without altering its antigenicity (or lack thereof). The crosslinking or curing agent should itself be histocompatible or, in other words, any residue of the curing or crosslinking agent should not be cytotoxic or otherwise undesirable. An example of a crosslinking agent which is not acceptable is formaldehyde, which is both cytotoxic and carcinogenic.

In the context of discussing the pericardium, it should also be noted that pericardial tissue is a sheet material which is different on its two sides. Lining the interior of the pericardial sac is a thin, moist membrane; the outside surface of the pericardium is dry and relatively rougher. The significance of this difference will become apparent later in the description of the invention.

In the most preferred embodiment of the invention, a human patient's own pericardium is used to create a heart valve graft when replacement of the mitral or tricuspid valves is indicated. The pericardium is surgically incised, cut to shape and sutured into a ring (alternatively the pericardium may be sutured into a tube and then cut to shape), stabilized in a crosslinking or curing agent, usually liquid, and surgically implanted into the mitral or tricuspid valve locus in the heart. Alternatively, the pericardial tissue may be stabilized first, then cut to shape and sutured. In fact, after the pericardium is excised, cutting, stabilizing (crosslinking) and suturing may take place in any order, although after the pericardium is stabilized it must be thoroughly rinsed. A typical protocol would include stabilizing the pericardial tissue for ten minutes in the glutaraldehyde solution, followed by a five-minute rinse with running sterile water, but this protocol is exemplary only. It is within the skill of the art to stabilize (crosslink) and to rinse human tissue.

An important aspect of the invention is the shape into which the pericardial tissue is cut. FIG. **1** illustrates the shape of the cut pericardium according to the preferred embodiment of the present invention. The cut pericardium forms a heart valve **10** having an anterior leaflet **12**, a posterior leaflet **14**, a plurality of chordae tendineae **16** and papillary muscle graft tabs **18**. The chordae tendineae **16** are trabeculated or, in other words, cascade in a tier from the leaflets **12**, **14** to the papillary muscle graft tabs **18**. In other words, the chordae tendineae **16** are most numerous where they directly append the leaflets **12**, **14**, but between the leaflets **12**, **14** and the papillary muscle graft tabs **18** they converge, thus reducing the number of chordae **16** appended to the tabs **18**. The preferred embodiment of the invention includes about twenty chordae tendineae **16** directly appending the leaflets **12**, **14**, with those twenty chordae converging into about sixteen chordae at the interface between the chordae and the papillary muscle graft tabs. Incidentally, the study of normal heart anatomy reveals that about twenty chordae tendineae append the mitral valve leaflets, and thus the preferred embodiment recreates this normal anatomical feature of the heart.

As an alternative to the preferred embodiment, the cut pericardial tissue may incorporate fewer chordae **16**, and with reduced or eliminated trabeculation, than described above and still remain within the scope of the present invention. FIG. **4** shows a pericardium cut in accordance with an alternate embodiment of the invention, to yield a heart valve **40** in which fifteen chordae tendineae **46** which append the leaflets **42**, **44** connect directly to the papillary muscle graft tabs **48**, without converging.

Referring now to FIG. **2**, the heart valve **10** of FIG. **1** is shown in its annular and flattened orientation, after the anterior and posterior leaflets **12**, **14** are sutured together with a suture **15**. More than one suture may be used, but a single suture **15** is shown in FIG. **2** for clarity. The sheet is shown flat, with the chordae tendineae **16** and the papillary muscle graft tabs **18** literally piled in the center of the circular leaflets **12**, **14**. When the heart valve **10** is sutured into place within the patient's heart, attachment of the leaflets **12**, **14** in the actual valve location plus suturing of the papillary muscle graft tabs **18** to the adjacent papillary muscles, the configuration shown in FIG. **2** is lost and the heart valve **10** takes on the configuration shown in FIG. **3**.

FIG. **3** is a partial section of the human left atrium and ventricle, just anterior of the anterior leaflet of the mitral valve, showing the present heart valve in place in a human heart in the mitral position. The same structures as are visible in FIG. **1** may be seen in FIG. **3**. The anterior leaflet **12** and posterior leaflet **14** join at the anterior commissure **17**, opposite the posterior commissure **13**, and the papillary muscle graft tabs **18** are visibly grafted onto their respective papillary muscles. The suture **15** of the present heart valve preferably coincides with the anterior commissure **17**,

because this locus is relatively immobile within the heart, compared to the posterior commissure **13**, and thus exerts minimal stress on the suture **15**. Solid arrows show blood flow through the left ventricle and also illustrate the importance of the spaces between chordae tendineae—blood flows all through and around them during the pumping of the heart.

With continued reference to FIG. **3**, the sheet material taken from the pericardium has definite preferred right and wrong sides or, more specifically, has a side which should face the atrium and a side which should face the ventricle when the valve is closed. The side of the pericardium which bears the thin, moist membranous lining should face the atrium, and the dry, relatively rougher side **20** should face the ventricle for the purposes of the preferred embodiment of the invention. The reason is as follows. Blood flow from the atrium to the ventricle is largely passive flow, whereas blood flow through the ventricle is vigorous as a result of heart muscle pumping. In the unlikely event that any blood clots might form anywhere on the present mitral valve, they would theoretically tend to do so on the atrial side of the valve, where the relatively passive blood flow might permit it. However, on the ventricular side of the valve the strong blood flows minimize or eliminate any possibility of clot formation even on the dry and relatively rougher side **20** of the pericardial tissue. Thus, having the moist membrane of the pericardium face the atrium constitutes the preferred orientation, although it should be recognized that the present invention embraces the grafting of the shaped pericardium in the mitral or tricuspid valve positions in either of the two possible orientations.

If desired, a standard suture cuff may be used to reinforce the leaflets as the present valve is sutured into place. Alternatively, only the suture **15** need be reinforced with a small Dacron graft. The suture cuff would ordinarily be placed at the suture line of the leaflets on the moist membranous side of the pericardium. Other portions of the present mitral valve may conceivably be reinforced for suturing also, in the same way. In particular, thin strips of Gore-Tex polymer may be sutured alongside the chordae, to strengthen them. Generally, however, the heart valve of FIGS. **1** or **4**, or other heart valves according to the present invention, may be sutured into place during routine cardiac surgery by suturing the respective anatomical portions into their proper place. The upper edges of the anterior and posterior leaflets **12**, **14** (in other words, the edges opposite the chordae) may be trimmed by the surgeon at the time of suturing, for an exact fit. Ordinarily this trimming is done after the leaflets have been sutured into place.

As a general rule, the mitral valve has a diameter of about 28–40 mm, after the leaflets are sutured together as shown in FIG. **2**. Different hearts have different sizes and commensurately differing valve sizes, but when valves throughout this range can be prepared it is virtually certain that one of the sizes will fit any given human patient. As a practical matter, it is best to have a choice of three sizes accommodating the small valve (28–30 mm diameter) the medium valve (32–34 mm) and the large valve (36–38 mm).

In order to ensure availability of the above described range of sizes, as well as to assure rapid availability of a shaped, excised pericardium from the same surgical procedure, a preferred tool for implementing the present invention is a tool for cutting or stamping the pericardial sheet. Such a tool may be represented by FIG. **1** if the dotted line **22** represents the tool circumference, the solid lines represent the cutting blades and the view is sectional through the blades with the tool backing in the foreground. FIG. **5** discloses such a tool **100**, having a tool backing **122** bearing a blade **110** thereon, with each of the same heart valve shapes being defined by the shape of the blades as are shown in FIG. **1**, namely, the anterior leaflet **112**, the posterior leaflet **114**, the chordae **116** and the papillary muscle graft tabs **118**. Such a tool may be incorporated into a stamping machine so that an excised pericardium may be quickly and accurately cut to the necessary shape. Preferably, the tool has disposable blades or is disposable in entirety. If only the blades are disposable, then the tool itself must be autoclavable. The invention also embraces the use of a template for cutting the valve shown in FIG. **1**, although because the pericardium is tough and strong a cutting tool for machine assisted stamp cutting is preferable to a template for manual cutting. Even so, manual or power or laser cutting of the pericardium are all contemplated for possible use in the practice of the invention.

Additional chemical treatments of the present heart valve may be conducted without departure from the scope of the present invention. Anticalcification agents, in particular, may be contacted onto all or a portion of the valve to assure minimization or elimination of unwanted in vivo calcification of the valve. Aminooleic acid is a possible anticalcification agent; others are identified on an ongoing basis.

Although the invention has been described with particularity above, with respect to particular methods and materials, the invention is only to be limited insofar as is set forth in the accompanying claims.

I claim:

1. A method for repairing a human heart valve, comprising the steps of cutting a single sheet of a natural or artificial sheet material into the shape of an excised human heart valve including at least one trabeculated tier of chordae tendineae, said tier terminating in a papillary muscle graft tab, and surgically implanting the cut sheet material into the heart of a patient in whom heart valve repair is indicated.

2. The method according to claim **1** wherein said step of cutting a natural or artificial sheet material is conducted with a cutting tool having blades configured in the shape of an excised human heart valve.

3. The method according to claim **1** wherein said step of cutting a natural or artificial sheet material is conducted with a cutting tool having blades configured in the shape of an excised human mitral valve.

4. The method according to claim **3** wherein said sheet material is selected from the group consisting of autologous pericardium, autologous fascia lata, autologous dura mater, bovine pericardium, porcine pericardium and biocompatible polymer.

5. The method according to claim **4** wherein said sheet material is autologous pericardium.

6. The method according to claim **3** wherein said shape of an excised human mitral valve further comprises an anterior leaflet connected to a posterior leaflet, a plurality of papillary muscle graft tabs and a plurality of chordae tendineae connecting said leaflets to said papillary muscle graft tabs.

7. The method according to claim **3** wherein said shape of an excised human mitral valve includes about 20 chordae tendineae.

8. A cutting tool for preparing a human heart valve graft, comprising a backing and at least one blade configured in the shape of an excised human heart valve including at least one trabeculated tier of chordae tendineae, wherein said chordae tendineae have papillary muscle graft tabs appended thereto.

9. A cutting tool according to claim **8** wherein said at least one blade is disposable, said backing is autoclavable, and said tool is adapted for inclusion in a mechanical cutting system.

10. A cutting tool for preparing a human heart valve graft, comprising a substrate bearing cutouts defining the shape of an excised human mitral valve including chordae tendineae.

11. A method for repairing a human mitral valve, comprising the steps of:

excising at least a portion of the pericardium, in a single piece, of a patient in whom mitral valve repair is indicated;

cutting said pericardium into the shape of a human mitral valve including at least one trabeculated tier of chordae tendineae terminating in a papillary muscle graft tab;

curing the pericardium thus cut in a crosslinking solution, followed by rinsing; and

surgically implanting the cut and cured pericardium in the heart of a patient in whom mitral valve replacement is indicated.

12. The method according to claim 11 wherein said step of cutting said pericardium is conducted with a cutting tool having blades configured in the shape of an excised human mitral valve including chordae tendineae.

13. The method according to claim 11 wherein said shape of an excised human mitral valve including chordae tendineae further comprises an anterior leaflet connected to a posterior leaflet, a plurality of papillary muscle graft tabs and a plurality of chordae tendineae connecting said leaflets to said papillary muscle graft tabs.

14. The method according to claim 13 wherein said shape of an excised human mitral valve further includes about 20 chordae tendineae.

15. The method according to claim 14 wherein said chordae tendineae are trabeculated.

16. The method according to claim 14 wherein said crosslinking solution is aqueous glutaraldehyde.

* * * * *

US006638257B2

(12) **United States Patent**
Amplatz

(10) **Patent No.: US 6,638,257 B2**
(45) **Date of Patent: Oct. 28, 2003**

(54) **INTRAVASCULAR FLOW RESTRICTOR**

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(73) Assignee: **AGA Medical Corporation**, Golden Valley, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) **U.S. Cl.** **604/200**
(58) **Field of Search** 606/200, 110, 606/113, 114, 127; 623/1.12, 1.18, 1.49, 1.51, 1.5, 1.52

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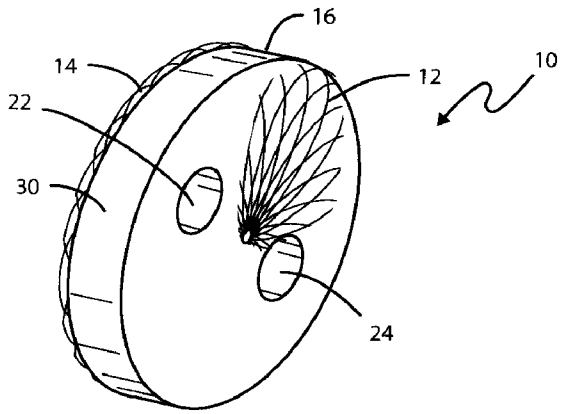
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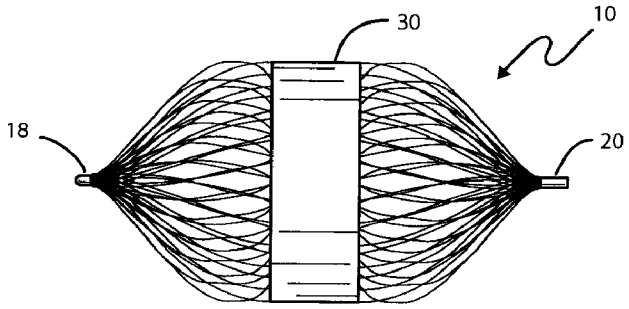
Primary Examiner—Michael J. Milano
Assistant Examiner—Nguyen Victor
(74) *Attorney, Agent, or Firm*—Thomas J. Nikolai; Nikolai & Mersereau, P.A.

(57) **ABSTRACT**

An intravascular flow restrictor comprises a braided tubular structure designed to be placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter but when ejected from the delivery catheter, assumes a substantially larger diameter disk shaped device having one or more longitudinal channels or passways therethrough.

18 Claims, 3 Drawing Sheets





WBH8
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences PVT, Inc.

WBH-Ref.: 272.0046OP

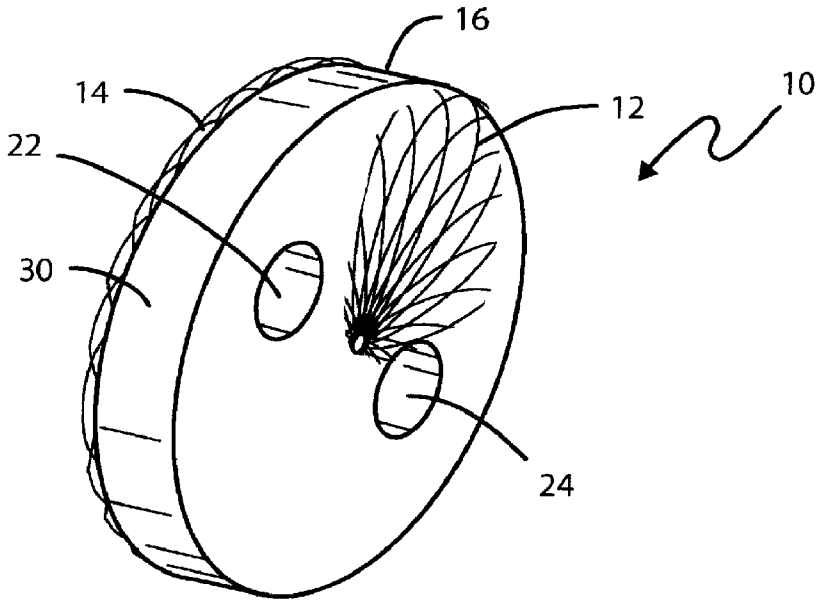


FIG. 1

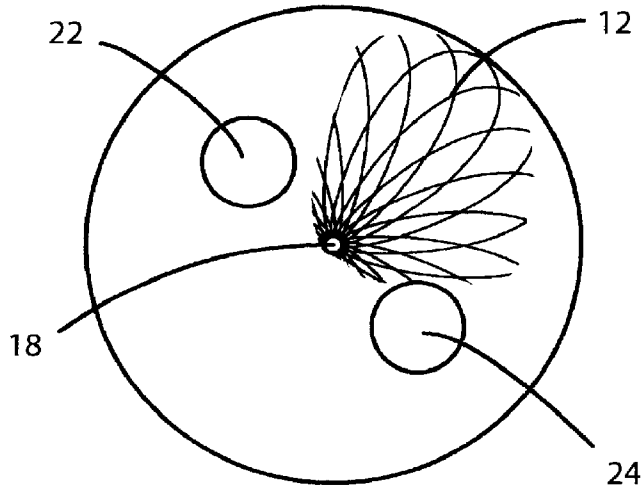


FIG. 2

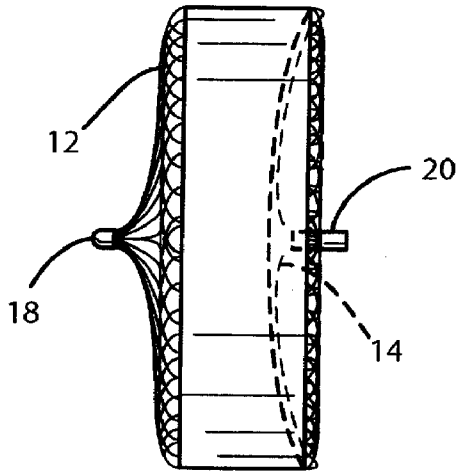


FIG. 3

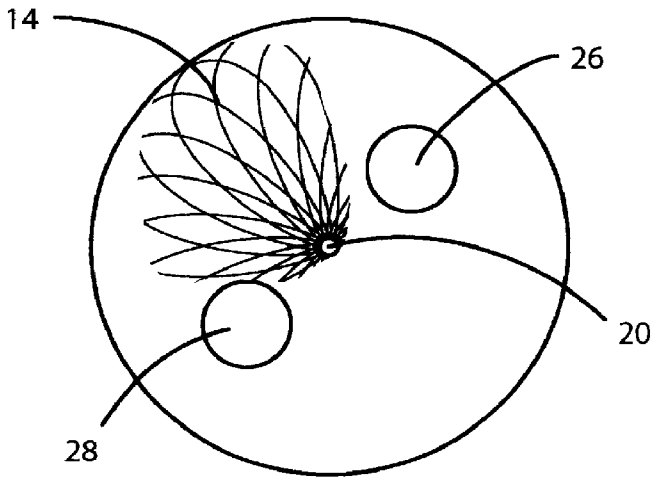


FIG. 4

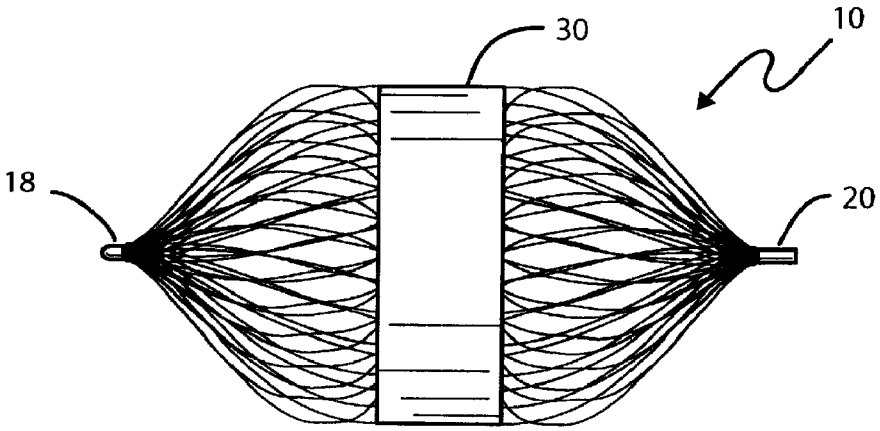


FIG. 5

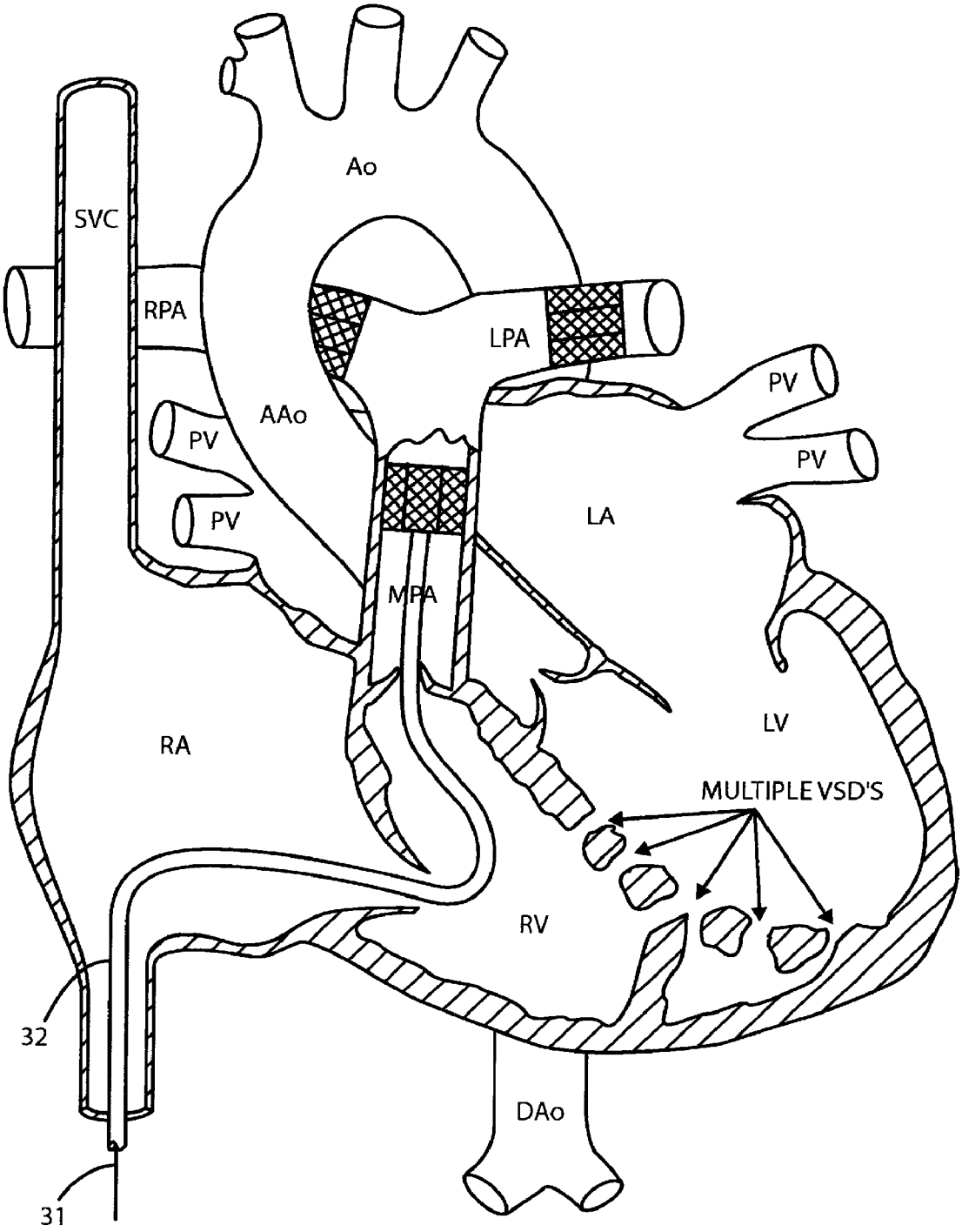

Ao
SVC
RPA
LPA
PV
AAo
PV
PV
PV
LA
MPA
RA
LV
MULTIPLE VSD'S
RV
32
DAo
31

FIG. 6

INTRAVASCULAR FLOW RESTRICTOR

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to intravascular devices for treating certain medical conditions, and, more particularly, relates to an intravascular flow restrictor for reducing blood pressure down stream of the location where the flow restrictor is placed.

II. Description of the Prior Art

In the normal heart, the right side pumps blood to the lungs, which is a relatively easy task, while the left side of the heart has the more difficult job of pumping blood all around the body. As a result, the pressure in the left ventricle (pumping chamber) is generally about five times that in the right ventricle, and the wall of the left ventricle is thicker than that of the right. There are a number of heart defects in which there is excessive blood flow to the lungs. Many defects that involve holes in the septum allow blood to flow from the high pressure left side of the heart to the lower pressure right side. This results in an increase in the pressure on the right and causes too much blood to be pumped to the lungs. The body's natural reaction to this is to constrict or narrow the blood vessels in the lungs in an effort to limit this excess blood flow. Over a period of time, this narrowing of the pulmonary arteries causes a thickening of the pulmonary arteries due to the increased workload, which leads ultimately to closure of smaller lung arteries which further reduces the blood flow into the lungs.

There is less and less left to right shunting of blood into the pulmonary arteries, and eventually the resistance is such that the shunt is reversed, i.e., right to left shunting occurs. This process is called pulmonary vascular disease and ultimately results in low oxygen levels and cyanosis and increased hemoglobin levels in the blood of the patient. It is the damage caused by prolonged pulmonary hypertension that generally prohibits late repair of cardiac defects. As children with Down's syndrome have a propensity to develop pulmonary vascular disease due to the fact that they tend to have larger holes in the heart, fewer small lung arteries and smaller airways, surgical repair is generally carried out fairly early in life, although timing will vary depending on the exact heart defect.

For example, in the case of ventricular septal defects (VSD), especially where there are multiple openings, it may not be possible to surgically close the defects. In the case of neonates, they may not be strong enough to survive an open-heart procedure required to repair multiple "Swiss cheese" septal defects. If an infant with VSD develops symptoms of congestive heart failure in the first few months of life, less traumatic palliative surgery may be attempted. Palliative surgery reduces the damage of the defect without correcting the underlying cause. One such palliative treatment is pulmonary artery (PA) banding. In the case of VSD, PA banding increases the resistance to blood flow through the pulmonary artery, preventing excessive shunting of blood from the left ventricle through the defects to the right ventricle.

In the case of an infant or young child with abnormally elevated pressure in the pulmonary artery, surgery is often considered too dangerous, but pulmonary banding may be effective. This procedure requires the surgeon to place a restrictive band around the pulmonary artery, thus reducing the blood flow into the lungs, and preventing the need for the body to form its own restriction. If successful, the normal development of pulmonary hypertension may be slowed or stopped, and surgical repair of the hole may be possible at a later date.

PA banding surgery, while less traumatic than open-heart surgery, still requires a thoracotomy to expose the pulmonary artery so that a constrictive band can be sutured around the pulmonary artery. The PA band reduces the diameter of the pulmonary artery and thereby restricts the amount of blood pumped into the lungs. Such an operation may reduce the blood flow from one-half to one-third of its previous volume. Pulmonary artery blood pressure distal to the band is reduced as a result of the volume restriction usually to about 50%–70% of the pulmonary artery pressure prior to banding.

While pulmonary artery banding is less risky than open heart surgery, it still carries the usual risks of surgery, such as bleeding, infection, pulmonary embolism, heart failure, etc. The special risk of the pulmonary artery banding procedure is making the band too tight or too loose. If it is too tight, too little blood will flow to the lungs and patient may become blue. If it is too loose, it will not eliminate the congestion of the lungs and will not protect the lungs from injury and pulmonary vascular disease.

Thus, a need exists for a non-surgical procedure, which is less traumatic than current procedures involving pulmonary artery banding, for restricting blood flow to the lungs in patients having congenital cardiac conditions which may cause pulmonary vascular disease such as, for example, left sided hypo plastic syndrome where flow restrictions are placed into the individual pulmonary arteries. The present invention meets that need without the risk of surgery, producing pain or large scar of the chest.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a device that is adapted to be placed and anchored within the vascular system using a transvascular approach for restricting or limiting blood flow to the lungs, liver or other organs. It comprises a collapsible medical device made from a plurality of metal strands that are braded into a woven metal fabric having a proximal end and a distal end, each end having a clamping member for securing each end of the woven metal fabric to thereby gather the strands and inhibit unraveling of the strands. The woven metal fabric has an expanded, preset configuration shaped to create a restriction in a blood vessel, the expanded preset configuration being generally in a shape of a round disk of a predetermined thickness dimension and outer diameter and having at least one lumen extending through the thickness dimension of the disk. The disk, formed from the woven metal fabric, is deformable to a lesser cross-sectional dimension for delivery by way of a guide catheter routed through a channel in a patient's body. The woven metal fabric has a memory property causing the device to return to its expanded, preset disk configuration when unconstrained.

The device is adapted to be deformed into its lesser cross-sectional dimension for placement in a catheter where the catheter may then be advanced through the vascular system until its distal end is disposed at a desired release site, such as beyond the ostium of the main pulmonary artery or into the individual right and left pulmonary arteries when treating pulmonary vascular disease. The device is then made to exit the distal end of the delivery catheter and when unconstrained, will lodge within the pulmonary artery and limit the volume of blood delivered from the right ventricle through the lumen of the device. The flow restrictor of the

present invention finds other applications in treating a variety of medical conditions as is hereinafter described and claimed.

In accordance with a further feature of the invention, the hollow interior of the disk-shaped device may include a fibrous material insert for enhancing the occlusion of blood flow through the device except by way of the device's lumen(s).

DESCRIPTION OF THE DRAWINGS

Other features and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

FIG. **1** is a perspective view of a collapsible medical device for use as a flow restrictor in its expanded state;

FIG. **2** is a front plan view of the device of FIG. **1**;

FIG. **3** is a side elevational view of the device of FIG. **1**;

FIG. **4** is a rear elevation of the device of FIG. **1** ;

FIG. **5** is a side elevational view of the device of FIG. **1** in its deformed, lesser cross-sectional dimension state; and

FIG. **6** is an anatomical drawing of the device of FIG. **1** installed as a flow restrictor in the main pulmonary artery of a heart.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a percutaneous catheter directed treatment of patients having malformed vascular system structures, such as shunt paths between the left and right side of the heart, transposition of the great arteries (TGA), transhepatic portosystemic shunts and protein-losing enteropathy following a Fontan operation.

As is illustrated in FIG. **1**, the device, when in its unconstrained state, comprises a disk-like device **10** having opposed ends **12** and **14** of a predetermined expanded diameter and a hollow central portion **16** between the two ends. The metal fabric from whom the device **10** is formed comprises a plurality of wire strands that are woven or braided into a tubular configuration and then heat set in a mold in a manner described in U.S. Pat. No. 6,123,715 to Curtis Amplatz, the contents of which are hereby incorporated by reference.

As is described in the '715 patent, the wire strands comprising the metal fabric are preferably formed from a metal or metal alloy which is both resilient and which can be heat-treated to substantially set a desired shape into the woven fabric. Thus, the metal strands may be a cobalt-based, low thermal expansion alloy commonly referred to as Elgiloy, a nickel-based high temperature, high-strength "super alloy" commercially available from Haynes International under the trademark "Hastelloy", a nickel-based heat treatable alloy, such as Incoloy produced by International Nickel Company as well as a number of different grades of stainless steel. These materials all exhibit a suitable amount of deformation induced when placed in a mold and subjected to an elevated temperature for a prescribed period of time. So-called shape memory alloys such as Nitinol are especially well suited to the present application.

A tubular metal braid segment having a predetermined number of strands and a desired pick is cut from a longer piece thereof after clamp rings are crimped onto the tubular structure at predetermined spaced-apart locations prior to cutting the strands at the outer ends of the clamp rings. The crimped clamp rings are best seen in FIG. **5** and are identified by numerals **18** and **20**, respectively and each may include an internally threaded bore, the purpose of which will be explained herein below.

Once an appropriately sized piece of the metal fabric is obtained, it is deformed to generally conform to a surface of a molding element. Placing the fabric within the mold functions reorient the relative position of the strands of the metal fabric from an initial order to a second, reoriented configuration. In the case of the present invention, the mold is generally cylindrical and of a predetermined length and diameter so that a braided device shaped within it is of a size allowing it to be placed within a tubular blood vessel, such as the pulmonary artery. After the braided device is placed in the mold, the mold and device are heated for a period of time sufficient to cause the tubular fabric, with its clamped ends, to take on the shape of the mold. The heat treatment depends primarily upon the metal or metal alloy employed for the wire strands and the time and temperatures are such that the device takes on the shape of the mold.

Those desiring additional information on the method for fabricating the flow restriction device of the present invention are again referred to the Amplatz '715 patent.

In forming the device **10**, one or more cylindrical rods (not shown) are fitted through the braided fabric before the assembly is placed in the mold. When the cylindrical rods are later removed following the heat treatment step, the device is left with apertures, as at **22** and **24**, formed through the end **12** of the device and apertures, as at **26** and **28**, are formed through the second end **14**. The aperture **22** is longitudinally aligned with the aperture **26** and the aperture **24** is longitudinally aligned with the aperture **28**. While the device illustrated in FIGS. **1–4** is shown as having two lumens through the thickness dimension of the device, a greater or fewer number may be formed so long as the effective cross-sectional area of the apertures provides a desired pressure drop there across.

To inhibit fluid flow through the restrictor device **10** except by way of the lumens, it may prove expedient to include a non-metallic fibrous material, such as-a polyester fabric, in the space between the two ends, being careful so that the fabric does not invade the openings defined by the apertures **22–28**. It has also been found expedient to wrap a PTFE fabric band **30** around the periphery of the device to inhibit tissue ingrowth. The use of band **30** makes it easier to retrieve the restrictor device **10** prior to the surgical repair of the defects.

In treating patients requiring pulmonary banding, the device **10** is first affixed to a threaded distal end of a pusher device, such as a cable or an elongated guidewire **31**, to a threaded bore on one of the clamps **18** or **20** and then drawn into a tubular loading member used to load the device **10** into the proximal end of a guiding catheter by stretching the device longitudinally to thereby greatly reduce its external diameter. Once the device, and the pusher device **31** affixed to it, are contained within the lumen of the guide catheter which is indicated generally by numeral **32** in FIG. **6**, the guide catheter is routed through the vascular system into the right atrium (RA) and then through the tricuspid valve into the right ventricle (RV) and, then, the main pulmonary artery (MPA) or alternatively in the right pulmonary artery (RPA) or the left pulmonary artery (LPA). With the distal end of the guide catheter in one of the MPA, the RPA and the LPA pusher device **31** is used to push the device **10** out from the confines of the distal end of the guiding catheter **32**, where-

upon the device **10** springs back to its normal unconstrained state where it becomes lodged crosswise in the selected pulmonary artery to thereby restrict blood flow from the right ventricle into the lungs. Blood flow is only permitted through the openings **22**, **24** and **26**, **28** formed through the thickness dimension of the device **10**. By appropriately sizing the openings, blood pressure in the right pulmonary artery (RPA) and the left pulmonary artery (LPA) can be maintained at a level that will not result in symptoms of congestive heart failure.

The device may be left in place for a sufficient period of time for an infant to reach a point where surgery to correct the septal defects can be better tolerated. At this time, the device **10** can be removed by catheter technique or surgery. The fabric band **30** covering the periphery of the device helps reduce tissue ingrowth, making it easier to withdraw the device **10** at the time that the septal defect(s) are repaired.

Without limitation, the tubular braid used in constructing the device **10** may have a relaxed diameter of about 30 mm with a pitch of about 50° and a pick of about 72. With such a construction, it may be advisable to include a fibrous mass within the confines of the device **10** to improve its occluding properties. We have found, however, that by increasing the braid pick to include up to 144 per linear inch, the need to include such a fibrous mass is eliminated. The braid itself is sufficiently dense to obstruct blood flow except through the preformed openings that extend through the thickness dimension of the device.

While the device **10** is preferably molded so as to have the configuration of a thin disk or a right circular cylinder, it has also been found desirable in some applications to have one of the end surfaces slightly convex and the opposite end surface slightly concave as is indicated in the side elevational view of FIG. **3**.

While the device of the present invention to this point has been described in connection with its use in controlling blood pressure in the pulmonary arteries for addressing pulmonary vascular disease to establish its utility, it may also be used in carrying out other medical procedures. Newborns having a heart defect know as Transposition of the Great Arteries (TGA) may undergo the Rashkind procedure referred to as a "balloon septostomy" or a variation thereof called a "blade septostomy". In a balloon septostomy a catheter with an uninflated balloon at its distal end is inserted into the vascular system and advanced into the heart. The balloon catheter is made to pass through an opening in the atrial septum called the "foramen ovale" into the left atrium. The balloon is then inflated and withdrawn, tearing the atrial septum as it is pulled back into the right atrium. The enlarged opening allows an increase of oxygenated blood flowing to the aorta and then to the body.

The device of the present invention can be employed to more precisely control the blood flow through the tear in the atrial septum. By selecting a flow restricting device with appropriately sized lumens therethrough, more precise control of oxygenated blood flow to the aorta can be realized. The device **10** can be inserted into the balloon-enlarged opening in a manner similar to the procedure previously described for placing the device in a pulmonary artery.

The device **10** may also find application in treating patients with portal hypertension because of transhepatic portosystemic shunts. This condition may lead to ectopic varices and gastrointestinal bleeding. By decreasing the blood pressure in the high pressure portal system, controlled level of occlusion of the large hepatic vein can be accomplished. The procedure involves passing a catheter through the right internal jugular vein into the right hepatic vein. A needle is then passed anteriorly into the portal vein. The tract is dilated and the device **10** may be inserted and used to maintain patency.

Yet another surgical procedure where the present invention finds application is in the fenestrated Fontan operation. One congenital heart abnormally leaves an infant with only a single functional ventricle. The right ventricle for delivering blood to the lungs may be non-functional. Dr. Francois Fontan came up with a surgical solution in which the vena cava carrying blood returning from the body is connected directly to the pulmonary arteries and thereby oxygenated. Many patients so treated, however, develop a condition called protein-losing enteropathy. Symptoms of this ailment include abdominal, shin and ankle swelling, diarrhea and abdominal discomfort. Where drug treatment fails, a more aggressive approach involves surgery to create a fenestration in the Fontan channel that allows shunting across from the right to the left side of the heart.

The present invention permits a minimally invasive catheterization procedure to create the fenestration and to then install an appropriately sized flow restrictor in the fenestration to better control the volume rate of flow through the fenestration by preventing occlusion, improving the patient's symptoms and thereby the degree of cyanosis.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:

1. A collapsible medical device, comprising a plurality of metal strands woven into a woven metal fabric having a proximal end and a distal end, each end having a means for securing each end attached to said woven metal fabric, thereby gathering said strands and inhibiting unraveling of the strands, said woven metal fabric having an expanded preset configuration shaped to create a restriction in a blood vessel, said expanded preset configuration being in a shape of a cylindrical disk of a predetermined thickness having at least one enlarged lumen extending through the thickness dimension of said disk through which blood may flow and deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the woven metal fabric having a memory property whereby the medical device tends to return to said expanded preset configuration when unconstrained.

2. The medical device as recited in claim **1**, wherein at least one of the said means for securing each end has a threaded bore adopted for rotational attachment to a delivery device.

3. The medical device as recited in claim **2**, further including an occluding fiber material retained within a hollow central portion formed by said woven fabric.

4. The medical device as recited in claim **1**, wherein the metal fabric is manufactured from an alloy selected from the group consisting of stainless steel, nickel-titanium, and cobalt-chromium-nickel.

5. The medical device as recited in claim **4**, further including an occluding fiber material retained within a hollow central portion formed by said woven fabric.

6. The medical device as recited in claim 1, further including an occluding fiber retained within a hollow central portion formed by said woven fabric.

7. A collapsible medical device, comprising: a tubular woven metal fabric including a plurality of braided strands and having a first end and a second end, each end having a clamp attached to said metal fabric to thereby gather said strands together and inhibit unraveling of the stands, said metal fabric having a collapsed configuration for delivery through a channel in a patient's body and a generally cylindrical disk-shaped expanded preset configuration, with an enlarge aperture formed through a thickness dimension thereof for substantially creating a restriction without totally occluding blood flow in a body organ.

8. The medical device as recited in claim 7 wherein one of said two opposed ends is concave.

9. The medical device as recited in claim 7 wherein a volume disposed between the first and second ends contains a non-metallic fibrous material.

10. The medical device as recited in claim 9 wherein each of the first and second ends includes said aperture, the apertures in the first and second ends being longitudinally aligned and not occluded by the fibrous material.

11. The medical device as recited in claim 10 and further including a band of non-metallic fibrous material covering a periphery of the cylindrical disk-shaped device.

12. The medical device of claim 11 wherein the band comprises PTFE.

13. A collapsible medical device, comprising a woven metal fabric including a plurality of braided strands and having a proximal end and a distal end, each end having a clamp attached to said tubular woven metal fabric to thereby gather said strands together and inhibit the strands from unraveling, said woven metal fabric having an expanded preset configuration shaped to create a restriction to blood flow in a body organ, said expanded preset configuration being disk-shaped and deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, wherein the expanded preset configuration comprises two expanded diameter end portions and a hollow central portion, said expanded diameter portions having a diameter to span a patient's pulmonary artery, the end portions and the central portion including enlarged openings of a predetermined size substantially less than the size of the expanded diameter portions therein through which blood may flow, the woven metal fabric having a memory property whereby the medical device tends to return to said expanded present configuration when unconstrained.

14. The medical device as recited in claim 13, wherein one of said clamps has a threaded bore adapted for rotationally receiving a delivery device.

15. The medical device as recited in claim 13, further including an occluding fiber contained within said hollow center portion.

16. The medical device as recited in claim 13, wherein the metal fabric is manufactured from an alloy selected from the group consisting of stainless steel, nickel-titanium, and cobalt-chromium-nickel.

17. The medical device as in claim 13 and further including a band of non-metallic fabric material covering a periphery of the central portion.

18. The medical device as in claim 17 wherein the band comprises PTFE.

* * * * *

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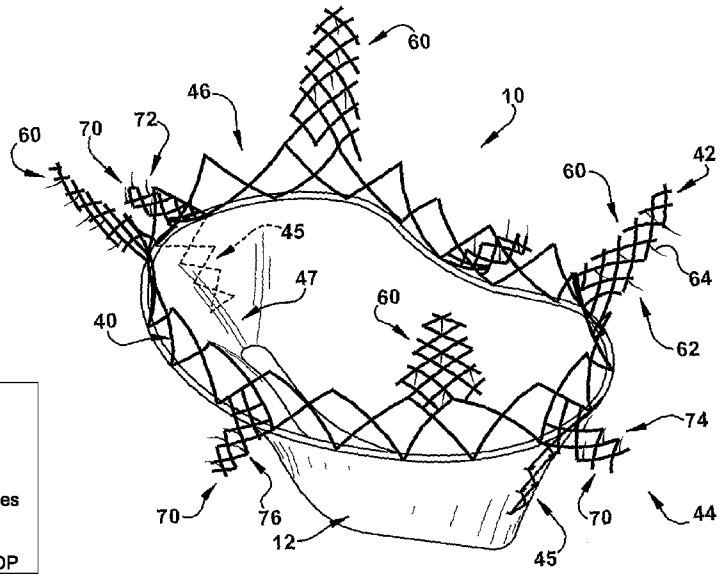
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(54) **Title:** APPARATUS AND METHODS FOR REPLACING A CARDIAC VALVE



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(57) **Abstract:** An apparatus (10) and method for replacing a cardiac valve includes an expandable support member (40) having oppositely disposed first (42) and second (44) ends, a main body portion (46) extending between the ends, and a prosthetic valve (12) within the main body portion. The main body portion has an annular shape for expanding into position in the amiulus of the valve. The first and second ends include a plurality of upper (60) and lower (70) wing members movable from a collapsed condition into an extended condition for respectively engaging a first section of cardiac tissue surrounding the valve and for engaging a portion of the native valve leaflets to pin the leaflets back against the annulus. The second end further includes at least two strut members (45) spaced apart from each other. A respective one of the strut members is attached to at least one commissural section of the prosthetic valve to prevent prolapse of the valve leaflets.

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APPARATUS AND METHODS FOR REPLACING A CARDIAC VALVE

Related Application

This application claims priority from U.S. provisional patent application Serial No. 60/654,725, filed on February 18, 2005, the subject matter of which is incorporated herein by reference.

Field of the Invention

The present invention relates to an apparatus and methods for treating a diseased cardiac valve, and is particularly directed to an apparatus and methods for the correction of mitral valve and tricuspid valve disorders via a minimally invasive or percutaneous approach.

Background of the Invention

There are two atrio-ventricular valves in the heart; one on the left side of the heart and one on the right side of the heart. The left side atrio-ventricular valve is the mitral valve and the right side atrio-ventricular valve is the tricuspid valve. Both of these valves are subject to damage and disfunction that requires that the valve be repaired or replaced.

The mitral and tricuspid valves differ significantly in anatomy. While the annulus of the mitral valve is generally D-shaped, the annulus of the tricuspid valve is more circular. The effects of the valvular dysfunction vary between the mitral valve and the tricuspid valve. Mitral valve regurgitation has more severe physiological consequences to the patient than does tricuspid valve regurgitation, a small amount of which is tolerable.

In mitral valve insufficiency, the valve leaflets do not fully close and a certain amount of blood leaks back into the left atrium when the left ventricle contracts. As a result, the heart has to work harder by pumping not only the regular volume of the blood, but also the extra volume of blood that regurgitated back into the left atrium. The added workload creates an undue strain on the left ventricle. This strain can eventually wear out of the heart and result in morbidity when the conditions are prolonged and severe enough. Consequently, proper function of the mitral valve is critical to the pumping efficiency of the heart.

Mitral and tricuspid valve disease is traditionally treated by either surgical repair with an annuloplasty ring or surgical replacement with a valve prosthesis. However, surgical valve replacement or repair is often an exacting operation that is done through a surgical technique where the thoracic cavity is opened. The operation requires use of a heart-lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves and/or annuloplasty rings are sewed in under direct vision. This operation exposes the patient to many risks especially in the elderly population. A percutaneous procedure that can be performed under local anesthesia in the cardiac catherization lab, rather than in cardiac surgery, could therefore offer tremendous benefits for these patients, many of whom have no options today. Consequently, an apparatus for replacing a diseased atrioventricular valve using a minimally invasive, percutaneous approach would be very helpful to provide additional opportunities to treat patients with severe valvular insufficiency, end stage heart failure, atrial fibrillation, and/or other associated arrhythmias.

Summary of the Invention

In one aspect of the present invention, an apparatus for replacing a cardiac valve having at least two native valve leaflets is provided. The apparatus comprises an expandable support member having oppositely disposed first and second ends and a main body portion extending between the ends. The main body portion of the support member has an annular shape for expanding into position in the annulus of the cardiac valve. The first end comprises a plurality of upper wing members that extend from the main body portion. Each of the upper wing members is movable from a radially collapsed condition into a radially extended condition for engaging a first section of cardiac tissue surrounding one side of the cardiac valve. The second end comprises a plurality of lower wing members that extend from the main body portion. Each of the lower wing members is movable from a radially collapsed condition into a radially extended condition for engaging a portion of the native valve leaflets to pin the leaflets back against the annulus of the native cardiac valve. The second end of the support member further includes at least two strut members that are spaced apart from each other. The at least two

valve leaflets are joined at at least two commissural sections that are spaced apart from each other. Each of the at least two commissural sections are attached to a respective one of the strut members to prevent prolapse of the valve leaflets. A prosthetic valve is secured within the main body portion of the support member. The prosthetic valve has at least two valve leaflets that are coaptable to permit unidirectional flow of blood.

In another aspect of the present invention, at least a portion of the support member is treated with at least one therapeutic agent for eluting into cardiac tissue.

In yet another aspect of the present invention, a method for replacing a cardiac valve having at least two native valve leaflets is provided. According to the inventive method, a prosthetic valve having at least two valve leaflets that are coaptable to permit unidirectional flow of blood is provided. The prosthetic valve includes an expandable support member having oppositely disposed first and second ends and a main body portion extending between the ends. The expandable support member further includes a plurality of upper wing members that extend from one end of the main body portion, and a plurality of lower wing members that extend from an opposite end of the main body portion. The second end of the support member further includes at least two strut members. The prosthetic valve includes at least two valve leaflets that are joined together at at least two commissural sections. Each of the at least two commissural sections are attached to a respective one of the strut members to prevent prolapse of the valve leaflets. The main body portion of the prosthetic valve is placed within the annulus of the cardiac valve to be replaced, and is then expanded into engagement with the annulus of the cardiac valve to secure the prosthetic valve in the annulus. The upper wing members are deployed from a radially collapsed condition into a radially extended condition into engagement with a first section of cardiac tissue surrounding one side of the cardiac valve. The lower wing members are deployed from a radially collapsed condition into a radially extended condition into engagement with a portion of the native valve leaflets to pin the leaflets back against the annulus of the native cardiac valve.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent to those skilled in the art to which the present invention relates upon reading the following description with reference to the accompanying drawings, in which:

Fig. 1 is a schematic sectional view of an apparatus for replacing a diseased cardiac valve in accordance with the present invention and illustrating the apparatus being delivered to the diseased valve in a collapsed condition through a percutaneous procedure;

Fig. 2 is a perspective view of the apparatus of Fig. 1 in a radially expanded condition;

Fig. 3 is a perspective view showing an alternative embodiment of the apparatus in Fig. 2;

Fig. 4 is a perspective view showing another alternative embodiment of the apparatus shown in Fig. 2;

Fig. 5 is a view similar to Fig. 1 illustrating the placement of the apparatus in the annulus of the cardiac valve in the expanded condition;

Fig. 6 is a schematic sectional view taken along 6-6 in Fig. 5;

Fig. 7 is a schematic top view taken along line 7-7 in Fig. 5 with parts omitted for clarity;

Fig. 8 is a schematic bottom view taken along line 8-8 in Fig. 5 with parts omitted for clarity;

Fig. 9 is a plan view of the apparatus in Fig. 4 illustrating an alternative embodiment of the apparatus;

Fig. 10 is a view similar to Fig. 9 illustrating another alternative construction of the apparatus;

Fig. 11 is a perspective view showing an alternative embodiment of the apparatus in Fig. 4 having artificial chordae; and

Fig. 12 is a schematic top view similar to Fig. 7 and illustrating an alternate embodiment of the apparatus.

Detailed Description of Embodiments

The present invention relates to an apparatus and methods for treating a diseased cardiac valve, and is particularly directed to an apparatus and methods for the correction of mitral valve and tricuspid valve disorders via a minimally invasive and/or percutaneous approach. As representative of the present invention, Figs. 1 and 2 illustrate an apparatus 10 that includes a prosthetic valve 12 for replacing a dysfunctional cardiac valve, such as a mitral valve 14, by inserting the prosthetic valve over the native mitral valve so that the prosthetic valve assumes the valvular function. It should be understood, however, that the apparatus 10 disclosed herein could also be used to replace other cardiac valves, such as a tricuspid, pulmonary, or aortic valve.

As shown in Fig. 1, the mitral valve 14 is located between the left atrium 16 and the left ventricle 18 and functions to prevent the backflow of blood from the left ventricle into the left atrium during contraction. The mitral valve 14 has a D-shaped annulus 20 that defines the opening between the left atrium 16 and the left ventricle 18. The mitral valve 14 is formed by two leaflets; namely, the anterior leaflet 22 and the posterior leaflet 24 (Fig. 6). The anterior leaflet 22 extends along the generally planar base of the D-shaped valve annulus 20, while the posterior leaflet 24 extends arcuately around the curved portion of the D-shaped annulus of the mitral valve 14. Chordae tendinea 26 (Fig. 1) extend between the free edges 28 of both leaflets 22 and 24 to the papillary muscles 30 in the left ventricle 18.

The apparatus 10 for replacing the dysfunctional mitral valve 14 includes an expandable support member 40 (Fig. 2), commonly referred to as a stent, and the prosthetic valve 12. The support member 40 has a known stent configuration that allows it to be collapsed and expanded. The support member 40 may be made from any suitable medical grade metal or plastic, including shape memory materials such as Nitinol, stainless steel, and/or titanium.

The support member 40 is annular in shape and includes oppositely disposed first and second ends 42 and 44 with a main body portion 46 extending between the ends. As shown in Figs. 2-8, when the support member 40 is

expanded, the main body portion 46 has a concave cross-sectional shape for conforming to the convex shape of the valve annulus 20.

The apparatus 10 may further include a layer 50 (Fig. 3) of biocompatible material covering at least a portion of the support member 40. The layer 50 of biocompatible material may be a synthetic such as Dacron® (Invista, Wichita, KS), Gore-Tex® (W. L. Gore & Associates, Flagstaff, AZ), woven velour, polyurethane, polytetrafluoroethylene (PTFE), or heparin-coated fabric. Alternatively, the layer 50 may be a biological material such as bovine or equine pericardium, peritoneal tissue, an allograft, a homograft, patient graft, or a cell-seeded tissue. The layer 50 can cover either the inside surface of the support member 40, the outside surface of the support member, or can be wrapped around both the inside and outside surfaces. The layer 50 may be attached around the entire circumference of the support member 40 or, alternatively, may be attached in pieces or interrupted sections to allow the support member to more easily expand and contract. As shown in Fig. 3, for example, only the main body portion 46 of the prosthetic valve 12 may be covered with the layer 50 of biocompatible material. Alternatively, the support member 40 may be entirely covered with the layer 50 of biocompatible material (Fig. 4).

The first end 42 of the support member 40 comprises a plurality of upper wing members 60 that extend integrally from the main body portion 46. In the embodiment illustrated in Figs. 1-8, there are four upper wing members 60 spaced about the circumference of the support member 40, but it should be understood that more or less than four upper wing members could be used. The upper wing members 60 are movable from the radially collapsed condition of Fig. 1 to the radially extended condition of Figs. 2-8. Each upper wing member 60 may also include at least one attachment mechanism 62, such as a barb 64 or suture, for embedding into a first section of cardiac tissue (*e.g.*, the wall of the left atrium 16) to help secure the support member 40 in the annulus 20 of the mitral valve 14.

The second end 44 of the support member 40 comprises a plurality of lower wing members 70 that extend integrally from the main body portion 46. In the embodiment illustrated in Figs. 1-8, there are four lower wing members 70 spaced about the circumference of the support member 40. More specifically, there are

first and second lower wing members 72 and 74, spaced approximately 180° apart, for positioning at the commissures of the native mitral valve 14, and third and fourth lower wing members 76 and 78 (Fig. 7), spaced approximately 180° apart, for positioning directly over respective central portions of the native leaflets 22 and 24. The third and fourth lower wing members 76 and 78 are spaced in-between the first and second lower wing members 72 and 74, respectively. It is contemplated, however, that more or less than four lower wing members 70 could be used. Further, it is contemplated that the third and fourth lower wing members 76 and 78 positioned over the leaflets 22 and 24 could be omitted completely.

Each of the lower wing members 70 is movable from the radially collapsed condition of Fig. 1 to the radially extended condition of Figs. 2-8 for engaging a portion of the native valve leaflets 22 and 24 to pin the leaflets back against the native valve annulus 20. The lower wing members 70 may also include at least one attachment mechanism 62, such as a barb 64 or suture, for embedding into at least one of the native valve leaflets 22 and 24 to help secure the support member 40 in the annulus 20 of the mitral valve 14.

The second end 44 of the support member 40 additionally includes at least two strut members 45. As shown in Fig. 2, the valve leaflets of the prosthetic valve 12 are joined together at at least two commissural sections 47 that are spaced apart from each other. Each of the at least two commissural sections 47 are attached to a representative one of the strut members 45 to prevent prolapse of prosthetic valve leaflets 90 and 92, described in detail below. The strut members 45 are securely attached to, and extend in a generally axial manner from, the support member 40. The strut members 45 are securely connected to the prosthetic valve 12 by sutures, for example, and may be made from any suitable medical grade metal or plastic, including shape memory materials such as Nitinol, stainless steel, and/or titanium. As illustrated in Fig. 2, the strut members 45 have a bare metal configuration and do not extend beyond the length of the prosthetic valve 12. It is contemplated, however, that the configuration of the strut members 45 may be varied as needed. For example, the strut members 45 may be

covered by a layer 50 of biocompatible material and extend beyond the length of the prosthetic valve 12.

The prosthetic valve 12 of the present invention may comprise a stentless prosthetic valve. By "stentless" it is meant that the valve components including the leaflets of the prosthetic valve 12 are not reinforced with a support structure, such as a stent or other similar structure. The prosthetic valve 12 is secured, for example, by sutures or other suitable means within the main body portion 46 of the support member 40.

The prosthetic valve 12 may be fixed and preserved using a variety of known methods. The use of chemical processes for the fixation and preservation of biological tissues have been described and are readily available in the art. For example, glutaraldehyde, and other related aldehydes have seen widespread use in preparing cross-linked biological tissues.

Glutaraldehyde is a five carbon aliphatic molecule with an aldehyde at each end of the chain, rendering it bifunctional. These aldehyde groups react under physiological conditions with primary amine groups on collagen molecules resulting in the cross-linking of collagen containing tissues. Methods for glutaraldehyde fixation of biological tissues have been extensively described and are well known in the art. In general, a tissue sample to be cross-linked is simply contacted with a glutaraldeyde solution for a duration effective to cause the desired degree of cross-linking within the biological tissue being treated.

Many variations and conditions have been applied to optimize glutaraldehyde fixation procedures. For example, lower concentrations have been found to be better in bulk tissue cross-linking compared to higher concentrations. It has been proposed that higher concentrations of glutaraldehyde may promote rapid surface cross-linking of the tissue, generating a barrier that impedes or prevents the further diffusion of glutaraldehdye into the tissue bulk. For most bioprosthesis applications, the tissue is treated with a relatively low concentration glutaraldehyde solution, *e.g.*, typically between 0.1%-5%, for 24 hours or more to ensure optimum fixation. Various other combinations of glutaraldehyde concentrations and treatment times will also be suitable depending on the objectives for a given application. Examples of such other combinations include,

but are not limited to, U.S. Pat. Nos. 6,547,827, 6,561,970, and 6,878,168, all of which are hereby incorporated by reference in their entirety.

In addition to bifunctional aldehydes, many other chemical fixation procedures have been described. For example, some such methods have employed polyethers, polyepoxy compounds, diisocyanates, and azides. These and other approaches available to the skilled individual in the art for treating biological tissues are suitable for cross-linking vascular graft tissue according to the present invention.

The prosthetic valve 12 may also be treated and preserved with a dry tissue valve procedure as described in U.S. Pat. No. 6,534,004, the entire contents of which are hereby incorporated by reference. Furthermore, the prosthetic valve 12 may be treated with anti-calcification solutions, such as XenoLogiX® treatment (Edwards Lifesciences, Irvine, CA) or the SynerGraft® (CryoLife, Inc., Kennesaw, GA) treatment process, and/or anti-calcification agents, such as alfa-amino oleic acid.

The prosthetic valve 12 can be made with only one piece of pericardial tissue, for example, as shown in Fig. 9. Where a single piece of pericardial tissue is used, a seam 96 is formed by suturing the ends of the tissue. Alternatively, the prosthetic valve 12 can be made with two pieces of pericardial tissue, one of which will form the first leaflet 90 and the other forms the second leaflet 92 of the prosthetic valve, as may be seen in Fig. 10. Where two pieces of pericardial tissue are used (Fig. 10), it is necessary to suture the tissue in two locations, thereby forming two seams 98 and 100. The seams 96, 98, and 100 are always placed at what will be the commissures of the prosthetic valve 12, where the first leaflet 90 meets the second leaflet 92.

Figure 11 illustrates an alternative embodiment of the present invention. The apparatus 10_a of Fig. 11 is identically constructed as the apparatus 10 of Figs. 2-8, except whereas described below. In Fig. 11, structures that are identical as structures in Figs. 2-8 use the same reference numbers, whereas structures that are similar but not identical carry the suffix "a".

As shown in Fig. 11, the apparatus 10_a includes an expandable support member 40 having a flexible configuration and a prosthetic valve 12_a. The support

member 40 is annular in shape and includes oppositely disposed first and second ends 42 and 44 with a main body portion 40 extending between the ends. The apparatus 10_a may further include a layer 50 of biocompatible material covering at least a portion of the support member 40.

The first and second ends 42 and 44 of the support member 40 respectively comprises a plurality of upper and lower wing members 60 and 70 that extend integrally from the main body portion 46. The upper and lower wing members 60 and 70 are movable from the radially collapsed condition of Fig. 1 to the radially extended condition of Fig. 11. Each upper wing member 60 may also include at least one attachment mechanism 62, such as a barb 64 or suture, for embedding into a first section of cardiac tissue (*e.g.*, the wall of the left atrium 16) to help secure the support member 40 in the annulus 20 of the mitral valve 14. The lower wing members 70 may also include at least one attachment mechanism 62, such as a barb 64 or suture, for embedding into at least one of the native valve leaflets 22 and 24 to help secure the support member 40 in the annulus 20 of the mitral valve 14.

The prosthetic valve 12_a of the apparatus 10_a (and also the previously described valve 12) may comprise a stentless prosthetic valve, for example, having dimensions that correspond to the dimensions of the native mitral valve 14. Where the prosthetic valve 12_a is comprised of biological material, the biological material can include a harvested biological material such as bovine pericardial tissue, equine pericardial tissue, porcine pericardial tissue, animal or human peritoneal tissue, or mitral, aortic, and pulmonary xenograft or homograft. The biocompatible material may also include a suitable synthetic material such as polyurethane, expanded PTFE, woven velour, Dacron®, heparin-coated fabric, or Gore-Tex®.

The prosthetic valve 12_a further includes first and second leaflets 90 and 92 that mimic the three-dimensional anatomical shape of the anterior and posterior leaflets 22 and 24, respectively, of the mitral valve 14. The valve leaflets of the prosthetic valve 12_a are joined together at at least two commissural sections 47 that are spaced apart from each other. The prosthetic valve 12_a also includes a distal end 86 that defines a first annulus 94 at which the first and second leaflets 90 and 92 terminate.

Additionally, the prosthetic valve 12_a includes first and second pairs 102 and 104, respectively, of prosthetic chordae 106 that project from the first and second leaflets 90 and 92 at the first annulus 94. Each of the prosthetic chordae 106 comprises a solid uninterrupted extension of biocompatible material. Each of the first pair 102 of prosthetic chordae 106 has a distal end 108 and each of the second pair 104 of prosthetic chordae has a distal end 110.

As shown in Fig. 11, the second end 44 of the support member 40 may additionally include at least two strut members 45_a spaced apart from each other. Each of the at least two commissural sections 47 of the prosthetic valve 12_a are attached to a respective one of the strut members 45 to prevent prolapse of the valve leaflets 90 and 92. The strut members 45_a are integrally connected to the support member 40 and extend in a generally axial manner along the prosthetic valve 12_a. The strut members 45_a may be attached to the distal ends 108 of the first pair 102 of the prosthetic chordae 106 by sutures, for example. Alternatively, the strut members 45_a may be attached to the distal ends 110 of the second pair 104 of the prosthetic chordae 106. It is contemplated that the configuration of the strut members 45_a may be varied as needed. For instance, the strut members 45_a may have a shorter length than the length of the strut members illustrated in Fig. 11. In this instance, the strut members 45_a may be attached at a position proximal to the distal ends 108 and 110 of the prosthetic chordae 106, such as at or near the first annulus 94 of the prosthetic valve 12_a.

The present invention may be treated with at least one therapeutic agent capable of preventing a variety of pathological conditions including, but not limited to, thrombosis, restenosis and inflammation. Accordingly, the therapeutic agent may include at least one of an anticoagulant, an antioxidant, a fibrinolytic, a steroid, an anti-apoptotic agent, and/or an anti-inflammatory agent.

Optionally or additionally, the therapeutic agent may be capable of treating or preventing other diseases or disease processes such as microbial infections, arrhythmias, and/or heart failure. In these instances, the therapeutic agent may include an antiarrhythmic agent, an inotropic agent, a chronotropic agent, and/or a biological agent such as a cell or protein. More specific types of these therapeutic

agents are listed below, including other types of therapeutic agents not discussed above.

Examples of acceptable therapuetic agents include Coumadin, heparin, synthetic heparin analogues (*e.g.*, fondaparinux), G(GP) II_b/III_a inhibitors, vitronectin receptor antagonists, hirudin, antithrombin III, drotrecogin alpha; fibrinolytics such as alteplase, plasmin, lysokinase, factor XIIa, factor VIIa, prourokinase, urokinase, streptokinase; thrombocyte aggregation inhibitors such as ticlopidine, clopidogrel, abciximab, dextrans; corticosteroids such as aldlometasones, amcinonides, augmented betamethasones, beclomethasones, betamethasones, budesonides, cortisones, clobetasol, clocortolones, desonides, desoximetasones, dexamethasones, flucinolones, fluocinonides, flurandrenolides, flunisolides, fluticasones, halcinonides, halobetasol, hydrocortisones, methylprednisolones, mometasones, prednicarbates, prednisones, prednisolones, triamcinolones; fibrinolytic agents such as tissue plasminogen activator, streptokinase, dipyridamole, ticlopidine, clopidine, and abciximab; non-steroidal anti-inflammatory drugs such as salicyclic acid and salicyclic acid derivatives, para-aminophenol derivatives, indole and indene acetic acids (*e.g.*, etodolac, indomethacin, and sulindac), heteroaryl acetic acids (*e.g.*, ketorolac, diclofenac, and tolmetin), arylpropionic acids (*e.g.*, ibuprofen and derivatives thereof), anthranilic acids (*e.g.*, meclofenamates and mefenamic acid), enolic acids (*e.g.*, piroxicam, tenoxicam, phenylbutazone, and oxyphenthatrazone), gold compounds (*e.g.*, auranofin, aurothioglucose, and gold sodium thiomalate), diflunisal, meloxicam, nabumetones, naproxen, oxaprozin, salsalate, celecoxib, rofecoxib; cytostatics such as alkaloids and podophyllum toxins such as vinblastin, vincristin; alkylants such as nitrosoureas and nitrogen lost analogues; cytotoxic antibiotics such as daunorubicin, doxorubicin, and other anthracyclins and related substances, bleomycin, and mitomycin; antimetabolites such as folic acid analogues, purine analogues and related inhibitors (*e.g.*, mercaptopurine, thioguanine, pentostatin, and 2-chlorodeoxyadenosine), pyrimidine analogues (*e.g.*, fluorouracil, floxuridine, and cytarabine), and platinum coordination complexes (*e.g.*, cisplatinum, carboplatinum and oxaliplatinum); tacrolimus, azathioprine, cyclosporine, paclitaxel, docetaxel, sirolimus; amsacrin, irinotecan,

imatinib, topotecan, interferon-alpha 2a, interferon-alpha 2b, hydroxycarbamide, miltefosin, pentostatin, porfimer, aldesleukin, bexarotene, and tretinoin; antiandrogens and antiestrogens; antiarrythmics, in particular antiarrhythmics of class I such as antiarrhythmics of the quinidine type (*e.g.*, quinidine, dysopyramide, ajmaline, prajmalium bitartrate, and detajmium bitartrate); antiarrhythmics of the lidocaine type, (*e.g.*, lidocaine, mexiletin, phenyloin, and tocainid); antiarrhythmics of class I C (*e.g.*, propafenone, flecainide (acetate)); antiarrhythmics of class II, including betareceptor blockers such as metoprolol, esmolol, propranolol, metoprolol, atenolol, and oxprenolol; antiarrhythmics of class III such as amiodaron and sotalol; antiarrhythmics of class IV such as diltiazem, and verapamil; and other antiarrhythmics such as adenosine, orciprenaline, and ipratropium bromide.

Other types of therapeutic agents may include digitalis glycosides such as acetyl digoxin/methyldigoxin, digitoxin, and digoxin; heart glycosides such as ouabain and proscillaridin; antihypertensives such as centrally effective antiadrenergic substances (*e.g.*, methyldopa and imidazoline receptor agonists); calcium channel blockers of the dihydropyridine type, such as nifedipine and nitrendipine; ACE inhibitors (*e.g.*, quinaprilate, cilazapril, moexipril, trandolapril, spirapril, imidapril, and trandolapril); angiotensin-II-antagonists (*e.g.*, candesartancilexetil, valsartan, telmisartan, olmesartan medoxomil, and eprosartan); peripherally effective alpha-receptor blockers such as prazosin, urapidil, doxazosin, bunazosin, terazosin, and indoramin; vasodilators such as dihydralazine, diisopropyl amine dichloroacetate, minoxidil, and nitropiusside-sodium; other antihypertonics such as indapamide, codergocrin mesilate, dihydroergotoxin methane sulphonate, cicletanin, bosentan, and fludrocortisone; phosphodiesterase inhibitors, such as milrinone and enoximone, as well as antihypotonics (*e.g.*, adrenergics and dopaminergic substances such as dobutamine, epinephrine, etilefrine, norfenefrine, norepinephrine, oxilofrine, dopamine, midodrine, pholedrine, and amezinium methyl) and partial adrenoceptor agonists (*e.g.*, dihydroergotamine); fibronectin, polylysines and ethylene vinyl acetates; and adhesive substances such as cyanoacrylates, beryllium, and silica.

Additional therapeutic agents may also include antibiotics and antiinfectives such as β-lactam antibiotics (*e.g.*, β-lactamase-sensitive penicillins, including benzyl penicillins (penicillin G) and phenoxymethylpenicillin (penicillin V)); β-lactamase-resistant penicillins, such as aminopenicillins, which include amoxicillin, ampicillin, and bacampicillin; acylaminopenicillins such as mezlocillin and piperacillin; carboxypenicillines and cephalosporins (*e.g.*, cefazolin, cefuroxim, cefoxitin, cefotiam, cefaclor, cefadroxil, cefalexin, loracarbef, cefixim, cefuroximaxetil, ceftibuten, cefpodoximproxetil, and cefpodoximproxetil); aztreonam, ertapenem, and meropenem; β-lactamase inhibitors such as sulbactam and sultamicillintosilates; tetracyclines such as doxycycline, minocycline, tetracycline, chlorotetracycline, oxytetracycline; aminoglycosides such as gentamicin, neomycin, streptomycin, tobramycin, amikasin, netilmicin, paromomycin, framycetin, and spectinomycin; makrolide antibiotics such as azithromycin, clarithromycin, erythromycin, roxithromycin, spiramycin, and josamycin; lincosamides such as clindamycin and lincomycin; gyrase inhibitors, such as fluoroquinolones, which include ciprofloxacin, ofloxacin, moxifloxacin, norfloxacin, gatifloxacin, enoxacin, fleroxacin, and levofloxacin; quinolones such as pipemidic acid; sulphonamides such as trimethoprim, sulphadiazin, and sulphalene; glycopeptide antibiotics such as vancomycin and teicoplanin; polypeptide antibiotics, such as polymyxins, which include colistin, polymyxin-b, and nitroimidazol derivatives (*e.g.*, metronidazol and tinidazol); aminoquinolones such as chloroquin, mefloquin, and hydroxychloroquin; biguanides such as proguanil; quinine alkaloids and diaminopyrimidines such as pyrimethamine; amphenicols such as chloramphenicol; rifabutin, dapsone, fusidinic acid, fosfomycin, nifuratel, telithromycin, fusafungin, fosfomycin, pentamidindiisethionate, rifampicin, taurolidine, atovaquone, and linezolid; virostatics such as aciclovir, ganciclovir, famciclovir, foscamet, inosine (dimepranol-4-acetamidobenzoate), valganciclovir, valaciclovir, cidofovir, and brivudin; tyrosine kinase inhibitors; anti-apoptotic agents such as caspase inhibitors (*e.g.*, fluoromethylketone peptide derivatives), calpain inhibitors, cathepsin inhibitors, nitric oxide synthase inhibitors, flavonoids,

vitamin A, vitamin C, vitamin E, vitamin D, pycnogenol, super oxidedismutase, N-acetyl cysteine, selenium, catechins, alpha lipoic acid, melatonin, glutathione, zinc chelators, calcium chelators, and L-arginine; warfarin; beta-blockers; diuretics; spirolactone; and natural products such as vinca alkaloids (*e.g.*, vinblastine, vincristine and vinorelbine).

As noted above, the therapeutic agent may also include a biological agent. The biological agent may include organic substances such as peptides, proteins, enzymes, carbohydrates (*e.g.*, monosaccharides, oligosaccharides and polysacchardies), lipids, phospholipids, steroids, lipoproteins, glycoproteins, glycolipids, proteoglycans, polynucleotides (*e.g.*, DNA and RNA), antisense polynucleotides (*e.g.*, c-myc antisense), antibodies (*e.g.*, monoclonal or polycolonal) and/or antibody fragments (*e.g.*, anti-CD34 antibody), bioabsorbable polymers (*e.g.*, polylactonic acid), chitosan, extracellular matrix modulators, such as matrix metalloproteinases (MMP), which include MMP-2, MMP-9 and Batimastat; and protease inhibitors.

Biological agents may include, for example, agents capable of stimulating angiogenesis in the myocardium. Such agents may include vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF), non-viral DNA, viral DNA, and endothelial growth factors (*e.g.*, FGF-1, FGF-2, VEGF, TGF). Other growth factors may include erythropoietin and/or various hormones such as corticotropins, gonadotropins, sonlatropin, thyrotrophin, desmopressin, terlipressin, oxytocin, cetrorelix, corticorelin, leuprorelin, triptorelin, gonadorelin, ganirelix, buserelin, nafarelin, and goserelin. Additional growth factors may also include cytokines, epidermal growth factors (EGF), platelet derived growth factor (PDGF), transforming growth factors-β (TGF-β), transforming growth factor-α (TGF-α), insulin-like growth factor-I (IGF-I), insulin-like growth factor-II (IGF-II), interleukin-1 (IL-1), interleukin-2 (IL-2), interleukin-6 (IL-6), interleukin-8 (IL-8), tumour necrosis factor-α (TNF-α), tumour necrosis factor-β (TNF-β), interferon-γ (INF-γ), colony stimulating factors (CSFs); monocyte chemotactic protein, and fibroblast stimulating factor 1.

Still other biological agents may include regulatory peptides such as somatostatin and octreotide; bisphosphonates (*e.g.*, risedronates, pamidronates, ibandronates, zoledronic acid, clodronic acid, etidronic acid, alendronic acid, and tiludronic acid); fluorides such as disodium fluorophosphate and sodium fluoride; calcitonin and dihydrotachystyrene; histamine; fibrin or fibrinogen; endothelin-1; angiotensin II; collagens; bromocriptin; methylsergide; methotrexate; carbontetrachloride and thioacetamide.

The present invention may also be treated (*i.e.*, seeded) with other biological agents, such as cells. Suitable cells may include any one or combination of eukaryotic cells. Additionally or optionally, the cells may be capable of producing therapeutic agents and/or genetically engineered to produce therapeutic agents. Suitable cells for use in the present invention include, for example, progentior cells such as adult stem cells, embryonic stem cells, and umbilical cord blood stem cells. The cells may be autologous or allogenic, genetically engineered or non-engineered, and may include, for example, mesenchymal or mesodermal cells, including, but not limited to, endothelial progenitor cells, endothelial cells, and fibroblasts. Mixtures of such cells can also be used.

A variety of *ex vivo* or *in vivo* methods can be used to deliver a nucleic acid molecule or molecules, such as a gene or genes, to the cells. For example, the cells can be modified (*i.e.*, genetically engineered) to produce or secrete any one or combination of the aforementioned therapeutic agents, including, but not limited to, anticoagulant agents, antiplatelet agents, antifibrinolytic agents, angiogenesis factors, and the like. *Ex vivo* gene transfer is a process by which cells are removed from the body using well known techniques, genetically manipulated, usually through transduction or transfection of a nucleic acid molecule into the cells *in vitro*, and the returned to the body for therapeutic purposes. This contrasts with *in vivo* genetic engineering where a gene transfer vector is administered to a patient resulting in genetic transfer into cells and tissues in the intact patient. *Ex vivo* and *in vivo* gene transfer techniques are well known to one of skill in the art.

To treat the present invention with at least one therapeutic agent, a variety of methods, agents, and compositions may be used. For example, the therapeutic agent can be simply linked to the stent surface, embedded and released from within

polymer materials, such as a polymer matrix, or surrounded by and released through a carrier. Several approaches to treating medical devices with therapeutic agents exist. Some therapeutic agents can be loaded directly onto metallic surfaces; however, a coating composition, typically comprised of at least one polymer and at least one therapeutic agent, is usually used to treat drug-eluting devices. The coating composition ensures retention of the therapeutic agent during deployment and modulates elution kinetics of the therapeutic agent. By altering the release kinetics of different therapeutic agents in the same coating composition, distinct phases of a given disease process may be targeted.

The present invention may be treated with a coating composition comprising at least one therapeutic agent and at least one polymer or oligomer material. The polymer(s) and/or oligomer(s) may be of various types and from various sources, including natural or synthetic polymers, which are biocompatible, biodegradable, bioabsorbable and useful for controlled release of the therapeutic agent. For example, synthetic polymers can include polyesters, such as polylactic acid, polyglycolic acid, and/or combinations thereof, polyanhydrides, polycaprolactones, polyhydroxybutyrate valerates, and other biodegradable polymers or mixtures of copolymers thereof. Natural polymeric materials can include proteins such as collagen, fibrin, elastin, extracellular matrix components, other biologic agents, and/or mixtures thereof.

The polymer material or mixture thereof of the coating composition can be applied with the therapeutic agent on the surface of the present invention and can comprise a single layer. Optionally, multiple layers of the polymer material can be applied to form the coating composition. Multiple layers of the polymer material can also be applied between layers of the therapeutic agent. For example, the polymeric layers may be applied sequentially, with the first layer directly in contact with the uncoated surface of the apparatus and a second layer comprising the therapeutic agent and having one surface in contact with the first layer and the opposite surface in contact with a third layer of polymeric material which is in contact with the surrounding tissue. Additional layers of the polymeric material and therapeutic agent can be added as required.

Alternatively, the coating composition can be applied as multiple layers comprising one or more therapeutic agents surrounded by polymer material. For instance, the coating composition can comprise multiple layers of a single therapeutic agent, one or more therapeutic agents in each layer, and/or differing therapeutic agents in alternating layers. Alternatively, the layers comprising the therapeutic agent can be separated from one another by a layer of polymer material.

The coating composition may further comprise at least one pharmaceutically acceptable polymers and/or pharmaceutically acceptable carriers, for example, non-absorbable polymers, such as ethylene vinyl acetate and methylmethacrylate. The non-absorbable polymer, for example, can aid in further controlling release of the therapeutic agent by increasing the molecular weight of the coating composition and thereby delaying or slowing the rate of release of the therapeutic agent.

The coating composition can be applied to the present invention using standard techniques to cover the entire surface of the apparatus, or partially, as a single layer in a dot matrix pattern, for example. The coating composition can be applied using various techniques available in the art, such as dipping, spraying, vapor deposition, an injection-like and/or a dot matrix-like approach. Upon contact of the coating composition with adjacent tissue where implanted, the coating composition can begin to degrade in a controlled manner. As the coating composition degrades, the therapeutic agent is slowly released into adjacent tissue and the therapeutic agent is eluted so that the therapeutic agent can have its effect locally.

Where the therapeutic agent comprises a biological agent, such as cells, the biological agent can be coated directly onto the surface of the present invention or, alternatively, they can be incorporated into the polymeric material (*e.g.*, into a polymer matrix). Such biological agents may also be included within at least one microscopic containment vehicle (*e.g.*, a liposome, nanocapsule, nanoparticle, micelle, synthetic phospholipid, gas-dispersion, emulsion, microemulsion, nanosphere, and the like) that can be stimulated to release the biological agent(s) and/or that release the biological agent(s) in a controlled manner. The microscopic

containment vehicle can be coated onto the surface of the present invention or incorporated into the polymeric material. Where the biological agent comprises cells, for example, the cells can be induced to produce, activate, and/or release their cellular products (including one or more therapeutic agents) by an external stimulation device (*e.g.*, an electrical impulse). Alternatively, cells can constitutively release one or more therapeutic agents at a desired level.

To enable delivery and deployment of the apparatus 10, the apparatus is positioned about a balloon 120 (Fig. 1) for expanding the main body portion 46 of the support member 40 into full and complete contact with the annulus 20 of the mitral valve 14. The balloon 120 may have an hourglass shape to conform to the concave cross-sectional configuration of the main body portion 46. The shape of the balloon 120 is defined by first and second bulb sections 122 and 124 connected by a center section 126. Each of these sections 122, 124 and 126 may have a D-shaped diameter (or other shaped diameter) to match the D-shaped diameter of the valve 14 and the prosthetic valve 12. The center section 126 of the balloon 120 has a smaller diameter than the bulb sections 122 and 124. The first and second bulb sections 122 and 124 and the center section 126 may be inflated together or separately. Further, the sections 122, 124 and 126 may have multiple chambers to accommodate multiple fluids (*i.e.*, an inflation fluid and a cooling fluid).

In addition, releasable constraining wires (not shown) are used to temporarily hold the upper wing members 60 and the lower wing members 70 in the radially collapsed conditions shown in Fig. 1 during delivery and placement of the apparatus 10. The constraining wires can be made from a variety of different materials including metals, polymers, synthetics, fabrics, and biological tissues. With the upper wing members 60, the lower wing members 70, and the main body portion 46 of the support member 40 in their collapsed conditions, the apparatus 10 is then loaded into the end of a 16 to 22 French catheter 128 in a known manner.

To replace the mitral valve 14 with the apparatus 10 using a percutaneous (or intravascular) approach, the apparatus is first sized for the particular mitral valve using fluoroscopic and/or echocardiographic data. The catheter 128 is then introduced into either the right or left jugular vein (not shown), a femoral vein (not shown), or the subclavian vein (not shown) using a known percutaneous technique,

such as the Seldinger technique, and is advanced through the superior or inferior vena cava (not shown) to approach the right atrium (not shown). The catheter 128 is passed through the interatrial septum (not shown) to reach the left atrium 16. From inside the left atrium 16, the apparatus 10 is then positioned within the annulus 20 of the mitral valve 14 as is shown in Fig. 1. It should be noted that the angular orientation of the apparatus 10 within the mitral valve 14 is important, so a diagnostic agent or agents, such as radiopaque markers (not shown), may be used to ensure the apparatus is rotated to the proper position prior to deployment.

Next, the catheter 128 is pulled back so that the support member 40 can expand to the condition shown in Fig. 2 in the annulus 20 of the native mitral valve 14. The balloon 120 is then inflated, which pushes the main body portion 46 of the support member 40 into engagement with the annulus 20 as shown in Fig. 5.

The constraining wires are then released, which allows the upper wing members 60 and the lower wing members 70 of the support member 40 to spring radially outward toward their expanded conditions illustrated in Figs. 2-8. The upper wing members 60, in their radially extended condition, extend transverse to the direction of blood flow through the prosthetic valve 12, and engage the wall of the left atrium 16. Where the attachment mechanism 62 comprises barbs 64 as shown in Fig. 5, the barbs embed into the wall of the left atrium 16 to help secure the support member 40 in the annulus 20 of the mitral valve 14.

As the lower wing members 70 move from their radially collapsed condition to their radially extended condition, each of the lower wing members engages a portion of the native valve leaflets 22 and 24. The first and second lower wing members 72 and 74 engage the commissures of the native mitral valve 14 (Fig. 5) , while the third and fourth lower wing members 76 and 78 engage respective central portions of the native valve leaflets 22 and 24 (Fig. 6). The barbs 64 on the lower wing members 70 embed into the native valve leaflets 22 and 24 to help secure the support member 40 in the annulus 20 of the mitral valve 14. In their radially extended condition, the lower wing members 70 pin the native leaflets 22 and 24 back against the valve annulus 20 so that the prosthetic valve 12 can assume the valvular function. With the apparatus 10 fully deployed, the balloon 120 is deflated and moved out of the valve annulus 20.

It should be noted that the engagement of the main body portion body 46 with the valve annulus 20, the engagement of the upper wing members 60 with the wall of the left atrium 16, and the engagement of the lower wing members 70 that pins the native valve leaflets 22 and 24 back against the valve annulus provides a unique three-way locking mechanism for securing the apparatus 10 in the valve annulus.

It is contemplated that the apparatus 10 according to the present invention could alternatively be placed by a retrograde, percutaneous approach. For example, the apparatus 10 may be urged in a retrograde fashion through a femoral artery (not shown), across the aortic arch (not shown), through the aortic valve (not shown), and into the left ventricle 18 where the apparatus may then be appropriate positioned in the native mitral valve 14.

Figure 12 illustrates another alternative embodiment of the present invention. The apparatus 10_b of Fig. 12 is identically constructed as the apparatus 10 of Figs. 2-8, except whereas described below. In Fig. 12, structures that are identical as structures in Figs. 2-8 use the same reference numbers, whereas structures that are similar but not identical carry the suffix "b".

As shown in Fig. 12, the apparatus 10_b comprises a tri-leaflet prosthetic valve 12_b. Examples of prosthetic valves, such as the prosthetic valves disclosed in U.S. Pat. No. 5,156,621, which is hereby incorporated by reference in its entirety, are known in the art. The tri-leaflet prosthetic valve 12_b, such as a porcine aortic valve, may be used in either the mitral or tricuspid position. The prosthetic valve 12_b may be made of other biological materials, including, but not limited to, aortic xenografts, bovine pericardial tissue, equine pericardial tissue, porcine pericardial tissue, peritoneal tissue, and a homograft or allograft. Additionally, the prosthetic valve 12_b may be made of any one or combination of biocompatible materials such as polyurethane, PTFE, expanded PTFE, Dacron®, woven velour, Gore-Tex®, and heparin coated fabric.

As may be seen in Fig. 12, in the tricuspid position, six lower wing members 70 may be used so that a lower wing member is positioned at each native commissure and directly over each native valve leaflet. The support structure 40 of the apparatus 10_b also includes at least three strut members 45 that are spaced

apart from each other. The valve leaflets of the prosthetic valve 12_b are joined together at at least three commissural sections 47. Each of the three commissural sections 47 are attached to a representative one of the strut members 45 to prevent prolapse of the valve leaflets 22 and 24. Other than this, the apparatus 10_b with the tri-leaflet prosthetic valve 12_b is deployed and functions as described above with regard to the previous embodiment. It should be understood that more or less than six lower wing members 70 could be used.

The present invention thus allows for the apparatus 10 to be delivered in a cardiac catheterization laboratory with a percutaneous approach under local anesthesia using fluoroscopic as well as echocardiographic guidance, thereby avoiding general anesthesia and highly invasive open heart surgery techniques. This approach offers tremendous advantages for high risk patients with severe valvular disease. It should be understood, however, that the present invention contemplates various other approaches, including standard open heart surgeries as well as minimally invasive surgical techniques. Because the present invention omits stitching of the apparatus 10 in the valve annulus 20, surgical time is reduced regardless of whether an open, minimally invasive or percutaneous approach is used.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. For example, it should be understood by those skilled in the art that the various portions of the support member 40 could be self-expanding or expanded by a change in temperature (because they are made from a shape memory material). Such improvements, changes and modifications within the skill of the art are intended to be covered by the appended claims.

Having described the invention, we claim:

1. An apparatus for replacing a cardiac valve having at least two native valve leaflets, said apparatus comprising:

an expandable support member having oppositely disposed first and second ends and a main body portion extending between said ends, said main body portion of said support member having an annular shape for expanding into position in the annulus of the cardiac valve;

said first end of said support member comprising a plurality of upper wing members that extend from said main body portion, each of said upper wing members being movable from a radially collapsed condition into a radially extended condition for engaging a first section of cardiac tissue surrounding one side of the cardiac valve;

said second end of said support member comprising a plurality of lower wing members that extend from said main body portion, each of said lower wing members being movable from a radially collapsed condition into a radially extended condition for engaging a portion of the native valve leaflets to pin the leaflets back against the annulus of the native cardiac valve;

said second end of said support member further including at least two strut members that are spaced apart from each other; and

a prosthetic valve secured within said main body portion of said support member, said prosthetic valve having at least two valve leaflets that are coaptable to permit unidirectional flow of blood, each of said at least two valve leaflets being joined together at at least two commissural sections that are spaced apart from each other, each of said at least two commissural sections being attached to a respective one of said strut members to prevent prolapse of said valve leaflets.

2. The apparatus of claim 1 wherein said plurality of upper wing members, in their radially extended condition, extend transverse to the direction of blood flow through said prosthetic valve.

3. The apparatus of claim 1 wherein at least one of said plurality of upper wing members includes at least one attachment mechanism for embedding into the first section of cardiac tissue to help secure said support member in the annulus of the cardiac valve.

4. The apparatus of claim 3 wherein said at least one attachment mechanism includes at least one barb.

5. The apparatus of claim 1 wherein at least one of said plurality of lower wing members includes at least one attachment mechanism for embedding into a portion of the native valve leaflets to help secure said support member in the annulus of the cardiac valve.

6. The apparatus of claim 1 wherein said main body portion has a concave cross-sectional shape for conforming to the convex shape of the annulus of the cardiac valve.

7. The apparatus of claim 1 wherein said plurality of lower wing members includes first and second lower wing members for positioning at the commissures of the native cardiac valve.

8. The apparatus of claim 7 wherein said first and second lower wing members are spaced approximately 180° apart.

9. The apparatus of claim 8 wherein said plurality of lower wing members further includes third and fourth lower wing members for positioning directly over respective central portions of the at least two native valve leaflets.

10. The apparatus of claim 9 wherein said third and fourth lower wing members are spaced approximately 180° apart and are located in-between said first and second lower wing members, respectively.

11. The apparatus of claim 1 wherein said plurality of lower wing members includes a first group of lower wing members for positioning at the commissures of the native cardiac valve.

12. The apparatus of claim 11 wherein said plurality of lower wing members further includes a second group of lower wing members for positioning directly over respective central portions of the at least two native valve leaflets, said first and second groups of lower wing members being arranged in an alternating fashion.

13. The apparatus of claim 1 wherein said plurality of lower wing members includes at least two lower wing members for positioning directly over respective central portions of the at least two native valve leaflets.

14. The apparatus of claim 1 further comprising a layer of biocompatible material covering at least a portion of said support member.

15. The apparatus of claim 1 wherein at least a portion of said support member is treated with at least one therapeutic agent for eluting into cardiac tissue.

16. The apparatus of claim 1 wherein a plurality of portions of said support member are separately treated with a different therapeutic agent.

17. A method for replacing a cardiac valve having at least two native valve leaflets, said method comprising the steps of:

providing a prosthetic valve that includes an expandable support member having oppositely disposed first and second ends and a main body portion extending between the ends, a plurality of upper wing members that extend from a one end of the main body portion, and a plurality of lower wing members that extend from an opposite end of the main body portion, the second end of the support member further including at least two strut members, the prosthetic valve having at least two valve leaflets that are joined together at at least two commissural sections, each of the at least two commissural sections being attached to a respective one of the strut members to prevent prolapse of the valve leaflets;

placing the main body portion of the prosthetic valve within the annulus of the cardiac valve to be replaced;

expanding the main body portion into engagement with the annulus of the cardiac valve to secure the prosthetic valve in the annulus;

deploying the upper wing members from a radially collapsed condition into a radially extended condition into engagement with a first section of cardiac tissue surrounding one side of the cardiac valve; and

deploying the lower wing members from a radially collapsed condition into a radially extended condition into engagement with a portion of the native valve leaflets to pin the leaflets back against the annulus of the native cardiac valve.

18. The method of claim 17 wherein said step of placing the main body portion of the prosthetic valve within the annulus of the cardiac valve to be replaced further comprises the steps of:

placing the support member around an inflatable balloon in a secured manner;

inserting the balloon and support member into an atrial chamber;

advancing the balloon until the support member is positioned within the annulus of the cardiac valve to be replaced; and

expanding the support member with the balloon so that the support member engages the annulus of the cardiac valve to secure the support member in the annulus.

19. The method of claim 18 wherein the balloon has an hourglass shape defined by first and second bulb sections connected by a center section having a smaller diameter than the bulb sections, said step of placing the support member around the balloon further comprising the step of positioning the support member about the center section.

20. The method of claim 19 wherein said step of advancing the balloon until the support member is positioned within the valve annulus further includes the step of positioning the first bulb section within the leaflets of the native valve so that when the balloon is inflated the first bulb pushes the valve leaflets back to protect the leaflets during expansion of the support member.

21. The method of claim 18 wherein said step of expanding the support member with the balloon so that the support member engages the annulus of the cardiac valve includes the step of conforming the main body portion to the shape of the valve annulus to help locate and secure the support member in the valve annulus by radially forcing the main body portion into the valve annulus.

22. The method of claim 17 wherein each of the plurality of wing members include at least one attachment mechanism for embedding into cardiac tissue.

23. The method of claim 22 wherein the attachment mechanism includes at least one barb extending from each of the wing members, said method further including the step of embedding the at least one barb into cardiac tissue to further secure the support member in the valve annulus.

24. The method of claim 23 wherein each of the wing members has a concave cross-sectional shape for conforming to the convex shape of the valve annulus, said method further comprising the step of pulling the wing members into a flatter cross-sectional shape with a constraining wire for placement of the support member, the at least one barb extending generally radially when the wing members are being held by the constraining wire.

25. The method of claim 24 further comprising the step of releasing the constraining wire after said step of expanding the support member with the balloon so that the upper wing members spring radially outward to engage the first section of cardiac tissue, and the lower wing members spring radially outward to engage a portion of the native valve leaflets.

26. The method of claim 25 wherein said step of releasing the constraining wire causes the at least one barb to embed into cardiac tissue in the distal direction.

27. The method of claim 17 wherein said step of inserting the balloon and the prosthetic valve into the heart chamber is done percutaneously via an intravascular catheter.

28. The method of claim 27 wherein said step of inserting the balloon and the prosthetic valve into the heart chamber is done via a minimally invasive approach.

29. The method of claim 27 wherein said step of inserting the balloon and the prosthetic valve into the heart chamber is done via an open-chest procedure.

30. The method of claim 17 wherein at least a portion of the support member is treated with at least one therapeutic agent for eluting into cardiac tissue, the method further comprising the step of allowing the at least one therapeutic agent to elute into the cardiac tissue.

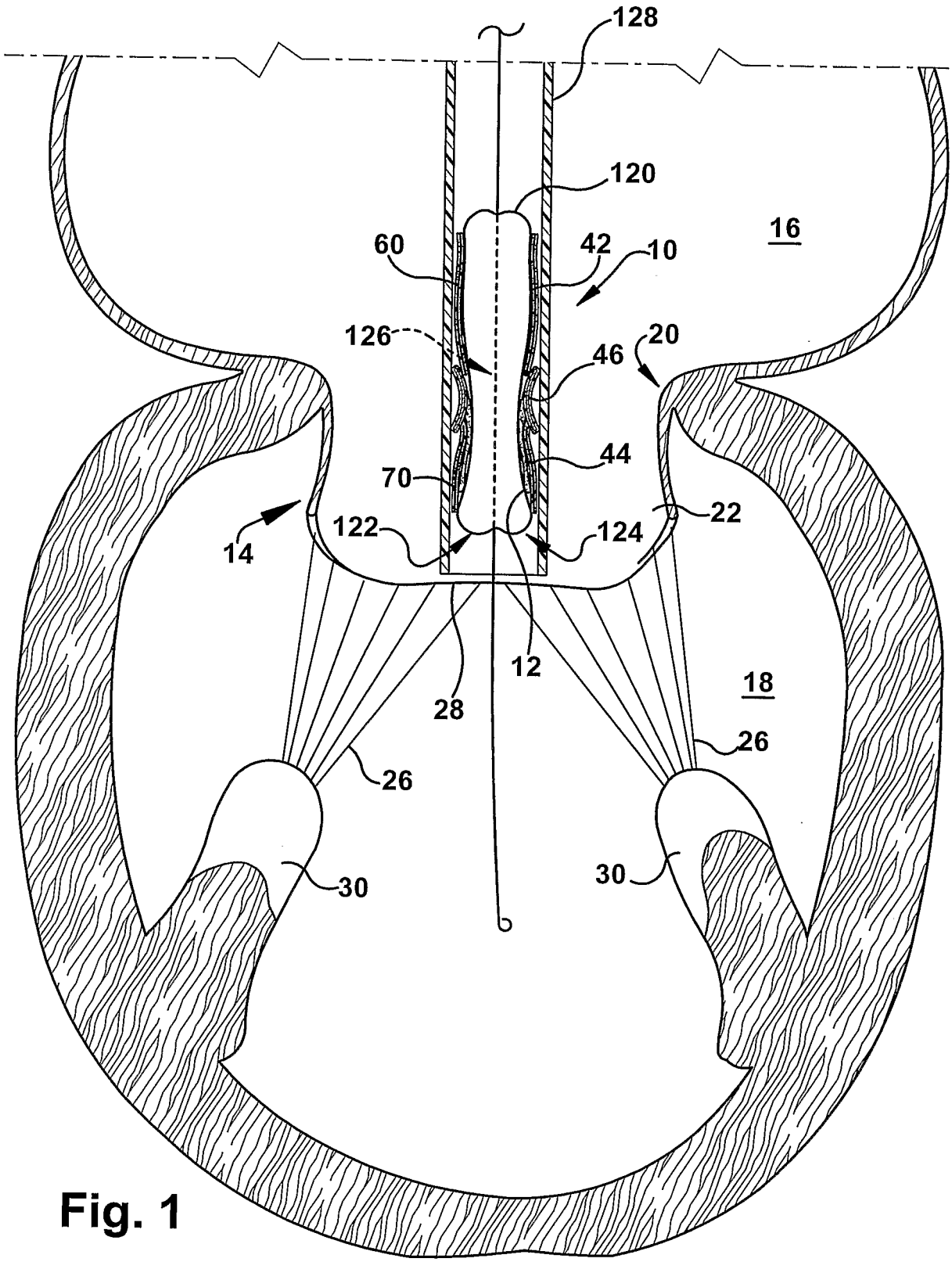


Fig. 1

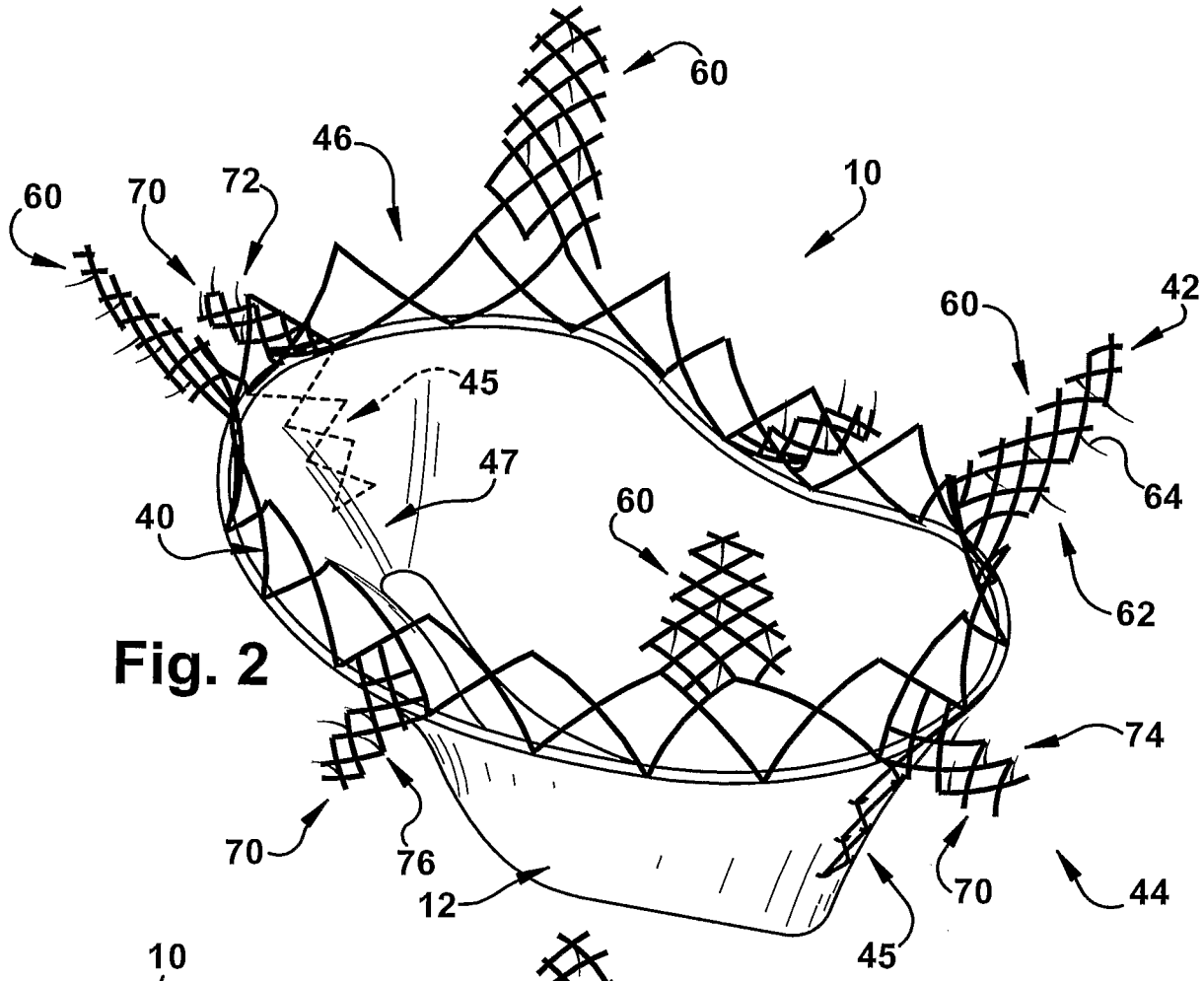

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Fig. 2

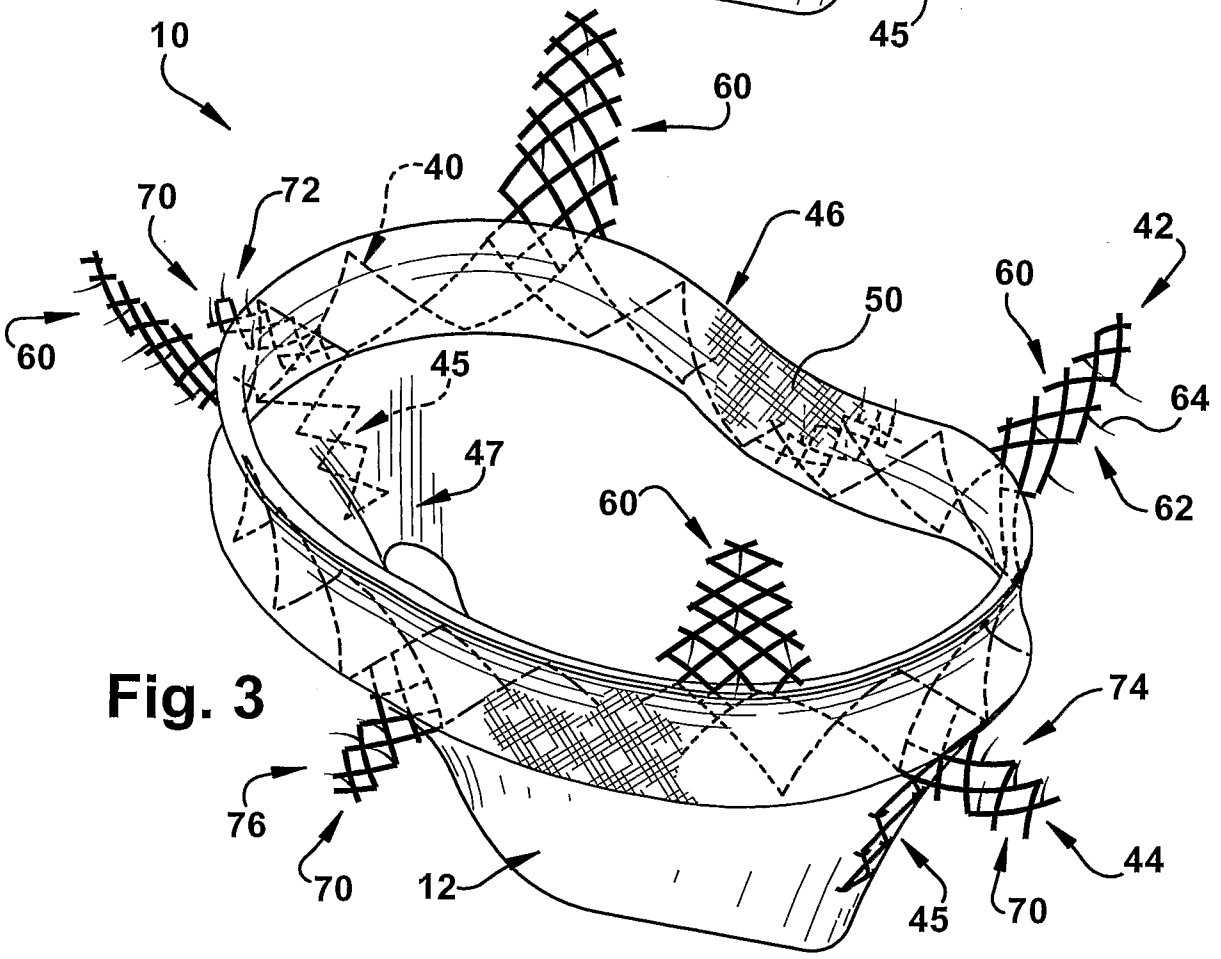

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Fig. 3

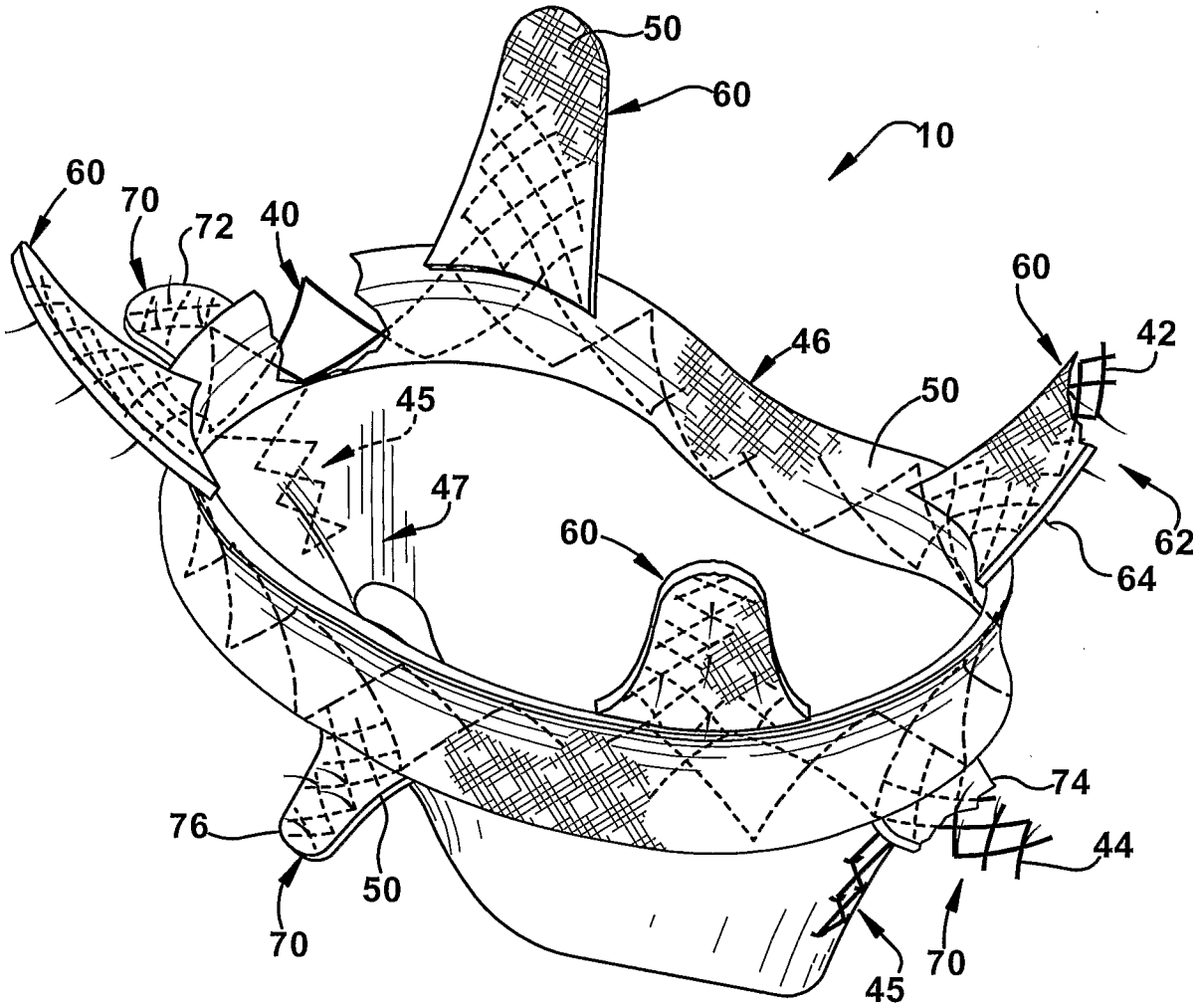


Fig. 4

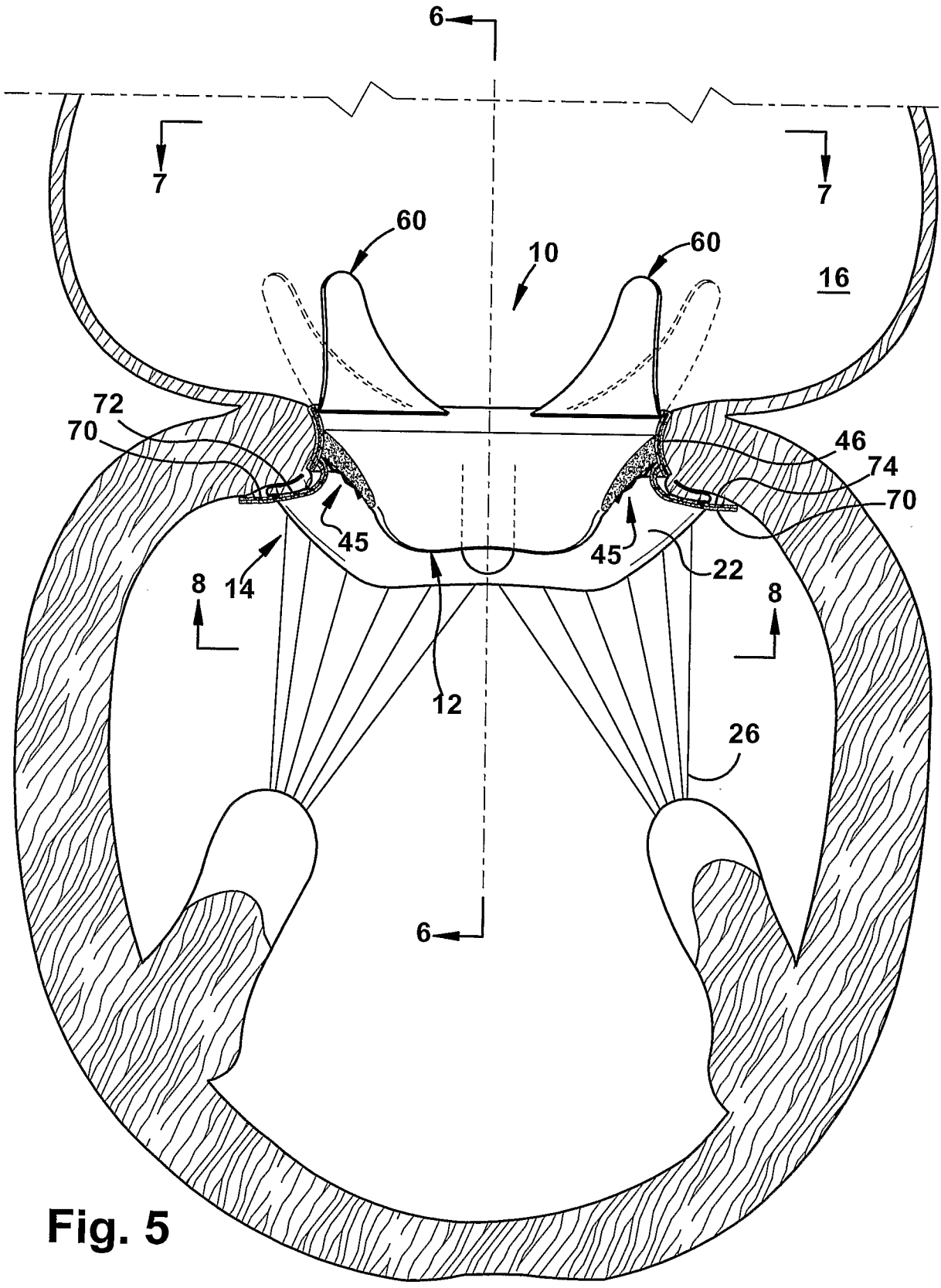


Fig. 5

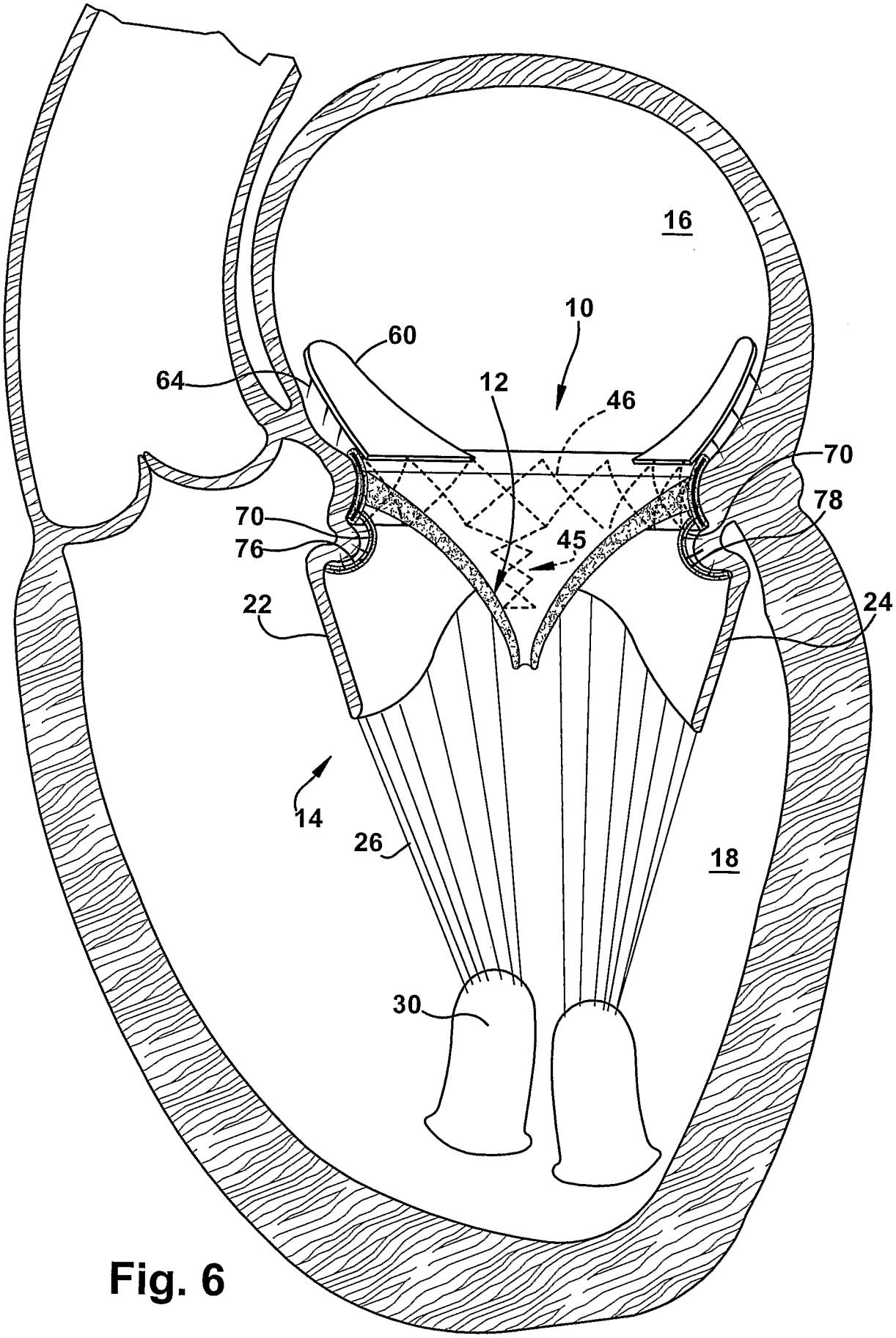


Fig. 6

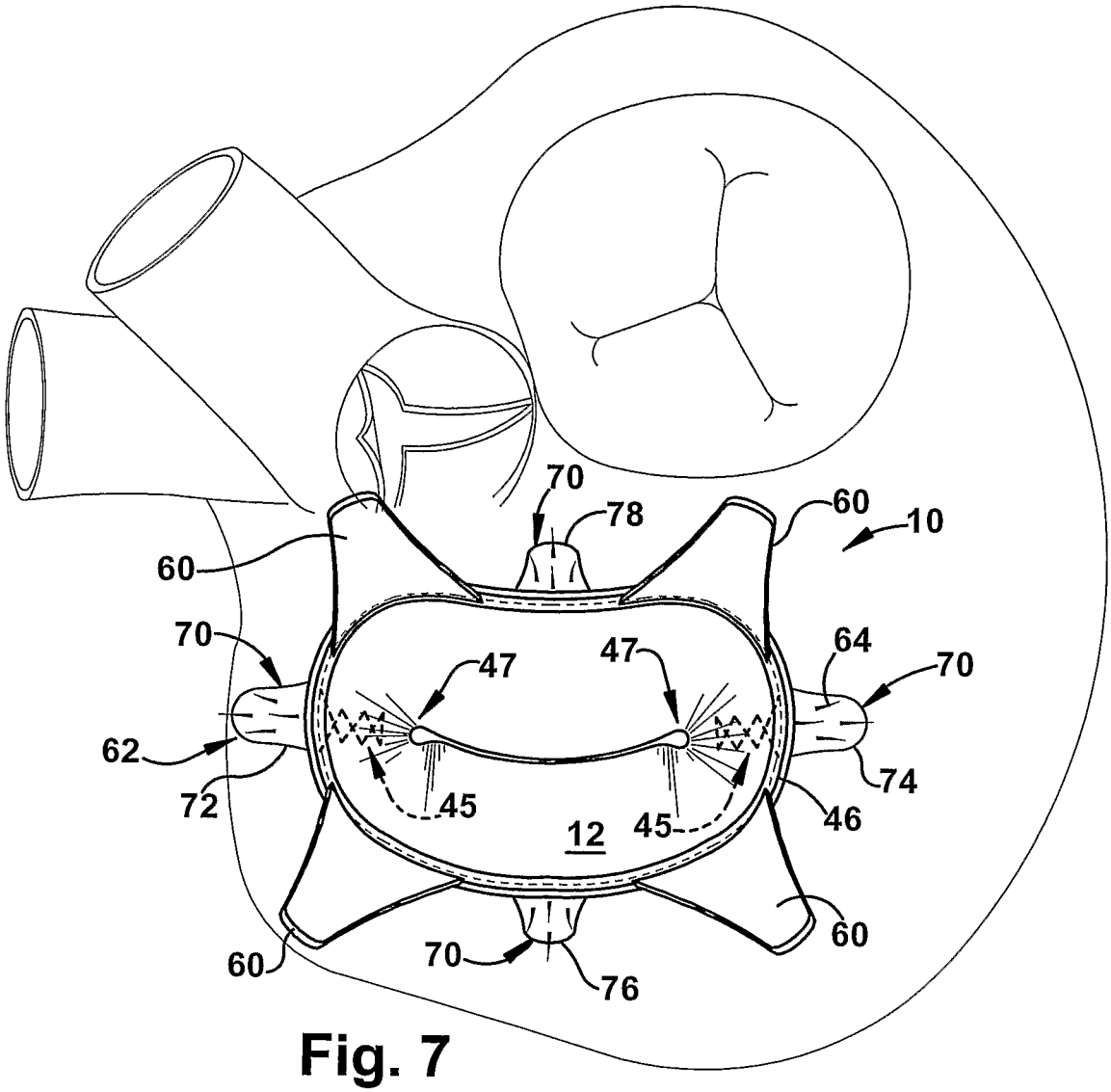

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Fig. 7

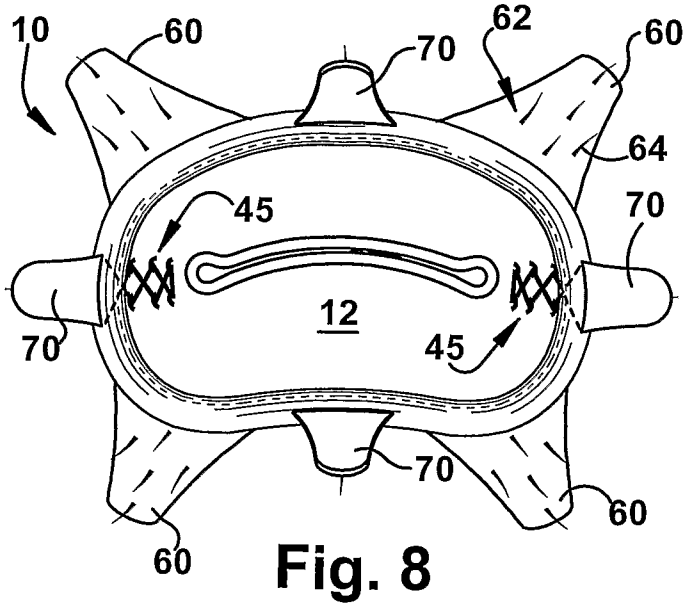

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Fig. 8

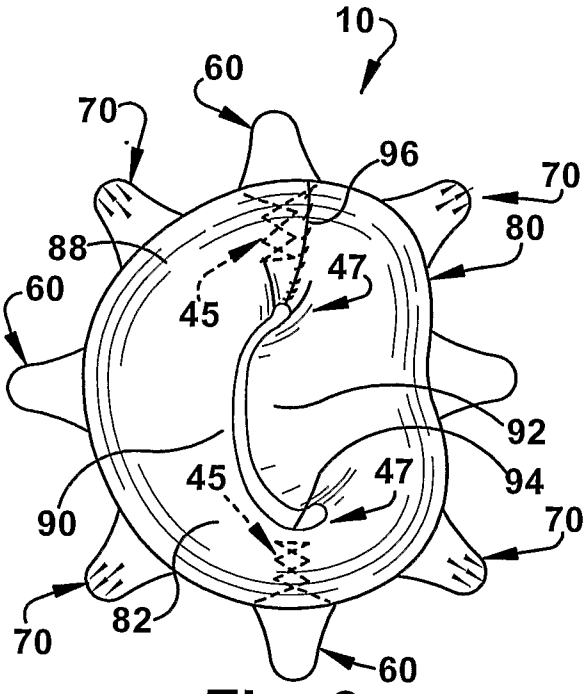


Fig. 9

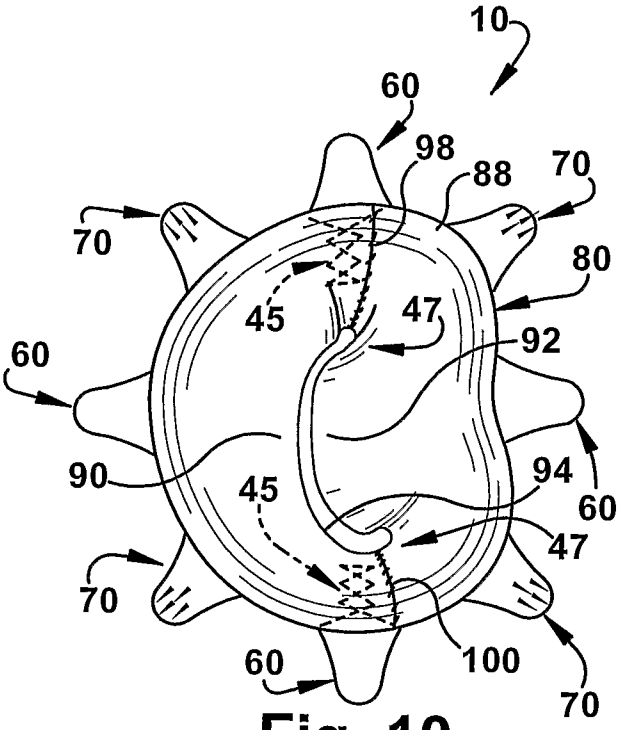


Fig. 10

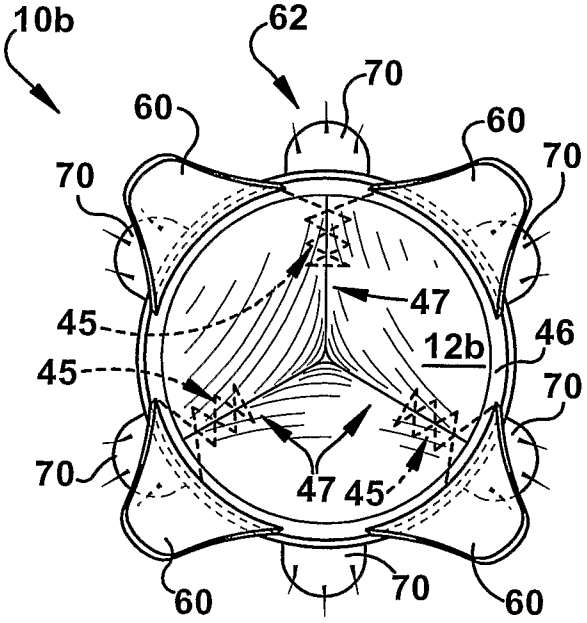


Fig. 12

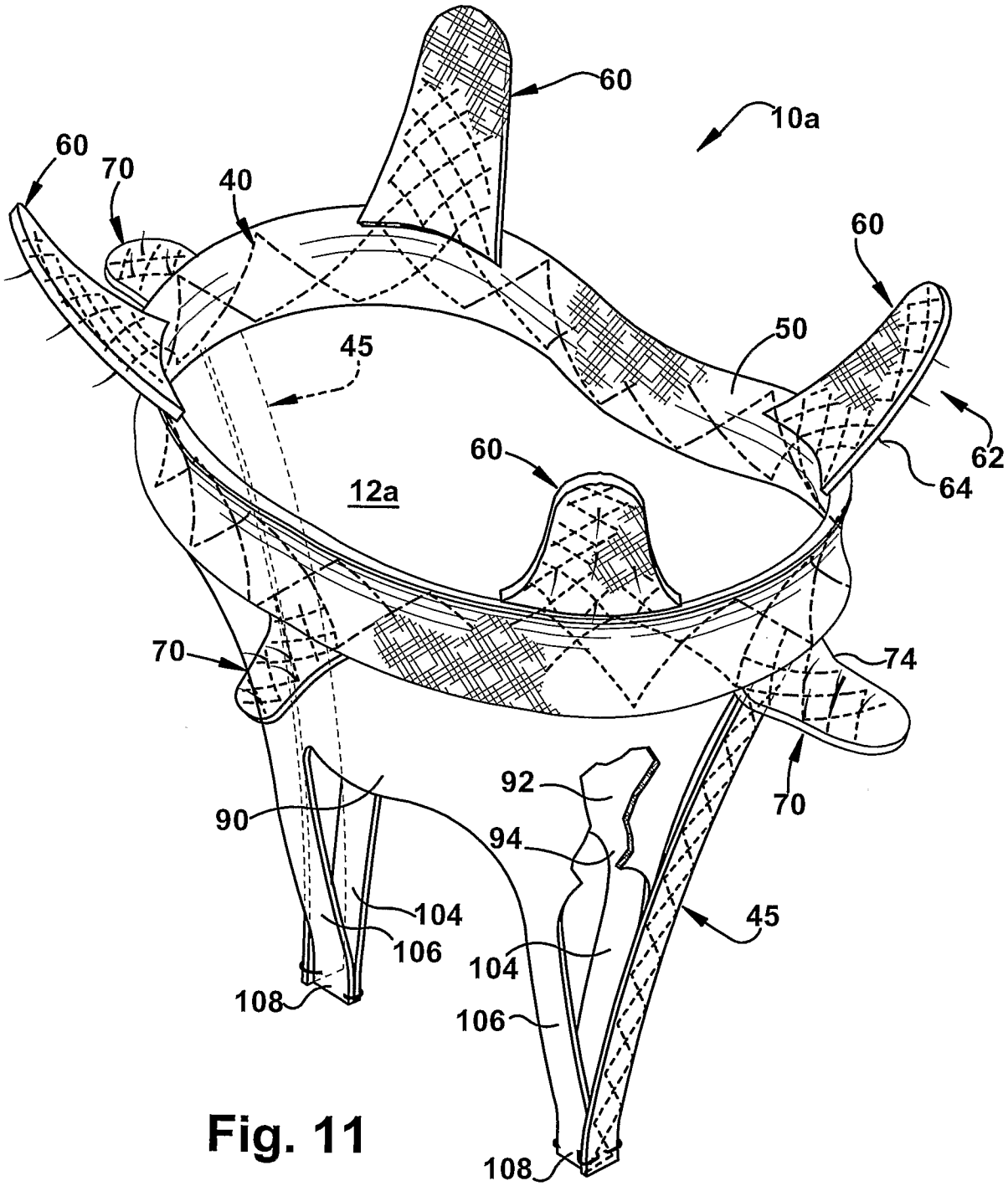

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Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/005858

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/023303 A1 (PALMAZ JULIO C ET AL) 30 January 2003 (2003-01-30) paragraph [0073] paragraph [0082] - paragraph [0087] figures 7-12b	1-16
A	WO 2004/103223 A (THE CLEVELAND CLINIC FOUNDATION) 2 December 2004 (2004-12-02) page 13, line 5 - page 17, line 21 figures 1-7	1,3-6
A	WO 03/028558 A (AMPLE MEDICAL CORPORATION; MACOVIAK, JOHN, A; CHANG, ROBERT, T; MACHOL) 10 April 2003 (2003-04-10) page 6, line 22 - line 27 figures 11,12	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 July 2006	17/07/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/005858

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-30
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 830
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/005858

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003023303 A1	30-01-2003	NONE	
WO 2004103223 A	02-12-2004	CA 2526347 A1	02-12-2004
		EP 1626682 A1	22-02-2006
WO 03028558 A	10-04-2003	CA 2455444 A1	10-04-2003
		CA 2462254 A1	10-04-2003
		CN 1610529 A	27-04-2005
		EP 1434621 A2	07-07-2004
		EP 1434542 A2	07-07-2004
		JP 2005504577 T	17-02-2005
		WO 03028802 A2	10-04-2003

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10/390,951 18 March 2003 (18.03.2003) US

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(72) Inventor; and

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(74) Agents: **JAMES, John, Christopher** et al.; One Edwards Way, Irvine, CA 92614 (US).

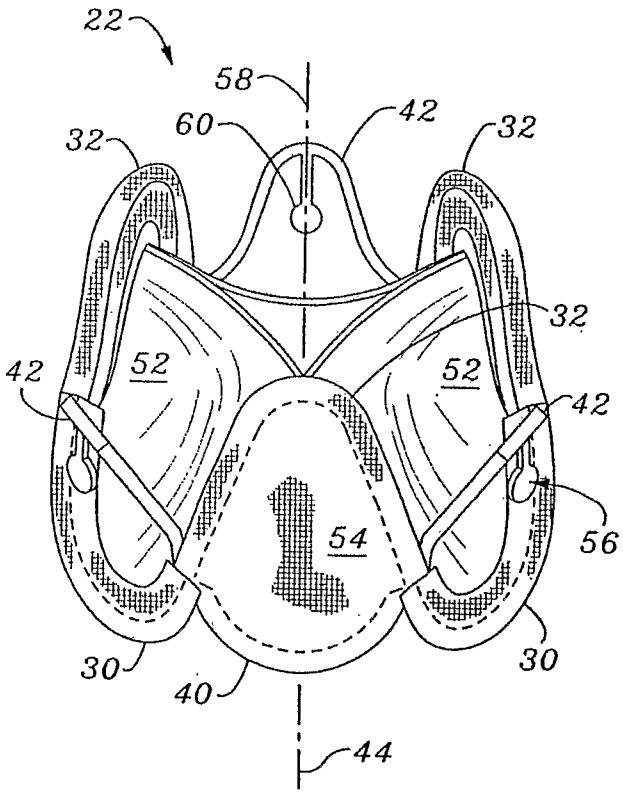
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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MINIMALLY-INVASIVE HEART VALVE WITH CUSP POSITIONERS



(57) Abstract: A prosthetic heart valve having an internal support frame with a continuous, undulating leaflet frame defined therein. The leaflet frame has three cusp regions positioned at an inflow end intermediate three commissure regions positioned at an outflow end thereof. The leaflet frame may be cloth covered and flexible leaflets attached thereto form occluding surfaces of the valve. The support frame further includes three cusp positioners rigidly fixed with respect to the leaflet frame and located at the outflow end of the support frame intermediate each pair of adjacent commissure regions. The valve is desirably compressible so as to be delivered in a minimally invasive manner through a catheter to the site of implantation. Upon expulsion from catheter, the valve expands into contact with the surrounding native valve annulus and is anchored in place without the use of sutures. In the aortic valve position, the cusp positioners angle outward into contact with the sinus cavities, and compress the native leaflets if they are not excised, or the aortic wall if they are. The support frame may be formed from a flat sheet of Nitinol that is bent into a threedimensional configuration and heat set. A holder having spring-like arms connected to inflow projections of the valve may be used to deliver, reposition and re-collapse the valve, if necessary.

WBH12
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref. 1272.0040P

Edwards Lifesciences Corp. et al. v. Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 832
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

WO 2004/082527 A2

MINIMALLY-INVASIVE HEART VALVE WITH CUSP POSITIONERS

Field of the Invention

[0001] The present invention relates generally to medical implants, and more particularly to minimally-invasive or collapsible/expandable heart valves and methods of delivering and implanting such valves.

Background of the Invention

[0002] Prosthetic heart valves are used to replace damaged or diseased heart valves. In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. Prosthetic heart valves can be used to replace any of these naturally occurring valves, although repair or replacement of the aortic or mitral valves is most common because they reside in the left side of the heart where pressures are the greatest.

[0003] Where replacement of a heart valve is indicated, the dysfunctional valve is typically cut out and replaced with either a mechanical valve, or a tissue or bioprosthetic-type valve. Bioprosthetic-type valves are often preferred over mechanical valves because they typically do not require long-term treatment with anticoagulants. The most common bioprosthetic-type valves are constructed with whole porcine (pig) valves, or with separate leaflets cut from bovine (cow) pericardium.

[0004] Although so-called stentless valves, comprising a section of xenograft (e.g., porcine) aorta and valve, are available, the most widely used valves include some form of artificial leaflet support. One such support is an elastic "support frame," sometimes called a "wireform" or "stent," which has a

plurality (typically three) of large radius U-shaped cusps supporting the cusp region of the leaflets of the bioprosthetic tissue (i.e., either a whole valve or three separate leaflets). The free ends of each two adjacent cusps converge somewhat asymptotically to form upstanding commissures that terminate in U-shaped tips, each being curved in the opposite direction as the cusps, and having a relatively smaller radius. The support frame typically describes a conical tube with the commissure tips at the small diameter end. This provides an undulating reference shape to which a fixed edge of each leaflet attaches (via components such as fabric and sutures) much like the natural fibrous skeleton in the aortic annulus. Therefore, the alternating cusps and commissures mimic the natural contour of leaflet attachment. Importantly, the wireform provides continuous support for each leaflet along the cusp region so as to better simulate the natural support structure.

[0005] The support frame is typically a non-ferromagnetic metal such as ELGILOY (a Co-Cr alloy) that possesses substantial elasticity. A common method of forming metallic support frames is to bend a wire into a flat (two-dimensional) undulating pattern of the alternating cusps and commissures, and then roll the flat pattern into a tube using a cylindrical roller. The free ends of the resulting three-dimensional shape, typically in the asymptotic region of the cusps, are then fastened together using a tubular splice that is plastically crimped around the ends. See Figs. 3 and 4 of U.S. Patent No. 6,296,662 for a support frame that is crimped together at a cusp midpoint.

[0006] Some valves include polymeric "support frames" rather than metallic, for various reasons. For example, U.S. Patent No. 5,895,420 discloses a plastic support frame that degrades in the body over time. Despite some favorable attributes of polymeric support frames, for example the ability to mold the complex support frame shape, conventional metallic support frames are generally preferred for their elastic properties, and have a proven track record in highly successfully heart valves. For example, the CARPENTIER-EDWARDS

Porcine Heart Valve and PERIMOUNT Pericardial Heart Valve available from Edwards Lifesciences LLC both have ELGILOY support frames and have together enjoyed the leading worldwide market position since 1976.

[0007] A conventional heart valve replacement surgery involves accessing the heart in the patient's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart, allowing access to the thoracic cavity and heart within. The patient is then placed on cardiopulmonary bypass which involves stopping the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period.

[0008] Some attempts have been made to enable less traumatic delivery and implantation of prosthetic heart valves. For instance, U.S. Patent No. 4,056,854 to Boretos discloses a radially collapsible heart valve secured to a circular spring stent that can be compressed for delivery and expanded for securing in a valve position. Also, U.S. Patent No. 4,994,077 to Dobbin describes a disk-shaped heart valve that is connected to a radially collapsible stent for minimally invasive implantation.

[0009] Recently, a great amount of research has been done to reduce the trauma and risk associated with conventional open heart valve replacement surgery. In particular, the field of minimally invasive surgery (MIS) has exploded since the early to mid-1990s, with devices now being available to enable valve replacements without opening the chest cavity. MIS heart valve replacement surgery still typically requires bypass, but the excision of the native valve and implantation of the prosthetic valve are accomplished via elongated tubes or cannulas, with the help of endoscopes and other such visualization techniques.

[0010] Some examples of more recent MIS heart valves are shown in U.S. Patent No. 5,411,552 to Anderson, et al., U.S. Patent No. 5,980,570 to

Simpson, U.S. Patent No. 5,984,959 to Robertson, et al., U.S. Patent No. 6,425,916 to Garrison, et al., and PCT Publication No. WO 99/334142 to Vesely.

[0011] Although these and other such devices provide various ways for collapsing, delivering, and then expanding a "heart valve" per se, none of them disclose much structural detail of the valve itself. For instance, the publication to Vesely shows a tissue leaflet structure of the prior art in Fig. 1, and an expandable inner frame of the invention having stent posts in Figs. 3A-3C. The leaflets are "mounted to the stent posts 22 in a manner similar to that shown in Fig. 1." Likewise, Anderson describes mounting a porcine valve inside of an expandable stent "by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in Fig. 2." Such general disclosures stop short of explaining how to construct a valve in a manner that maximizes long-term efficacy. In particular, the particular means of attaching the leaflets to the MIS stent is critical to ensure the integrity and durability of the valve once implanted. All of the prior art MIS valves are inadequate in this regard. Furthermore, use of conventional support stents or wireforms is difficult in MIS valves because of the need to compress the valve into a relatively small diameter delivery package, which creates material challenges.

[0012] Some MIS valves of the prior art are intended to be used without removing the natural valve leaflets. Sometimes the natural leaflets are heavily calcified, and their removal entails some risk of plaque particles being released into the bloodstream. Therefore, some of the MIS valves are designed to expand outward within the annulus and native leaflets, and compress the leaflets against the annulus. The relatively uneven surface of the calcified annulus and leaflets creates sizing problems and may complicate the delivery and placement steps. Prior art MIS valves are essentially tubular stents embellished with a native xenograft valve. The implant methodology is simply the conventional balloon expansion technique or pushing a self-expanding version from the end

of a catheter. Minimal control over the placement of the valve is provided or contemplated.

[0013] Despite some advances in MIS valve design, there remains a need for an MIS valve that is durable and which has a more flexible delivery and implantation methodology.

Summary of the Invention

[0014] The present invention provides improved prosthetic heart valves that can be implanted in a minimally-invasive manner, but which also has aspects that make it useful for conventional surgeries. The valves and implant tools and methods described herein provide a highly adaptive and simple to use endovascular delivery option for cardiac surgeons or cardiologists because of features that facilitate implantation. The valve is designed to be expelled from a delivery tube in an implant area and then expanded and/or positioned to contact the surrounding tissue without additional anchoring structures. Further, the valve and implant tools permit repositioning and even recollapse of the valve if needed.

[0015] In accordance with a first aspect of the invention, a prosthetic heart valve support frame comprises a leaflet frame and three cusp positioners. The leaflet frame has a continuous, undulating shape that mimics the natural fibrous structure of an aortic valve. The leaflet frame has three cusp regions alternating with and intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the support frame and circumferentially about a flow axis defined within the support frame. The three commissure regions are positioned at an outflow end of the support frame and circumferentially about the flow axis. The three cusp positioners are rigidly fixed with respect to the leaflet frame and are disposed circumferentially about the flow axis. Each cusp positioner is located at the outflow end of the support frame and intermediate two of the commissure regions of the leaflet frame.

[0016] The leaflet frame and the cusp positioners may be formed integrally as a single piece. Desirably, the support frame is formed by a process comprising providing a two-dimensional blank of the support frame, and forming the two-dimensional blank into the three-dimensional heart valve support frame. The leaflet frame and the cusp positioners may be made of Nitinol, preferably with a martensitic transition temperature of less than about 5° C and an austenitic transition temperature of more than about 20° C.

[0017] Each cusp positioner of the heart valve support frame desirably has a U-shape with an apex of the U-shape pointing toward the outflow end of the support frame and two legs of the U-shape pointing toward the inflow end. Each of the two legs of each U-shaped cusp positioner may be rigidly fixed to the continuous leaflet frame at a location approximately midway between a cusp region and a commissure region thereof. An anti-migration member such as an elongated section terminating in an enlarged and rounded head can be rigidly fixed to each cusp positioner to project therefrom. The cusp positioners may flare outwardly from the rest of the support frame to better contact surrounding tissue.

[0018] The support frame further may include three cusp connectors rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis. Each cusp connector is located at the inflow end of the support frame and intermediate two of the cusp regions of the leaflet frame. Each cusp connector desirably has a U-shape with an apex of the U-shape pointing toward the inflow end of the support frame and two legs of the U-shape pointing toward the outflow end. In a preferred embodiment, the leaflet frame, cusp positioners, and cusp connectors are formed integrally as a single piece, and the three cusp positioners and three cusp connectors define a continuous, undulating shape that generally mimics the shape of the leaflet frame but is rotated 60° about the flow axis therefrom.

[0019] Another aspect of the invention is a collapsible prosthetic heart valve that has a collapsible leaflet frame, three separate, flexible leaflets attached to the leaflet frame, and three cusp positioners rigidly fixed with respect to the leaflet frame. The leaflet frame has three cusp regions intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the support frame. The three commissure regions are positioned at an outflow end of the leaflet frame and circumferentially about the flow axis. Each flexible leaflet has an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween. The leaflets attach around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions. The three cusp positioners are rigidly fixed with respect to the leaflet frame and are disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the leaflet frame and intermediate two of the commissure regions of the leaflet frame.

[0020] The heart valve may incorporate the aforementioned features of the support frame, for example a leaflet frame with a continuous, undulating shape that mimics the natural fibrous structure of an aortic valve, cusp connectors, and anti-migration members on each cusp positoiner. Desirably, an inflow periphery of the heart valve is defined along alternating and rigidly fixed cusp regions and cusp connectors. The inflow periphery may have an external fabric covering, and the heart valve may further includes a fabric panel defining an exterior surface of the heart valve between each pair of cusp positioner and cusp connector. Preferably, the leaflet frame has a fabric covering along substantially its entire length, the fabric covering defining a flange, and wherein the arcuate cusp edges of the flexible leaflets attach to the fabric covering flange. The fabric covering flange may project generally outward from the leaflet frame such that the cusp edges of the flexible leaflets extend radially

outward past and underneath the leaflet frame to be sewn to the fabric covering flange. Each flexible leaflet may have a pair of tabs extending on either side of its free edge, wherein two tabs of adjacent flexible leaflets meet and pass together to the outside of the adjacent commissure region of the leaflet frame and are attached thereto using sutures through the tabs.

[0021] In accordance with a still further aspect of the invention, a collapsible prosthetic heart valve comprises:

a continuous, collapsible leaflet frame having three U-shaped cusp regions intermediate three U-shaped commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the leaflet frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

a cloth covering extending around the leaflet frame; and

three separate, flexible leaflets attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions, the commissure edges of each leaflet further including a tab, wherein the tabs of two adjacent leaflets extend through the U-shape commissure region, diverge on the outside of commissure region, and are attached to the leaflet frame on the outside of the commissure region.

[0022] The present invention also encompasses a method of implanting a prosthetic aortic heart valve with a first step of providing a collapsible prosthetic heart valve having a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve. The valve includes three cusp positioners on the

outflow end and intermediate the three commissure regions. The method includes collapsing the prosthetic heart valve within a delivery tube, advancing the prosthetic heart valve within the delivery tube to an aortic annulus, expelling the prosthetic heart valve from the delivery tube by relative movement therebetween, expanding the prosthetic heart valve, and positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

[0023] The method preferably includes the step of connecting a holder having flexible members to the commissure regions of the prosthetic heart valve and utilizing the flexible members to perform the step of positioning the prosthetic heart valve. Flexible members of the holder may also be connected to the cusp positioners and utilized to perform the step of positioning the prosthetic heart valve, or to rotate the prosthetic heart valve during the step of positioning. Advantageously, the flexible members may be used to re-collapse the prosthetic heart valve after the step of expanding. The prosthetic heart valve is desirably expanded in a location that is inferior to a final implant position such that the cusp positioners contact the surrounding aortic annulus, and the step of positioning comprises displacing the valve in a superior direction to a final implant position. The cusp positioners may be flared outward to define a circle about a flow axis of the valve greater than a circle about the flow axis defined by the three commissure regions, such that the step of displacing the valve in a superior direction causes the outwardly flared cusp positioners to be channeled into perspective coronary sinuses.

[0024] In accordance with a preferred method, the collapsible leaflet frame is formed of a shape memory alloy having a martensitic transition temperature less than room temperature and an austenitic transition temperature less than body temperature, and the step of collapsing is done with the material of the leaflet frame at a temperature less than its martensitic transition

temperature. For example, the step of collapsing may be done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to below its martensitic transition temperature. In another aspect, the collapsible leaflet frame may be formed of a shape memory alloy having a memory condition in its expanded state, and wherein the step of expanding the prosthetic heart valve comprises both permitting self-expansion of the valve to an intermediate diameter and then using a physical expander to increase the diameter of the valve to the memory condition of the leaflet frame.

[0025] A further method of implanting a collapsible prosthetic heart valve provided by the present invention comprises first providing a self-expanding valve comprised of a material displaying hysteresis in the elastic or superelastic region. The valve is permitted to self-expand to a first diameter, and then the valve is assisted with a physical expander such as a balloon to further expand to a second diameter.

[0026] The prosthetic heart valve may includes a collapsible leaflet frame formed of a shape memory alloy having a martensitic transition temperature less than room temperature and an austenitic transition temperature less than body temperature, and the method may further include a step of collapsing the valve with the material of the leaflet frame at a temperature less than its martensitic transition temperature. Fir example, the step of collapsing may be done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to below its martensitic transition temperature.

[0027] The prosthetic heart valve may have a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve, and three cusp positioners on the outflow end and intermediate the three commissure regions. In this case, the method may further include:

collapsing the prosthetic heart valve within a delivery tube;

advancing the prosthetic heart valve within the delivery tube to an aortic annulus;

expelling the prosthetic heart valve from the delivery tube by relative movement therebetween;

expanding the prosthetic heart valve by the steps of permitting self-expansion and assisting further expansion; and

positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

Brief Description of the Drawings

[0028] Fig. 1 is a partial view of a patient's heart generally vertically section through the left ventricle and associated heart valves, and illustrating the implantation approach of a catheter-based prosthetic valve of the present invention;

[0029] Fig. 2A is a vertical sectional view through an aortic annulus and an exemplary prosthetic heart valve of the present invention implanted therein;

[0030] Fig. 2B is a top plan view of the implanted prosthetic heart valve of Fig. 2A;

[0031] Figs. 3A-3C are perspective, top plan, and bottom plan views, respectively, of the prosthetic heart valve of Fig. 2A;

[0032] Fig. 4 is a plan view of a prosthetic heart valve support frame of the present invention in a two-dimensional blank form prior to conversion to three-dimensional final form;

[0033] Fig. 5 is a perspective view of the prosthetic heart valve support frame of Fig. 4 in its three-dimensional final form with a leaflet frame and cusp positioners;

[0034] Figs. 5A and 5B are views of a portion of the three-dimensional heart valve support frame of Fig. 5 showing alternative cusp positioner configurations;

[0035] Fig. 6A is an elevational view of a partially assembled prosthetic heart valve as in Figs. 3A-3C;

[0036] Fig. 6B is an elevational view of the prosthetic heart valve of Fig. 6A fully assembled;

[0037] Fig. 7 is a plan view of an exemplary leaflet used in the prosthetic heart valves of the present invention;

[0038] Fig. 8 is a partial sectional view of a commissure region of the exemplary prosthetic heart valve taken along line 8-8 of Fig. 3B;

[0039] Fig. 9 is a sectional view through a portion of the support frame of the exemplary prosthetic heart valve, taken along line 9-9 of Fig. 8;

[0040] Fig. 10 is a sectional view through a commissure tip region of the exemplary prosthetic heart valve, taken along line 10-10 of Fig. 8;

[0041] Fig. 11 is a schematic perspective view of a prosthetic heart valve support frame of the present invention being loaded into a delivery catheter;

[0042] Fig. 12 is a perspective view of the support frame after having been loaded into a delivery catheter;

[0043] Figs. 13A-13B are perspective and elevational views of an exemplary compressible/expandable heart valve holder attached to a prosthetic heart valve of the present invention;

[0044] Fig. 14 is a perspective view of the expulsion of an assembled prosthetic heart valve and holder as in Figs. 13A and 13B from the distal end of a delivery catheter;

[0045] Fig. 15 is a bottom plan view of an exemplary compressible/expandable heart valve holder of the present invention;

[0046] Fig. 16 is a plan view of a multi-armed flexible portion of the holder of Fig. 15; and

[0047] Figs. 17A-17B are two views of a rigid portion of the holder of Fig. 15.

Description of the Preferred Embodiments

[0048] The present invention provides an improved minimally invasive (MIS) valve support frame, MIS valve, and methods of construction and delivery as described herein and shown in the accompanying drawings.

[0049] The invention pertains primarily to flexible leaflet heart valves and internal support frames, which are also referred to in the art as stents or wireforms. As mentioned above, the flexible leaflets can be formed from biological (e.g., bovine pericardium) or synthetic material. In this context, a "support frame" for a flexible leaflet heart valve provides the primary internal structural support for the leaflets, and substantially mimics the natural fibrous skeleton of the respective valve annulus. More specifically, each of the leaflets has an outer edge that is coupled to a portion of the support frame such that its inner edge is free to move within the orifice area of the valve, thus providing the opening and closing surfaces thereof. A biological xenograft valve can be used to provide the flexible leaflets in the valves of the present invention, though the internal support frame is particularly suited to receive individual leaflets.

[0050] The leaflet frames of the present invention have a continuous, undulating shape with three arcuate or U-shaped cusp regions on the inflow end separated by three upstanding and generally axially-oriented arcuate or U-shaped commissure regions on the outflow end. Around the circumference of the leaflet frame, the shape has an alternating structure of cusp-commissure-cusp-commissure-cusp-commissure, and generally describes a conical surface of revolution with the three commissures on the outflow end of the valve being closer together than the three cusps. Some support frames may alternatively describe a tubular surface of revolution about an axis. The cusp regions and

commissure regions are evenly distributed about a flow axis through the support frame, and therefore the three cusp regions are 120° apart from each other, and each of the three commissure regions is 120° apart from the next and 60° from the adjacent cusp regions.

[0051] The term "continuous" to describe the heart valve leaflet frame means that a single continuous and closed-shape line (i.e., loop) can be drawn following the sequential cusp and commissure regions, and "undulating" refers to the serpentine or alternating sinusoidal character of the line. More generally, a continuous, undulating heart valve leaflet frame approximates the shape of the natural fibrous tissue around the aortic valve annulus so as to mimic that natural support structure for optimum functionality of the prosthetic leaflets.

[0052] The present invention primarily pertains to prosthetic heart valves suitable for minimally invasive delivery and implantation. Such minimally invasive valves are capable of being compressed or collapsed into a small profile and delivered through a catheter or cannula (a tube) to the site of implantation for remote expansion and anchoring thereto. It should be understood, however, that certain aspects of the invention described herein are beneficial for prosthetic heart valves in general, and thus not all of the claims should be construed to require a minimally invasive valve.

[0053] Fig. 1 depicts a portion of a heart of a patient with the left ventricle LV, aortic valve AV, mitral valve MV, and ascending aorta AA shown in section. A delivery catheter or tube 20 is seen in position just prior to complete expulsion and expansion of a prosthetic heart valve 22 from a distal end thereof for implant at the aortic valve AV annulus. The aortic valve AV leaflets L may first be excised prior to implant of the valve 22, or more preferably the leaflets L remain in place and are expanded outward and compressed against the lumen of the aortic valve AV annulus upon expansion of the valve. The distal end of the delivery tube 20 may optionally be stabilized by a balloon 24 (shown in phantom) inflated against the lumen of the ascending

aorta AA, or through other means. The delivery tube 20 is preferably inserted in the vasculature of the patient using a larger diameter introducer 26 through a peripheral vessel such as the femoral artery or femoral vein. Alternatively, the peripheral vessel may be the internal jugular vein, the subclavian artery, the axillary artery, the abdominal aorta, the descending aorta, or any other suitable blood vessel. The introducer 26 may be inserted by surgical cut down or percutaneously using the Seldinger technique.

[0054] Figs. 2A and 2B illustrate the prosthetic heart valve 22 implanted at the aortic valve AV annulus. The heart valve 22 includes three cusps 30 on an inflow end (one of which is not visible) and three commissures 32 on an outflow end. The direction of blood flow BF is indicated with an arrow in the ascending aorta AA. The natural leaflets are desirably compressed against the lumen of the aortic valve annulus by the prosthetic heart valve 22, as seen in Fig. 2B. The valve 22 is oriented about a flow axis such that the commissures 32 are generally aligned with the native commissures C, while the cusps (not shown but intermediate the commissures 32) are generally aligned with the natural cusps/leaflets L. The heart valve 22 contacts the lumen wall of the aortic valve AV annulus and desirably retains its position due to friction therebetween. In this regard, the heart valve 22 expands from its delivery configuration shown in Fig. 1 to the expanded configuration in Figs. 2A and 2B.

[0055] The valve 32 contacts the lumen wall around the entire periphery of the inflow end thereof and in certain areas adjacent to the inflow periphery, as will be explained below. The inflow periphery is defined by the lower ends of the cusps 30 as well as by the lower ends of three cusps connectors 40 that extend between and fill the gaps between the cusps 30. Additionally, the heart valve 22 includes three cusp positioners 42, two of which are visible in Fig. 2A, that are rigidly fixed with respect to an internal valve support frame and are each located generally at the outflow end of the valve intermediate two of the commissures 32. With reference to Fig. 2B, the cusp positioners 42 are evenly

distributed about a central flow axis 44, and when implanted align with the native leaflets L. The cusp positioners 42 preferably extend radially farther outward than the commissures 32 and compress the leaflets L against the natural sinus cavities formed just above the aortic valve AV annulus. Coronary ostia CO open from two of the three sinus cavities, as seen in Fig. 2A, and the cusp positioners 42 are sized and placed by the operator to avoid occluding flow through the coronary ostia CO. The advantageous structure and function of these cusp positioners 42 will be more fully explained below.

[0056] With reference now to Figs. 3A-3C, the exemplary prosthetic heart valve 22 will be more fully described. The shape of an internal support frame 50 seen in Fig. 5 generally governs the shape of the valve 22. As mentioned, the valve 22 includes the aforementioned cusps 30 and commissures 32 evenly distributed about a flow axis 44. The cusps 30 and cusp connectors 40 define a scalloped inflow periphery of the valve 22, while the outflow periphery is defined by the three commissures 32 and the three cusp positioners 42. The entire internal support frame 50 except for the cusp positioners 42 is covered over with one or more layers of material, the exterior layer of which is typically a fabric as shown (but not numbered). The use of a fabric such as polyethylene terephthalate provides a matrix into which surrounding tissue can grow to help anchor the valve in place.

[0057] Three flexible leaflets 52 mount to the valve 22 in a trifoil configuration with free edges 53 thereof arranged to meet or coapt in the middle of the valve and provide one-way occlusion. An outer edge of each leaflet 52 attaches to the valve 22 between two of the commissures 32 and around one of the cusps 30. An exemplary structural attachment of the leaflets 52 to the internal support frame 50 will be described below.

[0058] As mentioned, each cusp connector 40 extends between two of the cusps 30. A panel of fabric or other material 54 covers an area between the inflow or lower edge of each cusp connector 40 and the corresponding

commissures 32. Some of this panel of fabric 54 desirably contacts the lumen wall of the aortic valve AV annulus to help prevent leakage around the valve.

[0059] The exemplary cusp positioners 42 each have an inverted U-shape with an apex pointed toward the outflow end of the valve 22 and two legs extending generally toward the inflow end and connecting with the remainder of the valve. The term "U-shape" is intended to cover all configurations that have two legs and an apex therebetween. Other figurative descriptions such as V-shaped, bell-shaped, sinusoidal, arcuate, or the like are therefore encompassed by the term "U-shape". It is contemplated, however, that the cusp positioners 42 could assume other forms, such as a generally linear, cantilevered arm extending upward from the midpoint of each cusp 30. In whatever form, the cusp positioners 42 provide the valve 22 with three points of contact with the surrounding tissue that is midway between the three commissures 32 so as to help stabilize and anchor the valve in its implant position. Moreover, the cusp positioners 42 desirably perform the function of compressing the native leaflets L outward against the sinus cavities, at least in those procedures where the leaflets L are not excised.

[0060] The leaflets L in a diseased valve may be less than flexible, and indeed may be highly calcified. It is often considered preferable to avoid removing the leaflets L so as to avoid disturbing the calcification or other stenotic material that has built up around the leaflets. Therefore, the present invention desirably provides structure to compress the native leaflets L outward against the aortic wall sinus cavities and hold the leaflets in that position so as to avoid flapping and potentially interfering with blood flow through the prosthetic valve. The inverted U-shape of the cusp positioners 42 is believed to provide effective structure to both anchor the valve in the aortic valve AV annulus and also control, or corral, if you will, the obsolete native leaflets L. At the same time, the cusp positioners 42 are relatively minimal in total area so as to avoid unduly interfering with back flow of blood on the outflow side of each of the

leaflets 52, or to the coronary ostia CO. Therefore, the cusp positioners 42 are desirably defined by relatively thin members, as shown, as opposed to walls or panels, or the like. Multiple cusp positioners 42 per valve cusp 30 are conceivable, though the total solid volume taken up by the cusp positioners should be kept to a minimum so as to minimize the risk of occluding the coronary ostia CO.

[0061] The axial height of the cusp positioners 42 relative to the commissures 32 is seen best in Fig. 2A (and in Fig. 6B). Preferably, the commissures 32 are slightly taller than the cusp positioners 42, although such an arrangement is not considered mandatory. The main consideration in the size of the cusp positioners 42 is to avoid occluding the coronary ostia CO. Therefore, as seen in Fig. 2A, the cusp positioners 42 contact the surrounding aortic valve AV lumen wall just below the coronary ostia CO. Of course, the anatomy of each patient differs slightly from the next, and the precise position of the coronary ostia CO cannot be predicted with absolute certainty. Furthermore, the final location of the cusp positioners 42 is dependent on the skill of the cardiac surgeon or cardiologist. In the ideal situation, however, the cusp positioners 42 are positioned just below and aligned circumferentially with the coronary ostia CO as seen in Figs. 2A and 2B.

[0062] Figs. 2B and 3B-3C illustrate the relative outward radial position of the cusp positioners 42 with respect to the commissures 32 therebetween, and with respect to the cusp connectors 40. As seen in the isolated view of the heart valve support frame 50 in Fig. 5, the cusp positioners 42 are angled or flared outward from the remainder of the support frame. This outward flaring helps ensure good contact between the apex of the cusp positioners 42 and the surrounding walls of the aortic valve AV sinus cavities. In this regard, the outer configuration of the heart valve 22 is designed to maximize contact with the aortic valve AV lumen wall both in the annulus and for a short distance into each sinus cavity. This extensive surface contact between the prosthetic valve

22 and the surrounding tissue may obviate the need for sutures, staples, sharp barbs or other such anchoring structure, although such structure could be used in conjunction with the valve. The valve 22 is merely expelled from the end of the delivery tube 20 (Fig. 1), expanded with or without assistance of a balloon, and held in place by frictional contact between the inflow periphery against the annulus, and between the cusp positioners 42 and the sinus cavities (or intervening native leaflets).

[0063] Each cusp positioner 42 further includes at least one anti-migration member 56 rigidly fixed thereto and designed to help anchor the support frame 50 to the surrounding tissue. In the illustrated embodiment, the anti-migration members 56 each preferably includes an elongated section 58 terminating in an enlarged and rounded head 60, the configuration thus somewhat resembling a spoon. The anti-migration member 56 desirably projects out of the plane defined by the associated cusp positioner 42, and may extend generally axially in the inflow direction from the apex thereof, as seen in Fig. 3A. When the valve 22 is implanted, the anti-migration members 56 are designed to contact and become somewhat entrapped in the native leaflets. Therefore, the anti-migration members 56 act as a rounded barb of sorts to maintain the valve 22 in its implant position. The members 56 also may help prevent flapping of the native leaflets in the swirling blood flow. Numerous other configurations are contemplated, the general idea being that the anti-migration member 56 enhances the ability of the associated cusp positioner 42 to anchor to the surrounding tissue. In this regard, the term "anti-migration member" is meant to include any structure that enhances such anchoring, including both blunt and sharp structures (i.e., barbs).

[0064] Various procedures and apparatuses for converting a two-dimensional blank such as shown in Fig. 4 to the three-dimensional form of Fig. 5 are described in more detail in co-pending U.S. Patent Application Serial No. 10/251,651, filed September 20, 2002, and entitled continuous heart valve

support frame and method of manufacture. In short, the process involves bending the two-dimensional blank 70 around a cylindrical or conical mandrel and altering the material so as to retain its three-dimensional shape. For example, various nickel-titanium alloys (Nitinol) may be easily bent around a mandrel and then set into that shape using heat treatments.

[0065] In an exemplary embodiment of the present invention, the internal support frame 50 of the valve 22 is made of a material that is highly flexible so as to permit maximum relative movement between the valve cusps and commissures, and in some cases to permit constriction into a small profile diameter for minimally invasive delivery to an implantation site. At the same time the support frame must possess a minimum amount of stiffness to provide the desired support to the leaflets. Therefore, there is a balance obtained between the requisite flexibility and stiffness.

[0066] The material for the internal support frame is desirably "elastic," which means that it has the capacity to rebound from imposed strain. Various NITINOL alloys are especially suitable for making the internal support frame of the present invention as in certain circumstances they are considered to be "superelastic." Other materials that may be used include ELGILOY, titanium, stainless-steel, even polymers, and similar expedients. These latter materials do not display superelasticity but are still elastic. Other materials may fit within this definition but they must be suitable for long-term implantation in the body.

[0067] The term "superelastic" (sometimes "pseudoelastic") refers to that property of some materials to undergo extreme strains (up to 8%) without reaching their failure stress limit. Some so-called shape memory alloys (SMAs) are known to display a superelastic phenomena or rubber-like behavior in which a strain attained beyond the elastic limit of the SMA material during loading is recovered during unloading. This superelastic phenomenon occurs when load is applied to an austenitic SMA article which first deforms elastically up to the yield point of the SMA material (sometimes referred to as the critical stress).

Upon the further imposition of load, the SMA material begins to transform into stress-induced martensite or "SIM." This transformation takes place at essentially constant stress, up to the point where the SMA material is completely transformed into martensite. When the stress is removed, the SMA material will revert back into austenite and the article will return to its original, pre-programmed programmed or memorized shape.

[0068] The support frame 50 is desirably constructed of a material that exhibits hysteresis in the elastic and/or superelastic region. "Hysteresis" indicates that when the material is strained beyond the "memory condition" (defined as unconstrained geometry) it produces a stress-strain curve that is different and higher than the stress-strain curve produced as the material attempts to return to its memory condition. An example of a material that exhibits such a hysteresis is NITINOL. The presence of this hysteresis implies that it requires a greater force to displace the material form its memory condition than the material exerts as it recovers to its memory condition.

[0069] When using NITINOL the shape set is done at a particular temperature for a period of time designed to ensure certain properties in the material. Namely, the martensitic transition temperature is desirably less than room temperature and the austenitic transition temperature is desirably less than body temperature. For instance, the temperature below which the material is in martensitic form is around 0-5° C, while the temperature above which the material is in austenitic form is around 20-25° C. When the material is shape set in this way, the heart valve 22 can be cooled, such as in an ice bath, just prior to implant to change the crystalline structure of the support frame 50 to martensite and create high flexibility so as to enable compaction thereof into a small diameter delivery profile. After implant and expansion, the temperature rises from body heat above the austenitic transition temperature and thus the support frame 50 possesses the desired degree of stiffness to properly support the leaflets.

[0070] The support frame 50 (and blank 70) includes a leaflet frame 72 defined by three cusp regions 74 intermediate three commissure regions 76. In Fig. 4 the leaflet frame 72 in the blank 70 exhibits a three-leaf clover shape, while in Fig. 5 the leaflet frame 72 has a continuous, undulating shape as described above. A second three-leaf clover shape can be seen in Fig. 4 formed by the three cusp connectors 40 and three cusp positioners 42. When bent into the three-dimensional configuration of Fig. 5, two continuous, undulating shapes can be seen oriented 60° with respect to one another about the central flow axis. Each cusp connector 40 includes an apex 80 and a pair of legs 82 that rigidly attach to the leaflet frame 72 at junction points 84. Likewise, each cusp positioner 42 includes an apex 90 and a pair of legs 92 that rigidly attach to the leaflet frame 72 at junction points 94. In the preferred and illustrated embodiment, the junction points 84 and 94 are coincident.

[0071] Figs. 5A and 5B show alternative cusp positioner configurations for the three-dimensional heart valve support frame 50 of Fig. 5. As mentioned above, the anti-migration members facilitate anchoring of the support frame 50 to the surrounding anatomy, and prevent axial and rotational movement of the valve 22. The anti-migration members 56 shown in Fig. 5 project generally axially in the inflow direction from the apex 90 of each cusp positioner 42. In Fig. 5A, a second anti-migration member 57 projects generally axially in the outflow direction from the apex 90 of each cusp positioner 42. In Fig. 5B, there are multiple anti-migration members 56 extending generally axially in the inflow direction. Various combinations, placements and orientations of these examples are contemplated, and the examples should not be considered limiting.

[0072] Fig. 6A shows the valve 22 almost completely assembled, but without the aforementioned cloth covers 54 that are seen in the fully assembled valve of Fig. 6B. The covers 54 help prevent leakage of blood around the implanted valve 22, and specifically in the areas between the each pair of cusps 30.

[0073] Fig. 7 illustrates an exemplary leaflet 52 in plan view. The free edge 50 is shown as linear, but may also be arcuate, angled, trapezoidal, or other configuration. Each leaflet includes a pair of opposed generally rectangular tabs 100 at either end of the free edge 53. An arcuate cusp edge 102 extends between the tabs 100 and opposite the free edge 53. The tabs 100 and arcuate cusp edge 102 are secured to the valve 22, and specifically along the contours of the leaflet frame 72 seen in Fig. 5.

[0074] Fig. 8 is an enlarged cutaway view of one of the commissures 32 of the valve 22 taken along line 8-8 of Fig. 3B and showing the internal construction thereof. The commissure region 76 of the leaflet frame 72 tapers down in the outflow direction to a closed tip 104. Attachment flanges 106 are formed adjacent the tip 104 and desirably include a plurality of assembly holes 108 sized to permit passage of sutures therethrough. The adjacent leaflets 52 come together in the commissure regions 76 and the tabs 100 thereof are folded away from each other on the exterior of the flanges 106.

[0075] As seen in Fig. 9, the cusp edge 102 of each leaflet 52 attaches with sutures 110 to a cloth flange 112 of a tubular fabric cover 114 around the leaflet frame 72. This configuration causes tensile forces imparted by the leaflets 52 to be transferred as much as possible to the frame 72 rather than being primarily borne by the attachment sutures 110.

[0076] Fig. 10 shows the attachment structure at the commissure tip 104, and specifically illustrates sutures 120 passing through the fabric cover 114, through the assembly holes 108, and through the folded leaflet tabs 100. A second suture 122 passes through the cloth flange 112, the leaflet tab 100, and cloth covers 54 (also shown in Fig. 6B). Because each of the leaflets 52 includes the tab 100 that extends to the outside of the leaflet frame 72, high forces that are seen with closing of the valve are less likely to pull the sutures 120 through the tabs. That is, the construction shown in Fig. 10 causes tensile

forces imparted by the leaflets 52 to be transferred as much as possible from the sutures 120, 122 to the frame 72, thus helping to prevent tearing of the flexible leaflets and rendering the valve 22 more durable.

[0077] Figs. 11 and 12 schematically illustrate a technique for loading a prosthetic heart valve of the present invention into a delivery tube. For the sake of clarity, only the support frame 50 is shown being loaded into the delivery tube 20. A plurality of sutures or other such flexible members or filaments 130 are shown looped through each of the commissure regions 76 of the support frame 50. These filaments 130 extend into the distal end of the delivery tube 20 and through its lumen to a proximal end (not shown) where they are connected to a tensioning device. In actual use, the filaments 130 would be threaded through the commissures 32 of the valve 22, avoiding the flexible leaflets. A loading adapter 132 couples to the distal end of the delivery tube 20. The adapter 132 includes an inner funnel-shaped opening 134. Tension on the filaments 130 pulls the commissures 32 of the valve into the funnel-shaped opening 134 which gradually compresses the valve into a diameter smaller than the lumen of the delivery tube 20. Once the valve 22 is positioned fully within the delivery tube 20, as seen in Fig. 12, the filaments 130 and adapter 132 are removed.

[0078] Figs. 13-17 illustrate a minimally invasive holder for use with the prosthetic heart valves of the present invention. Figs. 13A and 13B show the holder 150 attach to the heart valve 22 as described above. The holder 150 includes a multi-armed flexible portion 152 and a rigid portion 154 (seen in Figs. 17A-17B). The flexible portion 152 includes a plurality, at least three, but preferably six flexible members or arms 156 extending outward from a central circular disk 158. Each of the arms 156 terminates in a rounded end having an attachment aperture 160. The arms 156 are distributed evenly about the

circumference of the circular disk 158, and are arrayed to attach to each of the commissures 32 and cusp positioners 42 of the valve 22. Releasable sutures 162 or other such attachment structure are used for this purpose.

[0079] Fig. 14 shows the assembled holder 150 and valve 22 emerging from the distal end of a delivery tube 20. Prior to this stage, the flexible members or arms 156 are oriented generally axially within the tube 20 with the valve 22 also collapsed and having its outflow prongs coupled to the distal ends of the arms 156. The arms 156 of the holder 150 are sufficiently flexible to be compressed into the small profile required for delivery through the delivery tube 20. In this regard, the flexible portion 152 is desirably made of Nitinol. A handle 170 which may be flexible or rigid attaches to the holder 150 for manipulation thereof. Displacing the handle 170 in a distal direction with respect to the tube 20 therefore expels the valve/holder combination and the resiliency of the valve 22 and holder arms 156 causes them to spring outward. It should be understood that other designs of the holder 150 may be utilized, such as replacing the spring-like arms 156 with rigid members that are hinged and spring-biased.

[0080] Figs. 15-17 illustrate specifics of the exemplary flexible portion 152 and rigid portion 154. In a relaxed configuration, the flexible portion 152 is planar, and may be cut from a sheet of Nitinol. The rigid portion 154 includes a proximal face 180 that is sized approximately the same as the circular disk 158, and small enough to fit within the delivery tube 20. A central threaded bore 182 opens to the proximal face 180 for receiving the handle 170. Fig. 15 illustrates a number of sutures 162 threaded through the holder 150 and used to couple the holder to the six outflow prongs of the prosthetic heart valve 22. Desirably, these sutures 162 are anchored with respect to the holder and each one passes over a cutting guide in the holder such that the suture may be severed along its midpoint resulting in two free ends that can be pulled free of the valve.

[0081] The holder 150 is sufficiently flexible to be compressed into a

small profile and passed through the delivery tube 20. At the same time, the flexible portion 152 and multiple flexible arms 156 have a sufficient degree of torsional strength to permit the operator to rotate the valve 22 during the implant procedure. Furthermore, the arms 156 are shaped to contact the distal mouth of the delivery tube 20 when the assembly is pulled toward the tube which, due to their radial stiffness, causes the arms to bend back toward their axial orientation within the tube. Since the distal ends of the arms are coupled to at least three of the outflow prongs of the prosthetic heart valve 22, the valve constricts accordingly. Constriction of the valve 22 after having been fully expelled from the end of the delivery tube and expanded permits repositioning of the valve 22. That is, the cusp positioners 42 are designed to contact the sinuses cavities or aortic wall after the valve 22 expands, and the retraction/constriction option afforded by the holder 150 may be necessary to disengage the cusp positioners from the surrounding tissue to reposition or re-orient the valve. Furthermore, the valve 22 can be completely collapsed and retracted back into the delivery tube to permit removal in case the surgeon or cardiologist deems the valve unsuitable for whatever reason.

Method of Use

[0082] Prior to implant, the cardiac surgeon or cardiologist measures the aortic valve AV annulus using appropriate sizers, minimally invasive or not as the case may be, a number of which are available and which will not be further described herein. The correctly sized valve is then selected and compressed into the delivery catheter or tube 20, such as with the use of the loading adapter 132 having the inner funnel-shaped opening 134 as seen in Fig. 11. To facilitate this loading step, the inner support frame 50 of the valve 20 must be able to withstand high stresses without failure. One method is to form the support frame 50 from a material that has superelastic properties, for instance a Nitinol that has a martensitic transition temperature of less than about 5° C can be immersed in an ice bath to change its crystalline structure to

martensite, which is a superelastic phase. Once loaded into the delivery tube 20, the support frame 50 will not revert back to its original shape upon a temperature rise and thus does not exert undue outward force on the tube. The heart valve 22 may be loaded around an inflation balloon, but for the sake of a small profile the balloon is used after expulsion of the valve from the tube at the implantation site.

[0083] With reference again to Fig. 1, the delivery tube 20 is seen in position just prior to complete expulsion and expansion of the prosthetic heart valve 22 from a distal end thereof for implant at the aortic valve AV annulus. The distal end of the delivery tube 20 may optionally be stabilized by a balloon 24 (shown in phantom) inflated against the lumen of the ascending aorta AA, or through other means. The delivery tube 20 is preferably inserted in the vasculature of the patient using a larger diameter introducer 26 through a peripheral vessel such as the femoral artery or femoral vein. Alternatively, the peripheral vessel may be the internal jugular vein, the subclavian artery, the axillary artery, the abdominal aorta, the descending aorta, or any other suitable blood vessel. The introducer 26 may be inserted by surgical cut down or percutaneously using the Seldinger technique.

[0084] The prosthetic heart valve 22 is expelled from the delivery tube 20 by relative movement therebetween - i.e., by pushing the valve from the tube or by retracting the tube from around the valve. The valve 22 desirably self-expands into contact with the surrounding lumen wall, but may also be assisted with an inflation balloon or other such physical expander.

[0085] With reference to Figs. 2A and 2B, the cusps positioners 42 help guide the prosthetic heart valve 22 into position in the aortic valve AV annulus. As mentioned above, the cusp positioners 42 desirably flare outward from the rest of the valve structure and are thus configured to contact the sinuses of the aortic valve AV while the cusps 30 are sized to fit within the annulus. In accordance with one method of implantation, the surgeon or cardiologist expels the heart valve 22 below (i.e., toward the left ventricle) its optimum implant position, and then axially displaces the valve upward into the desired position.

Stated another way, the heart valve 22 is expanded in a location that is inferior to a final implant position such that the cusp positioners 42 contact the surrounding aortic annulus, and the valve is then repositioned by displacing the valve in a superior direction to a final implant position. As the valve 22 ascends, the cusp positioners 42 spring outward into the three valve sinuses and help rotationally orient the valve. That is, the sinuses channel the cusp positioners 42 and correct any rotational misalignment. Finally, the valve 22 is implanted with the cusp positioners 42 in the sinus cavities (preferably below the coronary ostia CO) and the cusps 30 and cusp connectors 40 forming a scalloped yet continuous contact wall against the aortic valve AV annulus or root.

[0086] As mentioned, a physical expander (e.g., balloon) may be used to radially outwardly expand the valve 22 (including the internal support frame 50) beyond its self-expanded diameter so that it is firmly anchored in place. A prosthetic valve possessing hysteresis that is held in a reduced (first or constrained) diameter will exert an outward radial force that is less than the force at which it will resist an inward radial force. Therefore, if deployed in-situ, the device is not expected to exert enough force on the vessel wall to expand to the desired diameter. However, if the expansion is assisted by means of a balloon or other physical expander, the hysteresis of the material will allow it to better maintain its diameter once that diameter is achieved. This is unlike a self-expanding device that relies solely on the outward radial force of the device to achieve its desired diameter. It is also unlike balloon expanded devices that rely on a balloon to plastically deform the device into the desired diameter. Although it is conceivable that a balloon or other physical expander could be used in a self-expanding device made of a material that does not display a hysteresis, the benefits would not be as great.

[0087] It will be appreciated that the invention has been described hereabove with reference to certain examples or preferred embodiments as shown in the drawings. Various additions, deletions, changes and alterations may be made to the above-described embodiments and examples, and it is intended that all such additions, deletions, changes and alterations be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve support frame, comprising:

a continuous, undulating valve leaflet frame that mimics the natural fibrous structure of an aortic valve, the leaflet frame having three cusp regions alternating with and intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the support frame and circumferentially about a flow axis defined within the support frame, the three commissure regions being positioned at an outflow end of the support frame and circumferentially about the flow axis; and

three cusp positioners rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the support frame and intermediate two of the commissure regions of the leaflet frame.

2. The heart valve support frame of claim 1, wherein the leaflet frame and the cusp positioners are formed integrally as a single piece.

3. The heart valve support frame of claim 2, wherein the support frame is formed by a process comprising:

providing a two-dimensional blank of the support frame; and

forming the two-dimensional blank into the three-dimensional heart valve support frame.

4. The heart valve support frame of claim 1, wherein the leaflet frame and the cusp positioners are made of Nitinol.

5. The heart valve support frame of claim 1, wherein the Nitinol has a martensitic transition temperature of less than about 5° C and an austenitic transition temperature of more than about 20° C.

6. The heart valve support frame of claim 1, wherein each cusp positioner has a U-shape with an apex of the U-shape pointing toward the outflow end of the support frame and two legs of the U-shape pointing toward the inflow end.

7. The heart valve support frame of claim 6, wherein each of the two legs of each U-shaped cusp positioner is rigidly fixed to the continuous leaflet frame at a location approximately midway between a cusp region and a commissure region thereof.

8. The heart valve support frame of claim 6, further including an anti-migration member rigidly fixed to each cusp positioner and projecting therefrom.

9. The heart valve support frame of claim 8, wherein each anti-migration member comprises an elongated section terminating in an enlarged and rounded head.

10. The heart valve support frame of claim 1, wherein the support frame further includes three cusp connectors rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp connector being located at the inflow end of the support frame and intermediate two of the cusp regions of the leaflet frame.

11. The heart valve support frame of claim 10, wherein each cusp connector has a U-shape with an apex of the U-shape pointing toward the inflow end of the support frame and two legs of the U-shape pointing toward the outflow end.

12. The heart valve support frame of claim 10, wherein the leaflet frame, cusp positioners, and cusp connectors are formed integrally as a single piece, and wherein the three cusp positioners and three cusp connectors define a continuous, undulating shape that generally mimics the shape of the leaflet frame but is rotated 60° about the flow axis therefrom.

13. The heart valve support frame of claim 1, wherein the cusp positioners flare outwardly from the rest of the support frame.

14. A collapsible prosthetic heart valve, comprising:

a collapsible leaflet frame having three cusp regions intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the support frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

three separate, flexible leaflets attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions; and

three cusp positioners rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the leaflet frame and intermediate two of the commissure regions of the leaflet frame.

15. The heart valve of claim 14, wherein each cusp positioner has a U-shape with an apex of the U-shape pointing toward the outflow end of the leaflet frame and two legs of the U-shape pointing toward the inflow end.

16. The heart valve of claim 15, wherein each of the two legs of each U-shaped cusp positioner is rigidly fixed to the continuous leaflet frame at a location approximately midway between a cusp region and a commissure region thereof.

17. The heart valve of claim 15, further including an anti-migration member rigidly fixed to each cusp positioner and projecting therefrom.

18. The heart valve of claim 14, wherein the heart valve further includes three cusp connectors rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp connector being located at the inflow end of the leaflet frame and intermediate two of the cusp regions of the leaflet frame.

19. The heart valve of claim 18, wherein each cusp connector has a U-shape with an apex of the U-shape pointing toward the inflow end of the leaflet frame and two legs of the U-shape pointing toward the outflow end.

20. The heart valve of claim 19, wherein the leaflet frame, cusp positioners, and cusp connectors are formed integrally as a single piece, and

wherein the three cusp positioners and three cusp connectors define a continuous, undulating shape that generally mimics the shape of the leaflet frame but is rotated 60° about the flow axis therefrom.

21. The heart valve of claim 18, wherein an inflow periphery of the heart valve is defined along the alternating and rigidly fixed cusp regions and cusp connectors.

22. The heart valve of claim 21, wherein the inflow periphery has an external fabric covering, and wherein the heart valve further includes a fabric panel defining an exterior surface of the heart valve between each pair of cusp positioner and cusp connector.

23. The heart valve of claim 14, wherein the leaflet frame has a fabric covering along substantially its entire length, the fabric covering defining a flange, wherein the arcuate cusp edges of the flexible leaflets attach to the fabric covering flange.

24. The heart valve of claim 23, wherein the fabric covering flange projects generally outward from the leaflet frame and the cusp edges of the flexible leaflets extend radially outward past and underneath the leaflet frame and are sewn to the fabric covering flange.

25. The heart valve of claim 14, wherein each flexible leaflet has a pair of tabs extending on either side of its free edge, wherein two tabs of adjacent flexible leaflets meet and pass together to the outside of the adjacent commissure region of the leaflet frame and are attached thereto using sutures through the tabs.

26. A collapsible prosthetic heart valve, comprising:

a continuous, collapsible leaflet frame having three U-shaped cusp regions intermediate three U-shaped commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the leaflet frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

a cloth covering extending around the leaflet frame; and

three separate, flexible leaflets attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions, the commissure edges of each leaflet further including a tab, wherein the tabs of two adjacent leaflets extend through the U-shape commissure region, diverge on the outside of commissure region, and are attached to the leaflet frame on the outside of the commissure region.

27. The prosthetic heart valve of claim 26, further comprising three cusp positioners rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the support frame and intermediate two of the commissure regions of the leaflet frame, each cusp positioner having a U-shape with an apex of the U-shape pointing toward the outflow end of the leaflet frame and two legs of the U-shape pointing toward the inflow end.

28. The heart valve of claim 26, wherein the heart valve further includes three cusp connectors rigidly fixed with respect to the leaflet frame and

disposed circumferentially about the flow axis, each cusp connector being located at the inflow end of the leaflet frame and intermediate two of the cusp regions of the leaflet frame.

29. The heart valve of claim 28, wherein an inflow periphery of the heart valve is defined along the alternating and rigidly fixed cusp regions and cusp connectors.

30. The heart valve of claim 26, wherein the leaflet frame has a fabric covering along substantially its entire length, the fabric covering defining a flange, wherein the arcuate cusp edges of the flexible leaflets attach to the fabric covering flange.

31. The heart valve of claim 30, wherein the fabric covering flange projects generally outward from the leaflet frame and the cusp edges of the flexible leaflets extend radially outward past and underneath the leaflet frame and are sewn to the fabric covering flange.

32. A method of implanting a prosthetic aortic heart valve, comprising:

providing a collapsible prosthetic heart valve having a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve, the valve further including three cusp positioners on the outflow end and intermediate the three commissure regions;

collapsing the prosthetic heart valve within a delivery tube;

advancing the prosthetic heart valve within the delivery tube to an aortic annulus;

expelling the prosthetic heart valve from the delivery tube by relative movement therebetween;

expanding the prosthetic heart valve; and

positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

33. The method of claim 32, further including:

connecting a holder having flexible members to the commissure regions of the prosthetic heart valve and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

34. The method of claim 33, further including:

connecting flexible members of the holder to the cusp positioners and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

35. The method of claim 33, further including utilizing the flexible members to rotate the prosthetic heart valve during the step of positioning.

36. The method of claim 33, further including utilizing the flexible members to re-collapse the prosthetic heart valve after the step of expanding.

37. The method of claim 32, wherein the prosthetic heart valve is expanded in a location that is inferior to a final implant position such that the cusp positioners contact the surrounding aortic annulus, and the step of positioning comprises displacing the valve in a superior direction to a final implant position.

38. The method of claim 37, wherein the cusp positioners are flared outward to define a circle about a flow axis of the valve greater than a circle about the flow axis defined by the three commissure regions, and wherein the step of displacing the valve in a superior direction causes the outwardly flared cusp positioners to be channeled into perspective coronary sinuses.

39. The method of claim 32, wherein the collapsible leaflet frame is formed of a shape memory alloy having an austenitic transition temperature less than body temperature, and wherein the step of collapsing is done with the material of the leaflet frame at a temperature at or below its martensitic transition temperature.

40. The method of claim 39, wherein the step of collapsing is done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to less than or equal to its martensitic transition temperature.

41. The method of claim 32, wherein the collapsible leaflet frame is formed of a shape memory alloy having a memory condition in its expanded state, and wherein the step of expanding the prosthetic heart valve comprises both permitting self-expansion of the valve to an intermediate diameter and then using a physical expander to increase the diameter of the valve to the memory condition of the leaflet frame.

42. A method of implanting a collapsible prosthetic heart valve, comprising:

providing a self-expanding valve comprised of a material displaying hysteresis in the elastic or superelastic region;

permitting the valve to self-expand to a first diameter; and

assisting the valve with a physical expander to further expand to a second diameter.

43. The method of claim 42, wherein the prosthetic heart valve includes a collapsible leaflet frame formed of a shape memory alloy having an austenitic transition temperature less than body temperature, and further including a step of collapsing the valve with the material of the leaflet frame at a temperature at or below its martensitic transition temperature.

44. The method of claim 43, wherein the step of collapsing is done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to less than or equal to its martensitic transition temperature.

45. The method of claim 42, wherein the physical expander is a balloon.

46. The method of claim 42, wherein the prosthetic heart valve has a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve, the valve further including three cusp positioners on the outflow end and intermediate the three commissure regions, the method further including:

collapsing the prosthetic heart valve within a delivery tube;

advancing the prosthetic heart valve within the delivery tube to an aortic annulus;

expelling the prosthetic heart valve from the delivery tube by relative movement therebetween;

expanding the prosthetic heart valve by the steps of permitting self-expansion and assisting further expansion; and

positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

47. The method of claim 46, further including:

connecting a holder having flexible members to the commissure regions of the prosthetic heart valve and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

48. The method of claim 47, further including:

connecting flexible members of the holder to the cusp positioners and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

49. The method of claim 47, further including utilizing the flexible members to rotate the prosthetic heart valve during the step of positioning.

50. The method of claim 47, further including utilizing the flexible members to re-collapse the prosthetic heart valve after the step of expanding.

Fig. 1

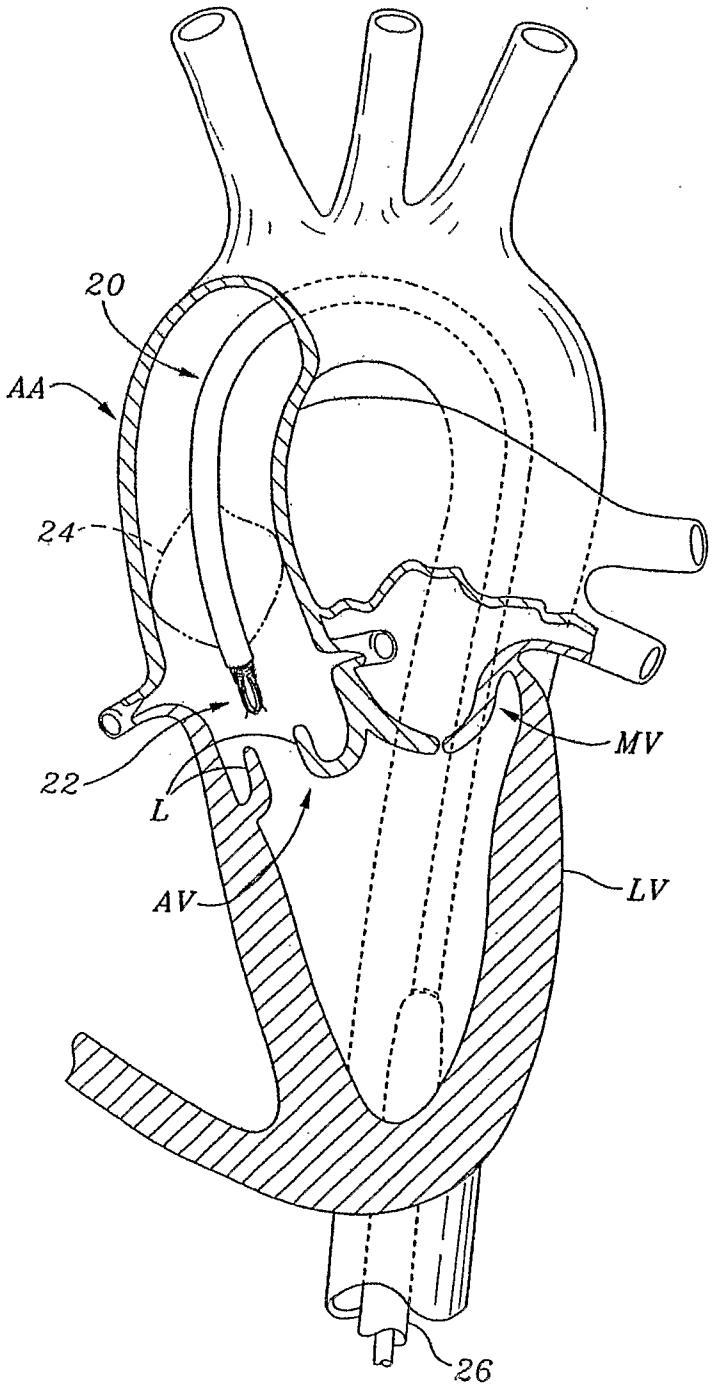


Fig. 2B

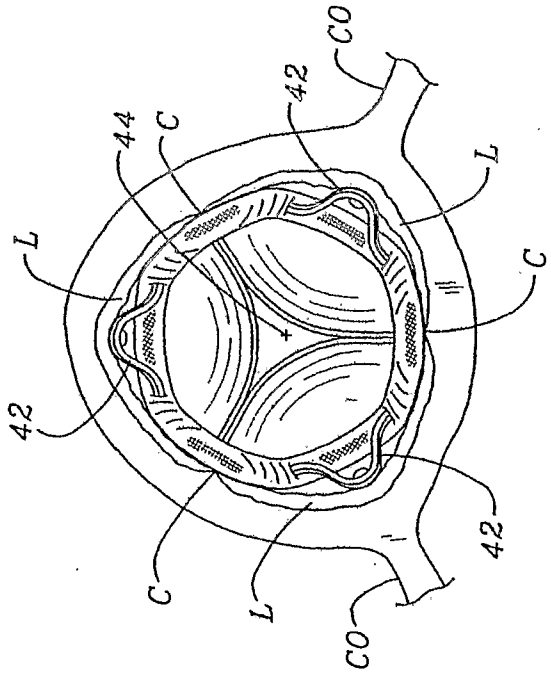


Fig. 2A

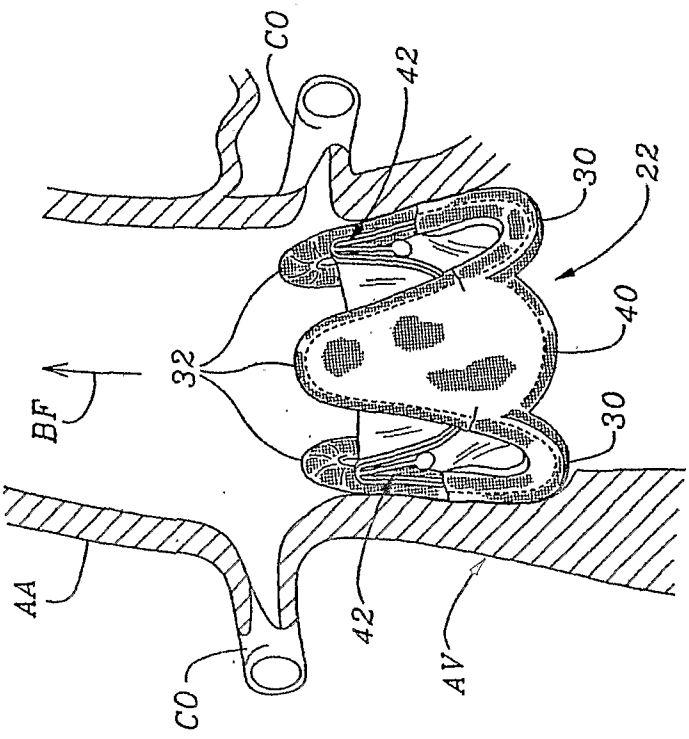


Fig. 3A

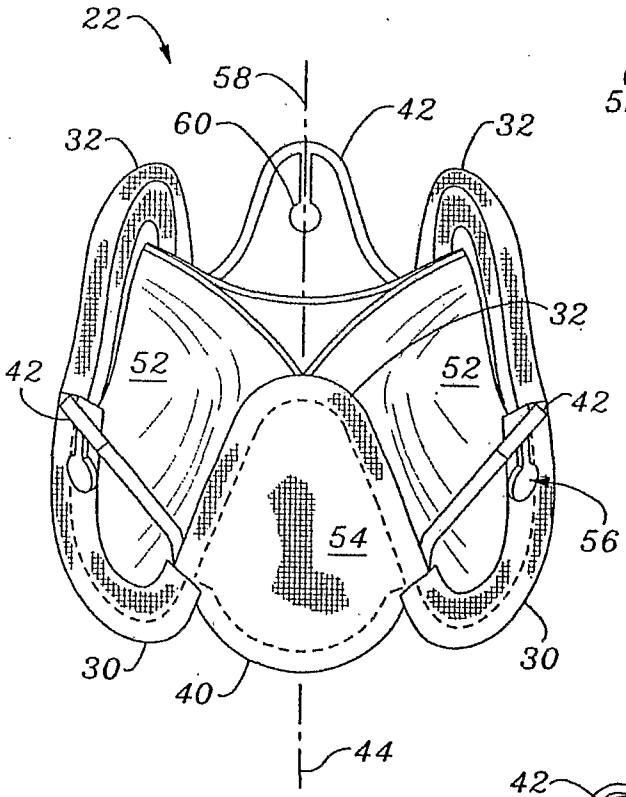


Fig. 3B

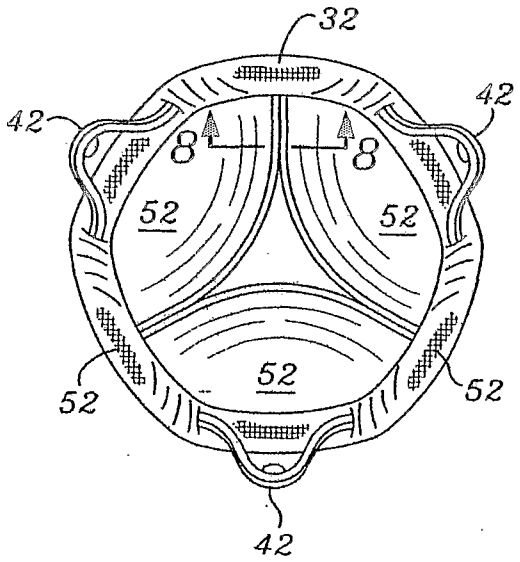


Fig. 3C

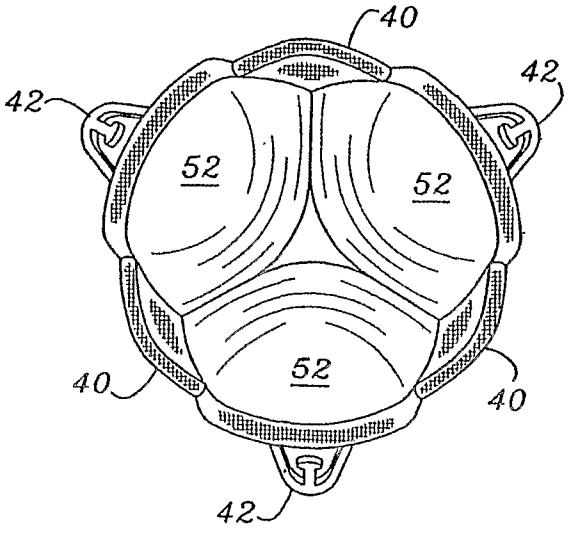


Fig. 4

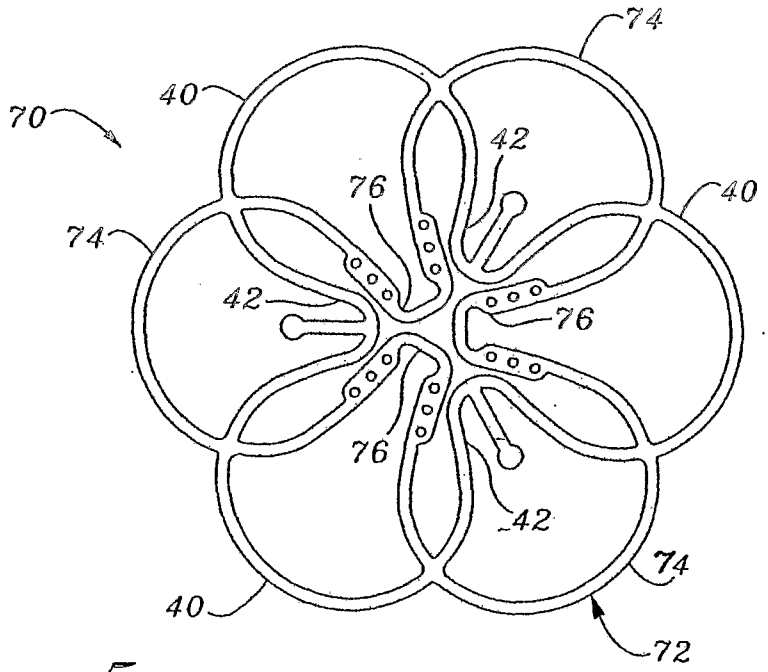
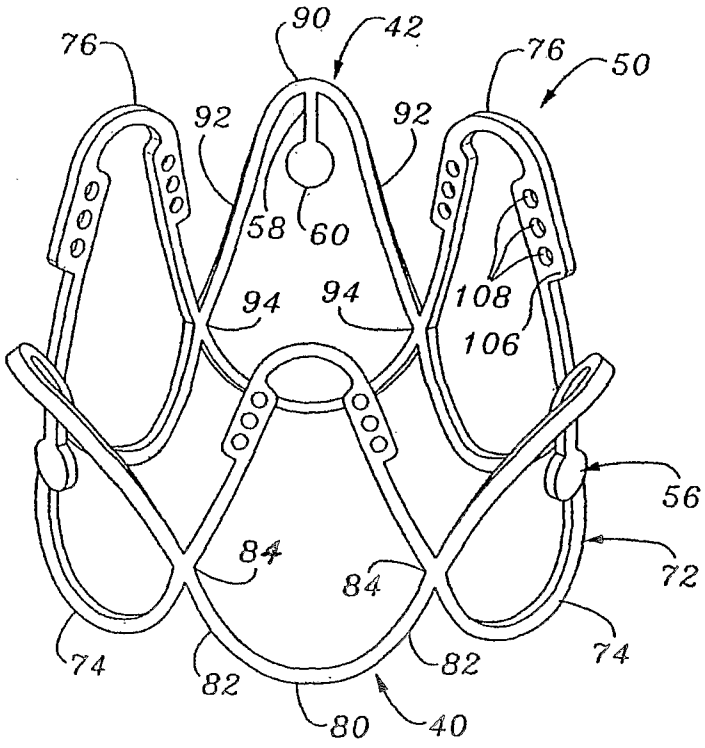


Fig. 5



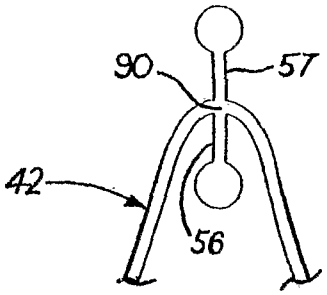


Fig. 5A

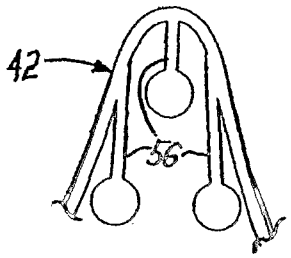


Fig. 5B

Fig. 6A

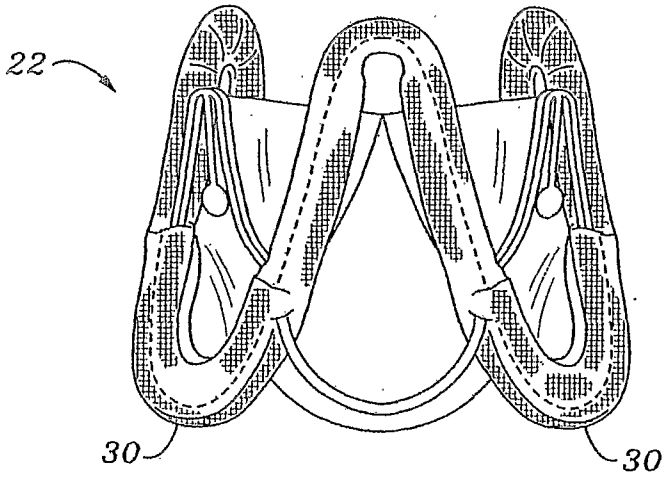


Fig. 6B

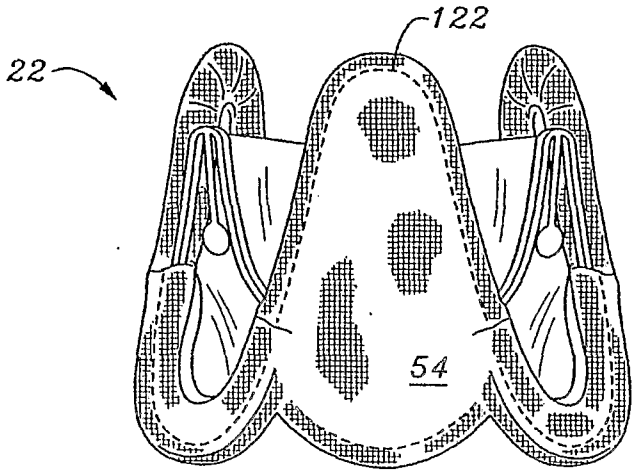


Fig. 7

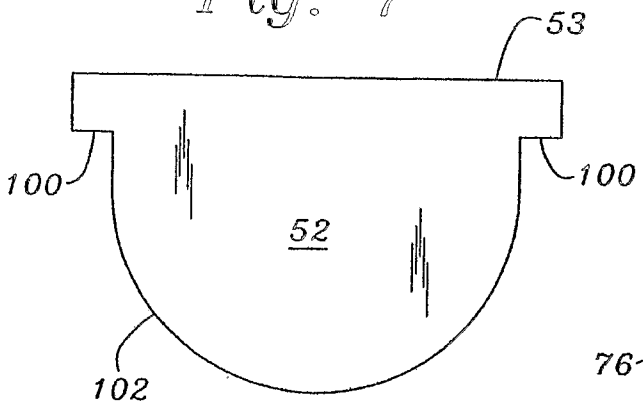


Fig. 8

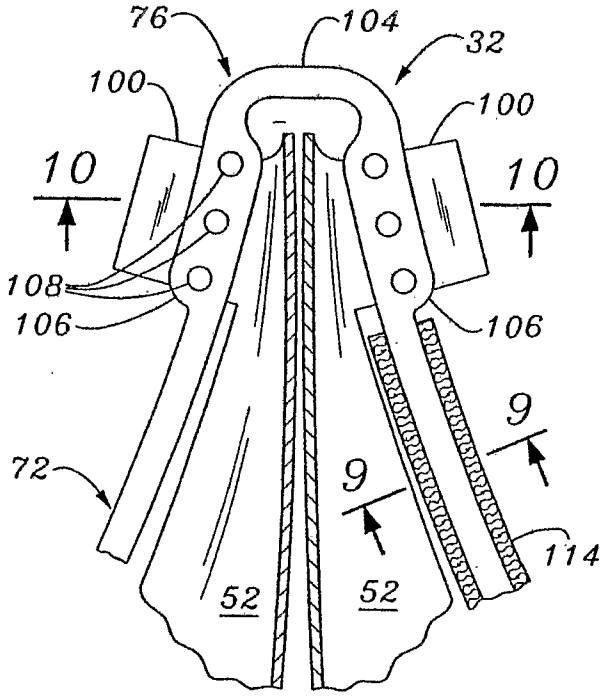


Fig. 9

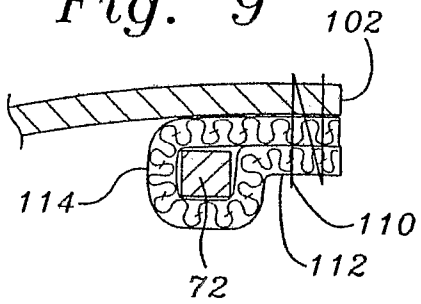


Fig. 10

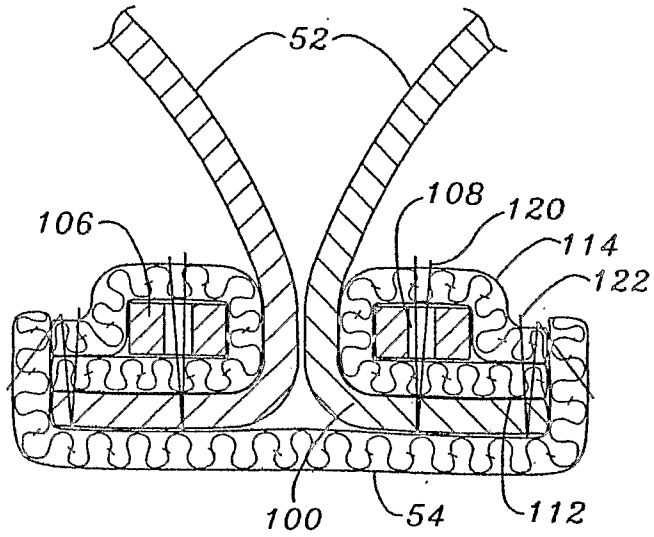


Fig. 11

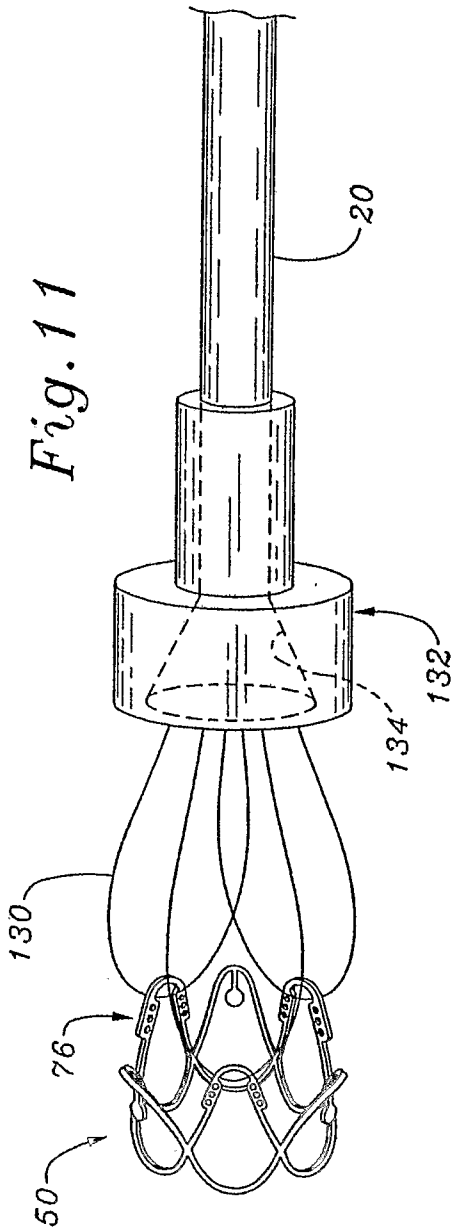


Fig. 12

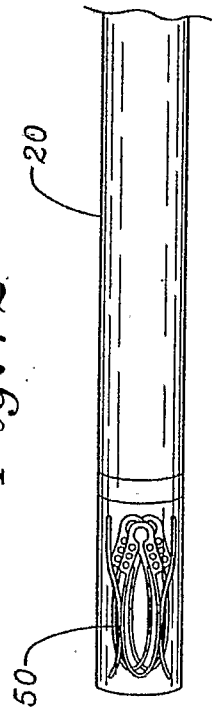


Fig. 13B

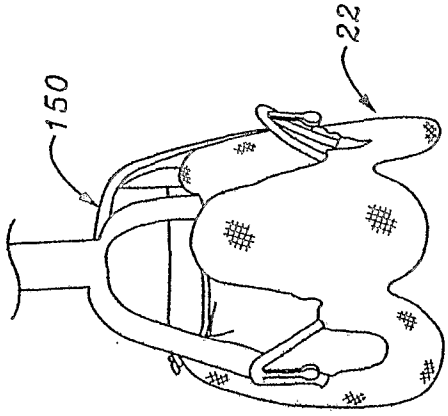


Fig. 14

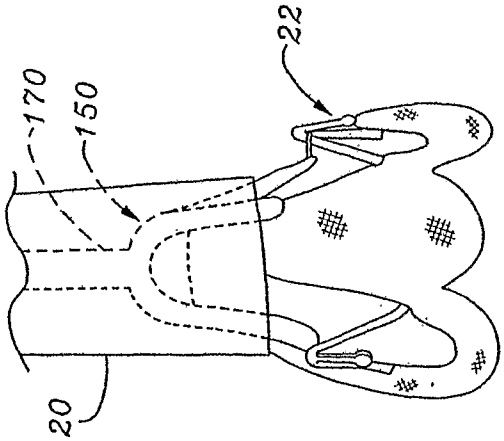


Fig. 13A

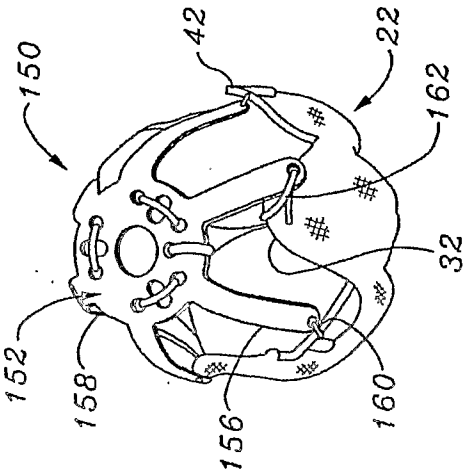


Fig. 16

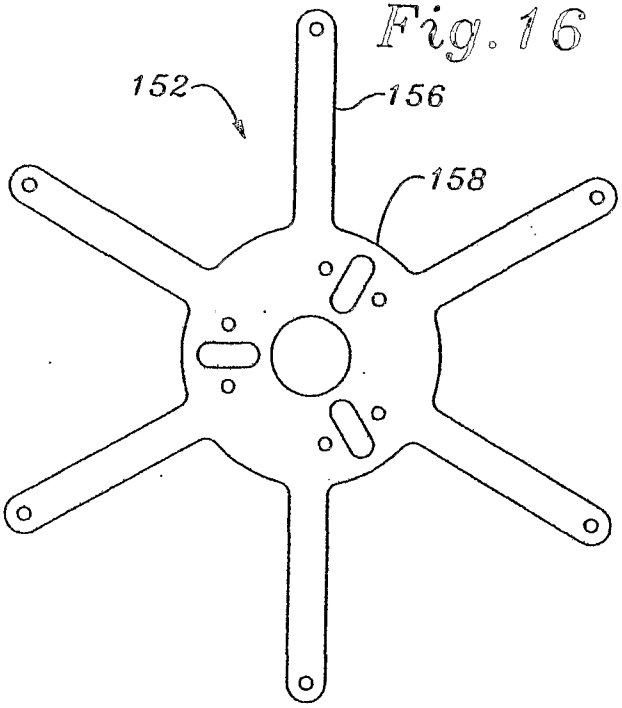


Fig. 17A

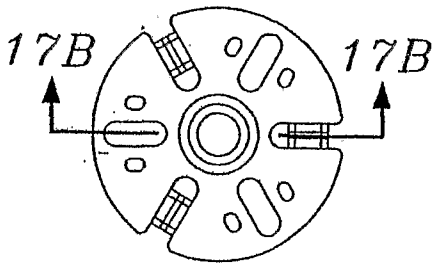


Fig. 17B

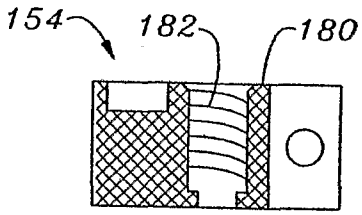
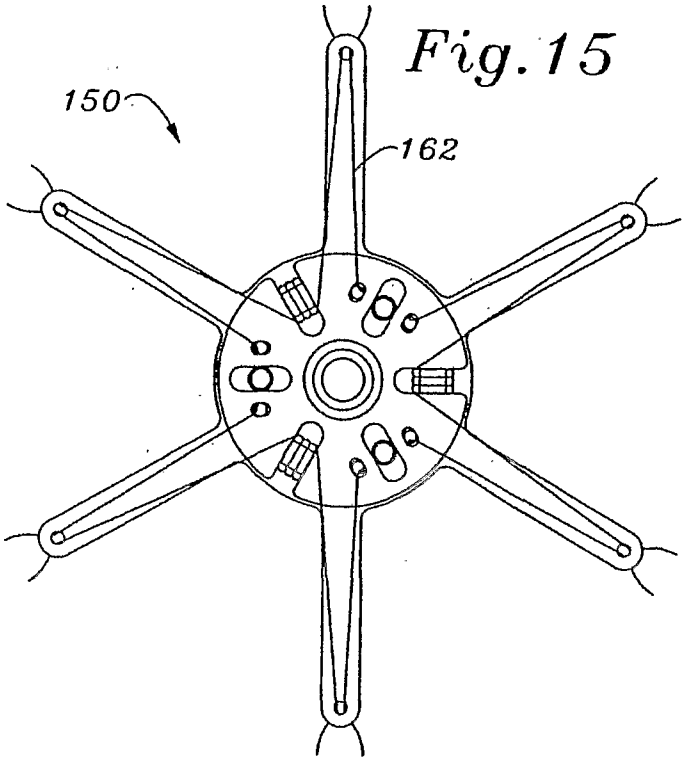


Fig. 15



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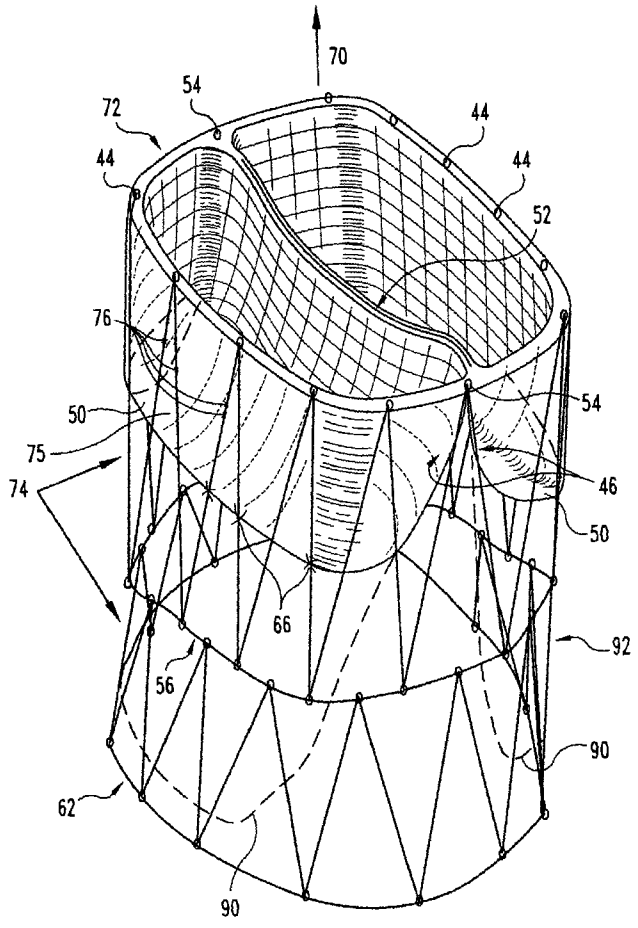
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[Continued on next page]

(54) Title: STENT VALVES AND USES OF SAME



(57) Abstract: The invention includes a medical device and more specifically relates to a valve found generally within a frame. In a preferred device, the frame preferably comprises a self-expanding stent frame, and the valve has at least one expandable and contractible pocket member within the stent frame for resisting and permitting fluid flow, respectively.

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STENT VALVES AND USES OF SAME

Background

Technical field of the invention:

The invention includes a medical device and more specifically to a valve found generally within a frame. In preferred devices the frame is comprised of a radially expandable stent which can be delivered through a delivery device such as a catheter.

Background of the invention:

Lower extremity venous hypertension in addition to venous insufficiency is a major cause of morbidity in the United States. Symptoms of venous disease include lower extremity edema, varicosities, skin pigmentation changes, skin ulceration, and general poor circulation. One solution to this problem is to replace the defective valve or the vein with a valve assembly.

Current valves include a pressure responsive, pressure directed ball movement valve assemblies. The problem with mechanical ball valves is that mechanical valves are susceptible to clot formation. Additionally, there are problems associated with long-term wear and tear on the device.

Artificial valves such as biological valves are also known. Biological valves include homografts, allografts, and xenografts. Problems associated with some biological valves include the supply of the

valves, immunity response, or problems associated with matching the size with the donor.

Finally other problems associated with valve repair include placement problems in which the device cannot be repositioned once it is ejected from the placement catheter, leakage that occurs around the valve, and emboli formation.

In light of this background, there remains a need for alternative and improved devices and methods for providing valvular function within vessels of the body. The present invention is addressed to these needs.

Summary of the Invention

Disclosed is a medical device comprising a frame that has a valve generally located within. In preferred forms of the invention, the frame is comprised of a radially-expandable stent (including especially a self-expanding stent), which can be delivered through a delivery device such as a catheter, and then deployed and expanded at a target site in a body lumen such as an artery or vein. For example, in one preferred use, such a stent and method are used to treat incompetent veins in the legs or feet.

Brief Description of the Drawings

FIGs. 1A to 3 demonstrate one embodiment of the invention comprising a stent.

FIGs. 4 to 8 demonstrate other embodiments of the present invention comprising the valve.

FIGs. 9 to 11 demonstrate embodiments that illustrate exemplary ways of attaching a plurality of stents.

FIGs. 12 to 15 demonstrate exemplary embodiments of the valve configuration in a variety of stent embodiments.

FIG. 16 demonstrates one aspect of the invention in situ.

FIGs. 17 to 19 demonstrate other alternative embodiments.

FIG. 20 depicts a medical assembly of the invention including a stent valve and a delivery device for the stent valve.

Detailed description of the invention

With reference to FIG. 15, shown is one embodiment of the present invention. The invention includes a frame such as a wire stent that has a lumen extending therethrough. Near one end of the stent is the valve assembly comprising some leaflets or cusps. A valve opening is generally located between the leaflets through which fluid flows. Although shown as a two leaflet valve, equally the invention can comprise, in any embodiment described herein, at least one leaflet such as two, three or four leaflets.

With respect to FIGs. 1A, 1B, and 1C, a frame is partially shown. The frame can comprise a stent 20. Choices of stent include a self expanding stent or a non-self expanding stent. In one embodiment of the present invention stent 20 is a self expanding stent such as the Gianturco stent available from Cook Inc. of Bloomington, IN as described in U.S. patent 4,580,568, the entire disclosure of which is expressly incorporated by reference herein. Such stent can be any length, but in one embodiment, the stent is about 15 mm long. Stent 20 includes a plurality of bends 22, which generally form the area in which the stent struts 24 reverses direction. Bends 22 are generally rounded to provide an atraumatic condition. Since the stent 20 is generally located in a vessel or body lumen of some type, the stent 20 can be cylindrical and therefore has a stent diameter 21 (shown in FIG. 3). In another embodiment, the stent 20 can also have a plurality of connectors 26 that connect adjacent struts 24. One way to provide a connector 26 is to dispose a solder

bead between the adjacent struts. However connector 26 can also be a suture, weld, adhesive, rod, clamp, or other well-known ways to connect adjacent struts 24. Connector 26 provides several non-critical advantages. Connectors 26 can attach adjacent struts 24 to minimize or prevent flaring of the ends of the stent 20. Furthermore, connector 26, if placed near the bend 22, can create a hole 28 wherein the boundaries of the hole are the wires of the stent operating in general conjunction with the connector 26. This creates a hole 28 through which a thread or suture can run. However, as shown in FIG. 1C, a separate prefabricated hole can be created by separately attaching a hole assembly, such as a cap 29 over the bend 22. In any case, one benefit of the connector 26 or cap 29 is that they increase the radiographic visualization of the invention. Particularly, if the connector 26 is a solder bead, it has increased radiopacity.

With respect to FIGs. 2A and 2B, shown is part of the stent in which connector 26 attaches adjacent struts 24. As mentioned above, a thread or suture can be threaded through the hole 28. A proximal suture 30 can be sewn through the stent proximal bends 22 or stent proximal ends 31 of the stent. Similarly, a distal suture 32 can be sewn through the stent distal end 33 or the stent distal bends 22 of the stent. One way to thread the suture is shown in FIG. 2B wherein the suture 35 (generically any suture) runs over the strut 24 to enter the hole 28, through hole 28 to come behind the same strut 24, over the strut 24 and across to the adjacent strut 24 running over the adjacent strut 24, behind the adjacent strut 24 to come from

behind and through hole 28, and then run subsequently over adjacent strut 24. Once the struts are connected via the suture, the suture can be pulled to a predetermined tightness to control the overall stent size. Accordingly, the stent can be so constructed to have a predetermined stent perimeter 34. To this end, the stent lumen 36 will also have an appropriate size. The stent can be constructed so as to have a different perimeter length at the proximal or distal ends.

With regard to FIG. 3, shown is a cylindrical stent 20 that has the proximal and distal sutures running through the bends 22 or holes 28 of the proximal and distal ends of the stent. By altering the tautness of the sutures, the size of the stent lumen 36, the stent diameter 86, and the stent perimeters 34, can be adjusted. As can be seen, distal perimeter suture 32 runs along the stent distal end 33, whereas proximal perimeter suture 30 runs along the stent proximal end 31. The respective sutures run through hole 28 of each bend 22.

With respect to FIGs. 4 and 5, the valve material 38 is shown, in this exemplary embodiment, as a sheet. In so constructing the valve 41, the valve material 38 is draped across the stent lumen 36 opening (such as shown on the proximal portion of the stent) and then pushed down into the stent lumen 36 itself. Excess material can be kept outside the stent, which will later become a potential fold-over 42. However, the excess material can also be trimmed off. The valve material 38 is connected to the stent, using for example, distal valve-stent suture 40. However, any well known ways to connect the valve to the stent is

contemplated, such as but not limited to, sutures, adhesives, folds, or the like. In one embodiment shown in FIG. 5, the valve-stent suture 40 can share the hole 28 with distal suture 32 near the stent perimeter 34.

The valve material 38 can be any biocompatible material such as polyethylene terephalate(PET), polypropylene(PP), polytetrafluorethylene(PTFE), or any polymer or derivative thereof, and also includes commercially known materials such as GORE-TEX, DACRON, or any other synthetic material. The preferred material 38 will be advantageously compliant and employed so as to permit effective value function as described herein and in the case of collapsible/expandable state devices will retain integrity and function when cycled between tehse states.

It is preferred to use a biomaterial that serves as a biocompatible scaffold with the ability to remodel host tissue. Accordingly, a naturally occurring biomaterial is highly desirable. One such biomaterial is collagen and more particularly, a collagen based biomaterial called extracellular matrix (ECM). Examples of ECM's include pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, dura mater, and small intestine submucosa One such biomaterial is the ECM, such as submucosa, and more particularly is small intestine submucosa (SIS). SIS can be made in the fashion described in Badylak et al., US Patent 4,902,508; Intestinal Collagen Layer described in US Patent 5,733,337 to Carr and in 17 Nature Biotechnology 1083 (Nov. 1999); Cook et al., WIPO Publication WO

98/22158, dated 28 May 1998, which is the published application of PCT/US97/14855; Gastric Submucosa as described in WO 98/26291 (PCT/US97/22729), claiming priority to US Provisional application 60/032,686; Liver tissue as described in WO 98/25637 (PCT/US97/22727), claiming priority to 60/032,680; Stomach Submucosa as described in WO 98/25636 (PCT/US97/23010), claiming priority to 60/032,683; and Urinary Bladder Submucosa as described in US Patent 5,554,389; all the disclosures of which are hereby expressly incorporated by reference. Irrespective of the origin of the valve material (synthetic versus naturally occurring), the valve material can be made thicker by making multilaminate constructs, for example SIS constructs as described in US Patents 5,968,096; 5,955,110; 5,885,619; and 5,711,969; the disclosures of which are entirely and expressly incorporated by reference.

With respect to FIGs. 6A and 6B, shown is the connection of the valve to the stent frame. As described above, the valve can be sutured at the distal portion of the stent using distal valve-stent suture 40. Similarly, the proximal portion of the valve can be sutured to proximal portion of the stent, and more particularly to proximal perimeter suture 30. Shown is the valve connected to the proximal portion of the stent at proximal valve-stent suture 44. Suture 44 can be through a bend 22 or can attach to the proximal perimeter suture 30. In a traditional Gianturco Z-stent, it is either an 8 (bend) point or 10 (bend) point stent, so one leaflet of the valve can be sutured to the four points of an 8 point stent thereby

comprising one half of the stent. To provide further integrity, the valve can be sutured at the proximal and distal end to the perimeter sutures themselves, without actually being sutured to any or all of the stent bends 22.

With respect to FIG. 6B, shown is the valve with the stent frame removed. Once the sutures are generally in place, the valve sheet 38 will form a valve pocket 46, extending inside the stent lumen in which the fluid will fill. Proximal valve perimeter 48 will have the sutures connecting the valve to the stent (not shown). Once the distal sutures are in place, the general shape will likely resemble a pocket with the pocket having a valve apex 50. There is a part of the valve that will form central valve portion 49 that is not directly sutured to the stent. This valve portion 49 will form the valve opening 52 through which fluid will pass. Thus, upon filling of the valve pocket 46, the fluid pressure will exert outwards causing valve portion 49 to extend outward. When it does, it will contact the other leaflets or cusps and form a seal to stop or impede fluid flow.

FIG. 7 shows a top view of the stent valve. In this particular non-limiting view, shown is the valve opening 52 in a slightly open configuration. Valve pockets 46 are shown in a slightly distended configuration. The valve is connected, for example, by sutures to the stent perimeter 34 and also forms a valve perimeter 48. Because of the opening and closing of the valve, there may be increased wear and tear at the valve-stent-opening connection. At this point, one embodiment of the present invention provides a

reinforcement at this point. For example, this reinforcement can be a plurality of reinforcement sutures 54, adhesive, another material, or any other mechanism that permits increased structural integrity.

FIG. 8 demonstrates a view of the stent valve once the distal portion of the valve is sewn to a distal bend 22 and also shows the proximal portion of the valve being connected to the proximal portion of the frame with one suture in the foreground, one suture in the background. In addition, the reinforcement suture 54 is found in the foreground. Although only two sutures 44 are seen at the proximal portion, it is of course well-understood that some or each of the proximal bend of the frame can be connected to the proximal portion of the valve. Similarly, although only one distal suture 40 is shown, there may be as many distal sutures necessary to connect the valve apex 50 or the distal portion of the valve to the frame. It is well understood that this may be just one distal suture or many distal sutures. Varying the number of distal sutures will vary the shape, tightness, and overall configuration of the valve, valve pocket 46, and the valve apex 50.

The valve opening 52 although already described above, is actually created in the final step of preparation of the preferred device manufacture. The construction mentioned above would be repeated on the other side of the valve to create the valve pocket 46, valve apex 50, and the like on the other side. At this point, though, there is no valve opening 52. The valve opening 52 is created by creating a slit in the sheet to create the opening. The slit can be sized according

to the intended flow rate of the passing fluid. Accordingly, a large slit would create a large valve opening or orifice and permits a large volume of fluid to pass therethrough. The slit can be created by poking a scalpel through it and running it to the desired length. However, due to potential fatigue at the orifice, another set of reinforcements may be added to the orifice perimeter. Therefore, as shown in FIGs. 7 and 8, an orifice reinforcement 53 may be created by any known conventional ways, such as sutures (resorbable or non-resorbable), adhesive, string, staples, rings, or the like.

Therefore, the stent valve as constructed can be using one stent with the valve material enclosed therein. Of course in the single stent configuration, the overall length can be adjusted by elongating the length of the struts 24. However, devices of the invention can be built using a plurality of stents to elongate the overall size of the stent, if desired. In this regard, it will be preferred that the length of the device 20 is sufficient to provide an aspect ratio (length to expanded diameter) sufficiently high to facilitate proper alignment of the device 20 within the vessel, with the axis of the device lumen generally aligned with the axis of the vessel. For example, devices having a ratio of length:expanded diameter of 1:1 or greater, or about 2:1 or greater, will be preferred. It will be understood that while such dimensions will advantageously facilitate placement of the inventive devices, they are not necessary to the broader aspects of the invention.

With reference to FIG. 15, shown is a double stent

structure with the valve. Returning now to FIG. 9, shown is a first stent 58 and a second stent 60. For the purposes of discussion only, first stent 58 is shown to be atop of the second stent 60. Ultimately as shown herein by way of example only, the valve will reside in the first stent 58. It should be noted however that the valve can reside in the second stent 60 also as shown in FIG. 17. Furthermore, the overall length can be increased by joining several stent valves together as shown in FIGs. 18 and 19, thereby having a plurality of stents, such as a first stent 58, second stent 60, and a third stent 61. The valve 41 can be placed in any or all stents, in any combination, for example, as shown by the dotted lines. In this regard, it is suggested and intended that many stents can be joined and that each or any stent may house a valve or plurality of valves. One benefit of having a plurality of stents is that upon ejection of the placement device, the invention will provide a self-aligning feature in the vessel. This is because the plurality of stents is generally longer with respect to the stent diameter, or the plurality of valve device(s), as discussed above.

Manufacture of the multi-stent or multi-valve device will generally follow the same construction as described above. The same considerations in making a single valve single stent device applies equally to the elongated device.

Returning now to FIGs. 9 and 10, shown are methods of connecting the first stent 58 and second stent 60. Equally, the construction shown from now on also includes construction of at least two stents or at

least two valves. First stent 58 and second stent 60 has bends 22 that are adjacent each other. Shown in FIG. 9 is where the first stent 58 has its bends beside the bends of the second stent 60 such that they are not touching each other (although they may touch). They are connected together in the manner described above, and for example by stent-stent suture 56. Stent-stent suture 56 can be resorbable or non-resorbable. This suture travels through the distal bends of the first stent 56 and the proximal bends of the second stent 60. The suturing pattern can be that described in FIG. 2B and the accompanying discussion. As shown in FIG. 10, the bends can be juxtaposed over each other to provide an overlap such that the stent-stent suture 56 will go through the bends at the same time. Therefore, the construction contemplates that the stent bends may touch, overlap, or not at all.

FIG. 11 shows one embodiment of the present invention in which the valve apex 50 is sutured to at least three bends: two bends of the first stent 56 and one bend of the second stent 60. In this regard, the valve also operates to keep the first stent 56 partially connected to the second stent 60. From the bends, a plurality of valve apex sutures 66 are seen. These sutures can emanate from the bends and each bend can have many valve apex sutures 66 that travel in many directions. Using multiple valve apex sutures 66 that emanate in many directions and using a plurality of bends (from either stent), generally functions to minimize any parachuting or inversion of the valve pocket 46.

FIG. 12 demonstrates a top view of the multi-stent

device in which the valve opening 52 is seen (in a closed position) and the valve pocket 46 and valve apex 50 is connected to three bends. Again it should be understood that many sutures may emanate from many bends from any stent.

As described earlier, the excess material can either be trimmed off or folded over the outer surface of the device. Shown in FIGs. 13A and 13B, is the excess material being folded over the device and attached at the distal end of the first stent 58. Shown in dotted lines is the first stent 58. FIG. 13B shows that the fold-over 42 provides a second material outer sheath so that the suture passes through the inside and outside material to increase structural integrity. Also, by folding over the excess material, a smoother surface is presented rather than the naked frame of the tip of the bend.

In all embodiments of the invention, the external surface of the frame can be covered with a sheath that is not necessarily the same material as the valve 41. For example, while the valve can be a naturally occurring material, the outer sheath can be synthetic material such as described herein. The sheath, therefore, can be the fold-over of the valve material, another type of naturally occurring material, or a synthetic material. Accordingly, the sheath may partially or totally cover the frame.

FIG. 14 shows an embodiment in which both the first stent 58 and second stent 60 are covered by the fold over 42. Here, the fold-over 42 is connected to the distal portion of the second stent 60. In this manner, the entire device may be covered with an outer

sheath of biomaterial. The benefit of doing so, especially if using SIS or other similar ECMs, is that the regrowth and endothelialization of the device embeds and encapsulates the frame. Accordingly, there is a reduced risk of device migration. Furthermore, due to the remarkable remodeling properties of SIS, the outer SIS sheath acts as a conduit for host tissue to infiltrate the device and remodel the valve itself. Over the course of months, the valves are replaced by host tissue and the SIS disappears.

FIG. 15 shows yet another embodiment of the present invention. In this demonstration, the valve is located in the first stent 58, sutured at the proximal end at the stent perimeter. The valve apex 50 is sewn somewhat proximal of the stent-stent suture 56. The valve apex 50 is sewn at the valve apex sutures 66 to an intermediate portion of the frame. To minimize parachuting or inversion, a valve intermediate portion 75 may be sutured using valve intermediate suture 76 to connect the valve to the frame. In addition, the valve may be so constructed to extend the valve's length to create an elongated valve pocket 90 (shown by the dotted lines). While the extended pocket 90 can be connected to the distal perimeter of the second stent distal suture 62, it can also be connected to an intermediate portion of the second stent.

With further reference to FIG. 15, it is seen that the valve opening 52 is a slit that extends across the first stent diameter 21 but terminates several millimeters before reaching the edge. In some embodiments, this distance could be 1-5 mm from the edge. Of course, it is understood that the invention

contemplates any distance that varies the length of the slit. Also, shown in FIG. 15, but equally applies to any device described herein, is an anchor 92, which can be anchor barbs 92. These barbs 92 can dig into the adjacent vessel wall to relatively affix the device at its location. Anchor 92, although shown as barbs, may include hooks, adhesives, knobs, a textured surface, or any other treated surface that facilitates relative affixation of the device in its location. Similarly, the outer surface of the fold-over or sheath can be so configured to provide anchoring.

FIG. 16 demonstrates the device upon implantation into the patient. Upon implantation the device generally resides in a vessel 80. For example, the vessel could be vein, artery or the heart or wherever a valve is necessary. In one preferred use, the vessel is an incompetent vein in the leg or foot of a patient. The device 20 reduces or prevents retrograde blood flow, while normal blood flow is permitted to travel through device 20. Illustrative veins in which the device 20 may be used include, for example, saphenous veins, femoral veins, popliteal veins, tibial veins, and the inferior vena cava.

The vessel 80 has an inner lumenal surface 82 in which the fluid flows. The fluid flow path is shown as fluid path 70. Vessel 80 also has a vessel diameter 84. The medical device, upon implantation, will also have a device outer stent diameter 86. The outer diameter 86 will be chosen to permit contact with the inner lumenal surface 82. The optimized fit will decrease the leakage around the device by contacting the inner lumenal surface 82. A tight fit can be

accomplished by sizing the stent diameter to be greater than the vessel diameter. For example, a stent diameter that is about 110 percent greater than (i.e. 1.1 times) the vessel diameter provides a good fit. Expanded stent diameters of about 10 mm to about 30 mm will be typical in many applications of the present invention. Again, while it is shown in this FIG. 16 that the valve is located in the first stent 58 and only the first stent 58 is covered by the fold-over 42 or sheath, it should be remembered that the valve could be located in the second stent 60. Similarly, the fold-over 42 or sheath could extend onto the second stent 60.

The standard method of deploying the medical device 20 in a vessel 80 involves the use of a medical assembly (see FIG. 20) including the device 20 and a delivery device such as a percutaneous delivery device, e.g. a catheter 100. The frame is configured to a contracted state, e.g. by resiliently forming the frame into a contracted configuration, to load into the delivery device (catheter). The catheter can be introduced into the patient via a suitable approach, for example through the jugular or femoral vein. To advance and deploy the device from the distal end of the delivery catheter, a pusher 101 is placed into the catheter lumen. When the device 20 is fully deployed, it assumes the second, expanded configuration within the vessel 80 as depicted in FIG. 16. The stent frame, being made of resilient material, conforms to the shape of the vessel wall such that when viewed on end, the device 20 has a circular appearance when deployed in a round vessel.

FIGs. 17, 18, and 19 show other described embodiments. FIG. 17 demonstrates the valve 41 in the second stent 60. In this embodiment, the valve apex 50 is connected to the second stent's distal perimeter. FIG. 18 demonstrates at least two stent frames connected together. In this particular embodiment, the valve is located in the first stent 58, with the valve apex 50 being connected at the first stent 58-second stent 60 junction. In dotted lines, however, there may be many stents, such as first stent 58, second stent 60, and third stent 61. The valve 41 may be found in any of the stents or in all. Similarly, in the three stent configuration, the valve may begin at the first stent and have the valve apex 50 be generally located in the third stent 61. FIG. 19 shows another embodiment of the present invention in which the valve 41 begins in the second stent 60 and extends into the third stent 61 thereby having the first stent 58 being empty.

Finally, since the device is located in an *in vivo* environment, the device may be treated with therapeutic agents to facilitate healing. For example, the frame may be treated with therapeutic agents such as anti-cancer drugs, plaque busters, anti-coagulants, or the like. Similarly, the valve material can be treated with therapeutics agents such as anti-cancer drugs, plaque busters, anti-coagulants, proteins, growth factors, proteoglycans, and the like. Furthermore, radiopaque agents may be added, such as tantalum, barium, bismuth, or the like to increase radiopacity. These ingredients can be bonded to the frame or the valve material such as rubbing the agent in, bonding it, adhering it, or

the like.

While the invention has been illustrated and described in detail in the drawings and the foregoing text, it is understood that these are only some embodiments and that the scope of the invention is not solely defined by the description herein but also by the appended claims. All modifications and changes that come within the spirit of the invention are hereby protected.

What is claimed is:

1. A stent valve, suitable for placement in a vessel, the vessel further having a diameter and an inner lumenal surface, comprising:

a) a stent having a diameter, a proximal end, and a distal end, the stent sized to permit contact with the inner lumenal surface of the vessel;

b) a valve having a proximal end and a distal end, the valve being at least partially located within an inner portion of the stent, wherein the valve comprises a biocompatible material.

2. The stent valve of claim 1, wherein the stent is a self-expanding stent.

3. The stent valve of claim 1, wherein a sheath partially covers the stent.

4. The stent valve of claim 3, wherein the sheath further comprises substantially biocompatible material.

5. The stent valve of claim 4, wherein the stent is a self-expanding stent.

6. The stent valve of claim 1, wherein the stent has a diameter greater than the vessel diameter.

7. The stent valve of claim 6, wherein the stent has a diameter 110 percent greater than the vessel diameter.

8. The stent valve of claim 6, wherein a sheath partially covers the stent.

9. The stent valve of claim 8, wherein the sheath comprises a biological material.

10. The stent valve of claim 9, wherein the sheath comprises tissue submucosa.

11. The stent valve of claim 10, wherein the submucosa further comprises at least one of a gastric, liver, intestinal, urinary, stomach, and genito-urinary tissue.

12. The stent valve of claim 1, wherein the valve further comprises at least one leaflet, wherein the at least one leaflet is capable of preventing a backflow of blood.

13. The stent valve of claim 1, wherein the valve proximal end is connected to the stent proximal end.

14. The stent valve of claim 13, wherein the valve proximal end is sutured to the stent proximal end.

15. The stent valve of claim 13, wherein the valve proximal end is sutured at least 4 times to the stent proximal end.

16. The stent valve of claim 13, wherein the

valve proximal end is sutured at least 7 times to the stent proximal end.

17. The stent valve of claim 1, wherein the valve distal end is connected to the stent distal end.

18. The stent valve of claim 1, wherein the valve distal end is sutured to the stent distal end.

19. The stent valve of claim 18, wherein the valve distal end is sutured at least 2 times to the stent distal end.

20. The stent valve of claim 18, wherein the valve distal end is sutured at least 3 times to the stent distal end.

21. The stent valve of claim 1, wherein an intermediate portion of the valve is connected to an intermediate portion of the stent.

22. The stent valve of claim 1, wherein an intermediate portion of the valve is connected to the stent distal end.

23. The stent valve of claim 1, wherein a valve opening extends substantially across the stent diameter.

24. The stent valve of claim 23, wherein the valve opening terminates at least 1 mm from a stent perimeter.

25. The stent valve of claim 23, wherein a reinforcement is generally located at a valve opening and a stent perimeter.

26. The stent valve of claim 1, wherein said stent is a radially expandable stent, said radially expandable stent having a first configuration adapted for delivery through a lumen of a delivery device, and a second configuration for conforming to an interior wall of a body vessel.

27. The stent device of claim 26, wherein the body vessel is a vein.

28. A medical device, suitable for placement in a vessel, the vessel further having a diameter and an inner lumenal surface, comprising:

a) at least one stent, the at least one stent having a proximal end, a distal end, and a lumen extending therethrough;

b) a valve having a proximal end and a distal end, the valve generally located within the lumen of the at least one stent;

c) the valve distal end being secured to an intermediate portion of the at least one stent; and

d) the valve further comprising a biological material.

29. A medical device, suitable for placement in a vessel, the vessel further having a diameter and an inner lumenal surface, comprising:

a) at least one stent, the at least one stent having a proximal end, a distal end, and a lumen extending therethrough;

b) a valve having a proximal end and a distal end, the valve generally located within the lumen of the at least one stent;

c) the valve distal end being secured to an intermediate portion of the at least one stent; and

d) the valve further having a valve opening, the valve opening also further comprising a reinforcement disposed on the valve opening.

30. A medical device, suitable for placement in a vessel, the vessel further having a diameter and an inner lumenal surface, comprising:

a) at least one stent, the at least one stent having a proximal end, a distal end, and a lumen extending therethrough;

b) at least one valve having a proximal end and a distal end, the valve generally located within the lumen of the at least one stent

c) the at least one valve distal end being partially secured to an inner portion of the at least one stent; and

d) the valve further comprising a biological material.

31. A radially-expandable stent valve device for placement in a body vessel, comprising:

a self-expanding stent frame, said self-expanding stent frame conformable to a first, contracted state adapted for delivery through a lumen of a delivery device, and a second, expanded state for conforming a lumen of the vessel;

a valve attached to said frame and functional to resist fluid flow in a first direction through said stent frame and permit fluid flow in a second direction through said stent frame opposite said first direction;

said valve comprising a compliant biocompatible material defining at least one pocket member within said frame, said pocket member having an opening for receiving fluid flowing in said first direction and adapted to thereupon expand, said pocket member further adapted to contract upon impingement with fluid flowing in said second direction; and

said biocompatible material sufficiently compliant and said pocket member defined wherein said valve remains functional after contraction of said stent frame to said first, contracted state and expansion of said stent frame to said second, expanded state.

32. The stent valve device of claim 31, wherein said valve comprises at least two of said pocket members.

33. A medical assembly, comprising a stent valve device of any of claims 2, 5, 26 and 29 received within a lumen of a delivery device.

34. A method for providing a valve in a body lumen, comprising:

providing a delivery device having a lumen having received therein a stent valve device of any of claims 2, 5, 26 and 29;

deploying said stent valve device from said delivery device within said body lumen.

35. The method of claim 34, wherein said body lumen is a venous lumen.

36. The method of claim 35, wherein said venous lumen is within a vein selected from a saphenous vein, a popliteal vein, a femoral vein, a tibial vein, and the inferior vena cava.

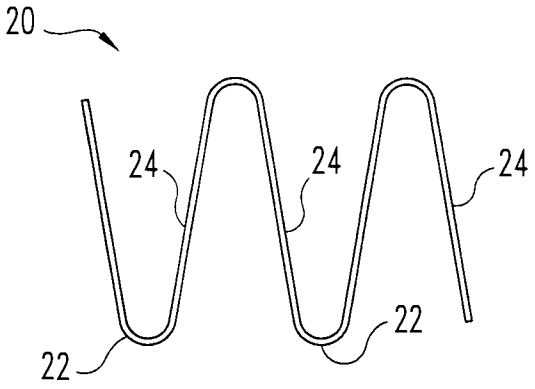


Fig. 1A

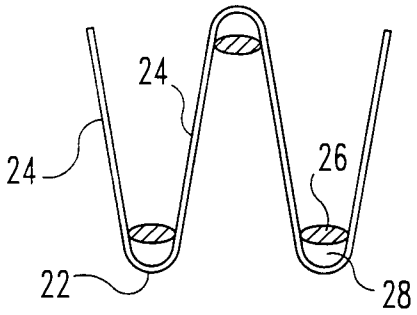


Fig. 1B

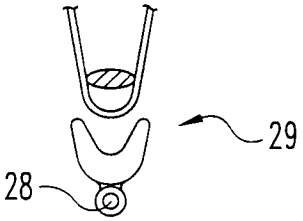


Fig. 1C

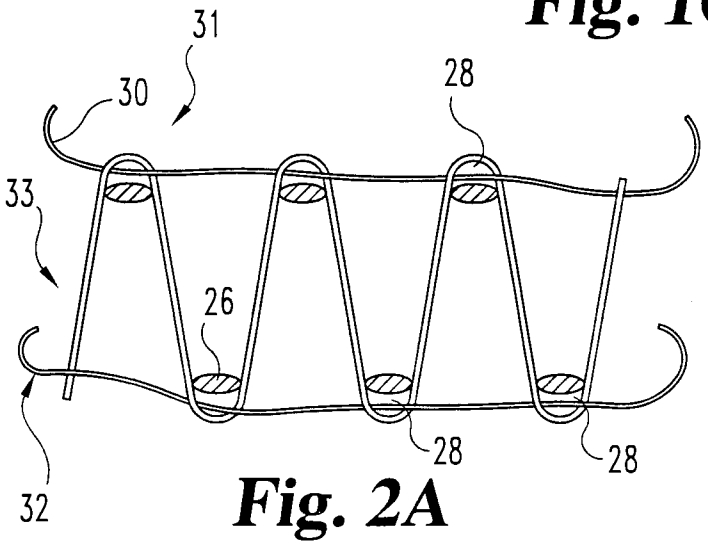


Fig. 2A

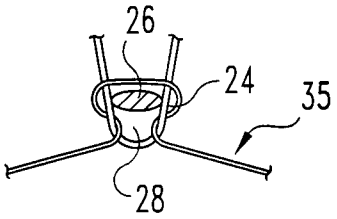


Fig. 2B

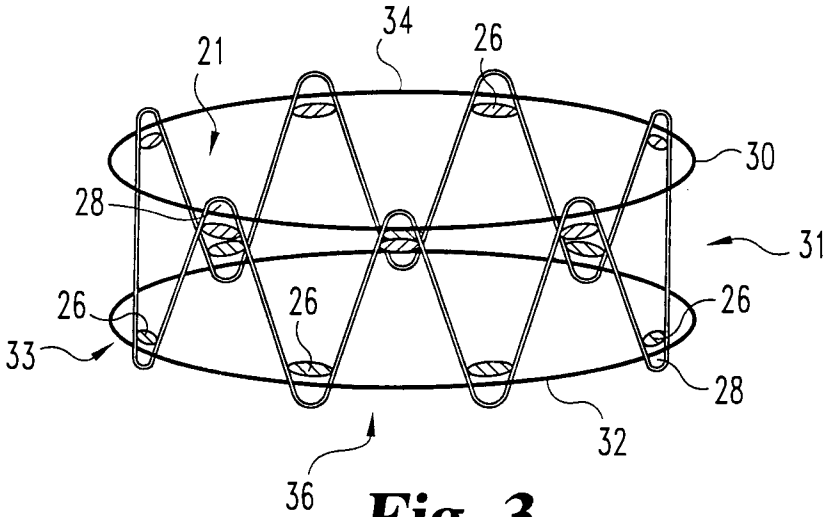


Fig. 3

Aortic Innovations, LLC, Exhibit 2040
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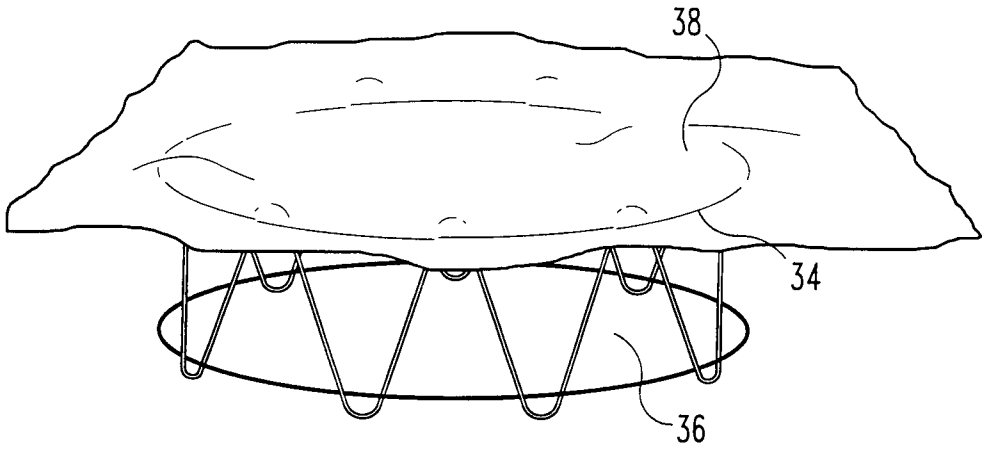


Fig. 4

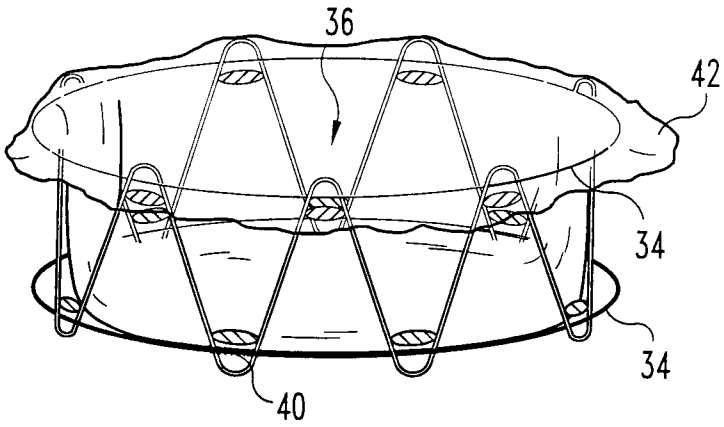


Fig. 5

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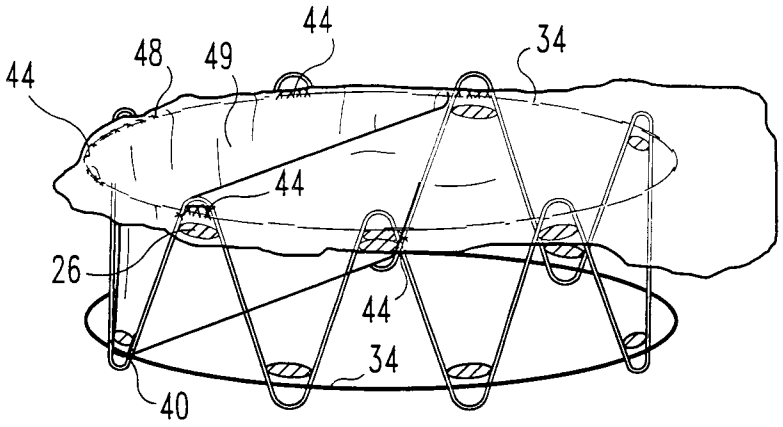


Fig. 6A

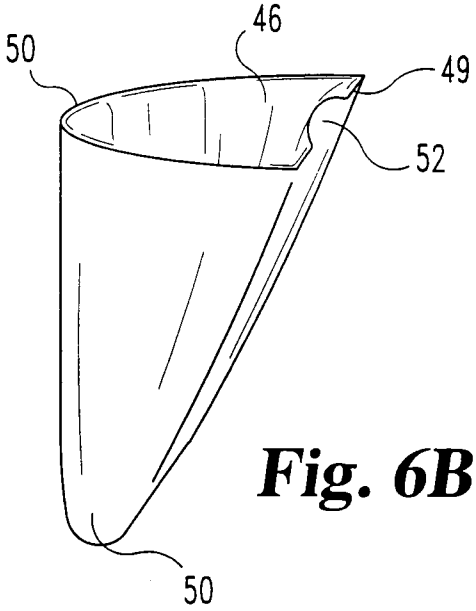


Fig. 6B

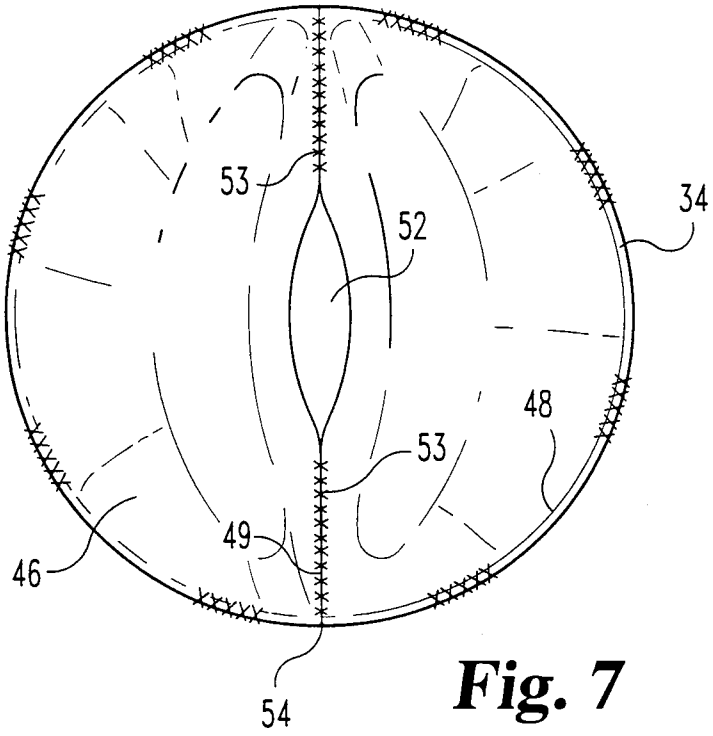


Fig. 7

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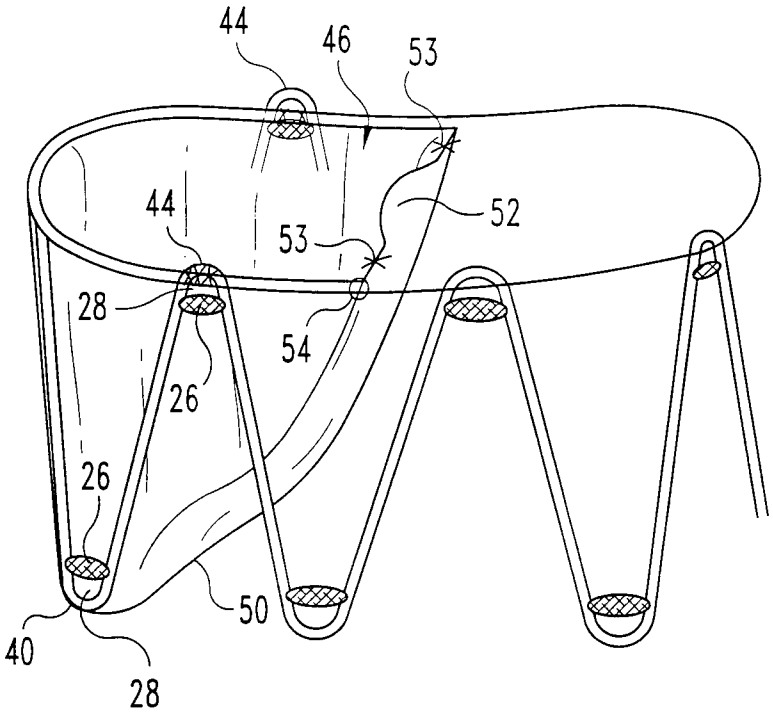


Fig. 8

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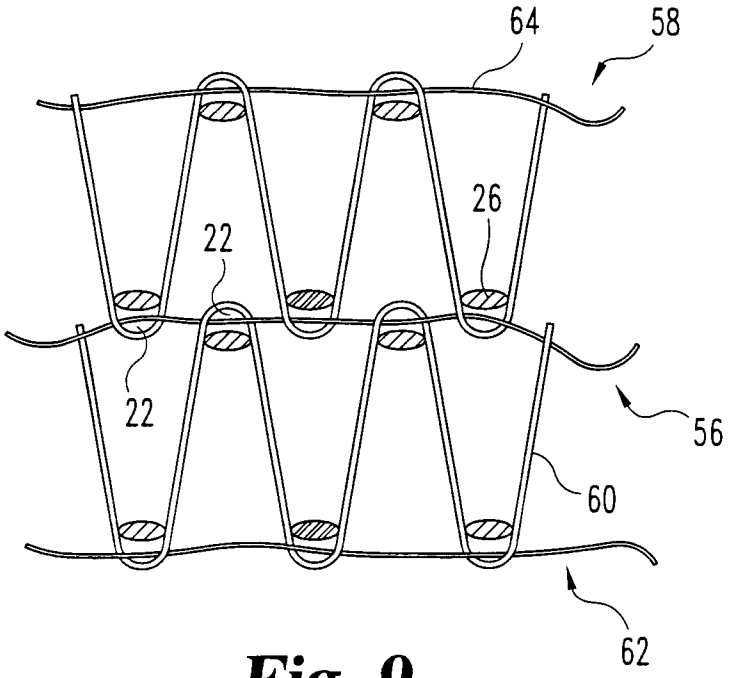


Fig. 9

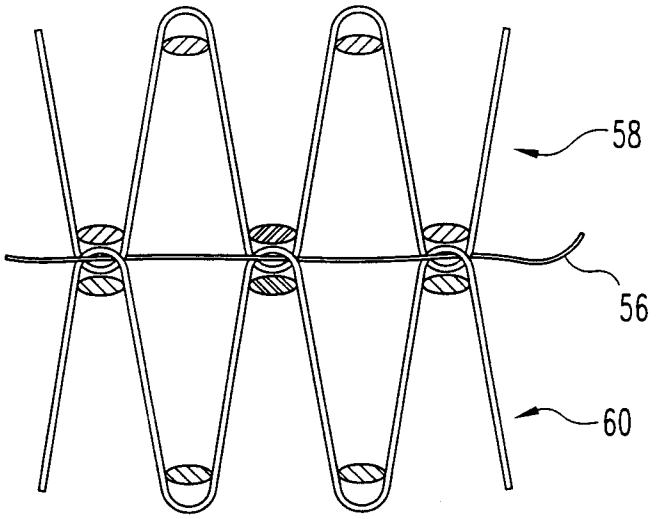


Fig. 10

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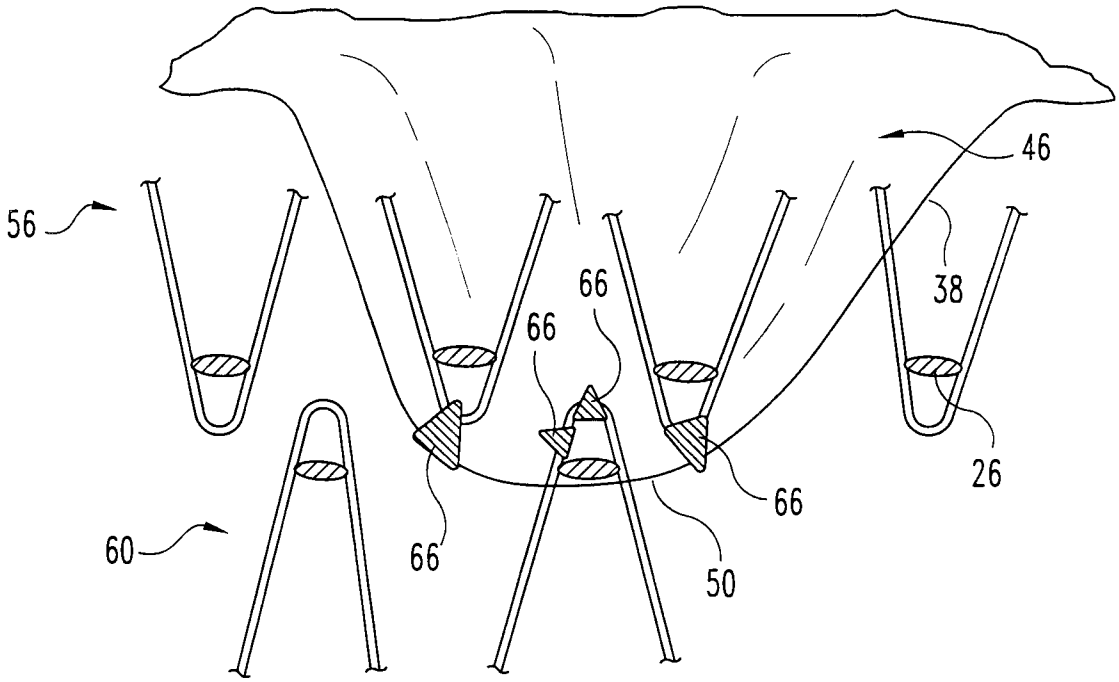


Fig.11

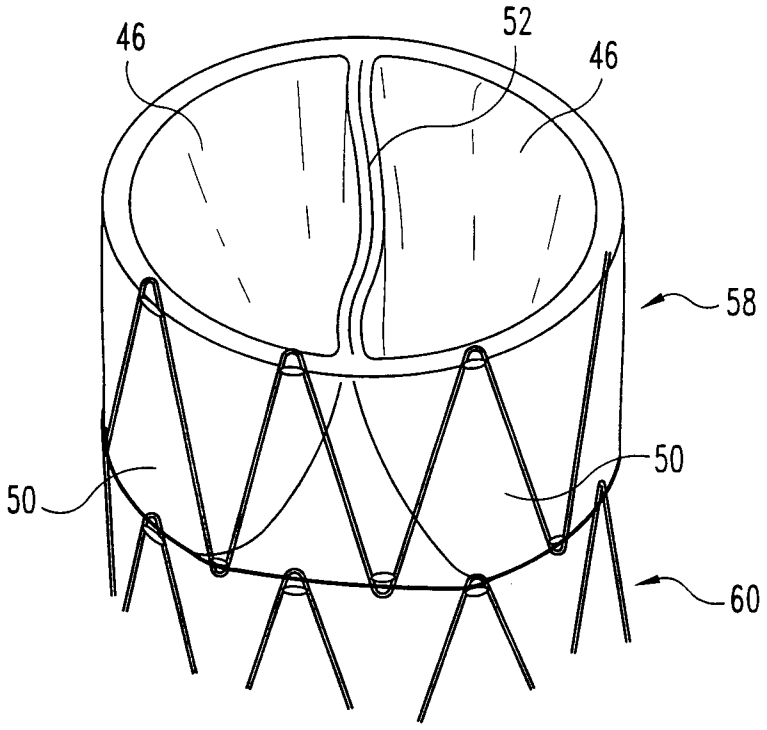


Fig. 12

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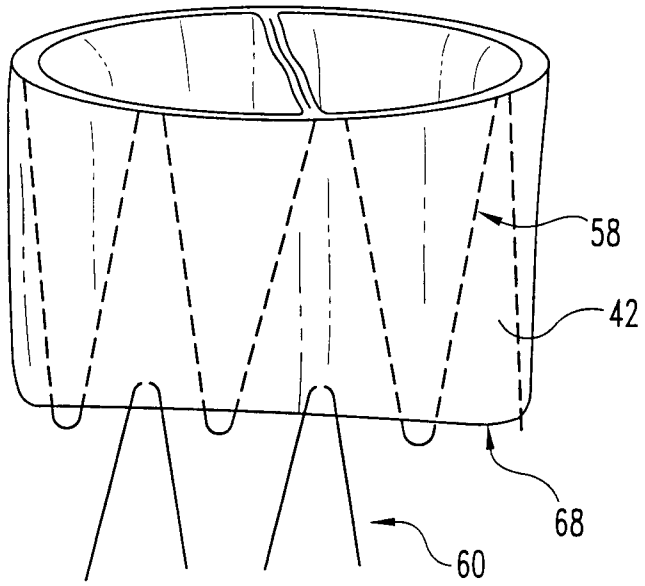


Fig. 13A

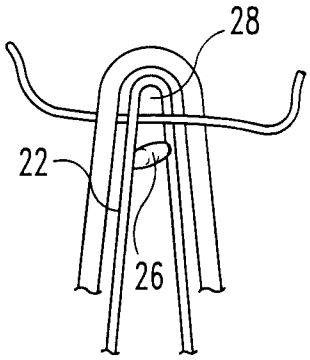


Fig. 13B

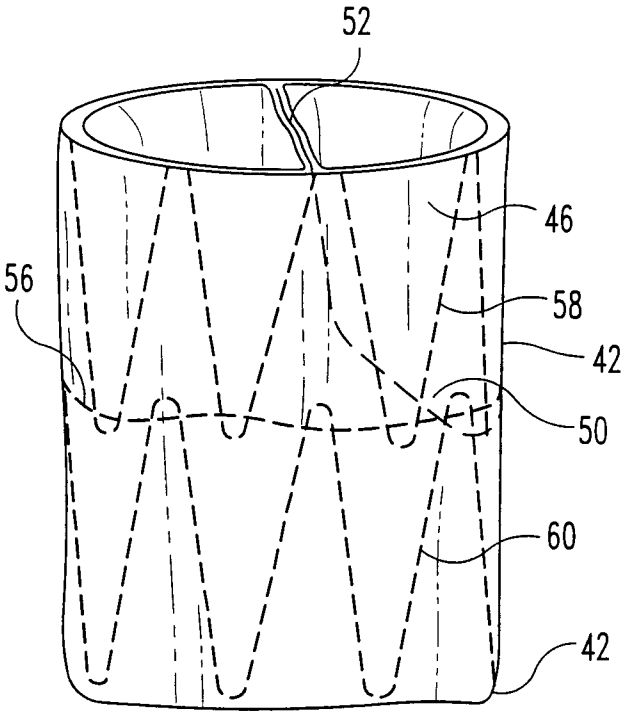


Fig. 14

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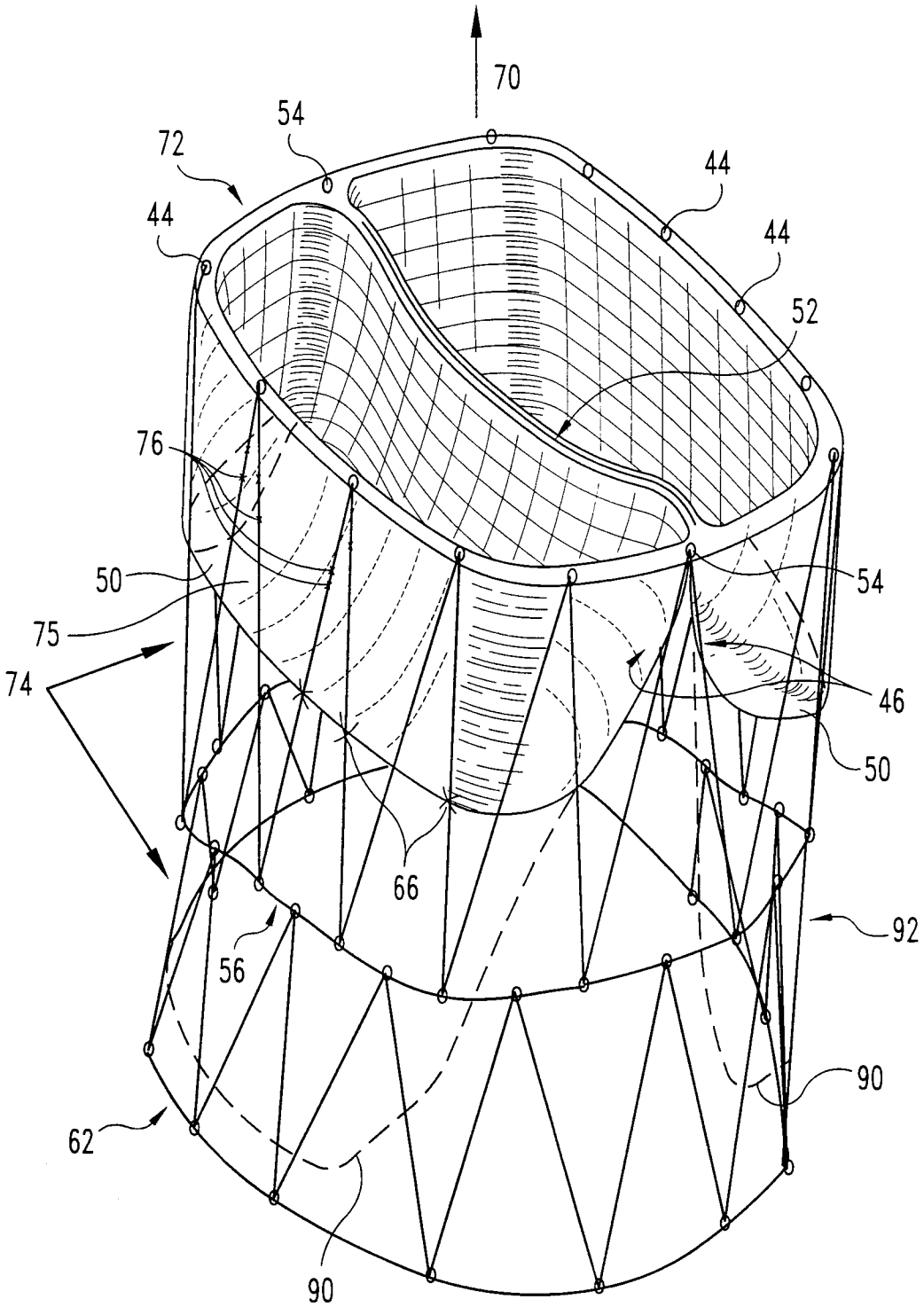


Fig. 15

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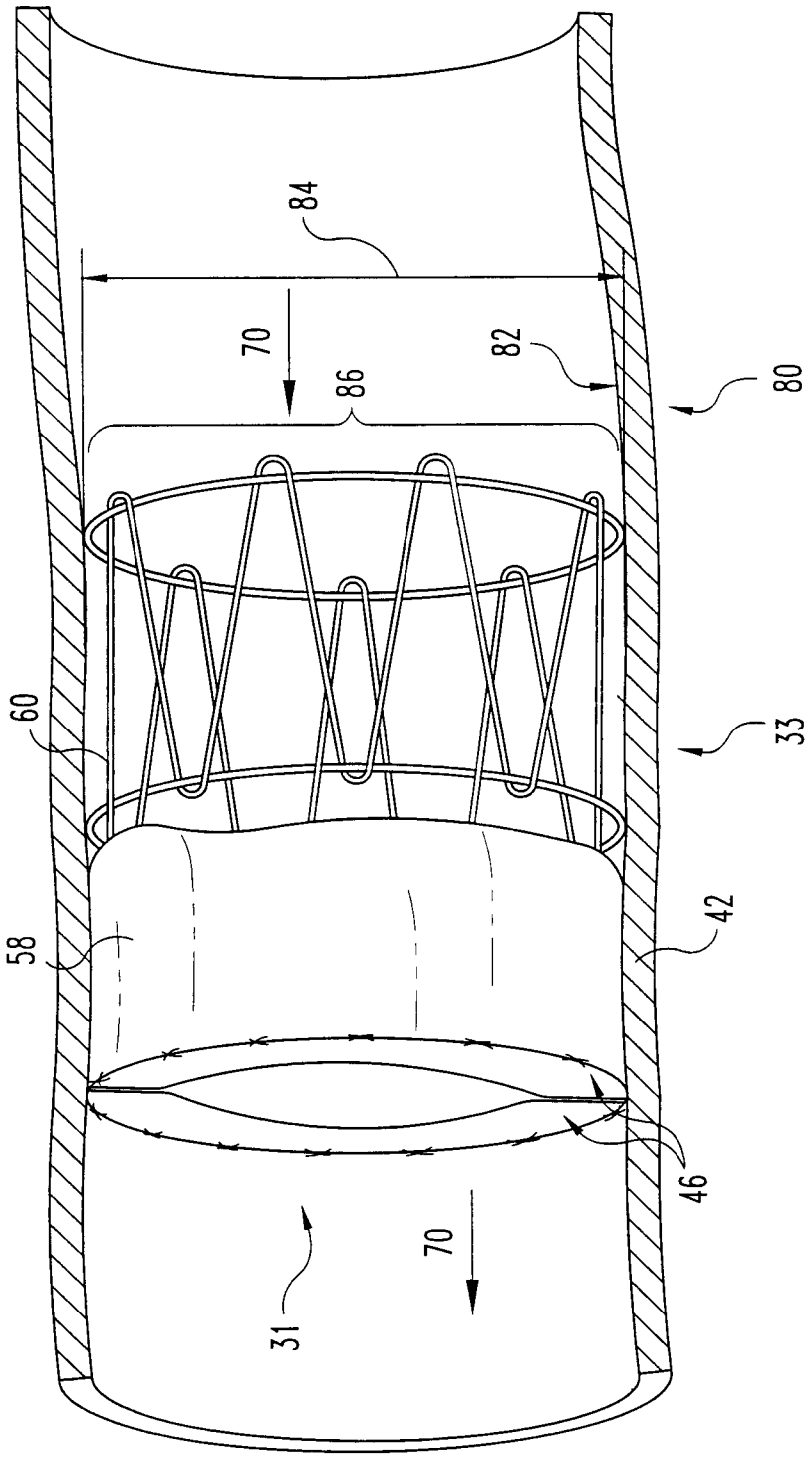


Fig. 16

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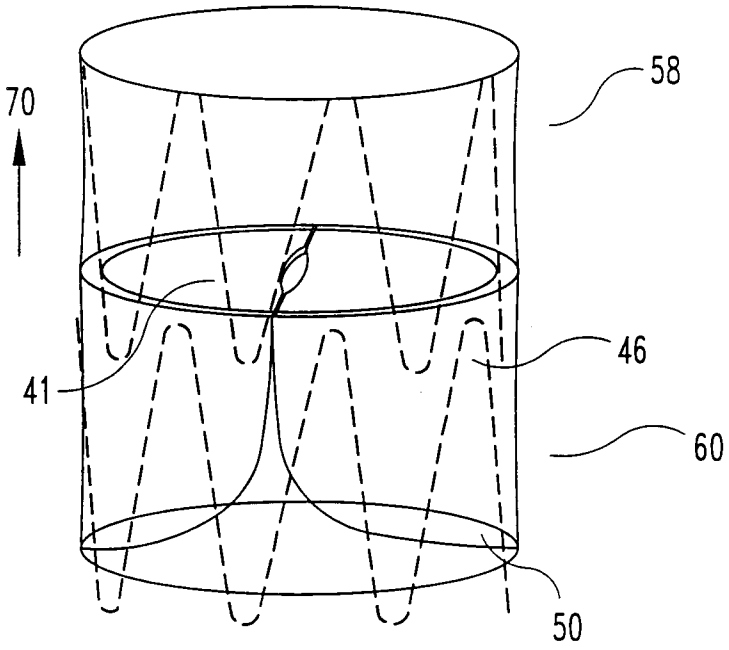


Fig. 17

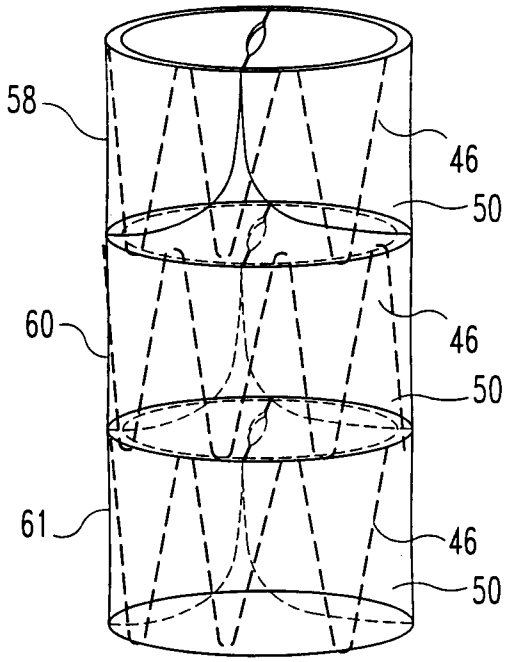


Fig. 18

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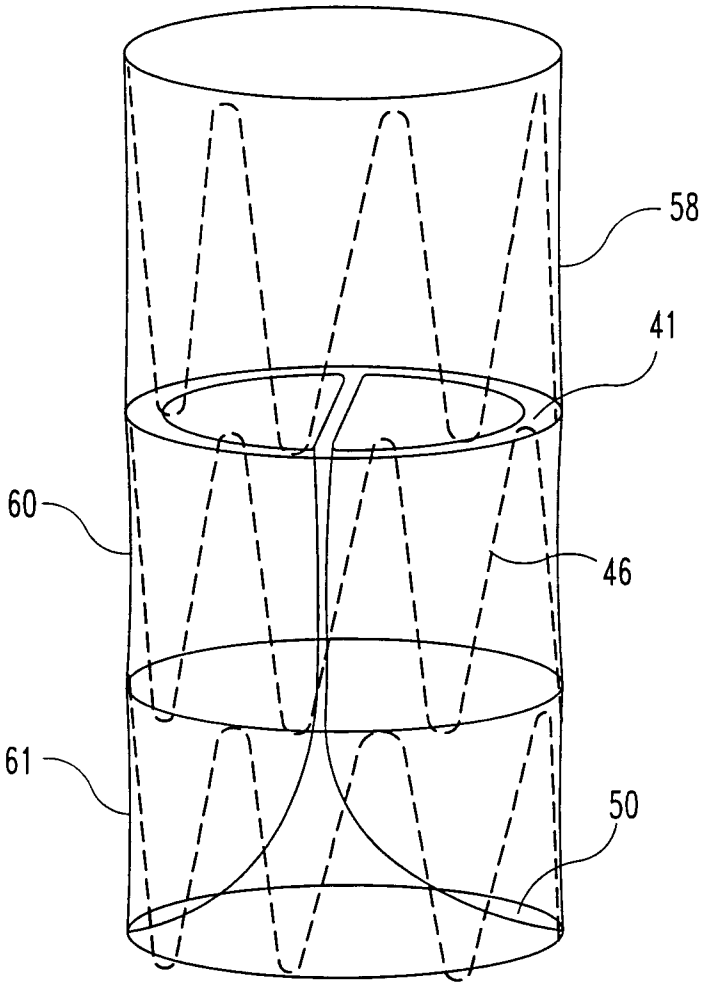


Fig. 19

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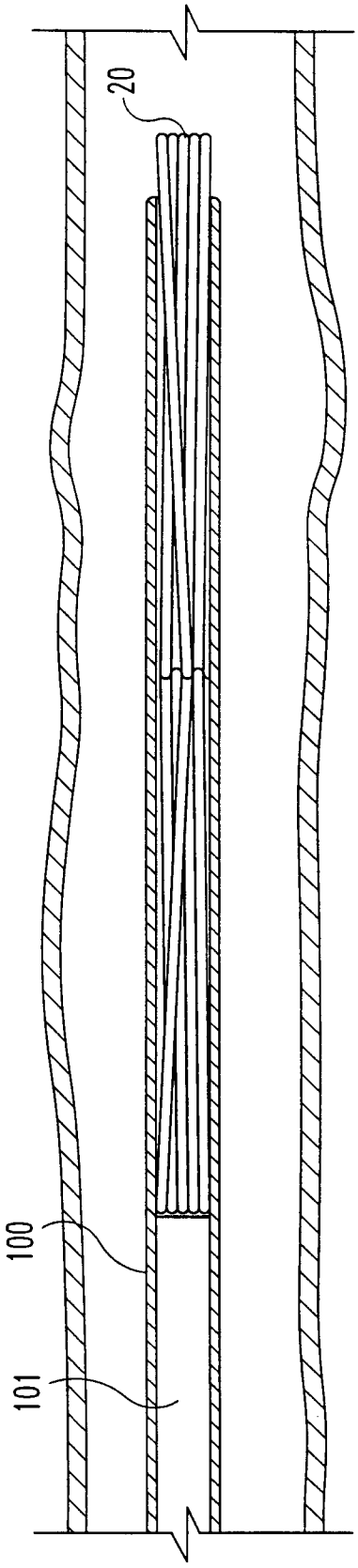


Fig. 20

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INTERNATIONAL SEARCH REPORT

Int ational Application No
PCT/US 01/03095

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropnate, of the relevant passages	Relevant to claim No.
X	EP 0 808 614 A (SAMSUNG ELECTRONICS CO LTD) 26 November 1997 (1997-11-26) claims; figures	1-5,12, 13,17, 22,23, 26,30,33
A	---	28,29, 31,32
X	US 5 855 601 A (CHUTER TIMOTHY A M ET AL) 5 January 1999 (1999-01-05) claims; figures	1-5, 12-14, 26,28, 30-33
A	---	15,16,29
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 May 2001	05/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

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INTERNATIONAL SEARCH REPORT

Inte. .ional Application No
PCT/US 01/03095

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 15224 A (KHOSRAVI FARHAD) 1 April 1999 (1999-04-01) page 5, line 23 -page 6, line 11; claims; figures	1,2,5-7, 21,24, 26,28, 30,33
A	---	3,12,31
X	EP 0 850 607 A (CORDIS CORP) 1 July 1998 (1998-07-01) column 1, line 3 - line 9; figures column 15, line 22 - line 49	1,12-14, 23,27,28
A	-----	29

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

Information on patent family members

In ational Application No
PCT/US 01/03095

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(71) Applicant: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92625 (US).

(72) Inventor: **SCHRECK, Stefan**; 2057 White Birch Drive, Vista, CA 92083 (US).

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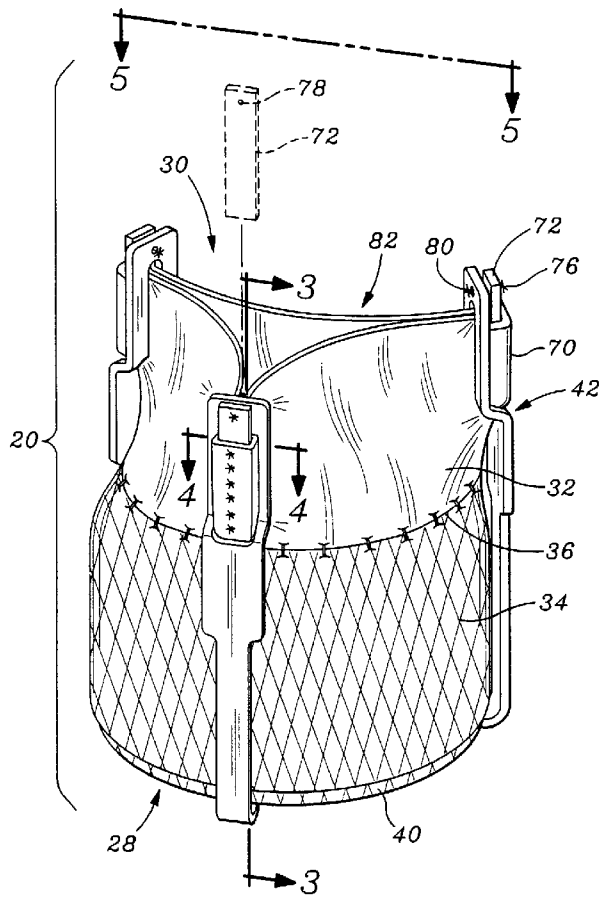
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(54) Title: MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE



(57) Abstract: Expandable heart valves for minimally invasive valve replacement surgeries are disclosed. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably, the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably, the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

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MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE

Field of the Invention

The present invention relates generally to medical devices and particularly to expandable heart valve prostheses especially for use in minimally-invasive surgeries.

Background of the Invention

Prosthetic heart valves are used to replace damaged or diseased heart valves. In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. Prosthetic heart valves can be used to replace any of these naturally occurring valves, although repair or replacement of the aortic or mitral valves is most common because they reside in the left side of the heart where pressures are the greatest.

Where replacement of a heart valve is indicated, the dysfunctional valve is typically cut out and replaced with either a mechanical valve, or a tissue valve. Tissue valves are often preferred over mechanical valves because they typically do not require long-term treatment with anticoagulants. The most common tissue valves are constructed with whole porcine (pig) valves, or with separate leaflets cut from bovine (cow) pericardium. Although so-called stentless valves, comprising a section of porcine aorta along with the valve, are available, the most widely used valves include some form of stent or synthetic leaflet support. Typically, a wireform having alternating arcuate cusps and upstanding commissures supports the leaflets within the valve, in combination with an annular stent and a sewing ring. The alternating cusps and commissures mimic the natural contour of leaflet attachment. Importantly, the wireform provides continuous support for each leaflet along the cusp region so as to better simulate the natural support structure.

A conventional heart valve replacement surgery involves accessing the heart in the patient's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart, allowing access to the thoracic cavity and heart within. The patient is then placed on cardiopulmonary bypass which involves stopping

the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period.

Recently, a great amount of research has been done to reduce the trauma and risk associated with conventional open heart valve replacement surgery. In particular, the field of minimally invasive surgery (MIS) has exploded since the early to mid-1990s, with devices now being available to enable valve replacements without opening the chest cavity. MIS heart valve replacement surgery still requires bypass, but the excision of the native valve and implantation of the prosthetic valve are accomplished via elongated tubes or cannulas, with the help of endoscopes and other such visualization techniques.

Some examples of MIS heart valves are shown in U.S. Patent No. 5,980,570 to Simpson, U.S. Patent No. 5,984,959 to Robertson, et al., and PCT Publication No. WO 99/334142 to Vesely. Although these and other such devices provide various ways for collapsing, delivering, and then expanding a "heart valve" per se, none of them disclose an optimum structure for tissue valves. For instance, the publication to Vesely shows a tissue leaflet structure of the prior art in Fig. 1, and an expandable inner frame of the invention having stent posts in Figs. 3A-3C. The leaflets are "mounted to the stent posts 22 in a manner similar to that shown in Figure 1." Such a general disclosure stops short of explaining how to construct an optimum valve. In particular, the means of attaching the leaflets to the MIS stent is critical to ensure the integrity and durability of the valve once implanted. All of the prior art MIS valves fall short in this regard.

In view of the foregoing, it is evident that an improved sewing ring that addresses the apparent deficiencies in existing expandable heart valves is necessary and desired.

Summary of the Invention

The present invention provides an expandable prosthetic heart valve for placement in a host heart valve annulus, comprising an expandable stent system adapted to be delivered in a collapsed state to an implantation site and expanded, and a plurality of prosthetic leaflets attached to the stent system. Each leaflet has an approximately semi-circular cusp edge terminating at each end in commissure portions, and a coapting edge extending between the commissure portions. Each leaflet is attached to the stent system substantially entirely along the cusp edge and at both commissure portions, with a coapting edge remaining unattached. The stent system may comprise an expandable

generally annular tissue-engaging base and an elastic generally annular wireform attached thereto. The base is adapted to be delivered in a radially collapsed state and expanded into contact with the host annulus. The annular wireform defines a plurality of upstanding commissures and a plurality of arcuate cusps between adjacent commissures, and the prosthetic leaflets are attached to the wireform along the cusps and commissures, wherein the wireform and leaflets are configured to be radially compressed.

In one embodiment, the heart valve includes a plurality of upstanding posts attached to one of the tissue-engaging base and elastic wireform, each post having a connector. A plurality of mating connectors are provided on the other of the tissue-engaging base and elastic wireform for mating with the post connectors. The posts and mating connectors may be provided for each commissure and each cusp of the elastic wireform so that the valve includes a number of posts and mating connectors equal to the number of commissures plus the number of cusps. Further, the expandable stent system may include an undulating wireform defining a plurality of commissures and a plurality of cusps between adjacent commissures. The cusp edge of each of the prosthetic leaflets attaches along a wireform cusp, and the commissure portions of each leaflet terminate in outwardly extending tabs that each attach to a wireform commissure, wherein tabs from adjacent leaflets are attached together at each of the wireform commissures.

In another aspect of the invention, an expandable prosthetic heart valve for placement in a host heart valve annulus is provided. The heart valve comprises an expandable stent portion and an elastic leaflet portion connectable to the stent portion. The stent portion defines an inflow end of the valve and is adapted to be delivered in a collapsed state and expanded into contact with the host annulus. The leaflet portion forms a one-way flow occluder on an outflow end of the valve and includes an elastic wireform defining alternating cusps and commissures and prosthetic tissue attached substantially entirely therealong. The stent portion desirably includes a tubular member and a plurality of connectors, and wherein a plurality of connectors are provided on the elastic wireform for mating with the tubular member connectors. The wireform connectors may be provided on each commissure and on each cusp of the wireform so that the valve includes a number of mating connectors equal to the number of commissures plus the number of cusps. In a preferred embodiment, the prosthetic tissue comprises a plurality of individual leaflets secured along the alternating cusps and

commissures of the elastic wireform. Additionally, the wireform may have a fabric covering, wherein the individual leaflets are stitched along the fabric covering. The fabric covering continues toward an inflow end of the valve in a skirt that surrounds the stent portion and is adapted to be captured between the expanded stent portion and the host annulus. A plurality of posts rigidly may connect to the stent portion and extend upward within the skirt into mating connection with the elastic wireform.

In a still further aspect, the present invention provides a two-part expandable prosthetic heart valve for placement in a host heart valve annulus, comprising:

a leaflet subassembly having a wireform defining a plurality of upstanding commissures and a plurality of arcuate cusps extending between adjacent commissures, a midpoint of each cusp being located approximately equidistant from the adjacent commissures;

a generally annular tissue-engaging base defining an axis; and

a system for connecting the leaflet subassembly and the tissue-engaging base, including a plurality of mating connectors on the leaflet subassembly and on the tissue-engaging base, wherein one connector each is provided at each commissure, and one at each cusp midpoint.

In the two-part heart valve, the tissue-engaging base preferably comprises an expandable tubular member that is deliverable to the host annulus in a collapsed state and expandable into contact with the host annulus to secure the valve therein. Furthermore, the tissue-engaging base forms an inflow end of the valve, and the system for connecting the leaflet subassembly and tissue-engaging base includes a plurality of posts coupled to the tubular member and having varying lengths extending away from the inflow end of the valve. A first plurality of posts each having a first length connects with the wireform commissures, and a second plurality of posts each having a second length connects with the wireform cusps shorter than the first length. The mating connectors may be configured to be joined together by axial compression, preferably with a snap-fit configuration.

A further aspect of the invention includes a prosthetic heart valve having a support stent and a flexible tubular member. The support stent includes a tubular base along an inflow end a plurality of generally axially-extending commissure posts disposed

evenly around the tubular base on an outflow end thereof. The flexible tubular member has a prosthetic section attached to the commissure posts so as to define a plurality of the prosthetic valve leaflets between the posts, and a fabric section connected to the base. The prosthetic section and fabric section are desirably both generally tubular and attached together at a seam, wherein the seam is spaced from the outflow end of the tubular base so that only the fabric section of the flexible tubular member contacts the tubular base. The commissure posts each may have an axial slot, wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post. A plurality of inserts sized larger than the slots may be provided, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot. In a preferred embodiment, the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180° to extend alongside the base and project beyond the base at the outflow end thereof.

A prosthetic heart valve of the present invention has a support stent including a tubular base along an inflow end. A plurality of generally axially-extending commissure posts each having an axial slot is disposed evenly around the tubular base on an outflow end thereof. A flexible tubular member having an outflow edge is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post. Further, a plurality of inserts sized larger than the slots are provided, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot, the outflow edge of the tubular member defining a plurality of valve leaflets. The tubular base may be plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

A method of minimally-invasive heart valve replacement surgery on a patient is also provided by the present invention. The method includes the steps of:

providing an annular tissue-engaging base, the base being expandable from a collapsed state;

providing a generally annular elastic wireform subassembly having a plurality of prosthetic leaflets connected thereto, the elastic wireform

subassembly having a relaxed, expanded size and a compressed, reduced size;

connecting the wireform and leaflets to the base to form a heart valve;

delivering the heart valve with the connected base in its collapsed state and wireform subassembly in its reduced size to an annulus of the patient's heart valve being replaced; and

expanding the base into its expanded state in contact with the annulus.

The step of delivering the heart valve to the annulus may be accomplished by passing the valve through the patient's vasculature or via a minimally-invasive port in the patient's chest. The tissue-engaging base may plastically-expandable from its collapsed state to its expanded state, and the step of expanding the plastically-expandable base comprises inflating a balloon within the annular base.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

Brief Description of the Drawings

Fig. 1 is an exploded perspective view of a first embodiment of an expandable heart valve of the present invention, including a support stent and a flexible tubular member;

Fig. 2 is an assembled perspective view of the expandable heart valve of Fig. 1;

Fig. 3 is a longitudinal cross-sectional view taken along line 3-3 through a commissure of the expandable heart valve of Fig. 2;

Fig. 4 is a transverse cross-sectional view taken along line 4-4 through the commissure of the expandable heart valve of Fig. 2;

Fig. 5 is a top plan view of the expandable heart valve of Fig. 2;

Fig. 6 is an exploded perspective view of a second embodiment of an expandable heart valve of present invention having two detachable components designed to be assembled post-storage, including a tissue-engaging base and a wireform-supported leaflet subassembly;

Fig. 7 is an assembled perspective view of the expandable heart valve of Fig. 6, with a fabric skirt removed to illustrate details of a connecting system between the base and leaflet subassembly;

Fig. 8 is a plan view of an insert used to both attach individual leaflets to commissures of the wireform, and connect the commissures of the leaflet subassembly to the tissue-engaging base of the expandable heart valve of Fig. 6;

Fig. 9 is a plan view of an individual leaflet for use in the expandable heart valve of Fig. 6;

Fig. 10 is a longitudinal cross-sectional view taken along line 10-10 of Fig. 7;

Fig. 11 is a transverse cross-sectional view taken along line 11-11 of Fig. 7;

Fig. 12 is a longitudinal cross-sectional view taken along line 12-12 of Fig. 7;

Fig. 13 is a top plan view of the expandable heart valve taken along line 13-13 of Fig. 7;

Fig. 14 is an enlarged perspective view of a commissure region of the expandable heart valve taken within the circle 14 of Fig. 7;

Fig. 15 is an enlarged plan view of the commissure region of the expandable heart valve taken within the circle 15 of Fig. 13; and

Fig. 16A-C illustrate a heart in section and several steps in a delivery and implantation procedure of the expandable valve of the present invention.

Description of the Preferred Embodiments

The present invention discloses two different expandable heart valves for implantation in a host annulus, or host tissue adjacent the annulus. The valves may be implanted in any of the four valve positions within the heart, but are more likely to be used in replacing the aortic valve because of the circular shape of the annulus.

It should also be noted that the specific constructional details, including materials and shapes, may be varied from those shown. For example, an expandable tubular base is used in both valve embodiments, and is described as being a plastically-expandable structure that radially expands into contact with the annulus tissue. Alternatively, the tubular base may be elastically- or self-expandable, or expandable on the application of heat (i.e., using shape memory material). Further, various means are known for plastically or elastically expanding structures into contact with anatomical passageways, and though the present invention illustrates and describes only one such structure, others may be used to practice the invention. For example, any plastically- or elastically-expandable structure may be modified so as to have a suitable diameter for heart valves

and used to practice the present invention. In addition, barbs, flanges, staples, and the like may be added to the tubular base for the purpose of greater attachment to the host tissue. In short, the present invention should not be construed to be limited to the particular structures and materials disclosed, the scope of the invention being solely defined by the appended claims.

With reference to Figs. 1-5, a first embodiment of an expandable prosthetic heart valve 20 is shown and described. The prosthetic heart valve 20 is assembled prior to storage. In a second embodiment, shown in Figs. 6-15, a second embodiment of an expandable heart valve is shown and described. Detachable components of the expandable heart valve in the second embodiment are separately stored, and assembled just prior to insertion and delivery to the host annulus, which provides certain advantages to be described.

Pre-Assembled Expandable Heart Valve

Fig. 1 illustrates the first embodiment of the expandable heart valve 20 exploded, with a flexible tubular member 22 separated from a support stent 24 along a central axis 26. Fig. 2 illustrates the flexible tubular member 22 attached to the support stent 24 to form the assembled heart valve 20. The heart valve 20 has an inflow end 28 (the lower end in the figure) and an outflow end 30 (the upper end in the figure).

The flexible tubular member 22 comprises a leaflet section 32 connected to a fabric section 34 at a seam 36. As illustrated, both the leaflet section 32 and fabric section 34 are desirably formed as tubes, such that the seam 36 defines a circle therebetween. Alternatively, the seam 36 may be other than circular if areas of the leaflet section 32 or fabric section 34 need to be expanded around their circumferential juncture. For example, the fabric section 34 may need to be increased in the commissure region of the valve 20, such as indicated by the dashed line 38 in Fig. 1. Whatever the configuration, the fabric section 34 has a minimum axial height indicated at **A**.

Desirably, the leaflet section 32 is formed from pericardial tissue, such as bovine or equine pericardium, suitably treated to render it biocompatible. Of course, any suitable leaflet material, including synthetics, may be used. The fabric section 34 is desirably a woven polyester, such as polyethylene terepthalate. Alternatively, the fabric section 34 may be formed of polytetrafluoroethylene (PTFE), or other suitable

biocompatible sheet material. Still further, the leaflet section 34 may extend the entire axial height of the flexible tubular member 22, with the fabric section 34 being wrapped around and attached to the inflow end.

As seen in Fig. 1, the support stent 24 comprises a tubular base 40 and a plurality of upstanding commissure posts 42 distributed evenly around the periphery thereof. That is, the tubular base 40 is provided at the inflow end 28 of the support stent 24, with the commissure posts 42 extending in the outflow direction. Desirably, there are three such commissure posts 42 disposed at 120° intervals about the circumference of the stent 24. The tubular base 40 has an axial height indicated at **B**, which height is less than the axial height **A** of the fabric section 34 of the flexible tubular member 22. The commissure posts 42 extending upward a sufficient distance such that the entire axial dimension of the support stent 24 is slightly greater than the axial dimension of the flexible tubular member 22, as indicated in the assembled view of Fig. 2.

The tubular base 40 comprises a plastically-expandable material that can be expanded into the configuration shown in the figures from a radially compressed configuration (not shown). In this regard, the illustrated tubular base 40 essentially comprises a non-self expanding stent that can be expanded from its compressed state using a balloon inflated from within the base, for example. Numerous configurations of such plastically-expandable tubes are available in the prior art, and as mentioned above, the present invention should not be considered limited to any one configuration. Moreover, in other configurations the base 40 may be self- or heat-expandable.

With reference to Fig. 1, each commissure post 42 attaches to or extends from an inflow rim 44 of the tubular base 40, continuing on the outside of the tubular base toward the outflow end in an elongated axially-extending lower section 46, and terminating in an axially extending upper section 48. The upper section 48 commences at a predetermined distance above an outflow rim 50 of the tubular base 40 and is stepped radially inward from the lower section 46 at a transition region 52. An axial slot 54 is provided in the upper section 48 and in the transition region 52. The width of the axial slot 54 is desirably constant in the upper section 48, but increases at a relief region 56 in the transition region 52.

In a preferred embodiment, the commissure posts 42 are formed of a biocompatible, elastic material, preferably metallic. For example, each commissure post

42 may be formed of stainless-steel, titanium, or Elgiloy. Alternatively, the commissure posts 42 may be a biocompatible polymer, such as Delrin or polyacetyl.

In a preferred embodiment, the support stent 24 is formed from a single piece of flat material. Specifically, the tubular base 40 initially comprises a flat, narrow strip of uniform width material with the commissure posts 42 extending from one long side thereof. Using conventional means, the narrow strip of material is then rolled into the tubular shape shown in the figures, and the juxtaposed narrow ends joined by, for example, crimping. Each of the commissure posts 42 is then bent 180° outward to project in the opposite direction from their original direction. Fig. 1 illustrates such a configuration in which a 180° bend 60 joins each commissure post 42 to the inflow rim 44. The radius of the bend 60 is such that a narrow space 62 is defined between the lower section 46 of each commissure post 42 and the exterior of the tubular base 40.

The flexible tubular member 22 attaches to the support stent 24 as seen in Fig. 2,with the leaflet section 32 connected to the commissure posts 42, and the fabric section 34 connected to the tubular base 40. More specifically, the fabric section 34 surrounds the tubular base 40 and extends toward the inflow rim 44 in the spaces 62 created inboard of each commissure post 42. Although not shown, the fabric section 34 may be attached to the exterior of the tubular base 40, such as by sutures passed through the fabric and through openings in the tubular base. Because the axial dimension **A** of the fabric section 34 is greater than the axial dimension **B** of the tubular base 40, the seam 36 is disposed above the outflow rim 50 (Fig. 1) of the base. This is more clearly shown in the cross-section of Fig. 3.

The leaflet section 32 is disposed substantially between the commissure posts 42, except for a number of loops 70 threaded outward through the axial slots 54. As seen Figs. 2-3, the loops 70 comprises regions of the tubular leaflet section 32 pinched and threaded through the axial slots 54. A plurality of inserts 72 are used to secure the loops 70 to the exterior of the commissure posts 42. That is, as seen Fig. 4, the inserts 72 each have a width **W** that is greater than the circumferential width of the axial slots 54. Because the inserts 72 are disposed within the loops 70, they prevent the loops from pulling inward again through the axial slot 54. A plurality of stitches 74 are preferably provided to secure the leaflet section 32 to the inserts 72. In addition, as seen in Fig. 3, stitching 76 passes through an aperture 78 in each insert 72, and through an aperture 80

provided in the outflow end of each commissure post 42. In this manner, each insert 72 is secured with respect to the support stent 24.

With reference to Figs. 2 and 5, a plurality of leaflets 82 are defined between the support stents 24 by the leaflet section 32. Specifically, where there are three stent post 24, a generally triangular arrangement of leaflets 82 remains unconstrained in the middle portion of the valve 20 and opens and closes depending on blood flow forces. Furthermore, the continuous flexible tubular member 22 provides a flow channel for blood through the valve 20. When the pressure differential is such that blood flows into the inflow end 28 of the valve 20, the leaflets 82 spread apart and the valve opens. Conversely, when the pressure differential reverses, the leaflets 82 come together, or coapt, to close the valve 20.

When the pressures are such that the valve closes, radially inward forces are imposed on the free edge of the leaflet section 32, which may tend to cantilever the support stents 24 inward a slight amount. Localized stresses on the leaflet section 32 are reduced at the connection with the stent supports 24, however, because of the use of the inserts 72 within the loops 70. That is, as best seen in Fig. 4, radially inward forces on the leaflets 82 as indicated by the arrow 84, pull the inserts 72 inward such that the leaflet material is clamped between each insert and the respective commissure post 42. Although stitching 74 through the leaflet section 32 is provided, such stitching is not subjected to direct tensile stresses, and thus is less likely to tear through the leaflet tissue.

Certain features of the valve 20 reduce wear typically associated with stent-leaflet dynamic contact. First, because the axial dimension **A** of the fabric section 34 is greater than the dimension **B** of the tubular base 40, any contact between the flexible tubular member 22 and the tubular base 40 (at the outflow rim 50) is between fabric and the base. That is, the leaflet section 32 is not placed in contact with the base 40, thus increasing the life of the valve. Additionally, the enlarged relief region 56 of the slot 54 in the transition region 52 helps reduce the rubbing that might otherwise occur between the commissure posts 42 and the leaflets 80. That is, the leaflet section 32 continues substantially axially downward from the loops 70, as seen in Fig. 3, and the relief region 56 provides a small gap in the transition region 52 between the leaflet tissue and the sides of the slot 54 to help prevent rubbing therebetween.

In use, the assembled heart valve 20 as seen in Fig. 2 is initially provided in a

radially compacted configuration (not shown). Preferably, the valve 20 is loaded about a balloon catheter and within a delivery cannula. The balloon catheter with the valve 20 loaded thereon is than passed through the patient's vasculature (or through an access port in the chest) into proximity with the host annulus. Alternatively, where the chest of the patient is opened, the reduced size valve 20 is inserted into position using a holder.

Once in position within the annulus of the valve being replaced, the balloon (or other expanding means) causes the tubular base 40 to expand into contact with the annulus. Actually, because the commissure posts 42 and fabric section 34 surround tubular base 40, these elements are compressed against the host annulus. Because the tubular base 40 is plastically-expandable, it substantially retains its expanded shape. A slight over-expansion of the tubular base 40 may be required to compensate for any elastic spring-back character of the material used. Again, barbs or staples may also be utilized to further secure the valve 20 and in place. Ultimately, the balloon catheter is deflated and removed from within the valve 20.

Expandable Heart Valve Assembled Post-Storage

Figs. 6-15 illustrate an expandable prosthetic heart valve 100 including, as best seen in Fig. 6, a leaflet subassembly 102 adapted to connect to a tissue-engaging base 104. The two components are both shown in Fig. 6 in their radially expanded configurations, though both are designed to be radially compressed and delivered through a catheter or cannula, for example. In contrast with the first embodiment, however, the two components are stored separately, and connected just prior to delivery into the body of the patient. In general, the two components provide a tissue-engagement ring and a relatively more flexible valve member having fluid occluding surfaces. It should be understood that configurations of these two connectable components other than those specifically shown may be encompassed by the appended claims.

As seen in Fig. 6, the leaflet subassembly 102 comprises an elastic wireform 106 supporting a plurality of prosthetic leaflets 108, and a fabric skirt 110. The wireform 106 comprises a continuous undulating pattern of alternating commissures 112 and cusps 114. Preferably, the valve 100 is a tri-leaflet type, such that the wireform 106 has three commissures 112 and three cusps 114, with three leaflets 108 support thereby. In particular, each leaflet 108 is desirably attached to adjacent commissures 112, and along

the entire arcuate cusp 114 therebetween. As will be described in more detail below, the leaflets 108 each attach to a fabric covering 116 around the wireform cusps 114. In a preferred embodiment, the elastic wireform 106 is formed of a biocompatible, elastic material, preferably metallic. For example, the elastic wireform 106 may be formed of stainless-steel, titanium, or Elgiloy. Alternatively, the elastic wireform 106 may be formed from a biocompatible polymer, such as Delrin or polyacetyl. In this sense, therefore, the term "wire" in wireform should not be construed as limiting the material to metallic.

Fig. 7 illustrates an assembled valve 100 with the fabric skirt 110 shown in Fig. 6 removed for clarity. That is, the fabric skirt 110 is sized to drape outside of and surround the tissue-engaging base 104, but is removed in Fig. 7 to show the connection details between the base and the leaflet subassembly 102. The valve 100 defines an inflow end 120 and an outflow end 122.

Fig. 9 illustrates an exemplary leaflet 108 having an arcuate cusp edge 124 opposite a linear coapting edge 126. The cusp edge 124 is generally semi-circular, and terminates at commissure portions 128. A pair of oppositely-directed tabs 130 extend outward from both ends of the coapting edge 126, and are seen in Fig. 6 prior to attachment to the wireform 106. That is, the tabs 130 from adjacent leaflets 108 join together and pass through the inverted U-shaped commissures 112 of the elastic wireform 106. In a preferred embodiment, each leaflet 108 is formed from pericardial tissue, such as bovine or equine pericardium, or a synthetic material, that has been suitably treated to render it biocompatible.

With reference again to Fig. 6, the cusp edge 124 of each leaflet 108 is shaped so as to follow a cusp 114 of the elastic wireform 106. The fabric skirt 110 extends to an inflow edge 132 from each of the cusps 114, and when the skirt is assembled to the tissue-engaging base 104, the inflow edge extends substantially to the inflow end 120 (Fig. 7) of the valve. The fabric skirt 110 further terminates at outflow edges 134 between adjacent wires of the wireform commissures 112, below the leaflet tabs 130 extending therethrough. The skirt 110 may be made of a biocompatible fabric such as polyester, or of other suitable biocompatible sheet material.

The leaflet subassembly 102 attaches to the tissue-engaging base 104 at discrete locations, securely coupling each of the commissures 112 and cusps 114 of the elastic

wireform 106 to the base. As seen best in Fig. 6, the tissue-engaging base 104 comprises a tubular plastically-expandable member 140 having an inflow rim 142 and outflow rim 144. A plurality of commissure posts 146 are either rigidly attached to, or securely coupled to, the tubular member 140 so as to extend generally axially beyond the outflow rim 144 in the outflow direction. Likewise, a plurality of cusp posts 148 are rigidly attached to, or securely coupled to, the tubular member 140 so as to extend beyond the outflow rim 144. Because the commissure posts 146 couple to the wireform commissures 112, they are longer than the cusp posts 148 that couple to the wireform cusps 114.

As illustrated, both the commissure posts 146 and cusp posts 148 extend through upper and lower sleeves 150a, 150b, respectively provided on the exterior of the tubular member 140, and are desirably axially secured therein. It should be noted that this is only one of numerous possible ways to rigidly couple upstanding posts to a plastically-expandable tubular member. However, the posts 146,148 are desirably located on the outside of the tubular member 140 so as not to interfere with a balloon for expanding the tubular member from the inside, nor to interfere with blood flowing through the valve. It should also be noted that in a reverse configuration, the posts 146, 148 may be initially attached to the wireform commissures 112 and cusps 114, respectively, as part of the leaflet subassembly 102 and subsequently connected to mating structures (not shown) provided on the tissue-engaging base 104.

A plurality of connectors are provided for attaching the elastic wireform 106 to the posts 146, 148 of the tissue-engaging base 104. In particular, as seen in Fig. 6, each commissure post 146 provides a lower commissure connector 160 thereon. Likewise, each cusp posts 148 provides a lower cusp connector 162. In the illustrate embodiment, the outflow end of each of the posts 146, 148 is bent 90° to face radially inward, and a groove formed therein defines the respective connectors 160,162.

Figs. 9-11 illustrate the configuration of the connection between the leaflet subassembly 102 and tissue-engaging base 104 at the commissures of the valve. With specific reference to Fig. 10, the lower commissure connector 160 of the commissure post 146 mates with an upper commissure connector 164 of an insert 166 (isolated in Fig. 8) secured to the wireform commissure 112. As seen in Fig. 11, adjacent leaflets 130 extend radially outward between spaced wires of the wireform 106 and wrap around the

insert 166 to be connected on an outer side thereof with a plurality of stitches 168. Fig. 8 illustrates one form of the insert 166 wherein the upper commissure connector 164 comprises a downwardly opening partial circle which mates with the groove of the lower commissure connector 160, as seen in Fig. 10. In this manner, the commissures 112 are securely fastened with respect to the tissue-engaging base 104 by virtue of the interaction between the lower commissure connector 160 and upper commissure connector 164.

With reference again to Figs. 6 and 7, a plurality of upper cusp connectors 170 attach to the approximate midpoint of each of the cusps 114 of the wireform 106. Each upper cusp connectors 170 is configured and positioned to mate with the lower cusp connector 162 formed on each of the cusp posts 140. Again, the upper cusp connector 170 may be provided with a downwardly opening partial circle that mates with the groove of the lower cusp connector 162.

With specific reference to Fig. 12, certain constructional details of the valve cusps are further illustrated. The fabric covering 116 of the wireform 106 is shown as a tube having an upper fabric extension 180 and a lower fabric extension 182 sandwiched around a radial portion 184 of the upper cusp connector 170. The upper cusp connector 170 extends outward and bends 90° downward to mate with the lower cusp connector 162. The upper fabric extension 180 continues outward and downward in the fabric skirt 110. The lower fabric extension 182 bends 180° underneath the cusp edge 124 of the respective leaflet 108. Stitching 186 secures the combined layers of the upper extension 180, radial portion 184, first part of the lower extension 182, leaflet cusp 124, and wrapped-around portion of the lower extension 182.

Desirably, both the insert 166 and upper cusp connector 170 are made from a suture-permeable material having sufficient strength to maintain the connections between the leaflet subassembly 102 and tissue-engaging base 104. For example, the insert 166 and connector 170 may be made of Delrin, or other suitable polymer. As illustrated, each of the connectors 164 and 170 are partial circles that fit around tubular grooves in the respective posts 146,148. Of course, other arrangements are possible, and the present invention should not be considered limited to those connectors illustrated.

As with the earlier embodiment, the valve 100 utilizes a low-stress connection between the leaflets 108 and the elastic wireform 106. In particular, as seen in Fig. 11, the provision of the insert 166 provides a clamping force during diastole between the

insert and the wireform 106 against the portion of the leaflets 108 therebetween. The stitching 168 is not subjected to direct tensile stresses, and there is thus less chance for tearing.

Leaflet subassembly 102 is desirably stored in its expanded state, as seen in Fig. 6 (which, as mentioned, does not illustrate the commissure attachment structure). That is, the wireform 106 and leaflets 108 may be stored immersed in a preservative such as glutaraldehyde in a sterile container until needed. In this regard, the prosthetic leaflets 108 remain in their functional shape during storage. This greatly reduces adverse wrinkling or other permanent or semi-permanent damage to the leaflets over time, and improves the quality of the valve 100. At the same time, the base 104 desirably does not include any bioprosthetic or otherwise perishable components, and thus may be stored in a separate dry sterile container. This method also permits the combination of different bases with any one leaflet subassembly 102, or visa versa. For example, the type of attachment mechanism (i.e., staples, barbs, sutures, etc.) of the base 104 to the annulus may be selected by the surgeon, with different bases being attached in different ways, and all being combinable with a particular leaflet subassembly 102. Also, the type of base may be selected based on patient indications; with a self-expanding base being preferred in some situations and a balloon-expanded base in others.

In use, the leaflet subassembly 102 is compressed from its expanded configuration to a size corresponding to the tissue-engaging base 104 in its compressed state (not shown). If the tissue-engaging base 104 is plastically deformable then it is initially supplied in its compressed state. Alternatively, a self-expandable base 104 will have to be compressed either before or after connection to the similarly configured leaflet subassembly 102. Compression of the leaflet subassembly 102 (and base if necessary) may be accomplished using a tapered mandrel through which the subassembly is passed, or with a cinch or other direct constricting means. The two components are then connected together, just prior to insertion into the patient's body, and the valve 100 delivered simultaneously to the host annulus site. To connect the two components, the fabric skirt 110 is passed around the outside of the commissure posts 146 and around the tubular member 140. Each of the upper connectors 164 and 170 are caused to mate with the lower connectors 160, 162. In the illustrated embodiment, such a mating operation simply requires forcing each of the partial circles defining the upper connectors over the

grooves defining the lower connectors. The partial circles open slightly, but then spring inward when the connectors snap together and the groove is fully seated.

There are a number of ways to deliver the valve 100 to the aortic annulus. For one, the tubular member 140 may be mounted around a balloon catheter and inserted via an introducer or other cannula into the patient's vasculature and to the aorta. Alternatively, an open-heart procedure or less-invasive port procedure may be utilized, with the tissue-engaging base 104 being delivered to the host annulus using a holder or other such means.

Fig. 16A depicts a sectional view of a heart 200 having a left ventricle chamber 202 opening to an ascending aorta 204 through an aortic annulus 206. The ascending aorta 204 continues over an aortic arch 208, and branches off into several upper body arteries 210 before descending to the abdominal aorta (not shown). As mentioned above, the expandable valves of the present invention can be delivered into proximity of the aortic annulus 206 in several ways, including through the patient's vasculature as shown.

In particular, a valve delivery catheter 212 is shown in the cutaway portion of the ascending aorta 204, having been introduced along the direction of the arrow 214 so that a distal end thereof lies adjacent the aortic annulus 206. The catheter 212 can be introduced percutaneously into the patient's arterial system (e.g. into a peripheral artery such as the femoral artery) and advanced to the ascending aorta 204. The catheter shaft preferably has a length of at least about 80 cm, usually about 90-100 cm, to allow transluminal positioning of the shaft from the femoral and iliac arteries to the ascending aorta. Alternatively, the shaft may have a shorter length, e.g. 20-60 cm, for introduction through the iliac artery, through the brachial artery, through the carotid or subclavian arteries, or through a penetration in the aorta itself. In the femoral approach, the catheter is long enough and flexible enough to traverse the path through the femoral artery, iliac artery, descending aorta and aortic arch. At the same time, the catheter has sufficient pushability to be advanced to the ascending aorta by pushing on the proximal end, and has sufficient axial, bending, and torsional stiffness to allow the physician to control the position of the distal end, even when the catheter is in a tortuous vascular structure. Alternatively, the catheter 212 may be passed through a port between ribs in the patient's thorax above the heart and through an incision in the aortic arch 208, in a so-called minimally-invasive procedure.

Techniques for introducing catheters into the human vasculature are well-known, and typically involve the introduction of a guidewire 216 first, followed by an obturator or dilator (not shown) within a sheath 218. The dilator facilitates introduction of the catheter sheath 218 into the vasculature, and is then removed, though the guidewire 216 typically remains in place. Subsequently, a valve of the present invention, such as valve 100 seen in Figs. 6-15, is delivered over the guidewire 216 and to the distal end of the sheath 218. In accordance with one aspect of the present invention, the valve 100 includes a balloon-expandable portion and thus is mounted over an expansion balloon 222. To facilitate passage of the valve 100 through the sheath 218, a pusher 224 may be used.

Fig. 16B illustrates a second step in the exemplary valve delivery procedure in which the sheath 218 is retracted in a proximal direction as indicated by arrow 226. Retraction of the sheath 218 exposes the valve 100, which is positioned within the aortic annulus 206 with the assistance of fluoroscopy and radiopaque markers, ultrasonic imaging, or the like. If the valve 100 includes self-expanding components, retraction of the sheath 218 releases the outer restraint on the valve and permits it to expand into contact with the annulus 206. In the illustrated embodiment, however, the tubular member 140 of the tissue-engaging base 104 is plastically-deformable and retains its radially constricted configuration after retraction of the sheath 218. Because of the rigid connections between the leaflet subassembly 102 and the base 104, the subassembly also remains in its constricted configuration.

Finally, in Fig. 16C, the balloon 222 is inflated to cause the tissue-engaging base 104 to radially expand into contact with the aortic annulus 206, as indicated by the arrows 230. Simultaneously, the leaflet subassembly 102 radially expands by virtue of the rigid connection with the base 104, and by virtue of its spring bias. A balloon inflation catheter 232 is seen projecting from the pusher 224 and through the leaflet subassembly 102. With reference back to Fig. 6, the fabric skirt 110 is captured between the tubular member 140 and the surrounding tissue, and is in direct contact therewith. Therefore, by virtue of the continuous connection between the cusp edges 124 of the leaflets 108 and the fabric skirt 110, the skirt forms a flow channel for blood entering the inflow end 120 of the valve 100. Again, the plastically-expandable tubular member 140 may be slightly over-expanded to account for any spring-back in the material. Further, as

mentioned above, the tubular member 140 may include staples or barbs or other such attachment structure for securely locating the valve 100 within the annulus 206.

Once the valve 100 is fully expanded and securely attached to the annulus 206, the balloon 222 is deflated and removed. Such an operation may include elongating the balloon 222 in the distal direction and reducing its radial dimension by, for example, twisting. Care must be taken so as not to damage the leaflets within the subassembly 102 during retraction of the balloon 222 therethrough. After the balloon 222 has been retracted within the sheath 218, the entire catheter 212 is removed from the patient.

The fully formed valve 100 has a number of distinct advantages over prior expandable valves. For example, as mentioned above, the prosthetic leaflets 108 may be stored in the final, uncompressed implantation shape. This is in contrast to prior expandable valves where the entire valve may be initially compressed such that the leaflets are stored in a compressed state. Consequently, valves of the prior art can be stored for years prior to use, and permanent wrinkling of the compressed leaflets may be a real problem.

Furthermore, each of the leaflets 108 is supported substantially entirely around the undulating wireform 106, which has proven to provide optimal valve performance. Also, separate leaflets are used as opposed to a continuous tube, as in the first embodiment. Additionally, the advantageous low-stress attachment structure of the leaflet tabs 130 to the wireform commissures 112 further increases the durability of the valve.

While the foregoing is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Moreover, it will be obvious that certain other modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. An expandable prosthetic heart valve for placement in a host heart valve annulus, comprising:

an expandable stent system adapted to be delivered in a collapsed state to an implantation site and expanded; and

a plurality of prosthetic leaflets attached to the stent system, each leaflet having an approximately semi-circular cusp edge terminating at each end in commissure portions, and a coapting edge extending between the commissure portions, each leaflet being attached to the stent system substantially entirely along the cusp edge and at both commissure portions, with a coapting edge remaining unattached.

2. The heart valve claim 1, wherein the expandable stent system comprises:

an expandable generally annular tissue-engaging base adapted to be delivered in a radially collapsed state and expanded into contact with the host annulus; and

an elastic generally annular wireform attached to the base and defining a plurality of upstanding commissures and a plurality of arcuate cusps between adjacent commissures, the prosthetic leaflets being attached to the wireform along the cusps and commissures, wherein the wireform and leaflets are configured to be radially compressed.

3. The heart valve of claim 2, including a plurality of upstanding posts attached to one of the tissue-engaging base and elastic wireform, each post having a connector, and wherein a plurality of mating connectors are provided on the other of the tissue-engaging base and elastic wireform for mating with the post connectors.

4. The heart valve of claim 3, wherein the posts and mating connectors are provided for each commissure and each cusp of the elastic wireform so that the valve includes a number of posts and mating connectors equal to the number of commissures plus the number of cusps.

5. The heart valve of claim 1, wherein the expandable stent system includes an undulating wireform defining a plurality of commissures and a plurality of cusps between adjacent commissures, wherein the cusp edge of each of the prosthetic leaflets attaches along a wireform cusp, and the commissure portions of each leaflet terminate in outwardly extending tabs that each attach to a wireform commissure, wherein tabs from adjacent leaflets are attached together at each of the wireform commissures.

6. The heart valve of claim 5, wherein the tabs from adjacent leaflets extend outward between spaced wires of the wireform commissure, and wherein inserts are provided around which the adjacent leaflet tabs wrap and are secured, the inserts being size larger than the distance that the wires of wireform commissure are spaced apart so as to maintain the leaflet tabs on the outside of the wireform commissure.

7. An expandable prosthetic heart valve for placement in a host heart valve annulus, comprising:

an expandable stent portion defining an inflow end of the valve adapted to be delivered in a collapsed state and expanded into contact with the host annulus; and

an elastic leaflet portion connectable to the stent portion to form a one-way flow occluder on an outflow end of the valve, the leaflet portion including an elastic wireform defining alternating cusps and commissures and prosthetic tissue attached substantially entirely along the cusps and commissures of the wireform.

8. The heart valve of claim 7, wherein the stent portion includes a tubular member and a plurality of connectors, and wherein a plurality of connectors are provided on the elastic wireform for mating with the tubular member connectors.

9. The heart valve of claim 8, wherein the wireform connectors are provided on each commissure and on each cusp of the wireform so that the valve includes a number of mating connectors equal to the number of commissures plus the number of cusps.

10. The heart valve of claim 7, wherein the prosthetic tissue comprises a plurality of individual leaflets secured along the alternating cusps and commissures of the elastic wireform.

11. The heart valve of claim 10, wherein the wireform has a fabric covering, and wherein the individual leaflets are stitched along the fabric covering, the fabric covering continuing toward an inflow end of the valve in a skirt that surrounds the stent portion and is adapted to be captured between the expanded stent portion and the host annulus.

12. The heart valve of claim 11, further including a plurality of posts rigidly connected to the stent portion and extending upward within the skirt into mating connection with the elastic wireform.

13. The heart valve of claim 10, wherein each leaflet has an approximately semi-circular cusp edge terminating at each end in commissure portions, and a coapting edge extending between the commissure portions, and the commissure portions of each leaflet terminate in outwardly extending tabs that each attach to a wireform commissure, wherein tabs from adjacent leaflets extend outward between spaced wires of the wireform commissure, and wherein inserts are provided around which the adjacent leaflet tabs wrap and are secured, the inserts being size larger than the distance that the wires of wireform commissure are spaced apart so as to maintain the leaflet tabs on the outside of the wireform commissure.

14. An expandable prosthetic heart valve for placement in a host heart valve annulus, comprising:

a leaflet subassembly having a wireform defining a plurality of upstanding commissures and a plurality of arcuate cusps extending between adjacent commissures, a midpoint of each cusp being located approximately equidistant from the adjacent commissures;

a generally annular tissue-engaging base defining an axis; and

a system for connecting the leaflet subassembly and the tissue-engaging

base, including a plurality of mating connectors on the leaflet subassembly and on the tissue-engaging base, wherein one connector each is provided at each commissure, and one at each cusp midpoint.

15. The heart valve of claim 14, wherein the tissue-engaging base comprises an expandable tubular member that is deliverable to the host annulus in a collapsed state and expandable into contact with the host annulus to secure the valve therein.

16. The heart valve of claim 15, wherein the tissue-engaging base forms an inflow end of the valve, and wherein the system for connecting the leaflet subassembly and tissue-engaging base includes a plurality of posts coupled to the tubular member and having varying lengths extending away from the inflow end of the valve, with a first plurality of posts each having a first length for connecting with the wireform commissures, and a second plurality of posts each having a second length shorter than the first length for connecting with the wireform cusps.

17. The heart valve of claim 16, wherein the mating connectors are configured to be joined together by axial compression.

18. The heart valve of claim 17, wherein the mating connectors are adapted to be snap-fit together.

19. A prosthetic heart valve, comprising

a support stent including a tubular base along an inflow end a plurality of generally axially-extending commissure posts disposed evenly around the tubular base on an outflow end thereof; and

a flexible tubular member having a prosthetic section attached to the commissure posts so as to define a plurality of the prosthetic valve leaflets between the posts, and a fabric section connected to the base.

20. The heart valve of claim 19, wherein the prosthetic section and fabric section are both generally tubular and attached together at a seam.

21. The heart valve of claim 20, wherein the seam is spaced from the outflow end of the tubular base so that only the fabric section of the flexible tubular member contacts the tubular base.

22. The heart valve of claim 19, wherein the commissure posts each have an axial slot, and wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post, and further including a plurality of inserts sized larger than the slots, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot.

23. The heart valve of claim 22, wherein the commissure posts are integrally formed with the base, the base and commissure posts being initially formed from a flat section of material, wherein the commissure posts initially extend from the inflow end of the base and are bent 180° to extend alongside the base and project beyond the base at the outflow end thereof.

24. The heart valve of claim 22, wherein the commissure posts each comprise:

a first axial section extending from the inflow end of the base and spaced radially therefrom;

a second axial section defining the outflow extent of the post and a portion of the axial slot, the second section being radially inwardly offset from the first section; and

a transition region between the first and second sections, wherein an enlarged portion of the axial slot is defined in the transition region.

25. The heart valve of claim 19, wherein the base is plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

26. A prosthetic heart valve, comprising:

a support stent including a tubular base along an inflow end and a plurality

of generally axially-extending commissure posts each having an axial slot and being disposed evenly around the tubular base on an outflow end thereof; and

a flexible tubular member having an outflow edge,

wherein the tubular member is primarily located within the posts except for a plurality of loops that extend outward through each slot on each post, and further including a plurality of inserts sized larger than the slots, each of which insert is captured within a loop extending outward through each slot to retain the loop through the slot, the outflow edge of the tubular member defining a plurality of valve leaflets.

27. The heart valve of claim 26, wherein the tubular base is plastically-expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus.

28. A method of minimally-invasive heart valve replacement surgery on a patient, comprising:

providing an annular tissue-engaging base, the base being expandable from a collapsed state;

providing a generally annular elastic wireform subassembly having a plurality of prosthetic leaflets connected thereto, the elastic wireform subassembly having a relaxed, expanded size and a compressed, reduced size;

connecting the wireform and leaflets to the base to form a heart valve;

delivering the heart valve with the connected base in its collapsed state and wireform subassembly in its reduced size to an annulus of the patient's heart valve being replaced; and

expanding the base into its expanded state in contact with the annulus.

29. The method of claim 28, wherein the step of delivering the heart valve to the annulus is accomplished by passing the valve through the patient's vasculature.

30. The method of claim 29, wherein the step of delivering the heart valve to the annulus is accomplished by passing the valve through a catheter introduced into a

peripheral artery.

31. The method of claim 30, wherein the step of delivering the heart valve to the annulus is accomplished by passing the valve through a catheter introduced into the femoral artery and advanced through the iliac artery, abdominal aorta and aortic arch.

32. The method of claim 28, wherein the step of delivering the heart valve to the annulus is accomplished via a minimally-invasive port in the patient's chest.

33. The method of claim 28, wherein the tissue-engaging base is plastically-expandable from its collapsed state to its expanded state.

34. The method of claim 33, including the step of expanding the tissue-engaging base by inflating a balloon within the tissue-engaging base.

35. A method of heart valve replacement surgery on a patient, comprising:

providing a two-part heart valve, each part being expandable from a collapsed state;

storing the two parts of the heart valve in separate sterile containers;

connecting the two parts to form a heart valve just prior to the surgery;

delivering the heart valve in its collapsed state to an annulus of the patient's heart valve being replaced; and

expanding the base into its expanded state in contact with the annulus.

36. The method of claim 35, wherein the step of delivering the heart valve to the annulus is accomplished by passing the valve through the patient's vasculature.

37. The method of claim 36, wherein the step of delivering the heart valve to the annulus is accomplished by passing the valve through a catheter introduced into a peripheral artery.

38. The method of claim 37, wherein the step of delivering the heart valve to

the annulus is accomplished by passing the valve through a catheter introduced into the femoral artery and advanced through the iliac artery, abdominal aorta and aortic arch.

39. The method of claim 35, wherein the step of delivering the heart valve to the annulus is accomplished via a minimally-invasive port in the patient's chest.

40. The method of claim 35, wherein the step of providing a two-part heart valve comprises:

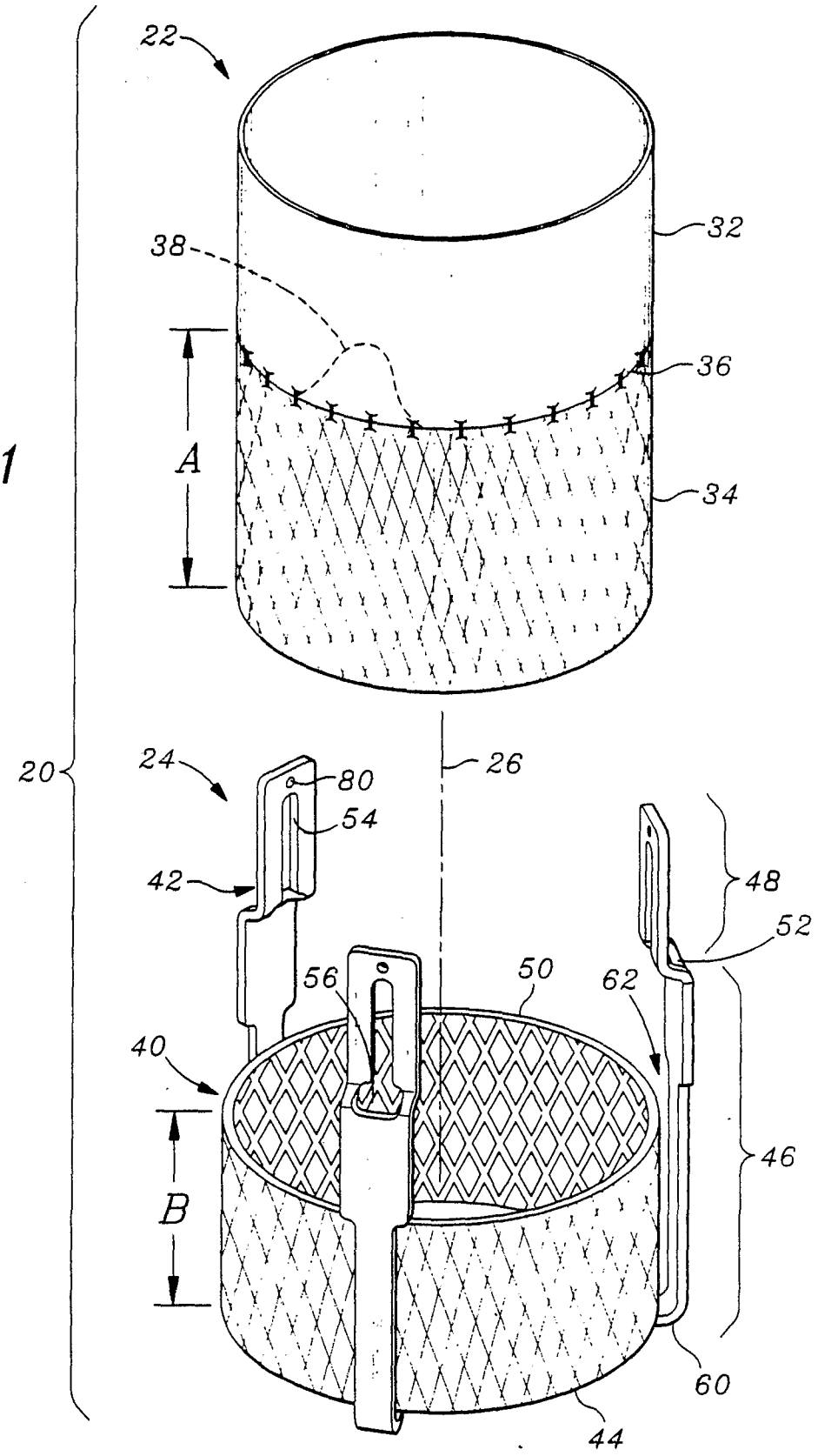
providing an annular tissue-engaging base, the base being expandable from a collapsed state; and

providing a generally annular elastic wireform subassembly having a plurality of prosthetic leaflets connected thereto, the elastic wireform subassembly having a relaxed, expanded size and a compressed, reduced size.

41. The method of claim 40, wherein the tissue-engaging base is plastically-expandable from its collapsed state to its expanded state.

42. The method of claim 41, including the step of expanding the tissue-engaging base by inflating a balloon within the tissue-engaging base.

Fig. 1



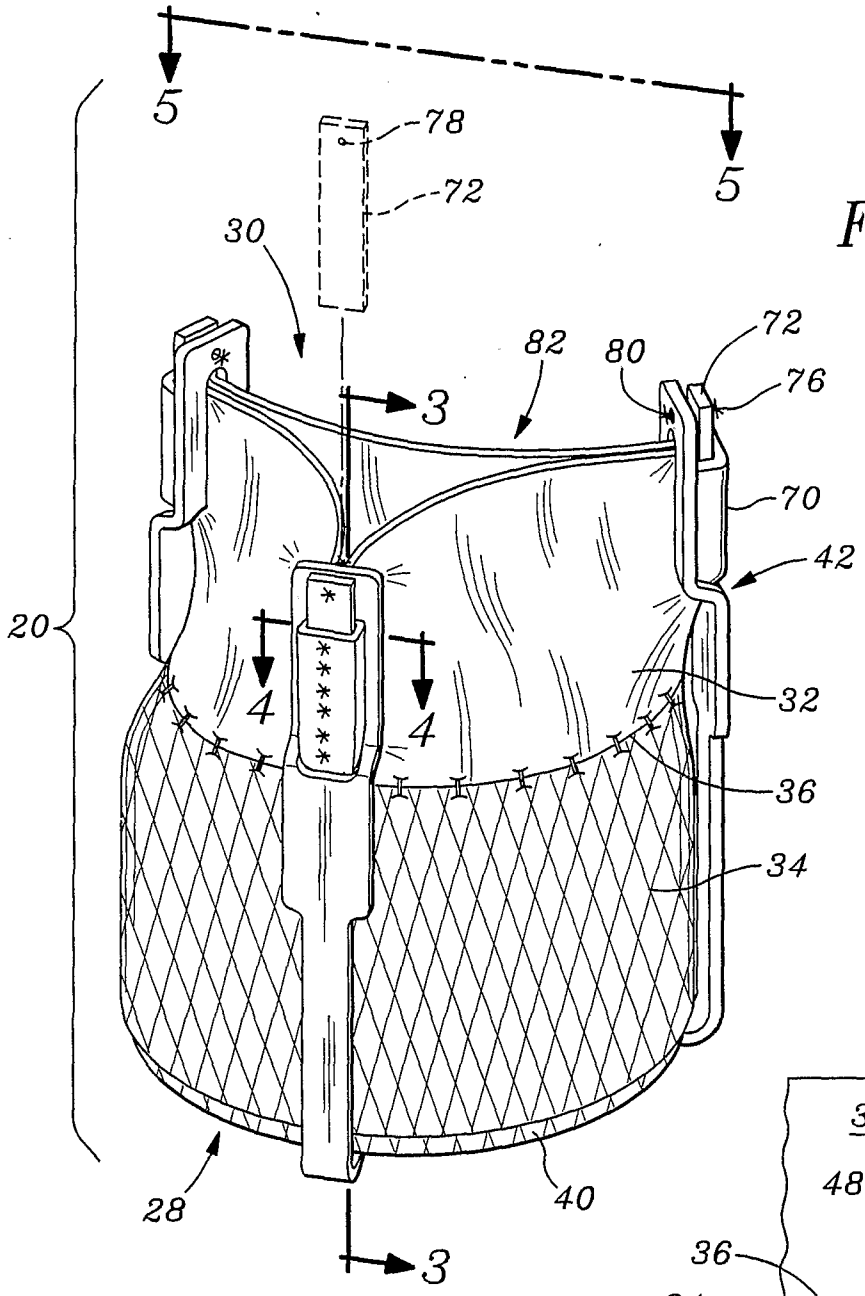

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Fig. 2

Fig. 3

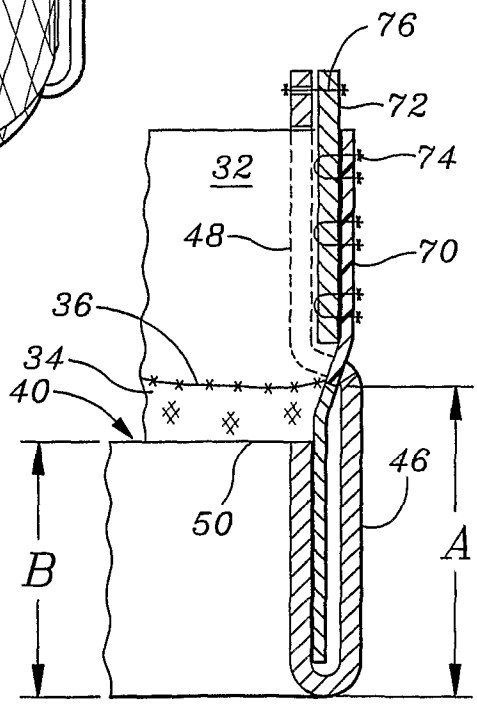

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Fig. 4

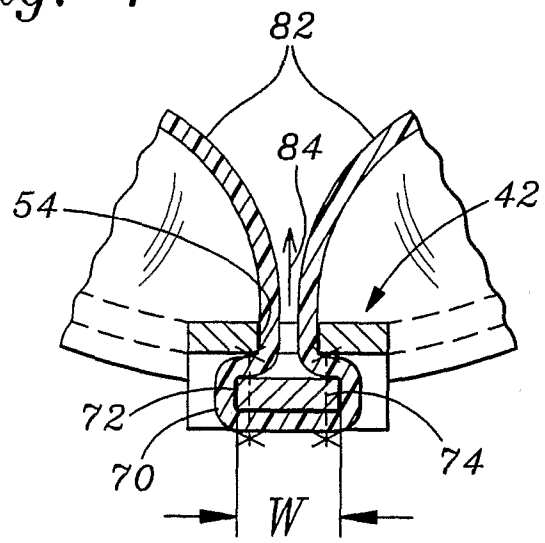


Fig. 5

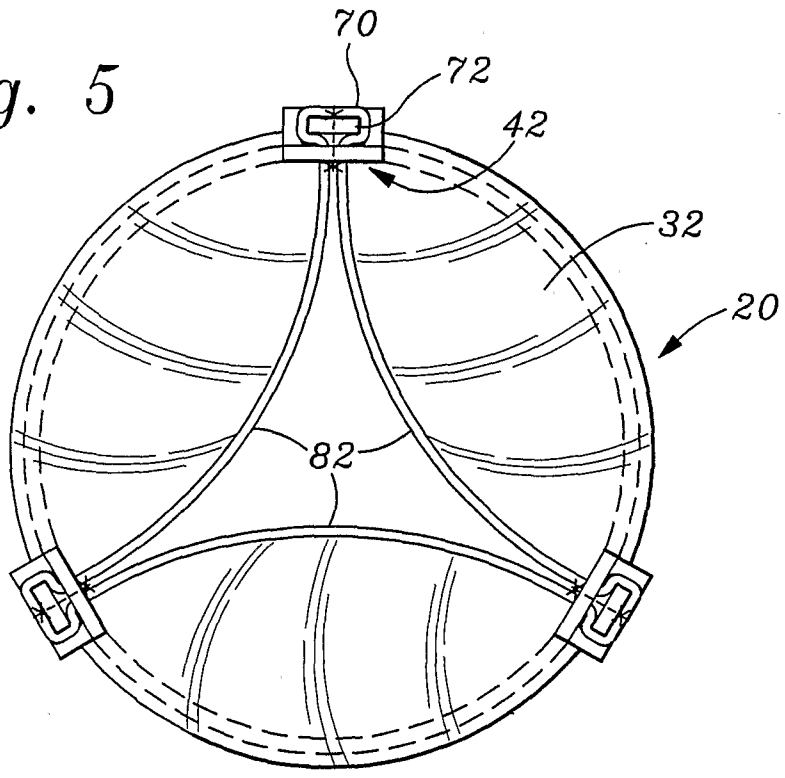


Fig. 6

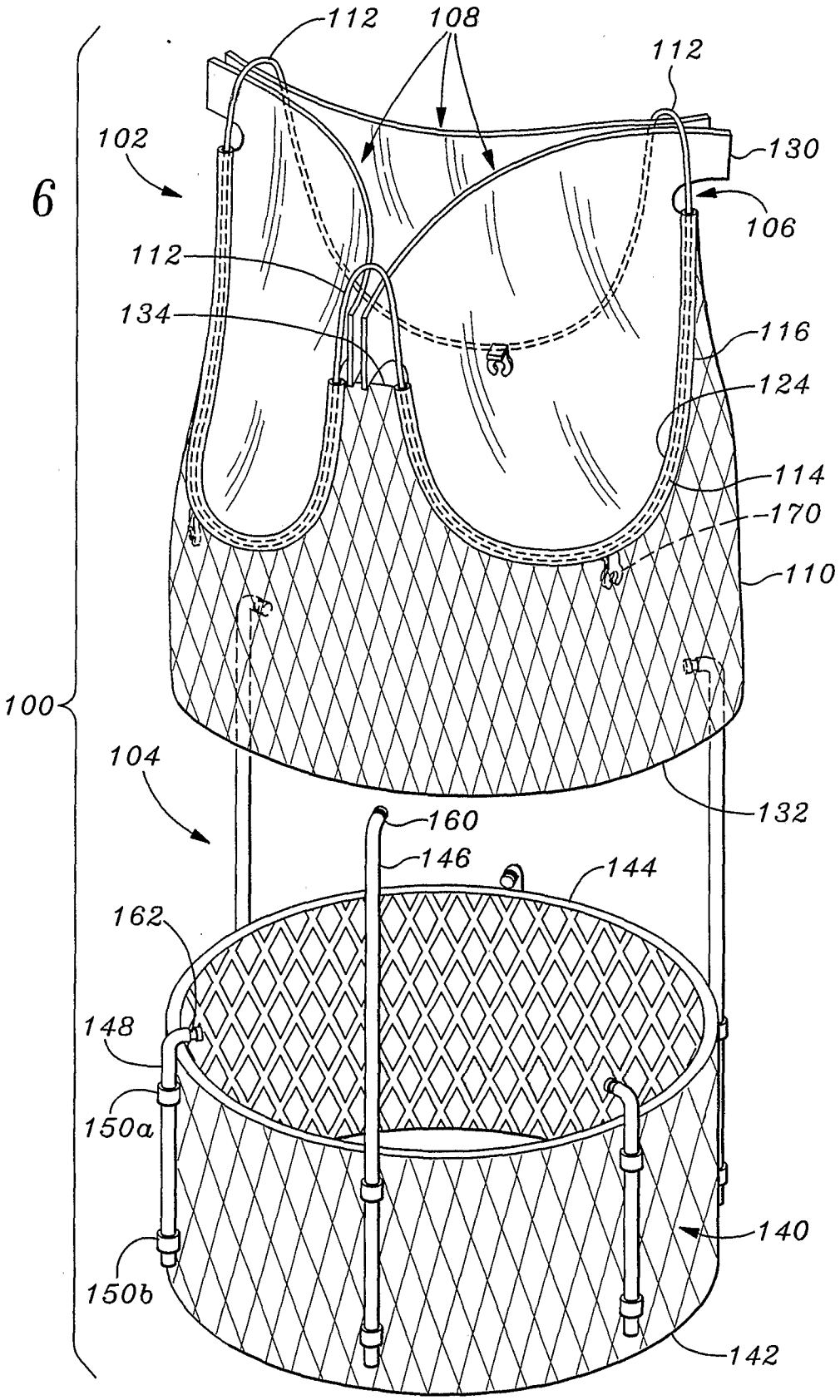

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Fig. 9

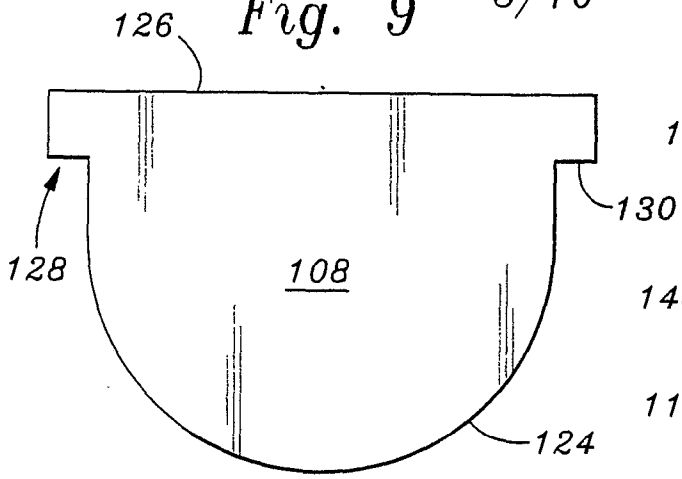
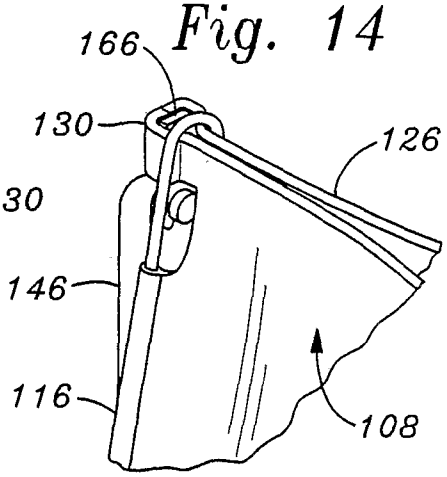


Fig. 14



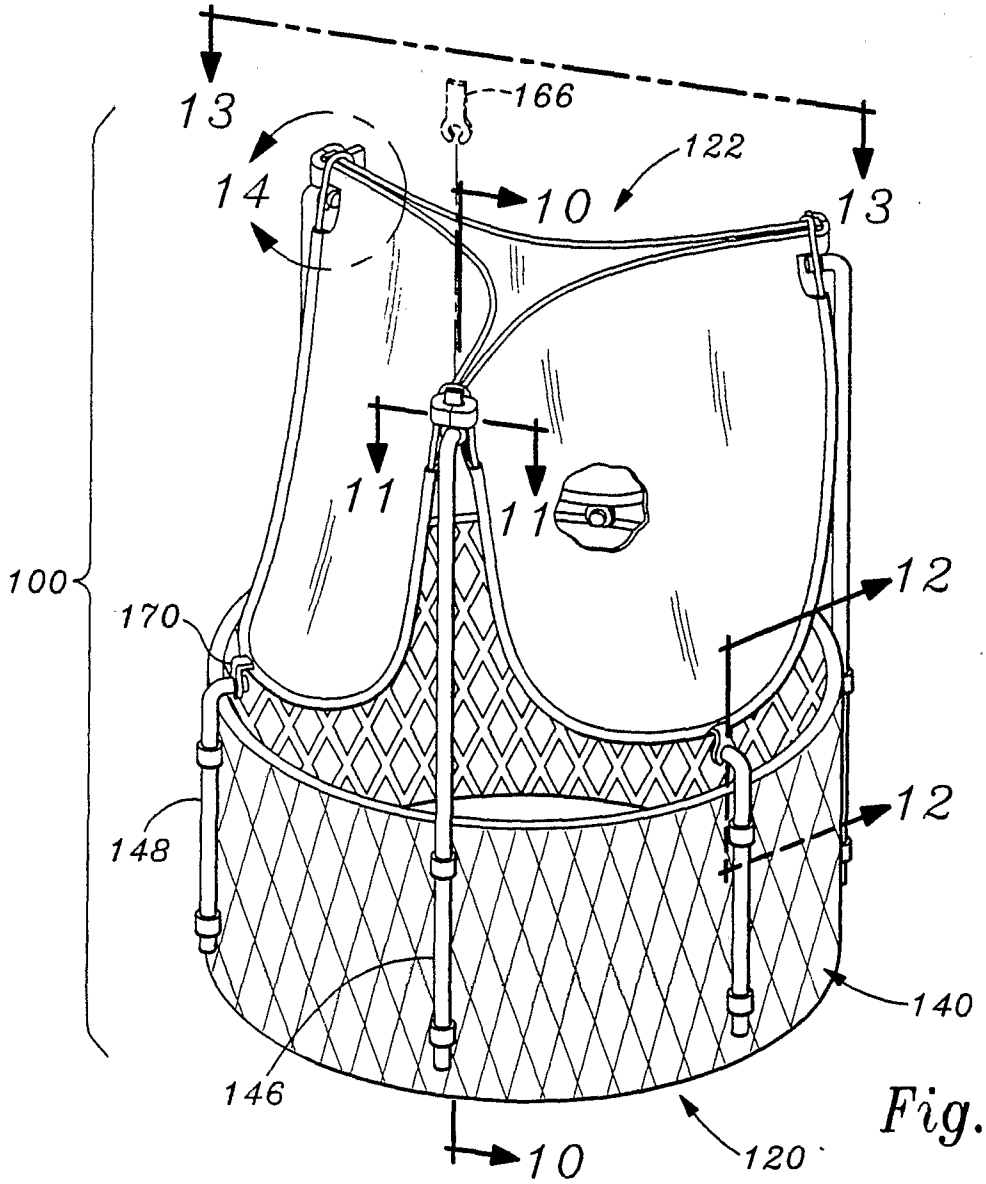


Fig. 7

Fig. 12

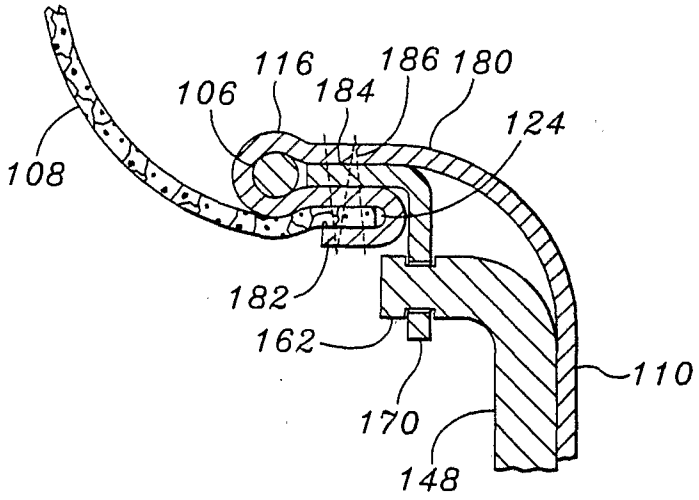


Fig. 8

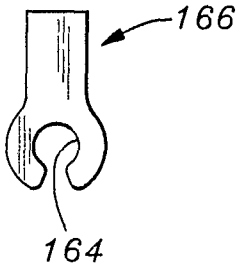


Fig. 10

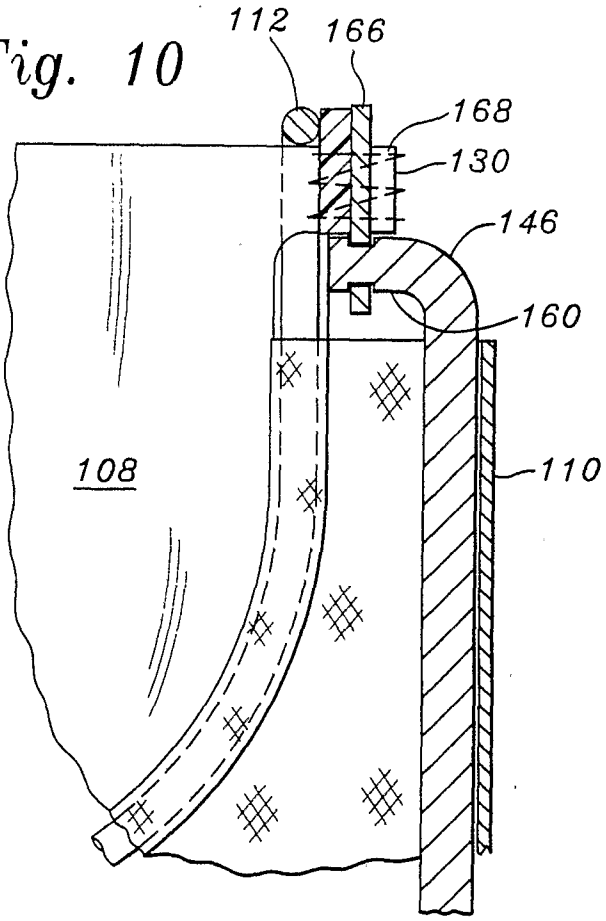


Fig. 11

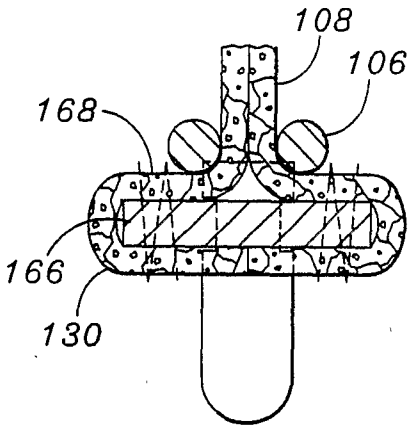


Fig. 15

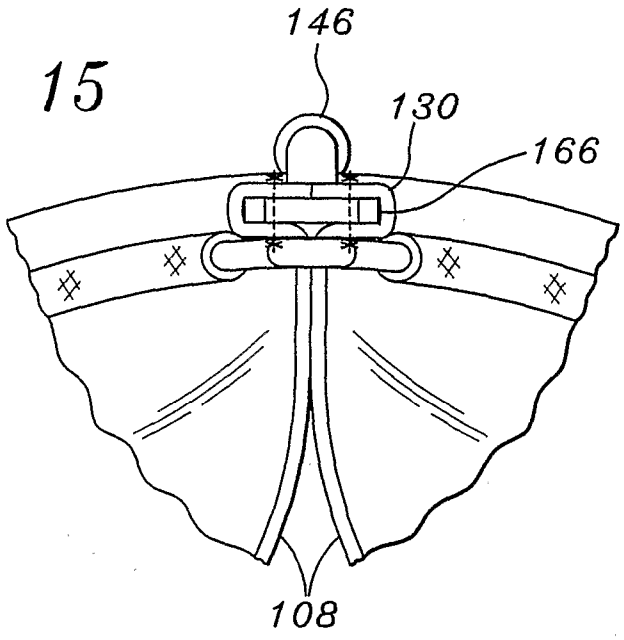
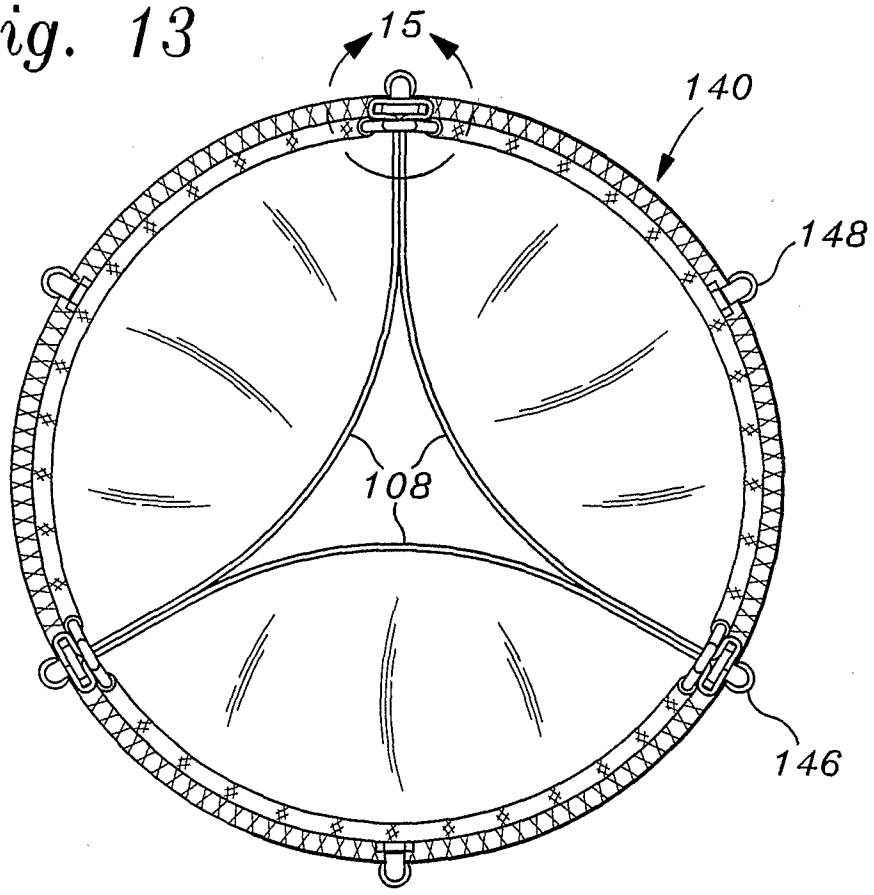


Fig. 13



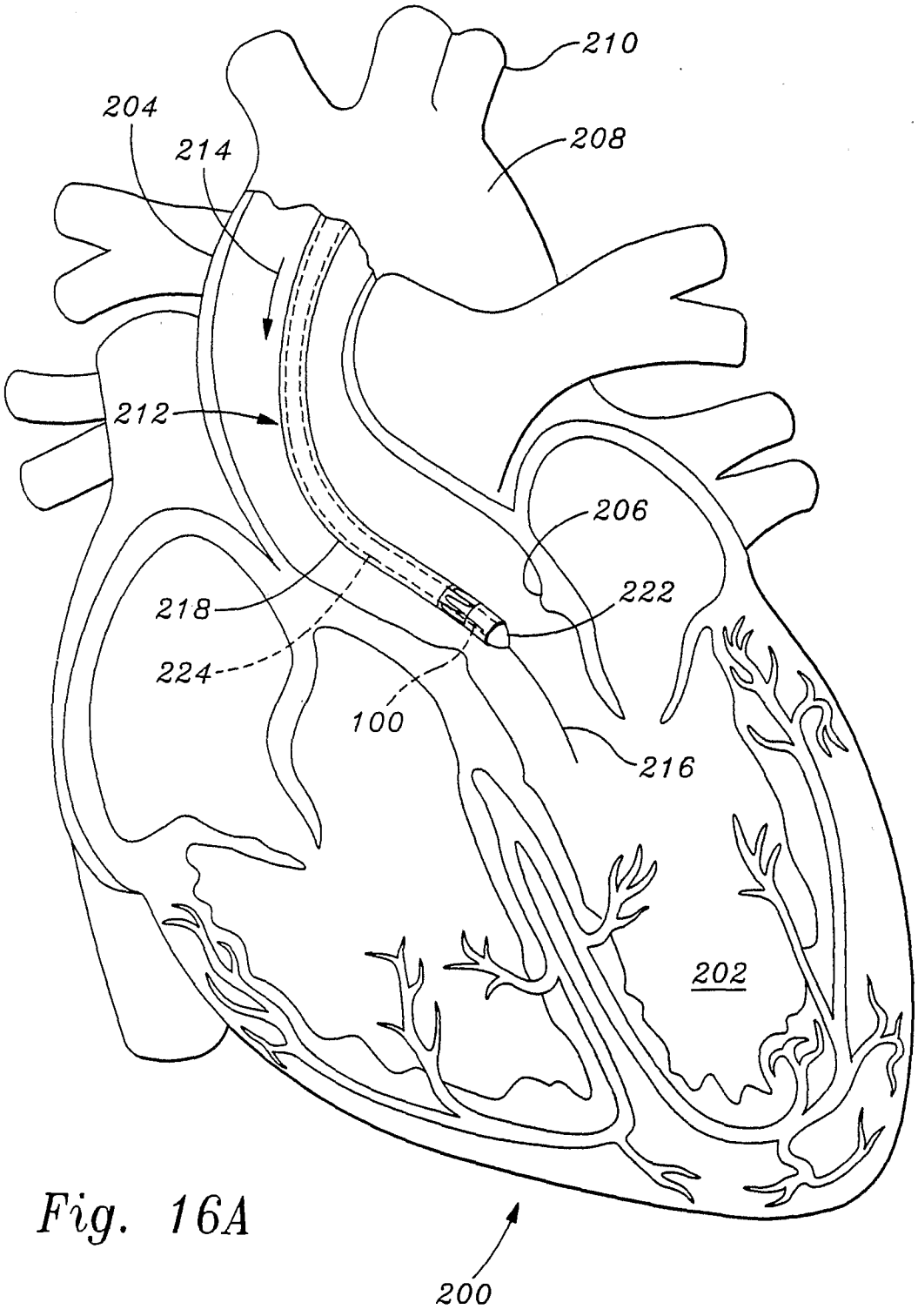


Fig. 16A

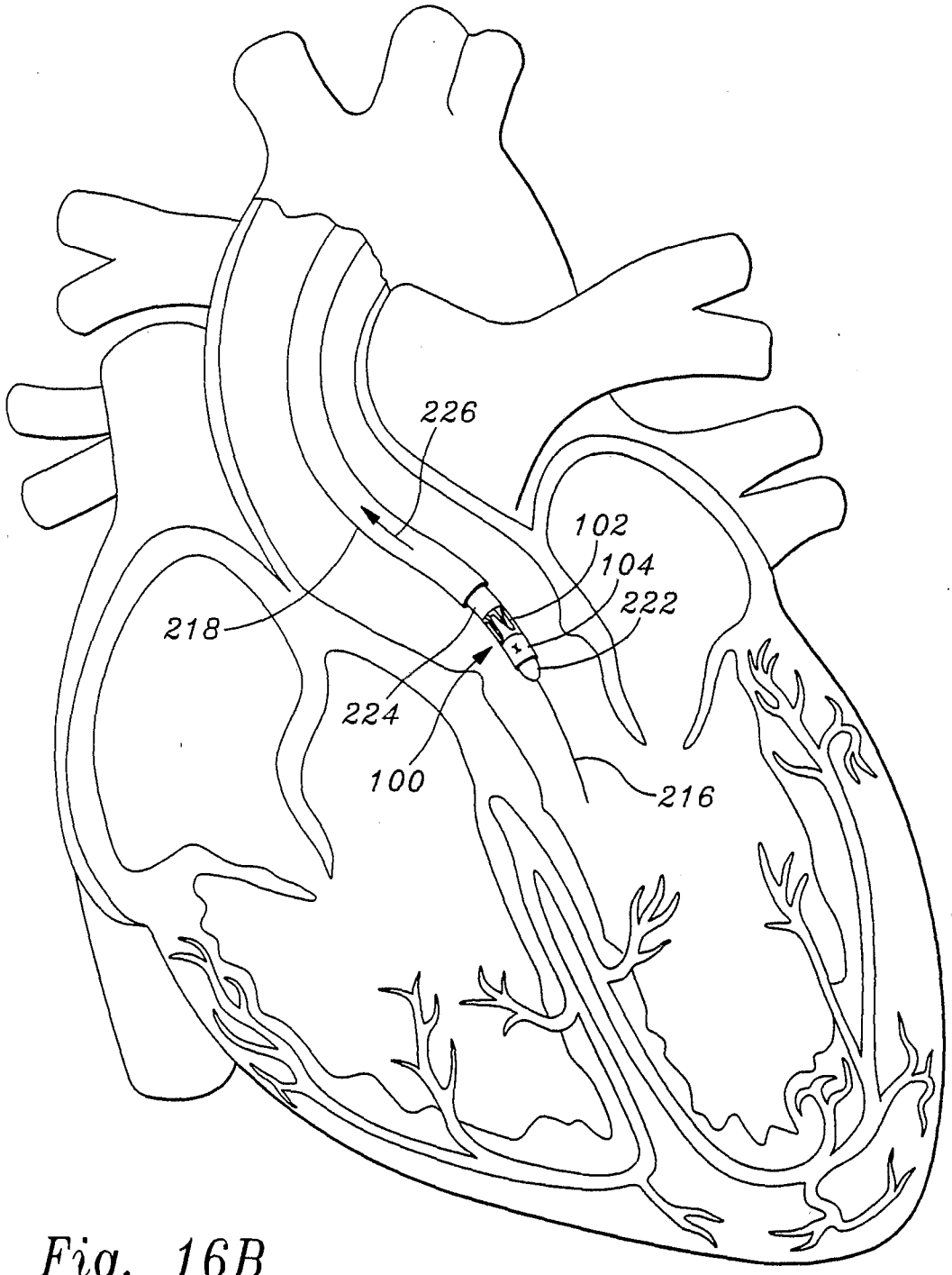


Fig. 16B

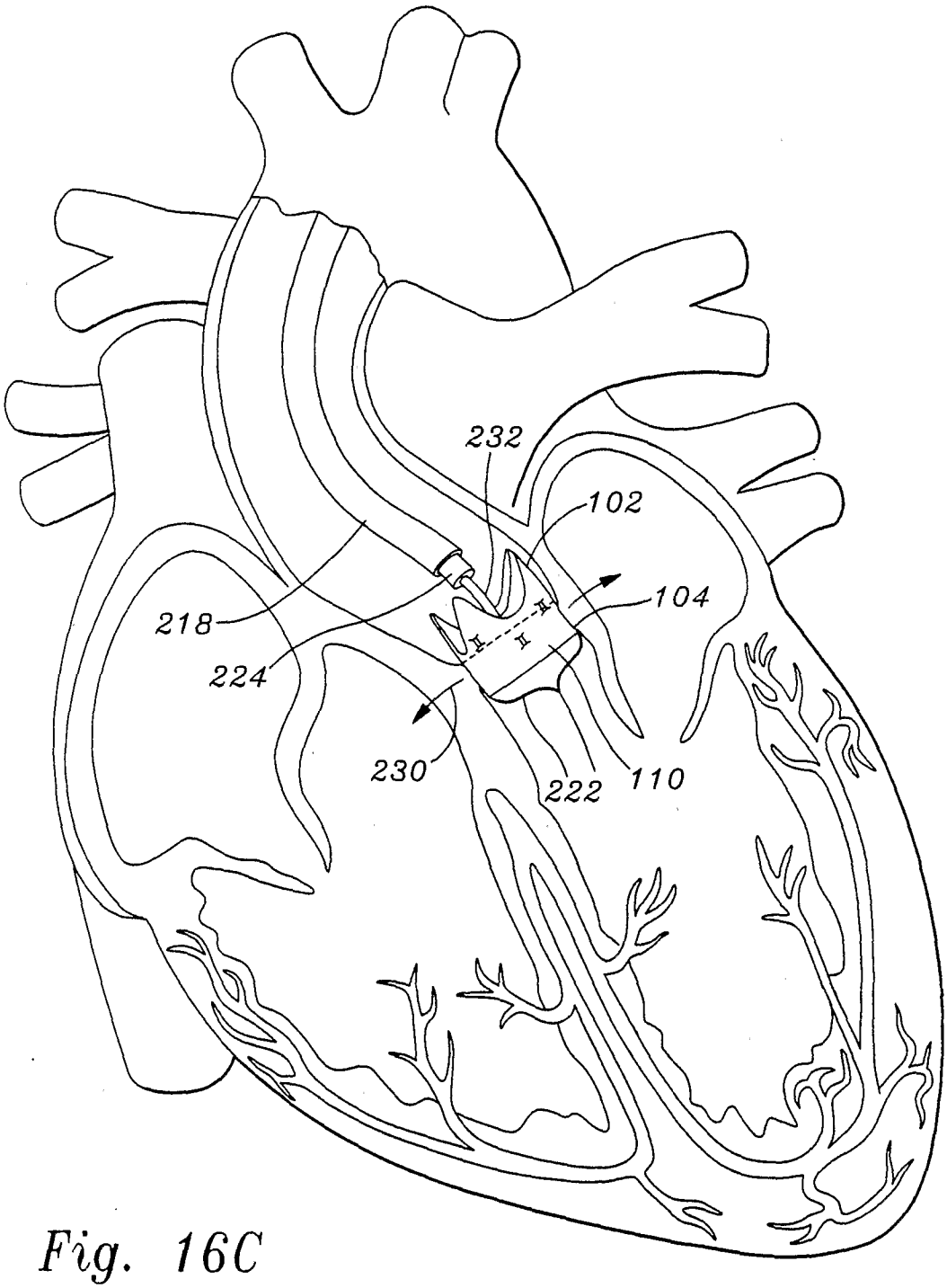


Fig. 16C

US 20040210304A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2004/0210304 A1

Seguin et al. (43) Pub. Date: Oct. 21, 2004

(54) PROSTHETIC VALVE FOR TRANSLUMINAL DELIVERY

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(73) Assignee: **COREVALVE, S.A.**, Paris (FR)

(21) Appl. No.: **10/772,101**

(22) Filed: **Feb. 4, 2004**

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/412,634, filed on Apr. 10, 2003, which is a continuation-in-part of application No. 10/130,355, filed on Nov. 26, 2002, and which is a continuation-in-part of application No. PCT/FR01/03258, filed on Oct. 19, 2001.
Said application No. 10/130,355 is a 371 of international application No. PCT/FR00/03176, filed on Nov. 15, 2000.

(30) **Foreign Application Priority Data**

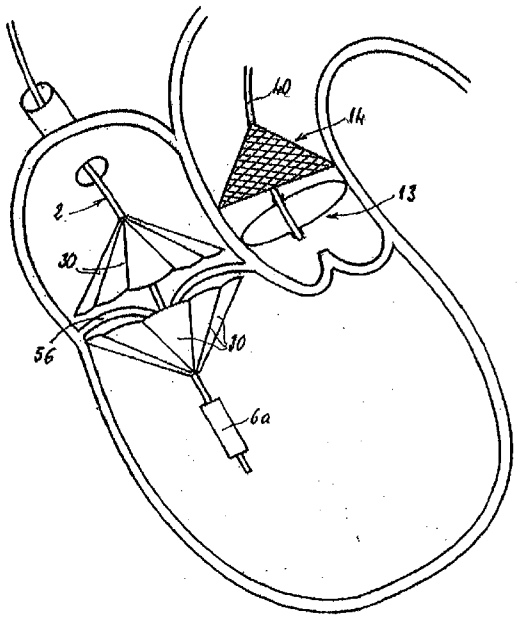
Oct. 31, 2000 (FR) 00/14028
Nov. 17, 1999 (FR) 99/14462

Publication Classification

(51) **Int. Cl.**[7] **A61F 2/24**
(52) **U.S. Cl.** **623/2.11**; 623/2.18; 623/1.16; 623/900

(57) ABSTRACT

A prosthetic valve assembly for use in replacing a deficient native valve comprises a replacement valve supported on an expandable valve support. If desired, one or more anchors may be used. The valve support, which entirely supports the valve annulus, valve leaflets, and valve commissure points, is configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is properly positioned. Portions of the valve support may expand to a preset diameter to maintain coaptivity of the replacement valve and to prevent occlusion of the coronary ostia. A radial restraint, comprising a wire, thread or cuff, may be used to ensure expansion does not exceed the preset diameter. The valve support may optionally comprise a drug elution component. The anchor engages the lumen wall when expanded and prevents substantial migration of the valve assembly when positioned in place. The prosthetic valve assembly is compressible about a catheter, and restrained from expanding by an outer sheath. The catheter may be inserted inside a lumen within the body, such as the femoral artery, and delivered to a desired location, such as the heart. A blood pump may be inserted into the catheter to ensure continued blood flow across the implantation site during implantation procedure. When the outer sheath is retracted, the prosthetic valve assembly expands to an expanded position such that the valve and valve support expand at the implantation site and the anchor engages the lumen wall. Insertion of the catheter may optionally be performed over a transseptally delivered guidewire that has been externalized through the arterial vasculature. Such a guidewire provide dual venous and arterial access to the implantation site and allows additional manipulation of the implantation site after arterial implantation of the prosthetic valve. Additional expansion stents may be delivered by venous access to the valve.



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Opposition against
EP 2 982 337 B1

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./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

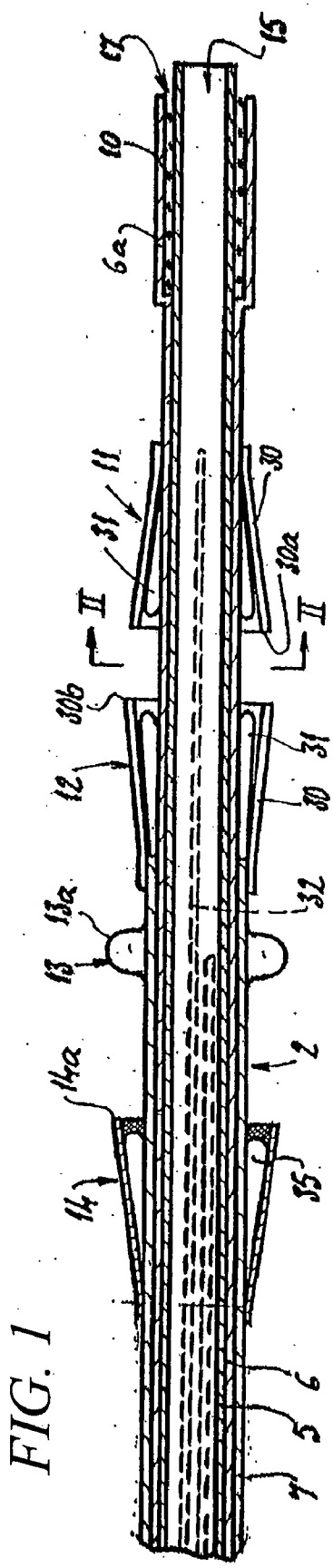


FIG. 1

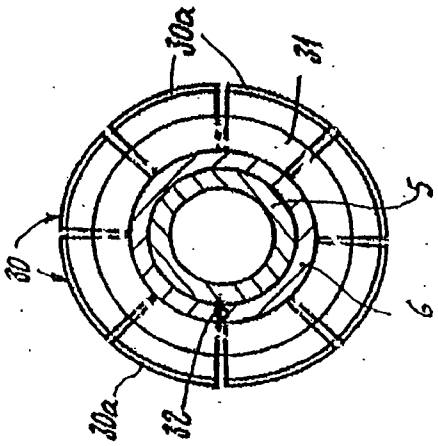


FIG. 3

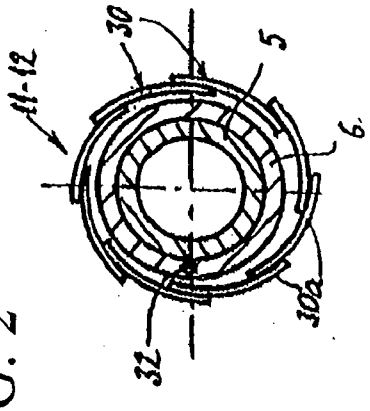


FIG. 2

FIG. 9

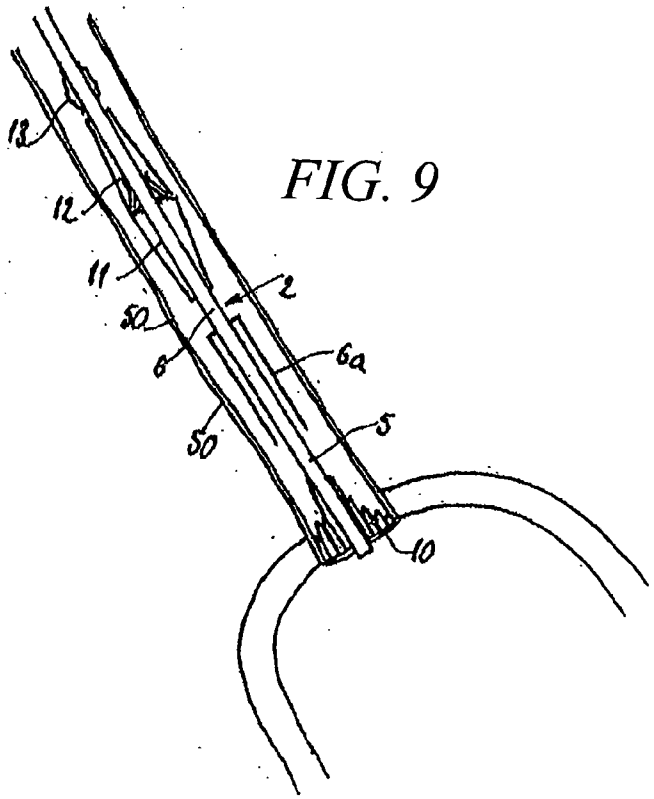


FIG. 10

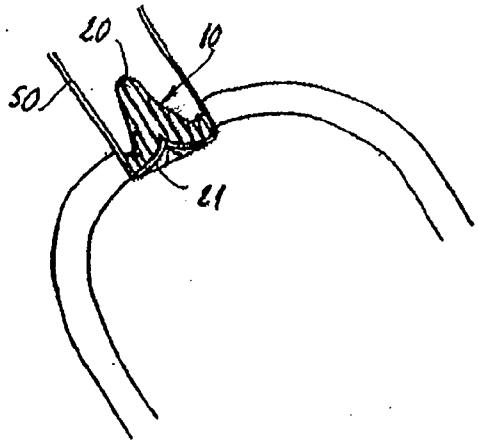
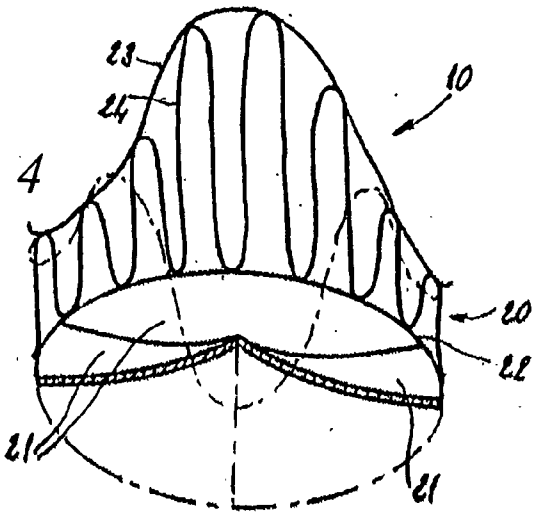


FIG. 4



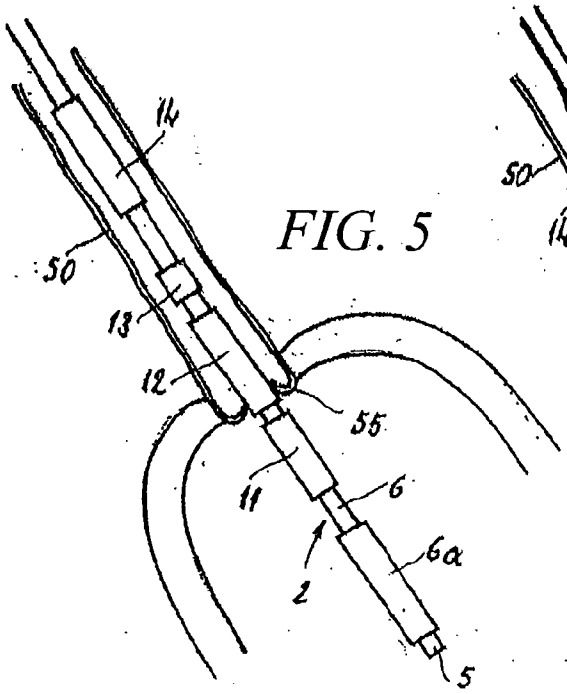


FIG. 5

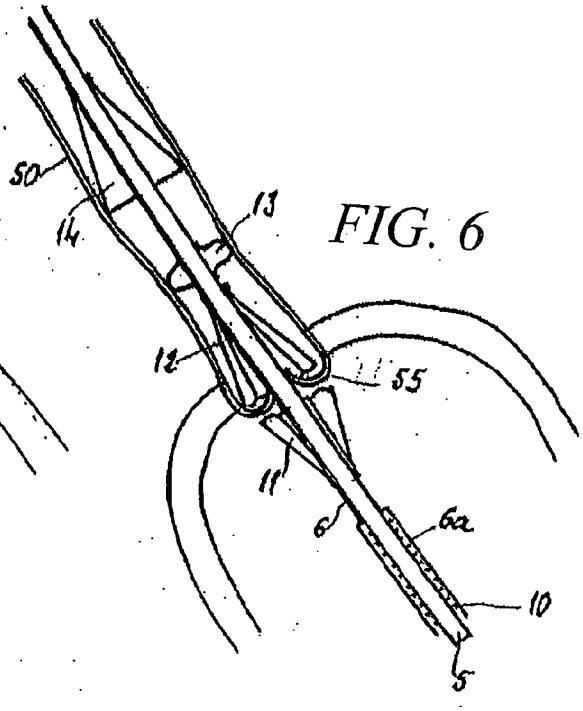


FIG. 6

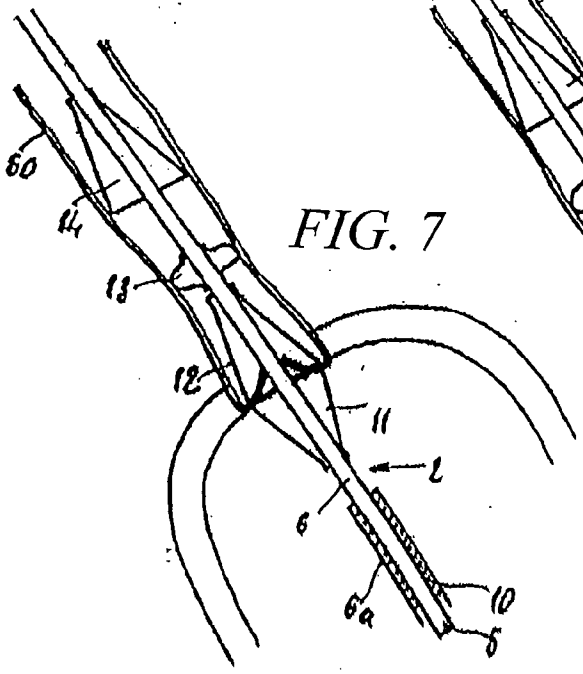


FIG. 7

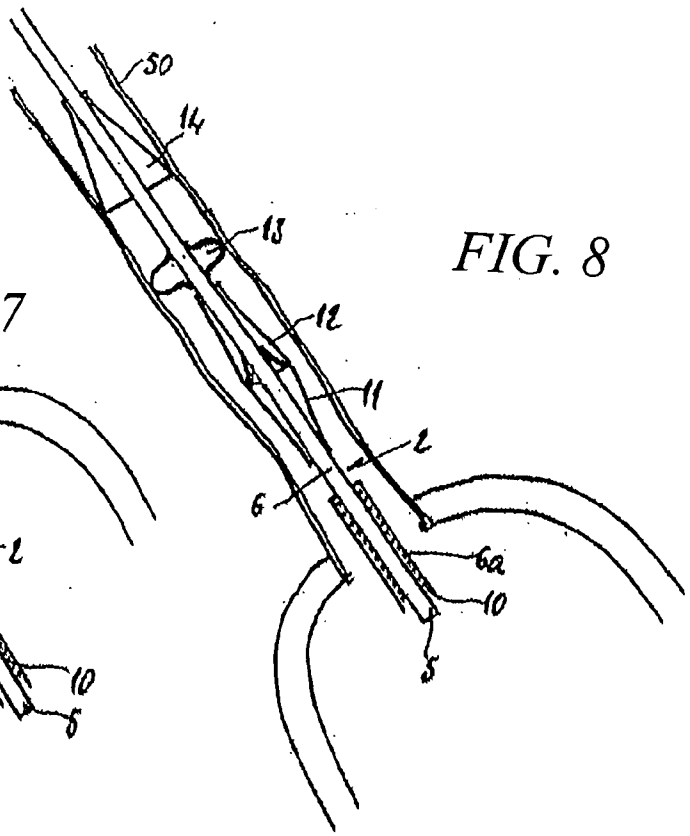


FIG. 8

FIG. 11

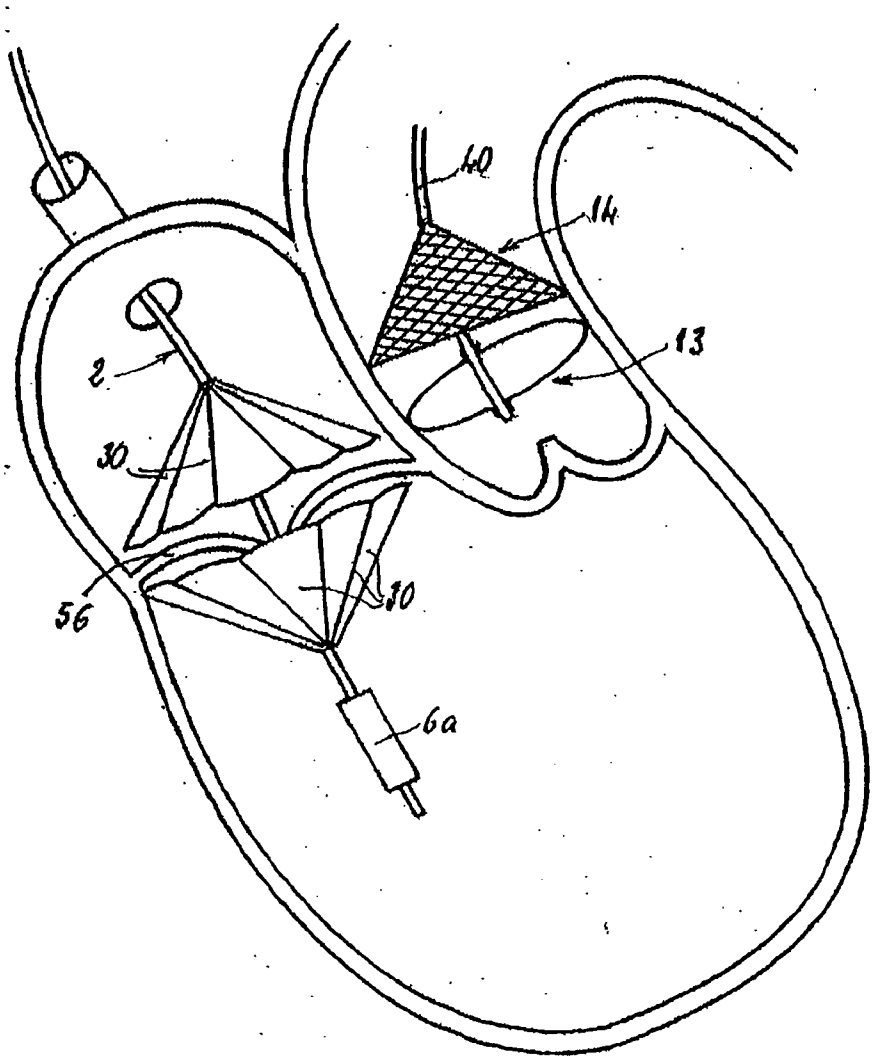




FIG. 12

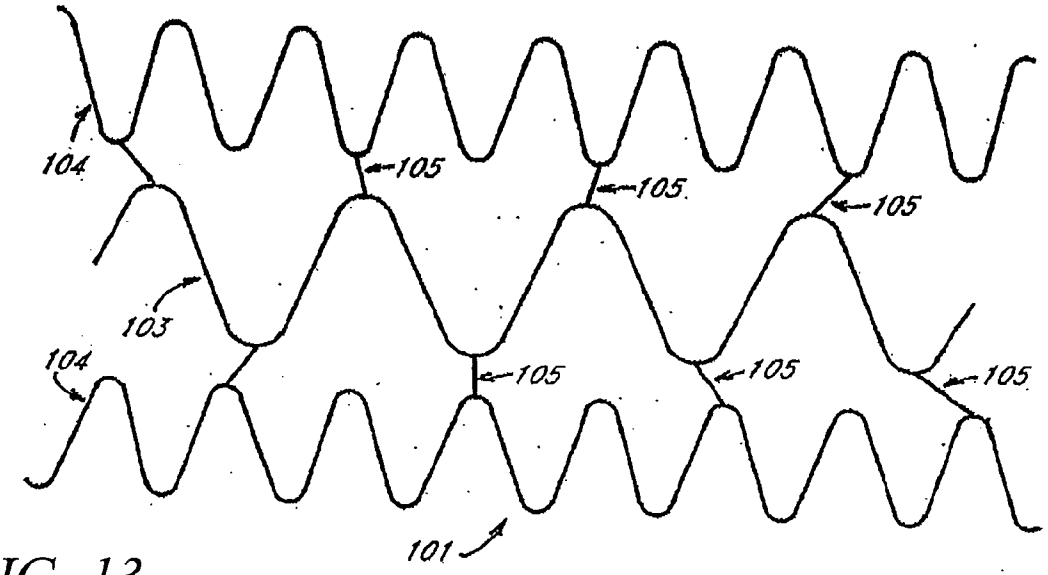

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FIG. 13

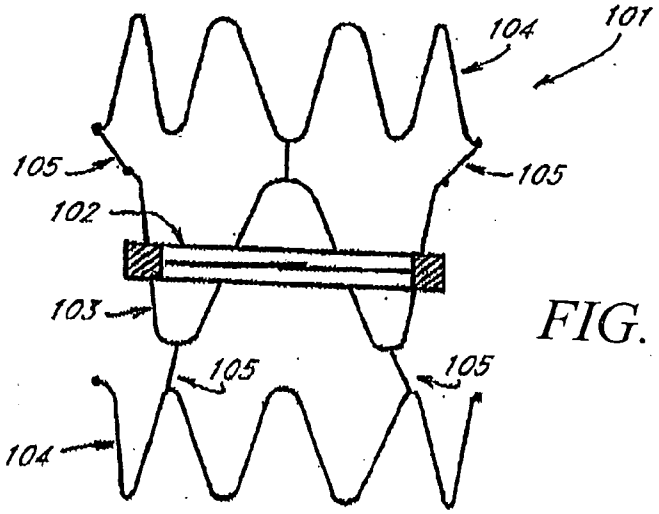

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FIG. 14

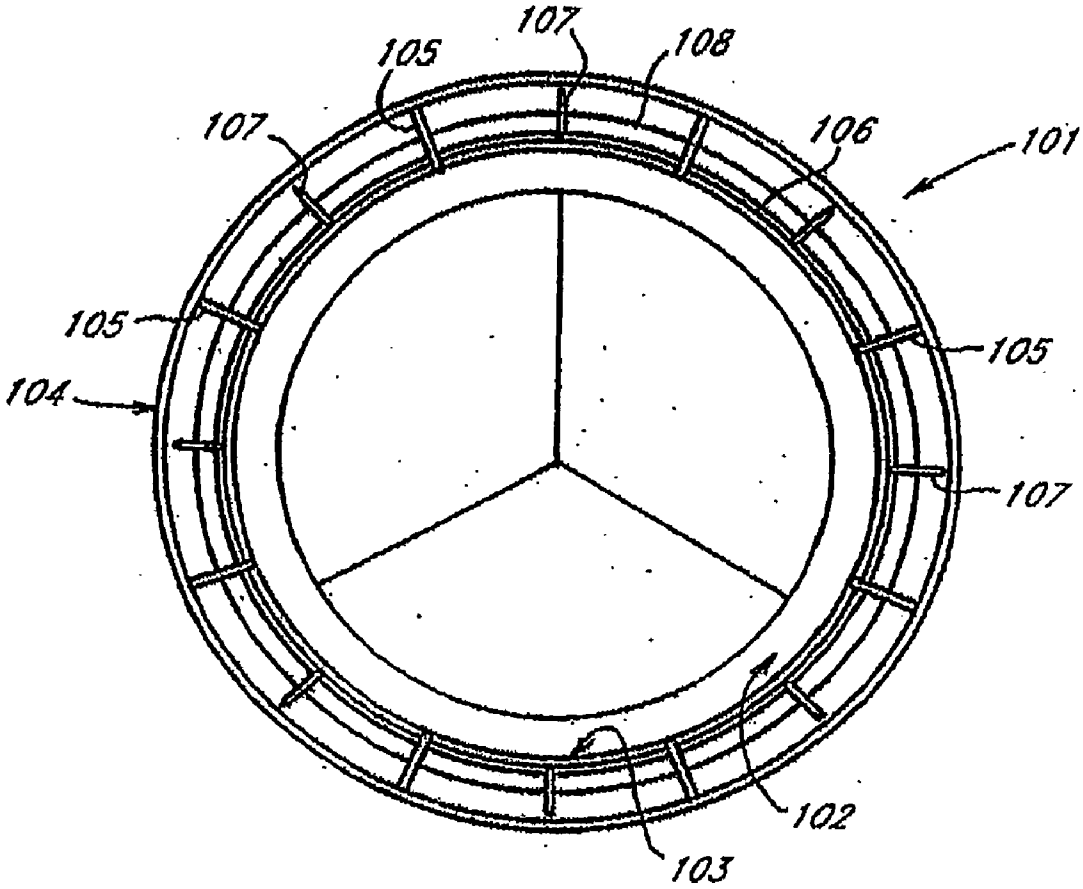

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FIG. 15

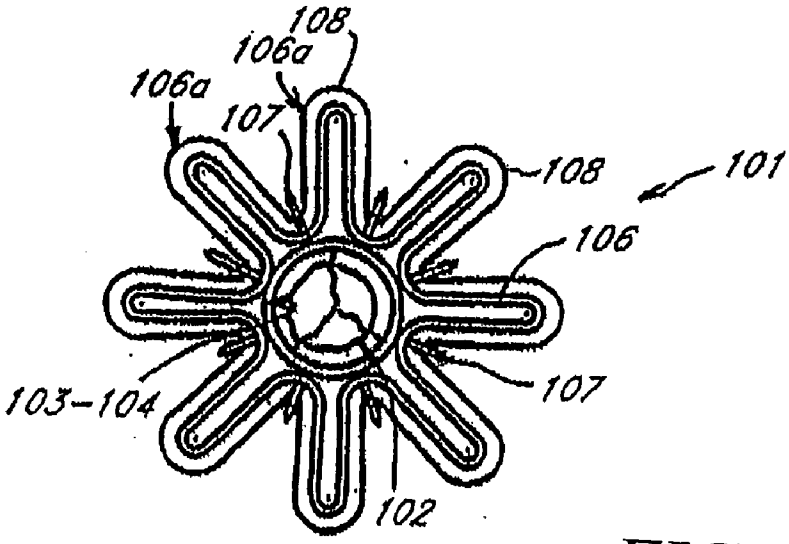

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FIG. 16

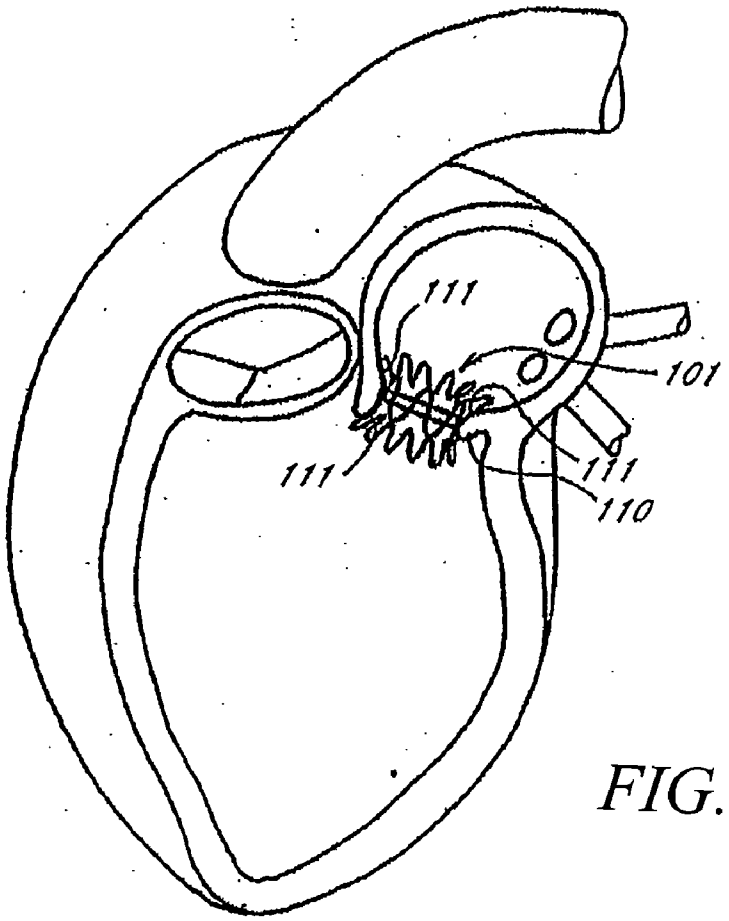


FIG. 17

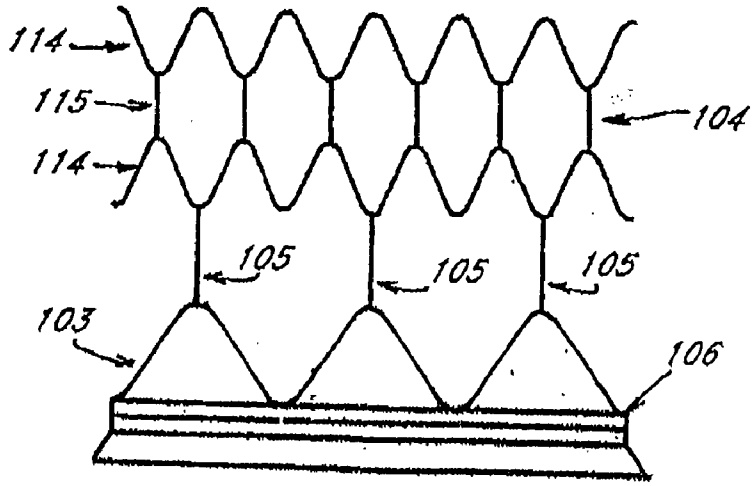


FIG. 18

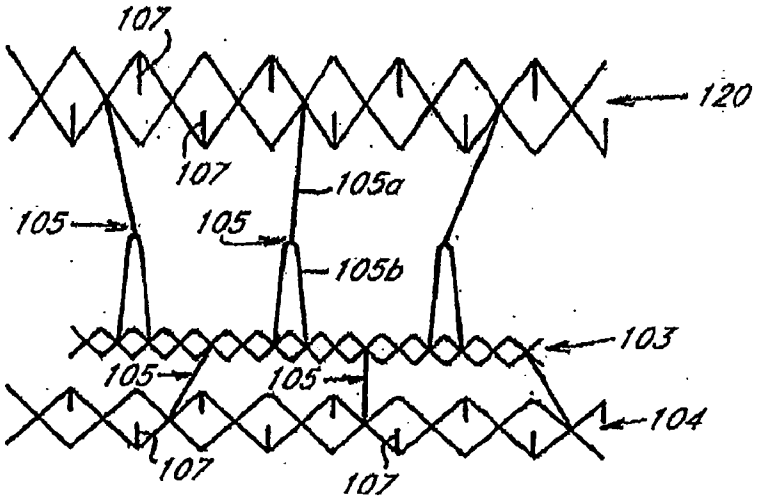

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FIG. 19

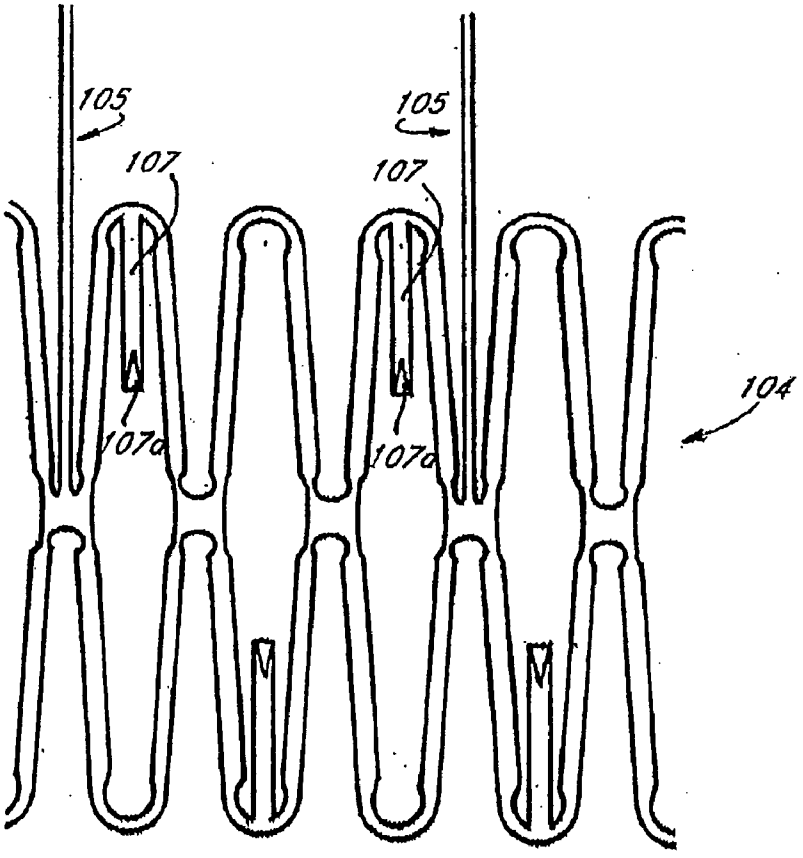

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FIG. 20

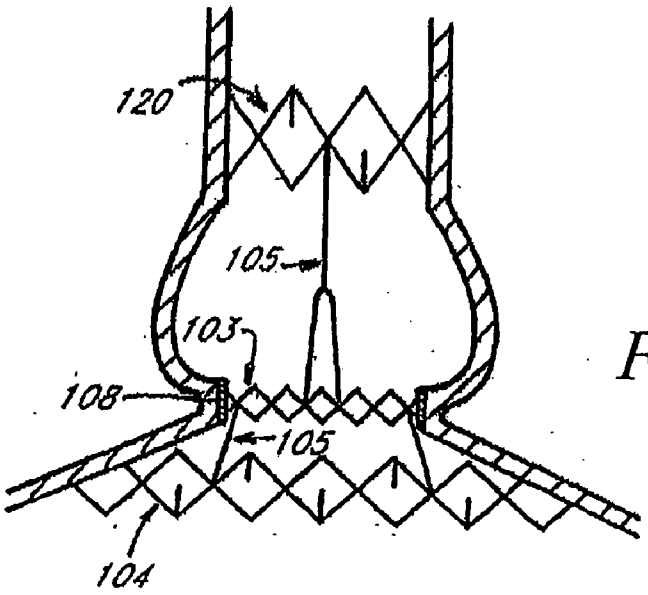

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FIG. 21

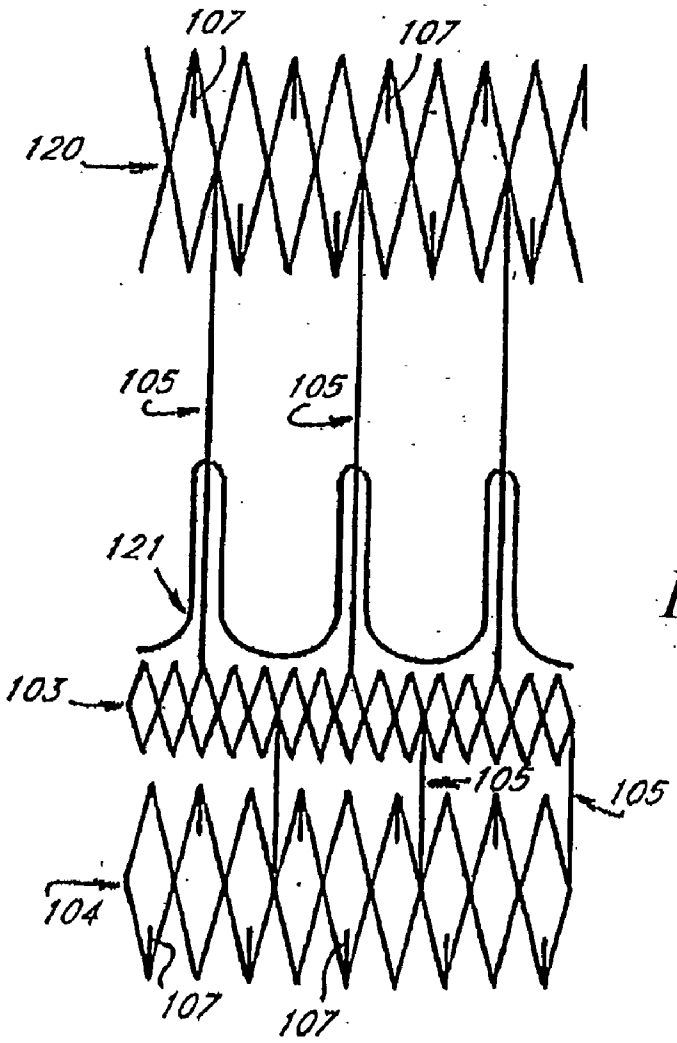

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FIG. 22

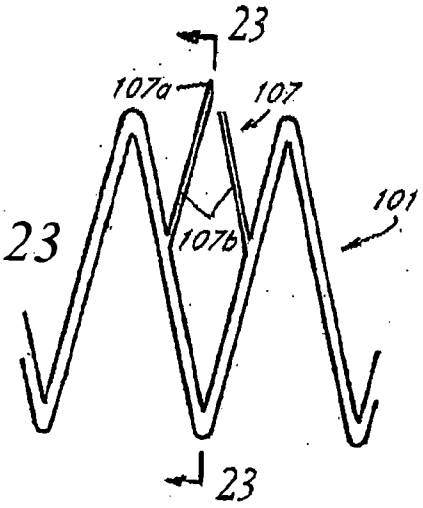


FIG. 23

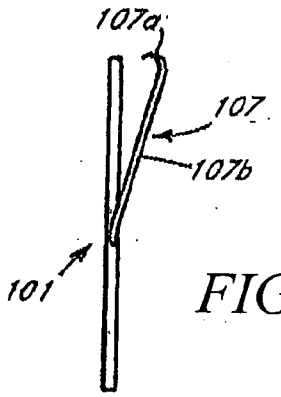


FIG. 24

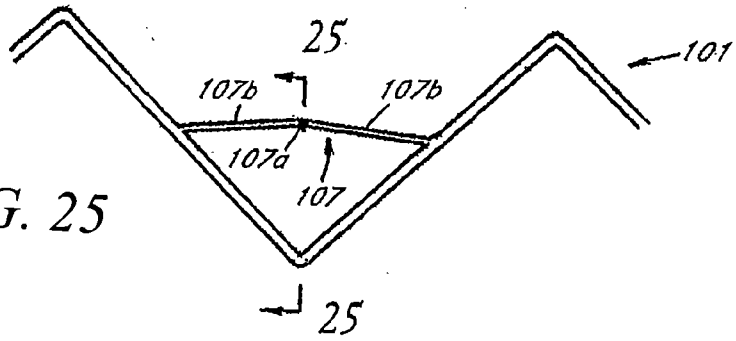


FIG. 25

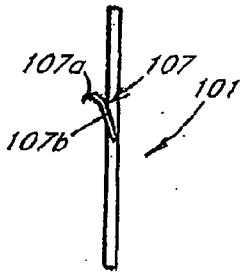


FIG. 26

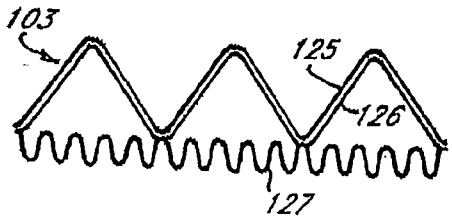


FIG. 27

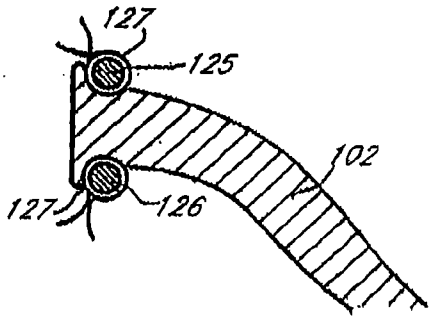


FIG. 28

FIG. 29

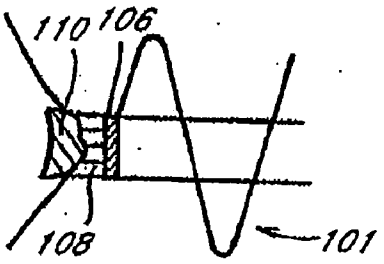
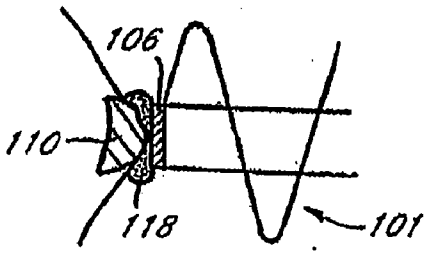
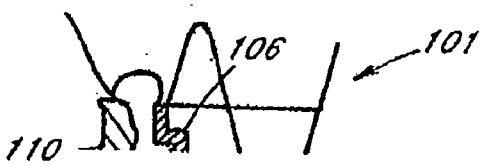


FIG. 30





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FIG. 31

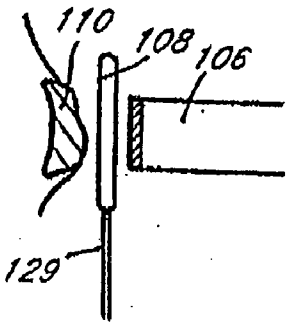


FIG. 32

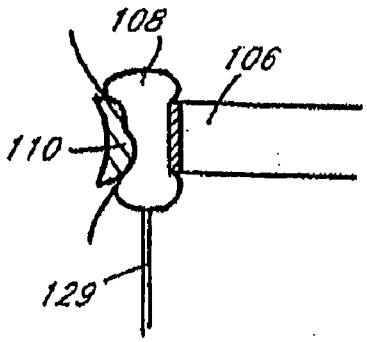


FIG. 33

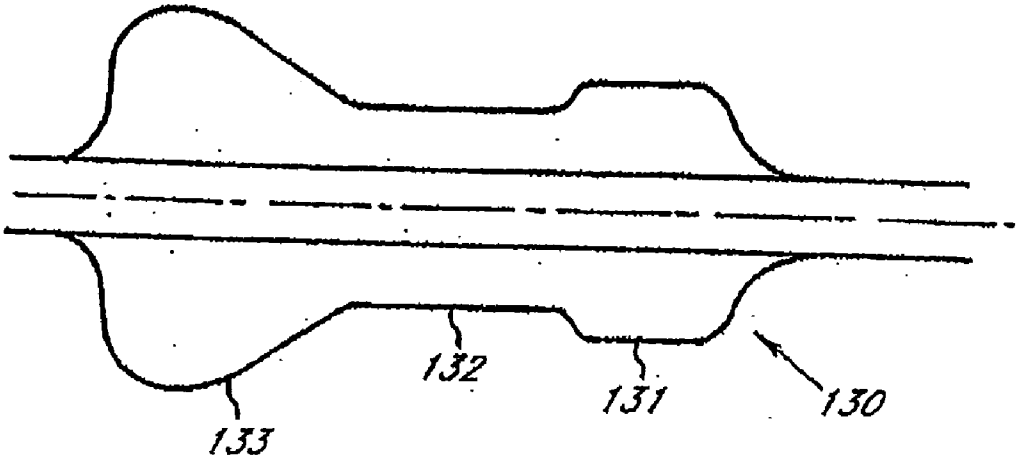


FIG. 34

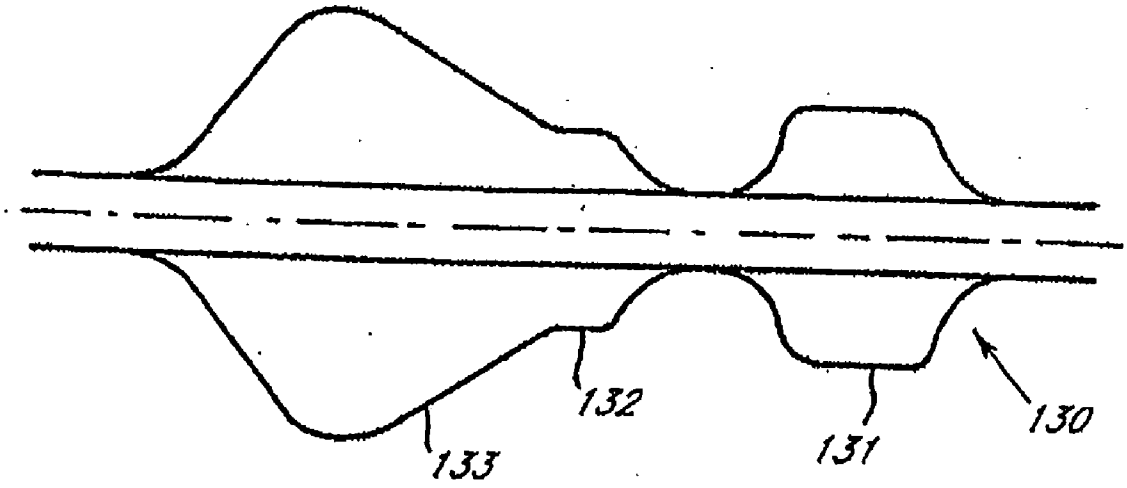


FIG. 35

FIG. 36

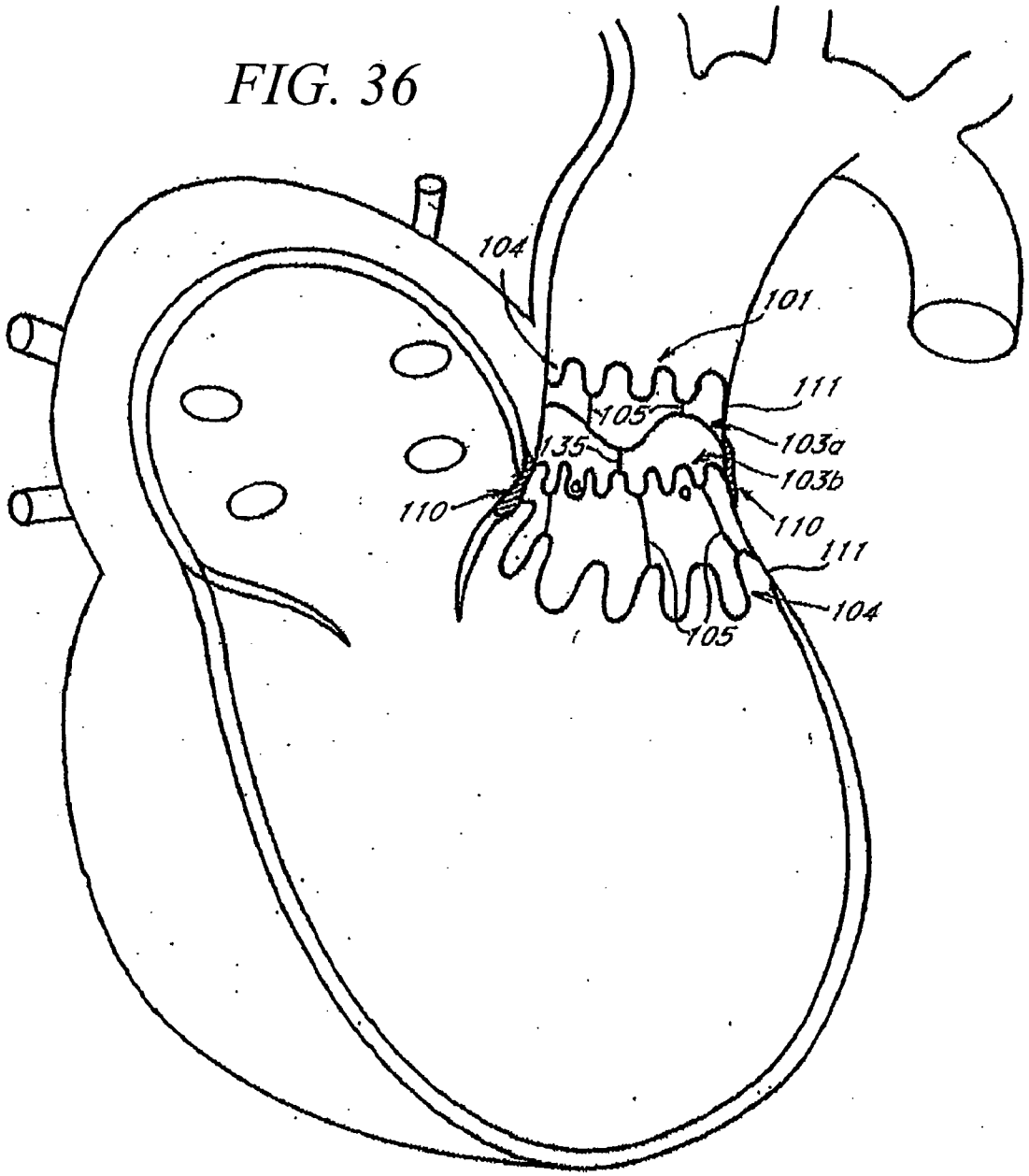
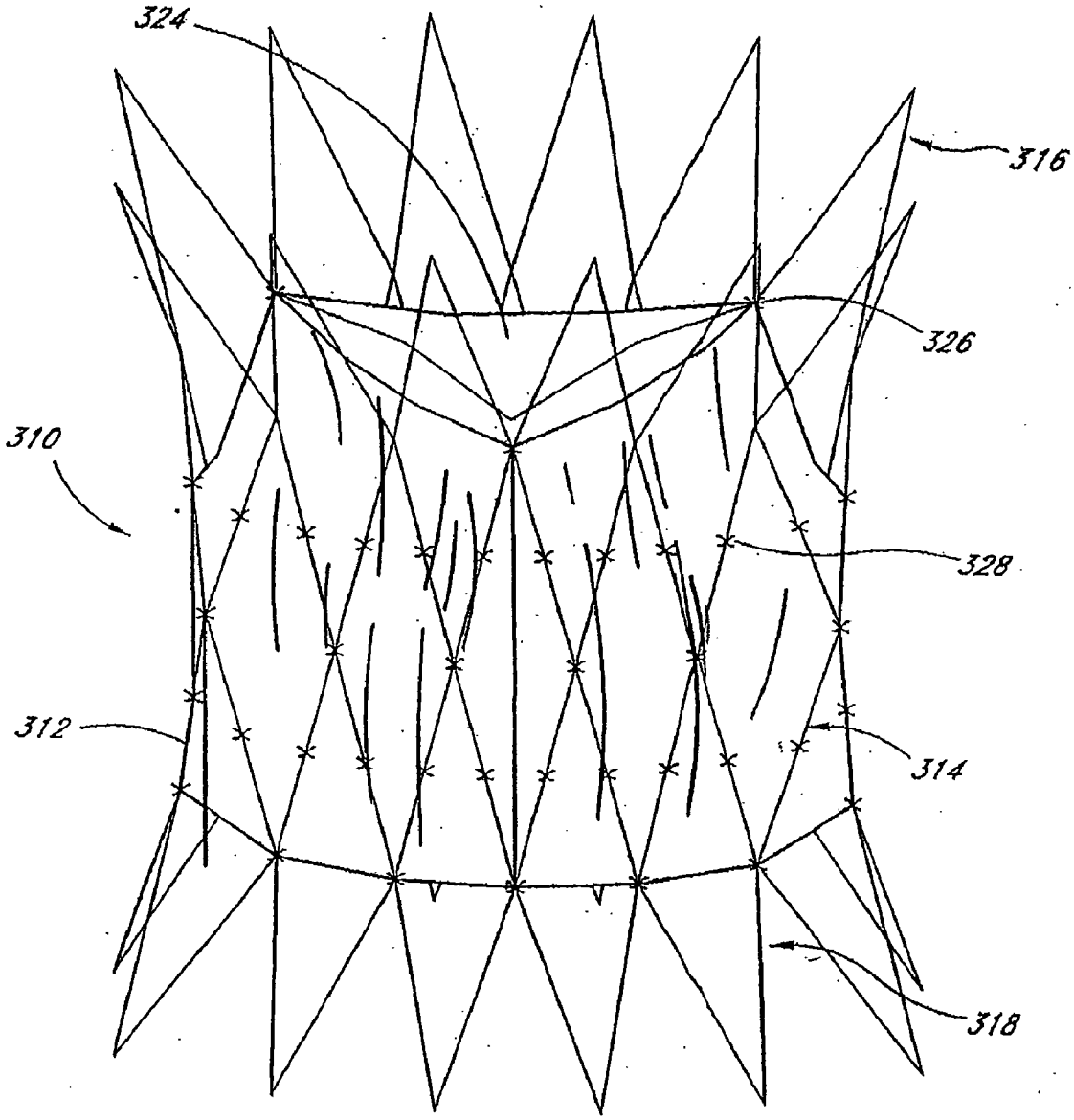


FIG. 37



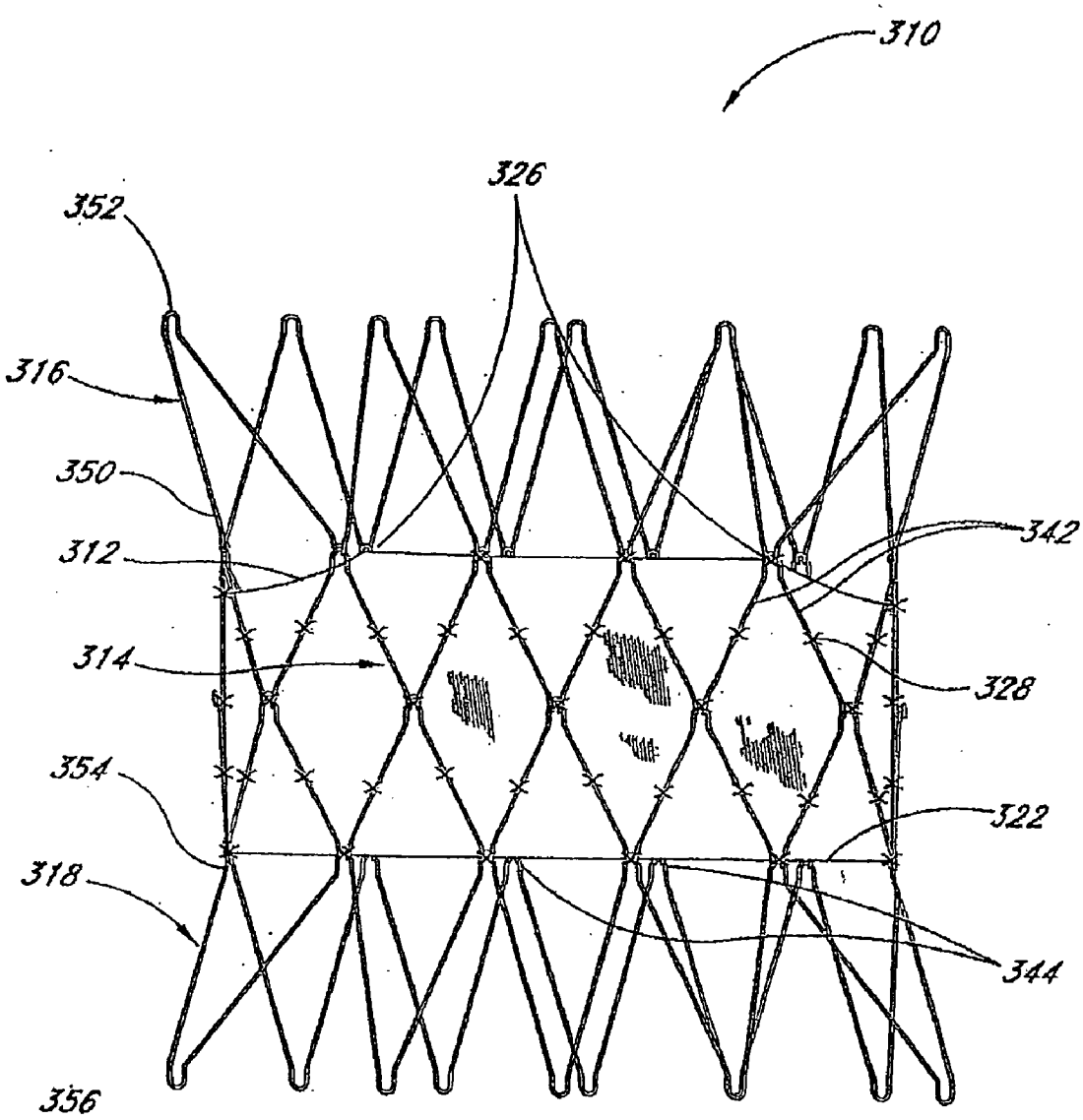


FIG. 38

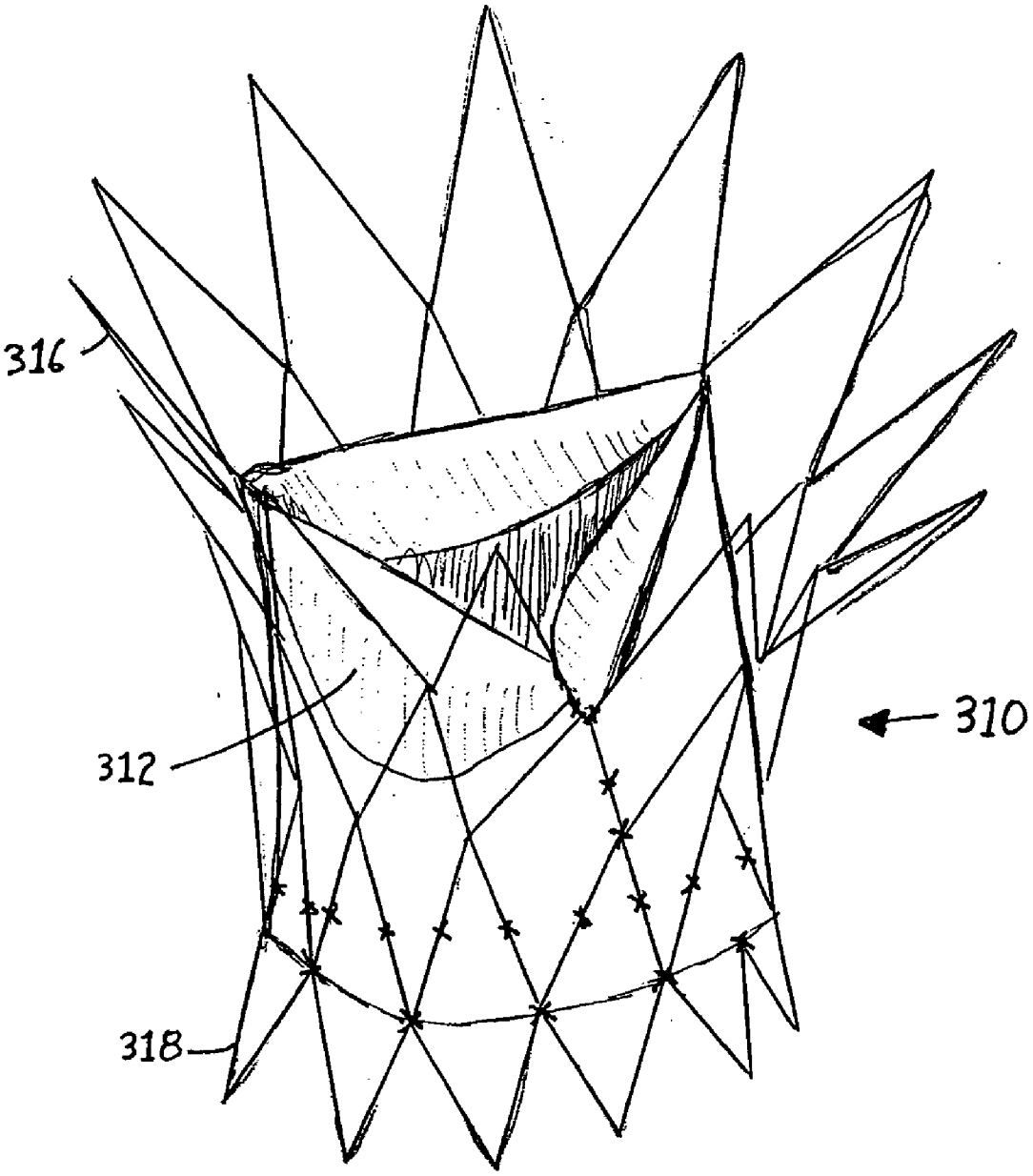


FIG. 39

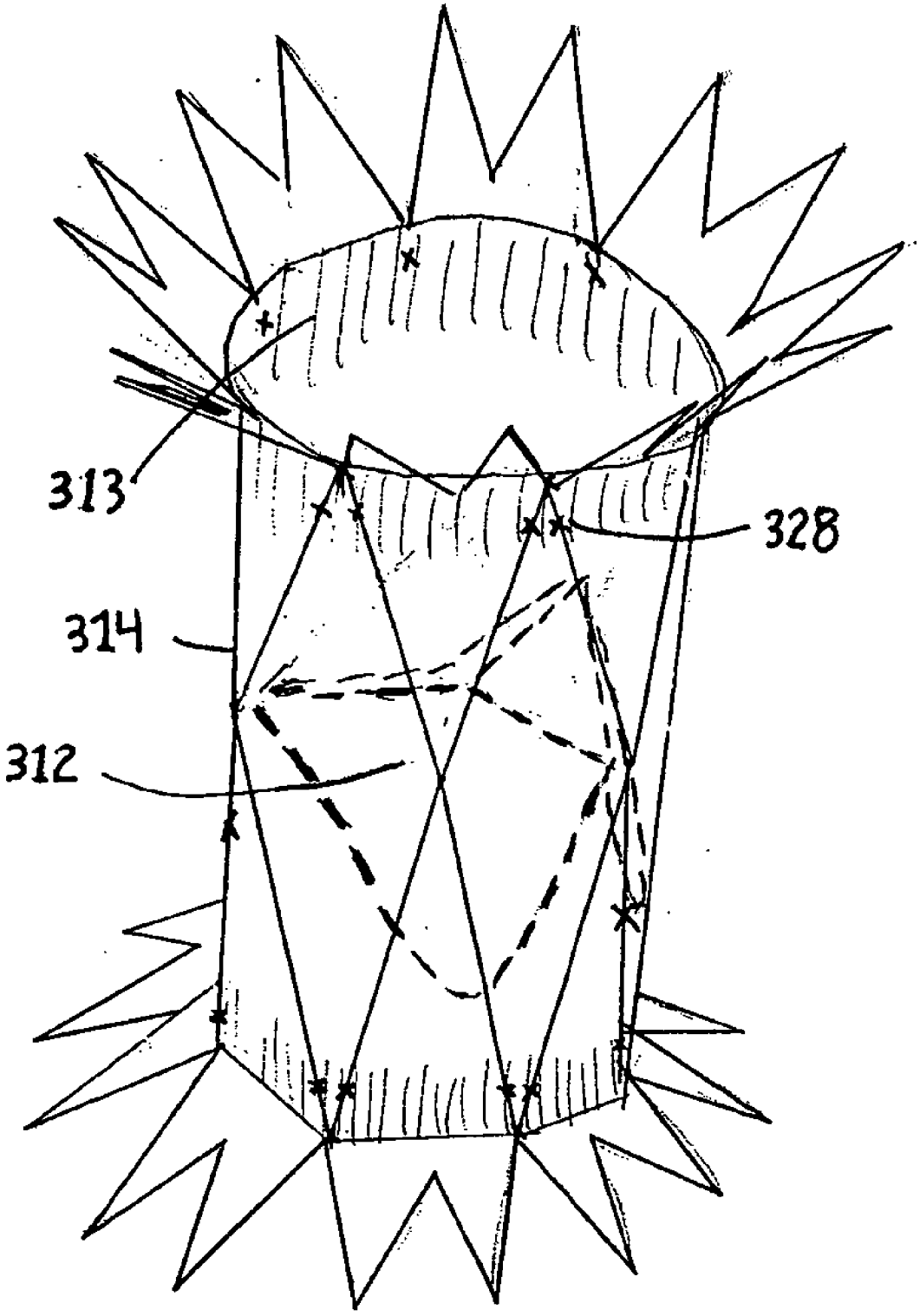


FIG. 40

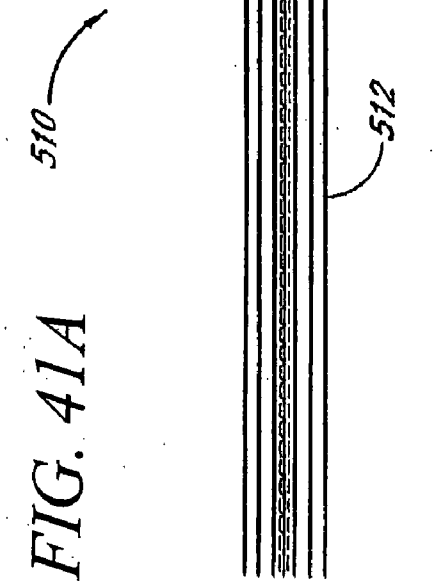


FIG. 41A

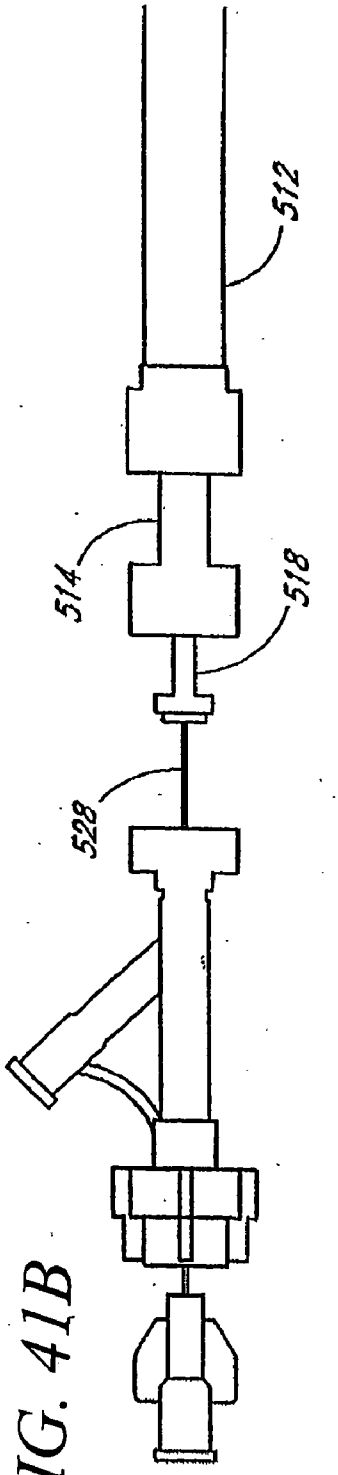


FIG. 41B

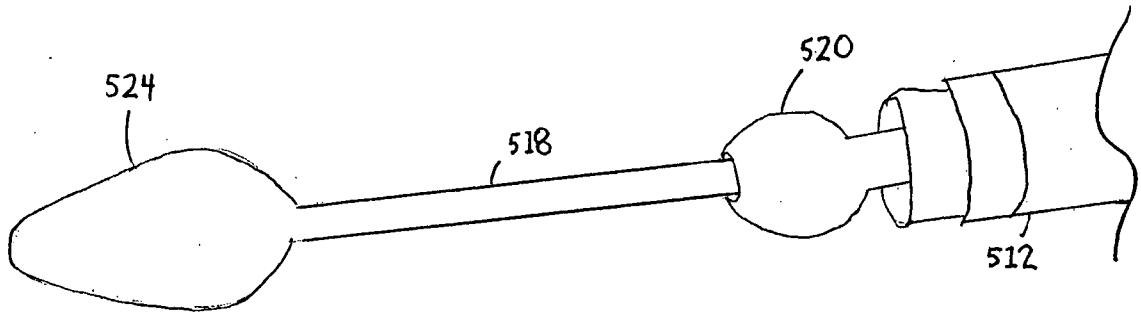


FIG. 42

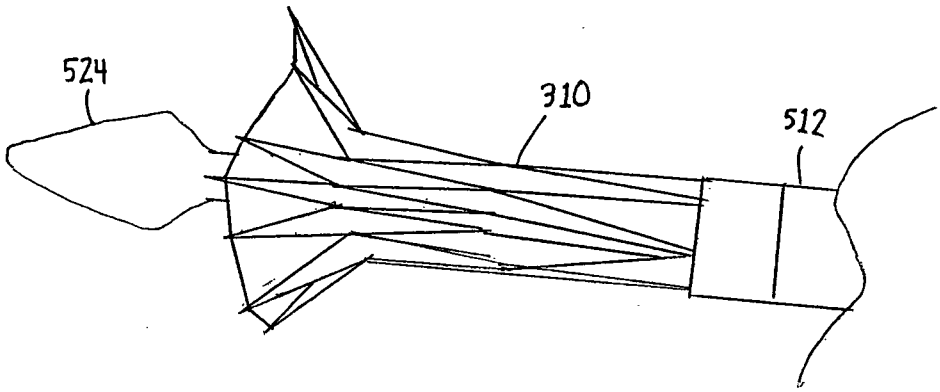


FIG. 43

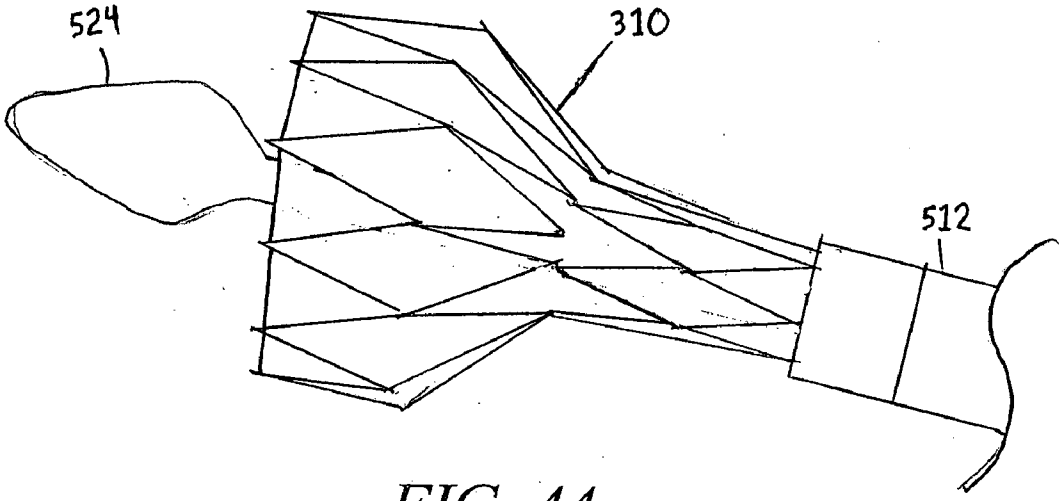


FIG. 44

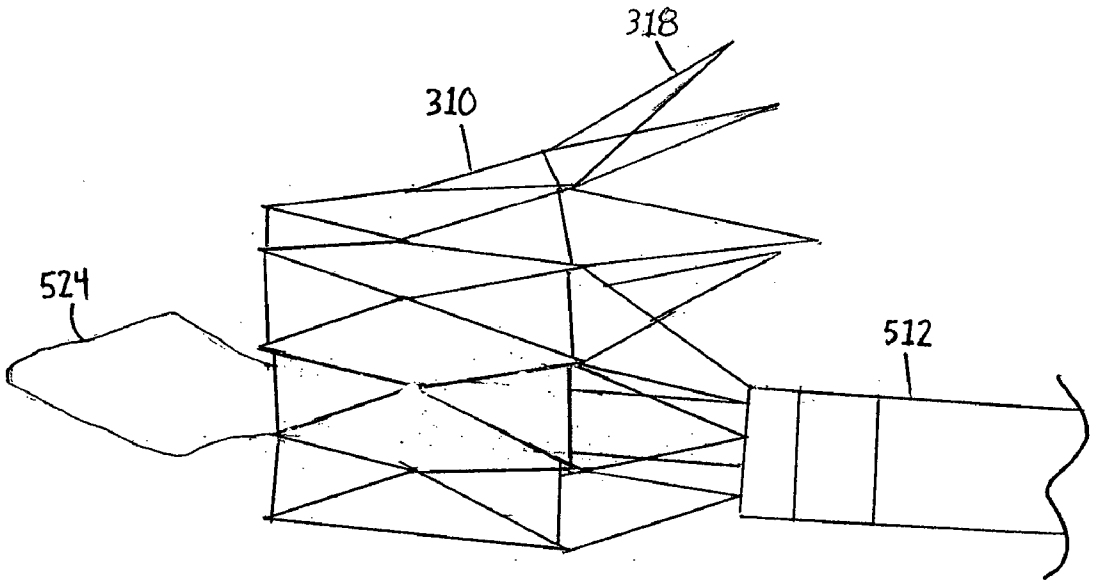


FIG. 45

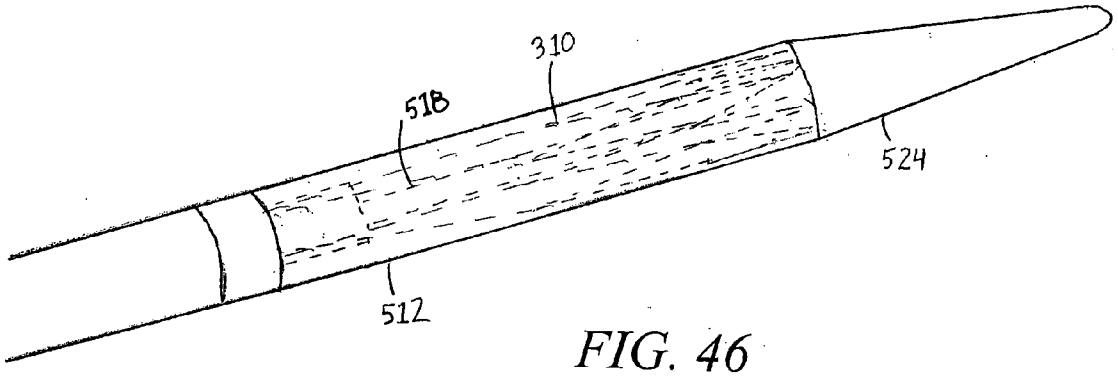


FIG. 46

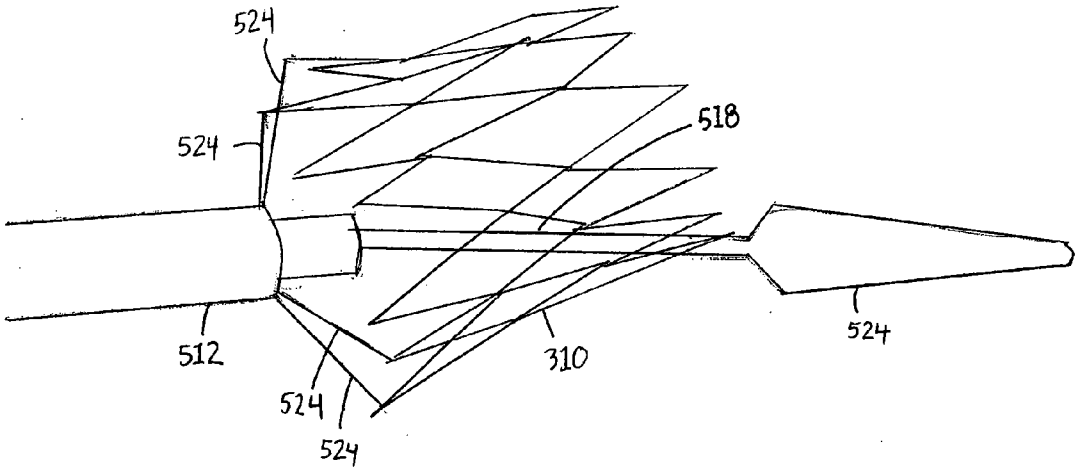


FIG. 47

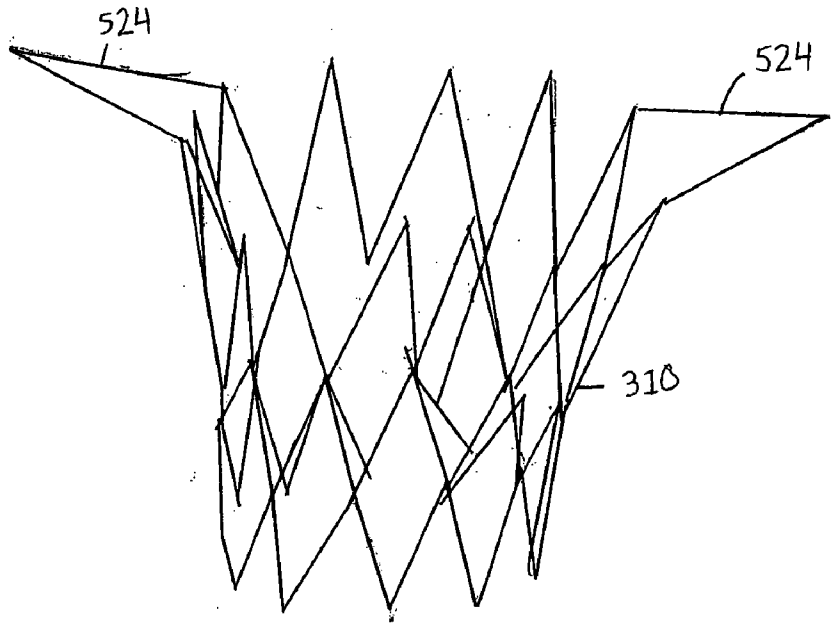


FIG. 48

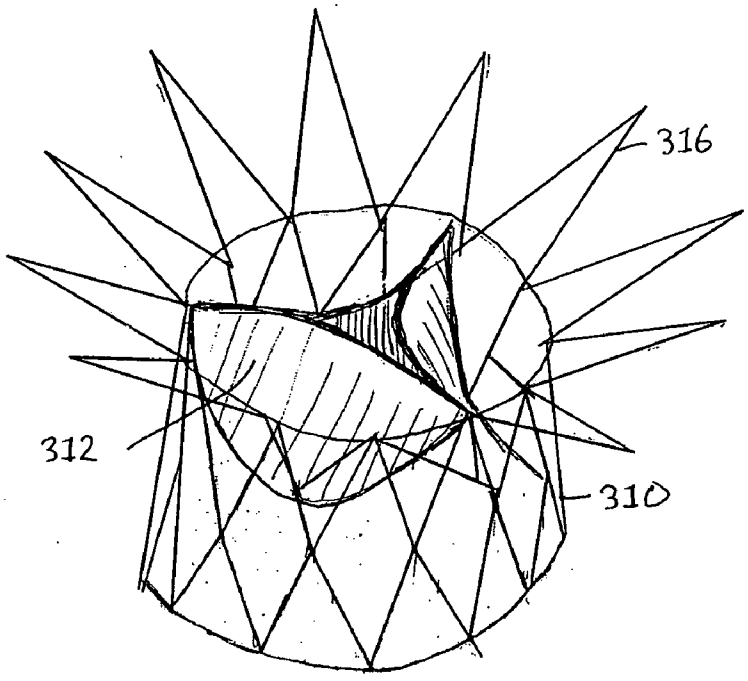


FIG. 49

FIG. 50

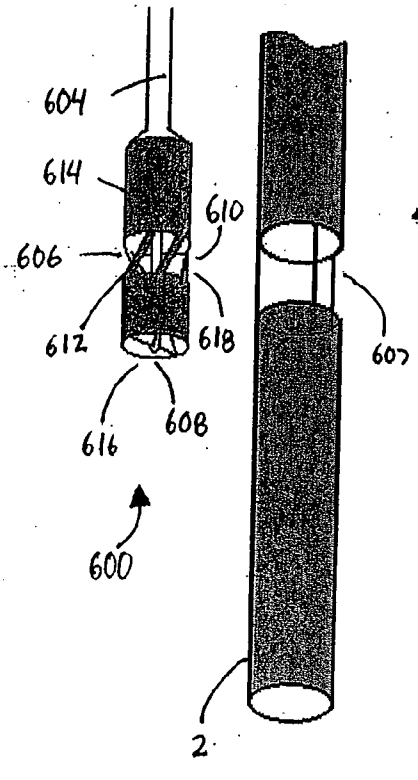


FIG. 51

FIG. 52

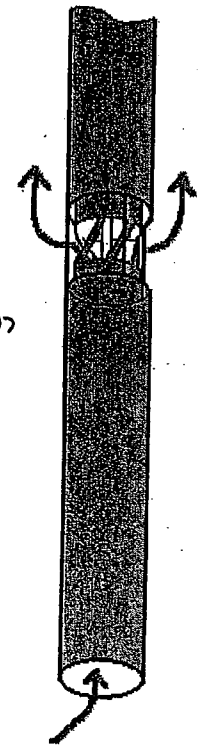


FIG. 53

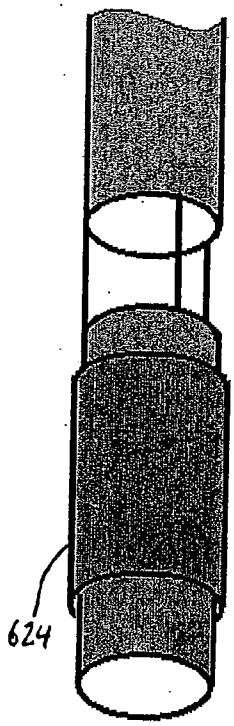
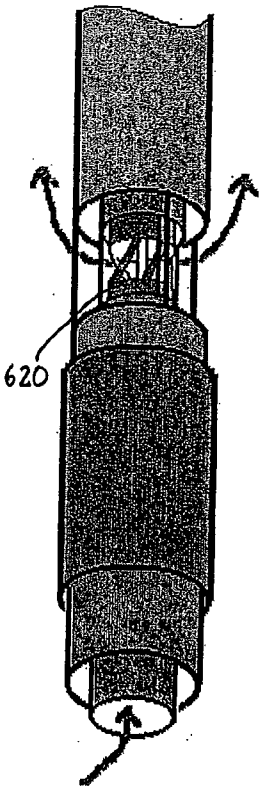


FIG. 54



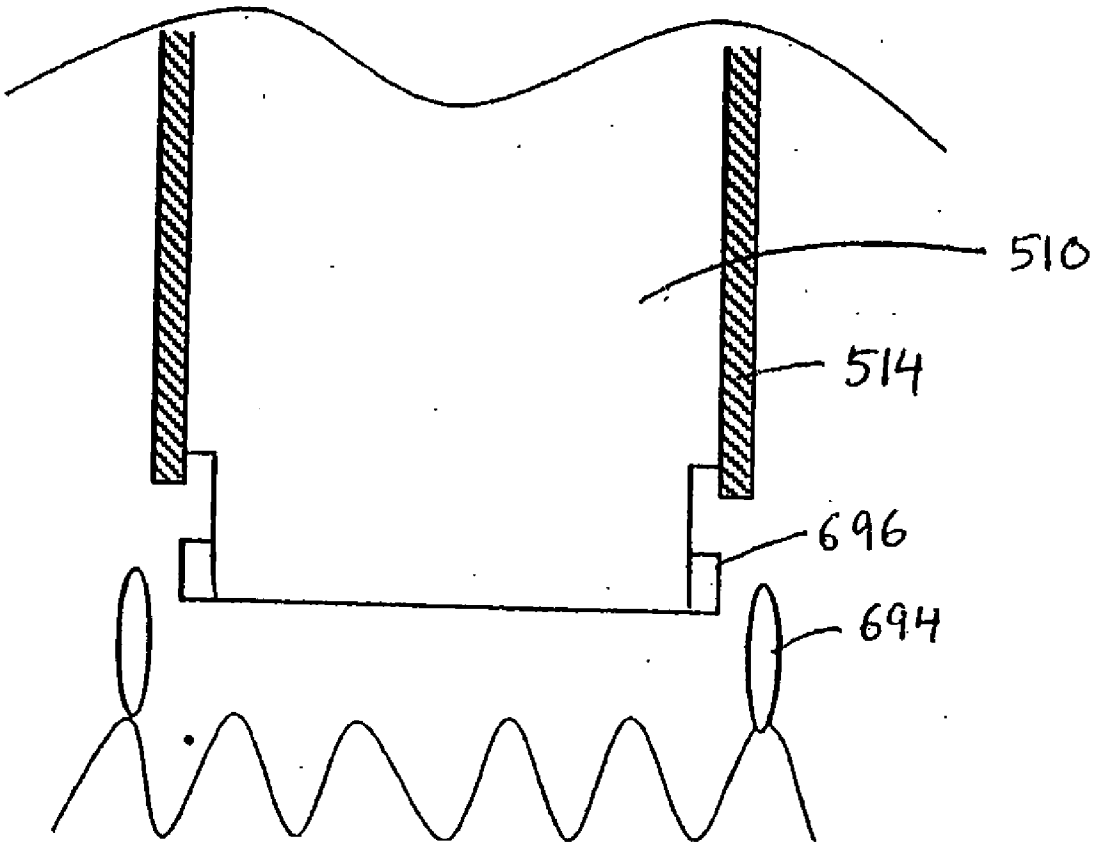


FIG. 55

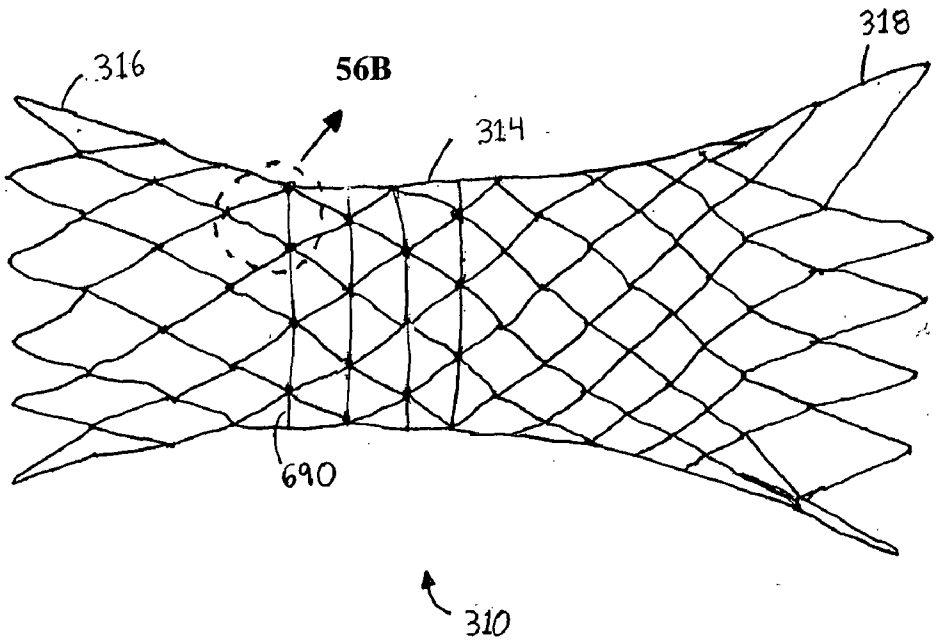


FIG. 56A

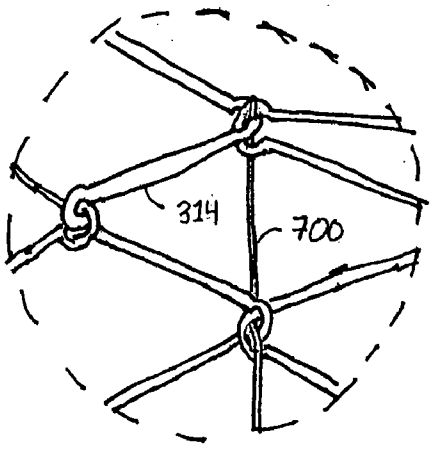


FIG. 56B

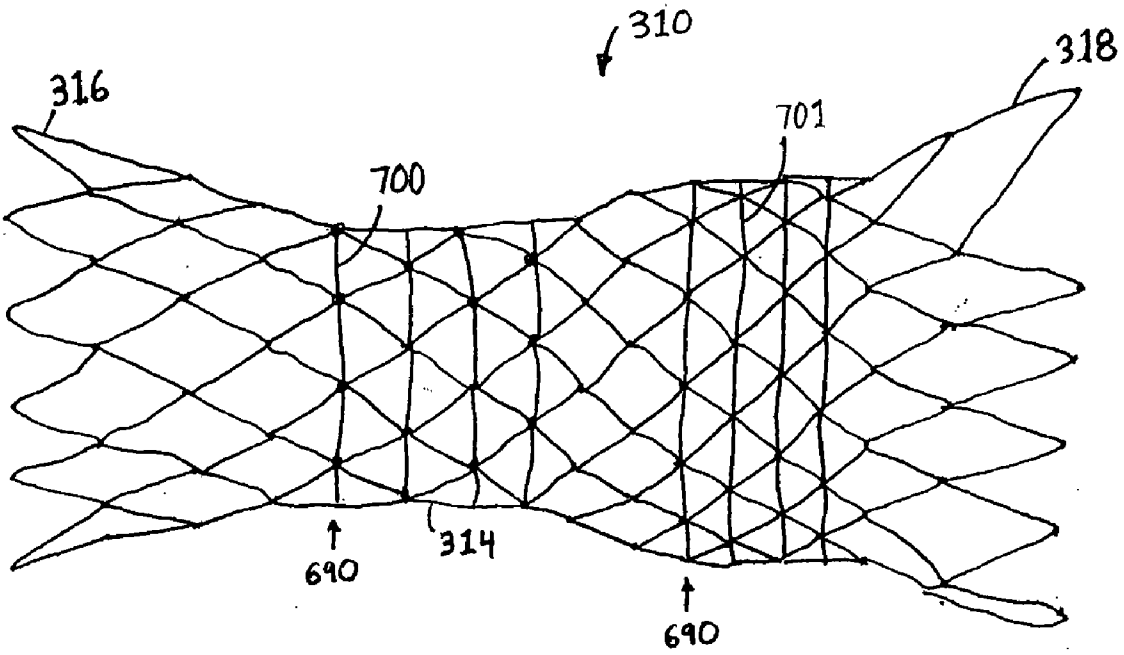


FIG. 57

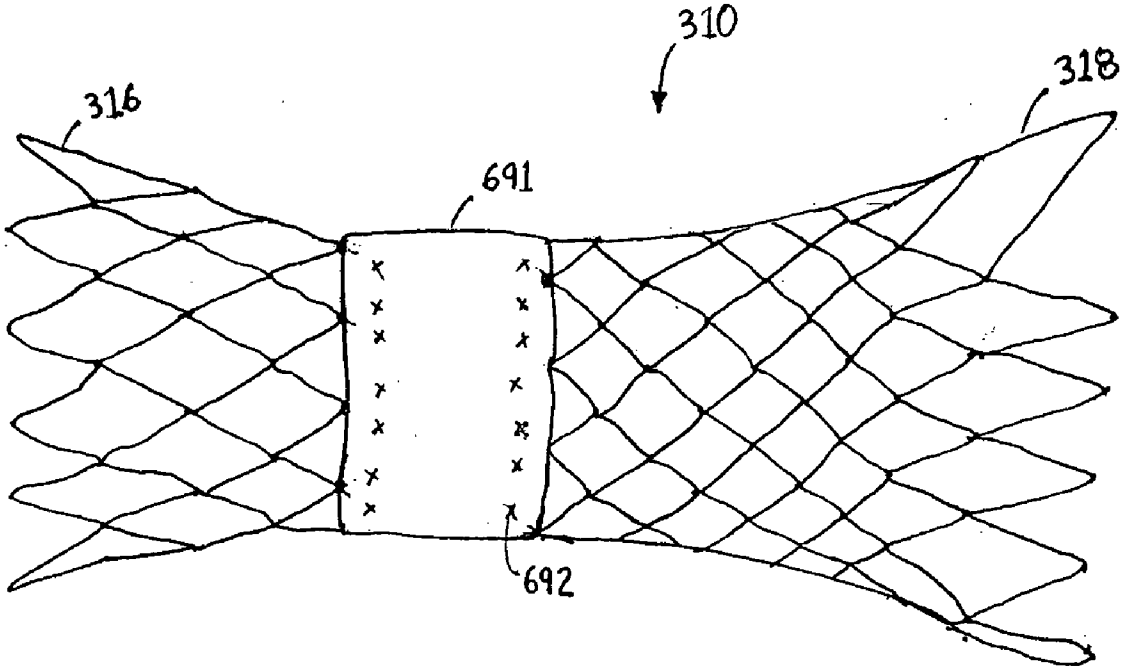


FIG. 58

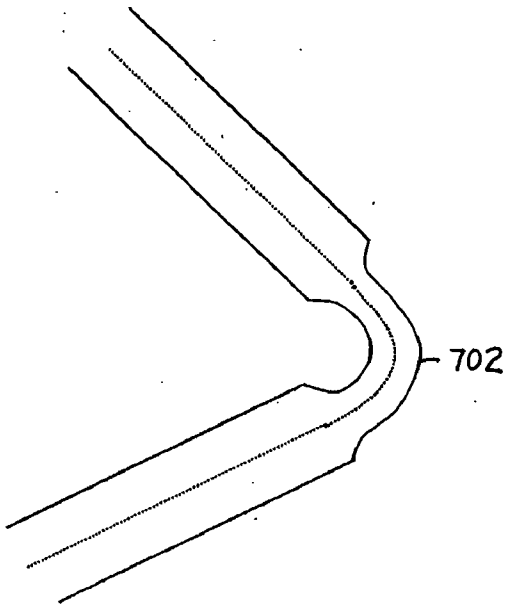


FIG. 59

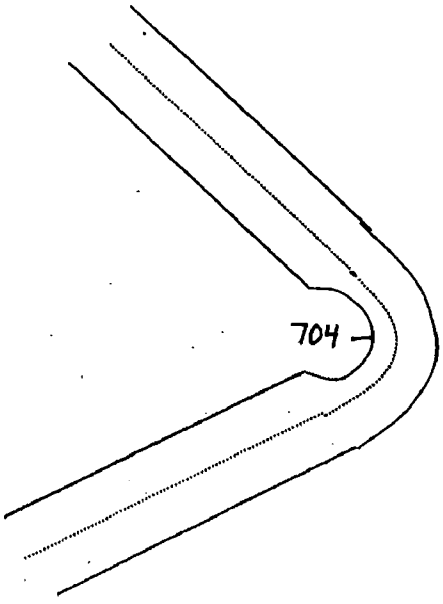


FIG. 60

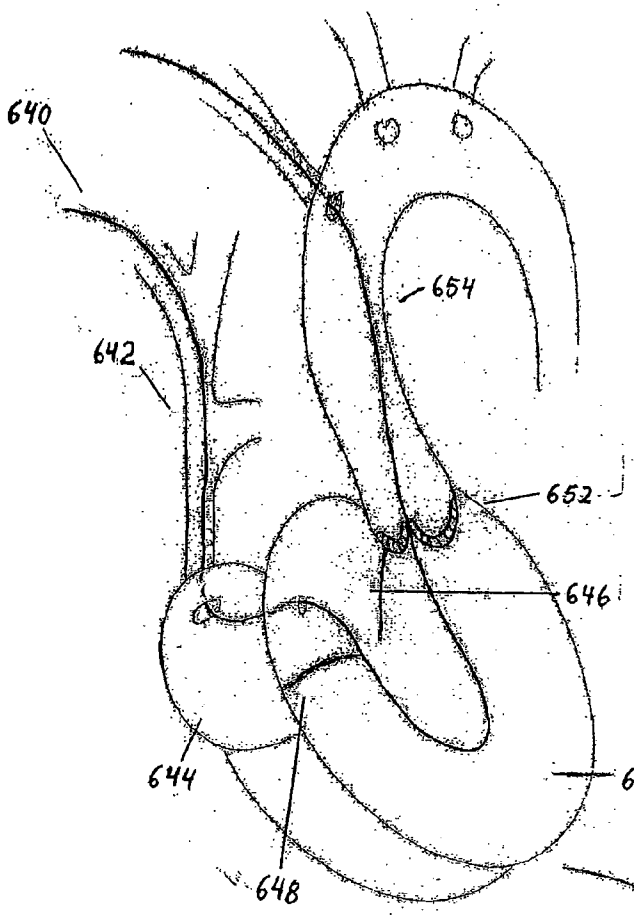


FIG. 61

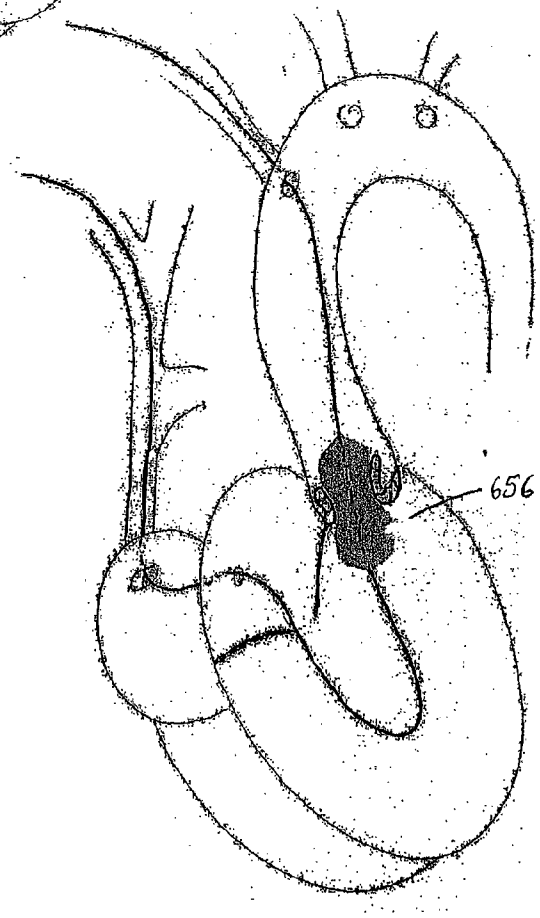


FIG. 62

FIG. 63

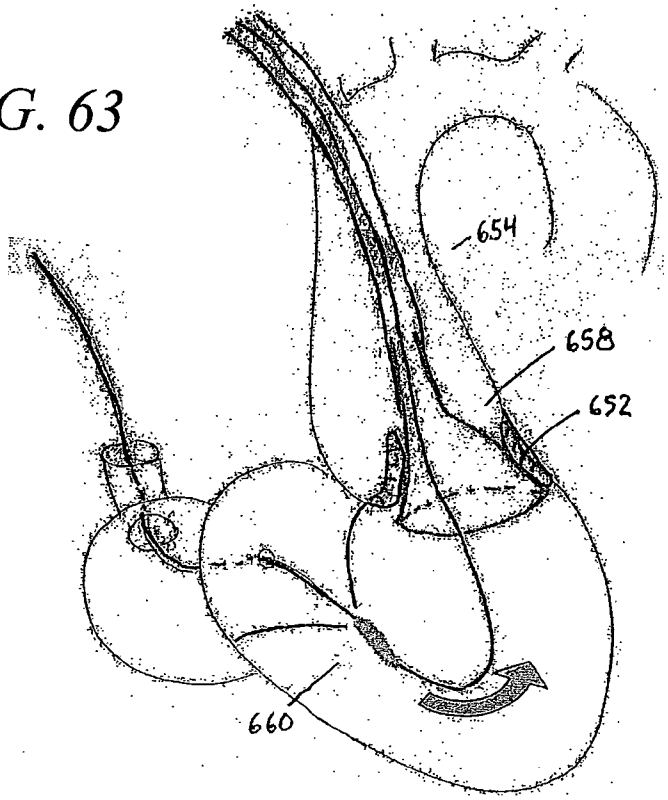


FIG. 64

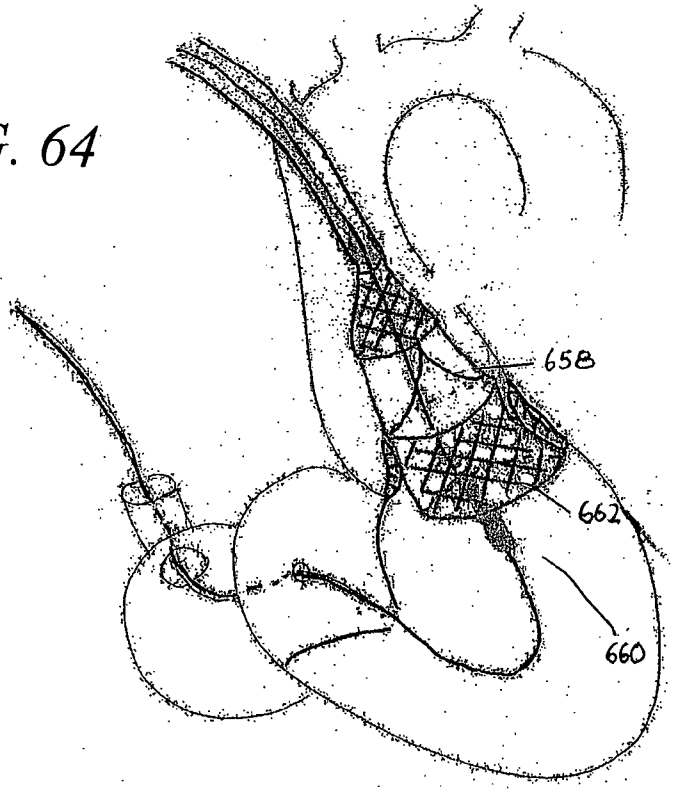
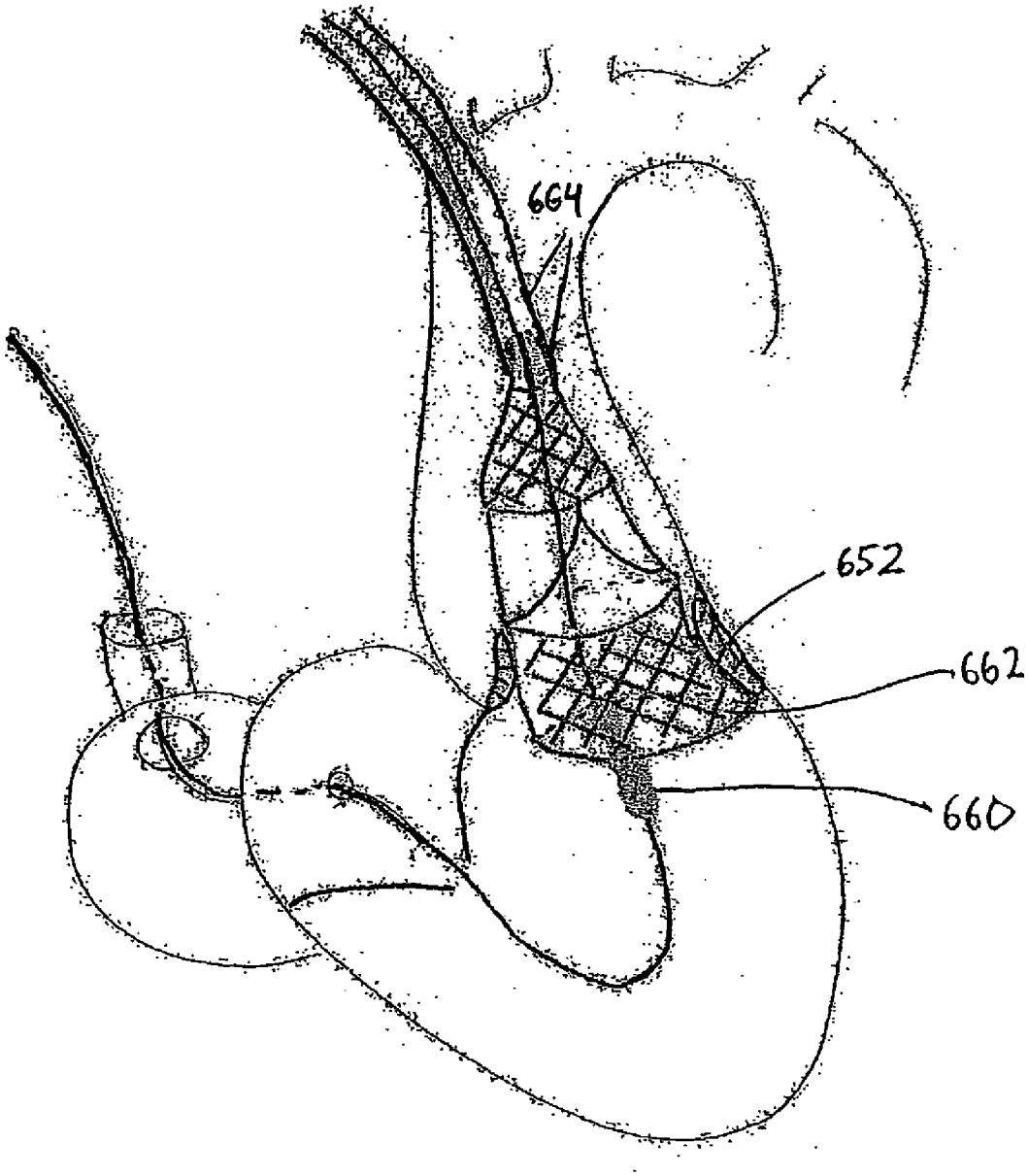


FIG. 65



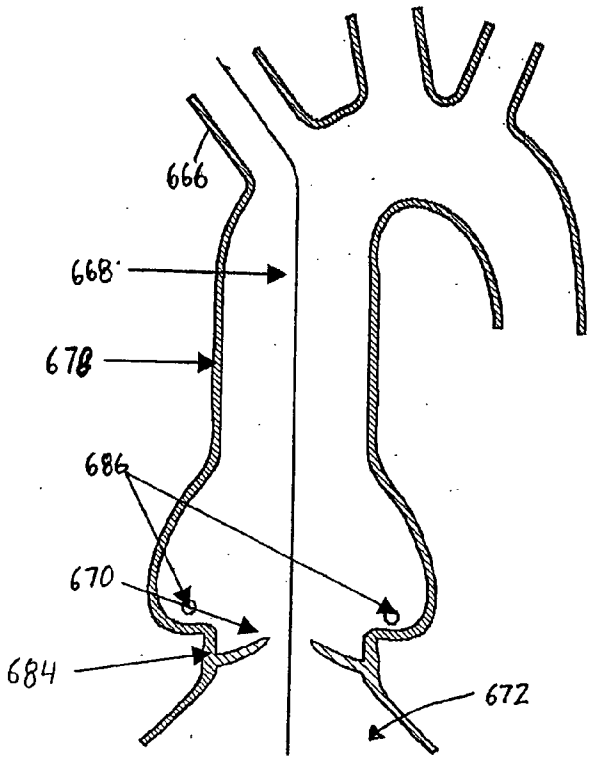
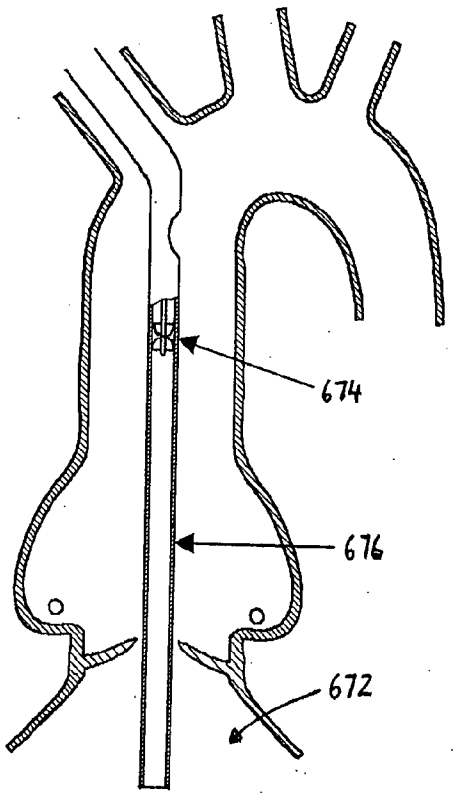


FIG. 66

FIG. 67



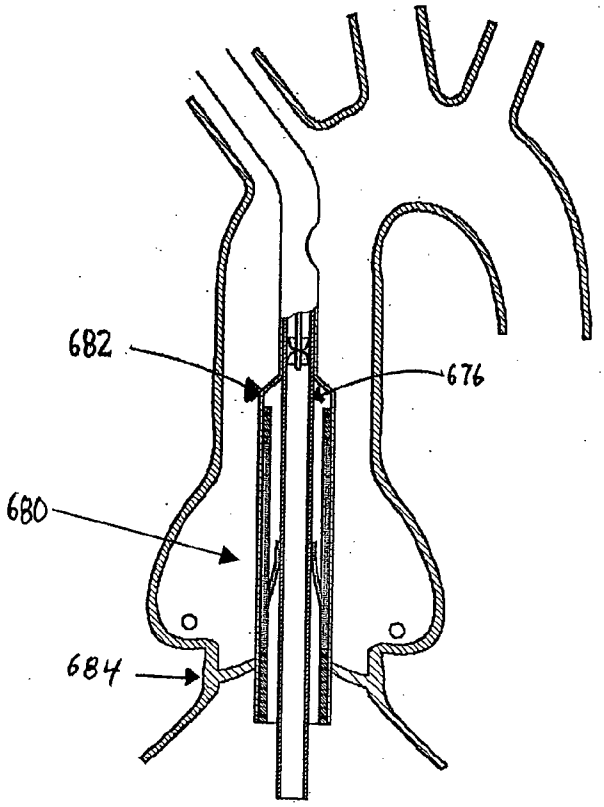


FIG. 68

FIG. 69

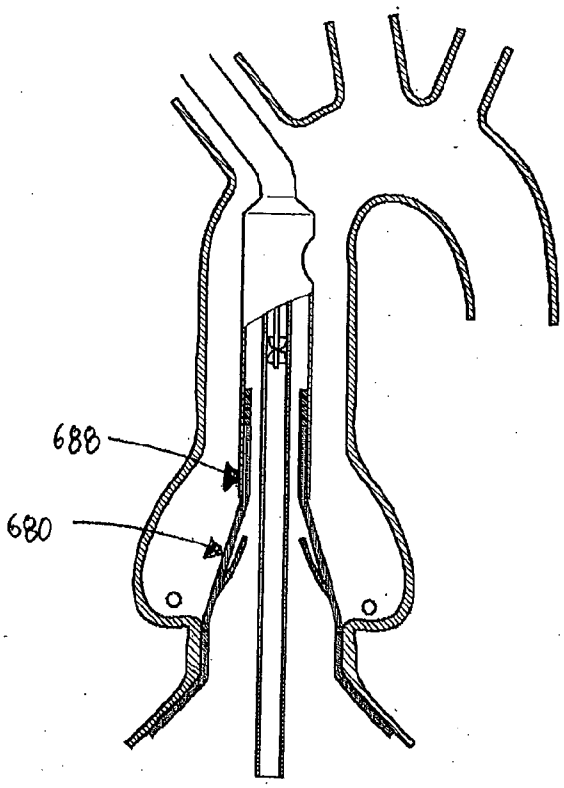


FIG. 70

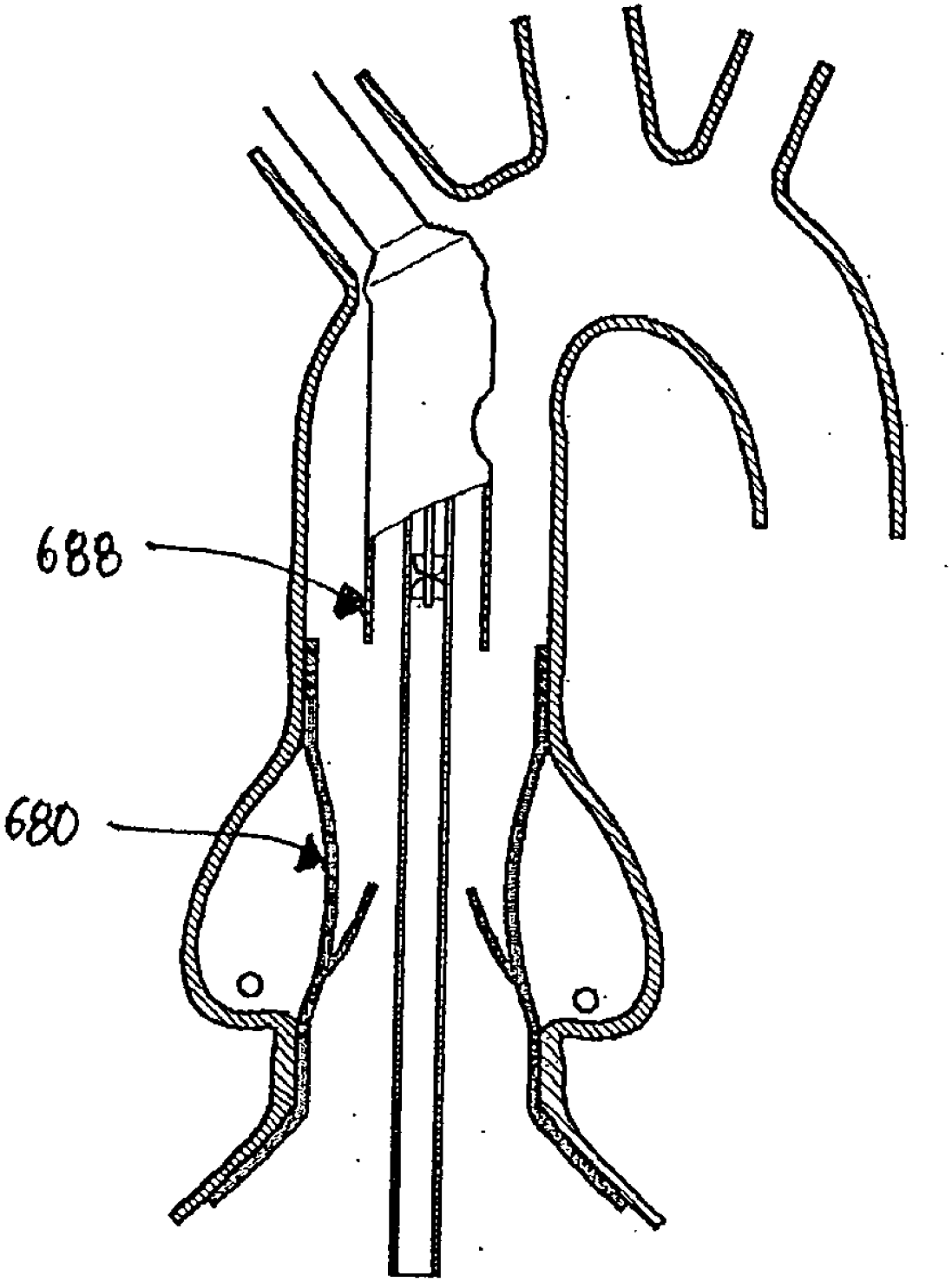




FIG. 71

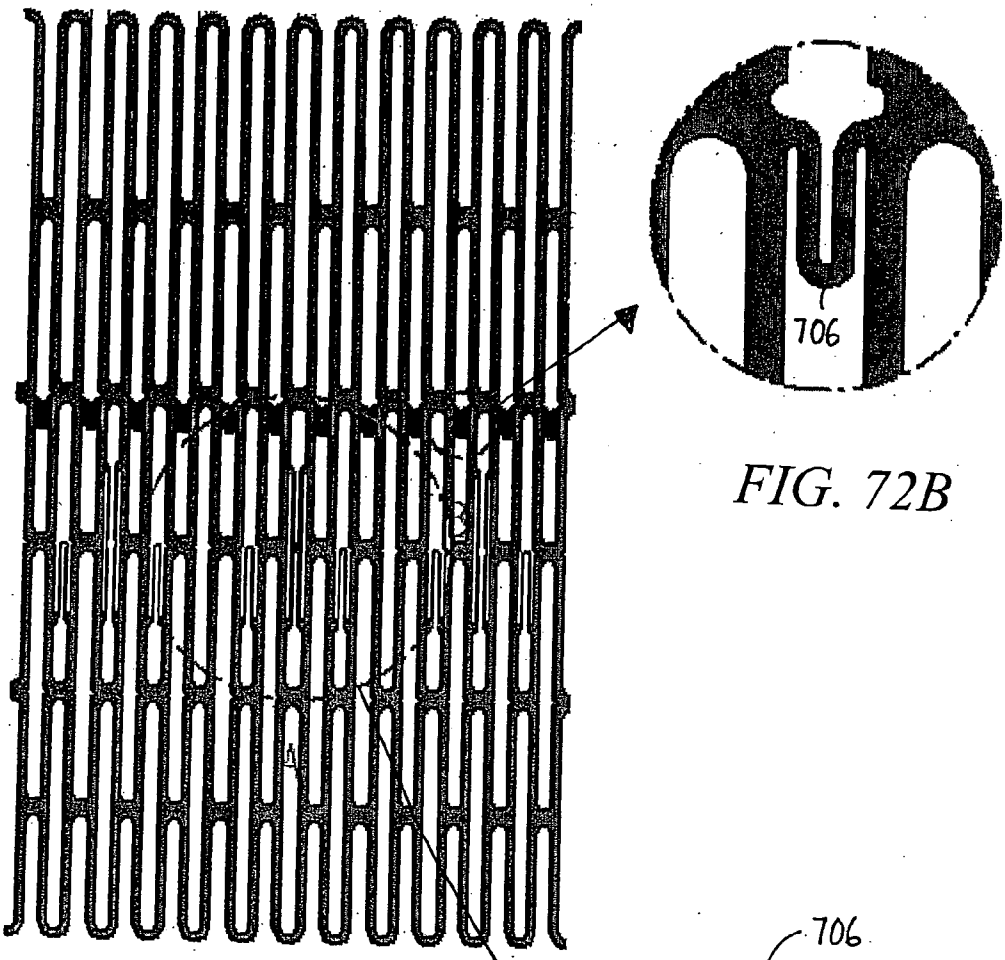


FIG. 72B

FIG. 72A

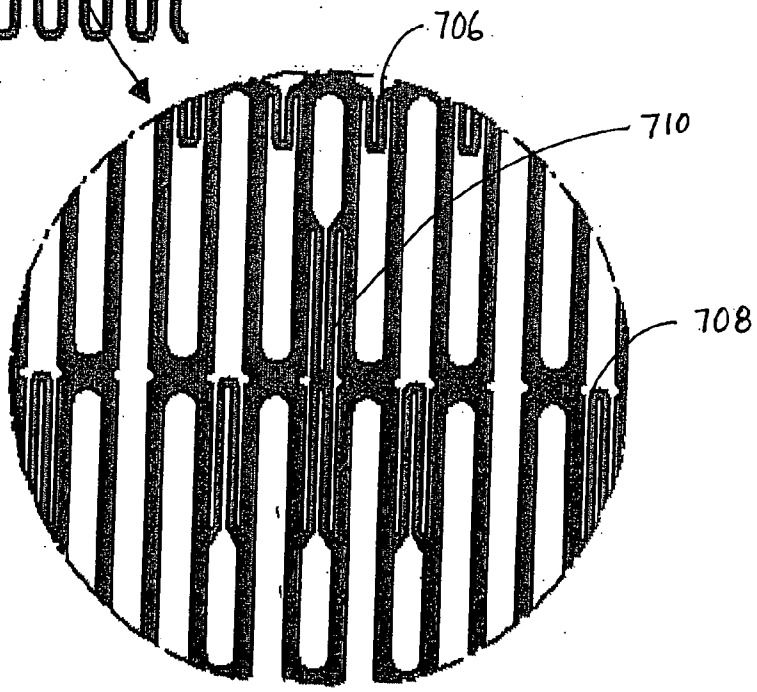


FIG. 72C

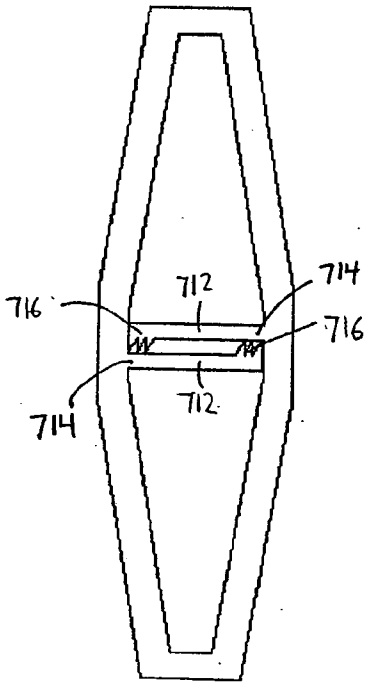


FIG. 73A

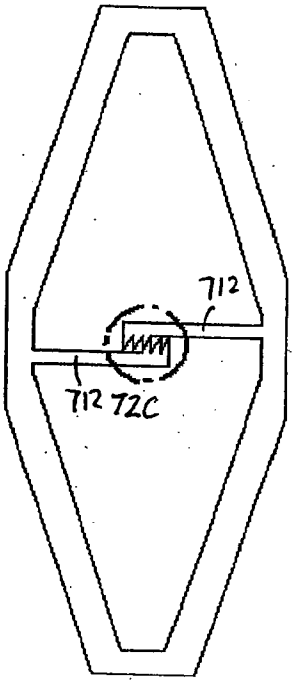


FIG. 73B

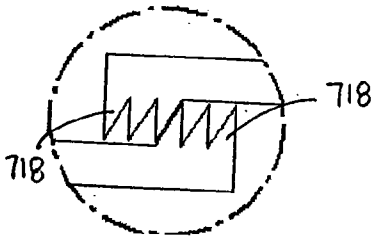


FIG. 73C

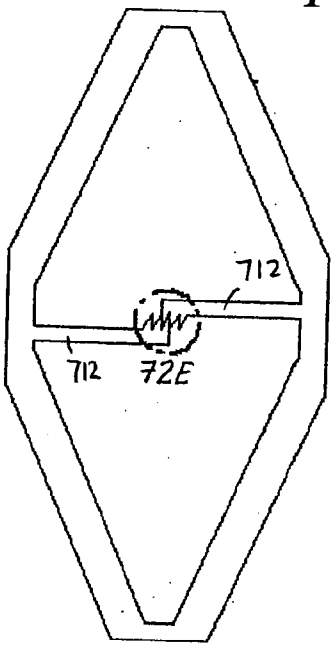


FIG. 73D

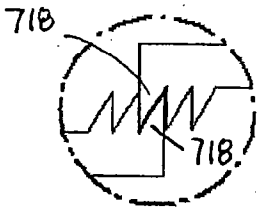


FIG. 73E

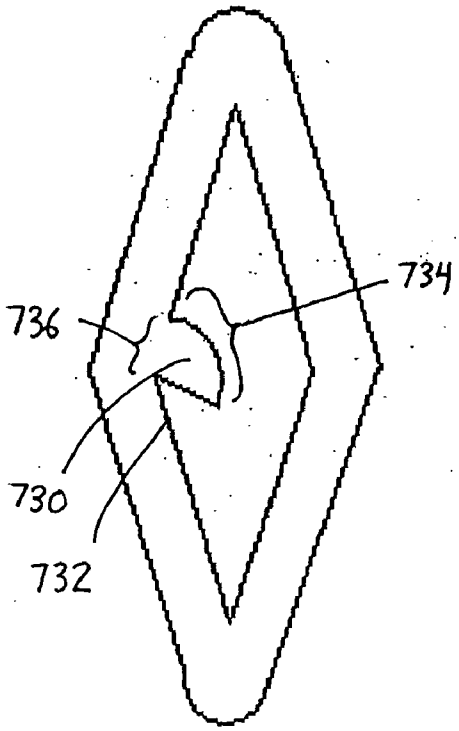


FIG. 74A

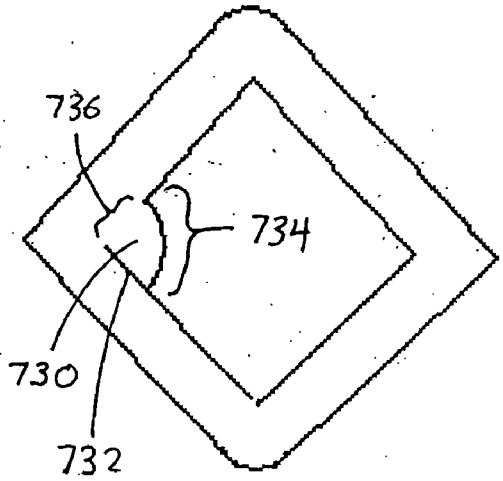


FIG. 74B

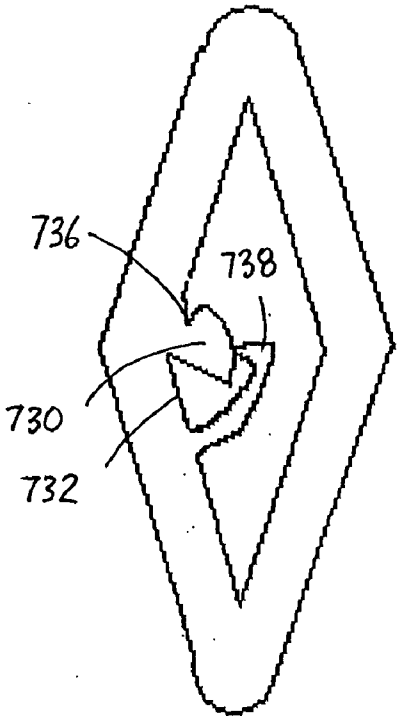


FIG. 75A

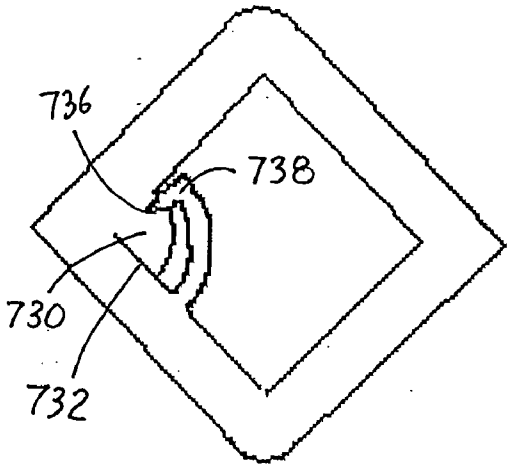


FIG. 75B

PROSTHETIC VALVE FOR TRANSLUMINAL DELIVERY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. Ser. No. 10/412,634 filed on Apr. 10, 2003, which is (1) a continuation-in-part of U.S. Ser. No. 10/130,355 filed on May 17, 2002, which is the U.S. national phase under § 371 of International Application No. PCT/FR00/03176, filed on Nov. 15, 2000, which was published in a language other than English and which claimed priority from French Application No. 99/14462 filed on Nov. 17, 1999, now French Patent No. 2,800,984, and (2) also a continuation-in-part of International Application No. PCT/FR01/03258 filed on Oct. 19, 2001, which was published in a language other than English and which claimed priority from French Application No. 00/14028 filed on Oct. 31, 2000, now French Patent No. 2,815,844.

FIELD OF THE INVENTION

[0002] The present invention relates to a prosthetic cardiac valve and related deployment system that can be delivered percutaneously through the vasculature, and a method for delivering same.

BACKGROUND OF THE INVENTION

[0003] Currently, the replacement of a deficient cardiac valve is often performed by opening the thorax, placing the patient under extracorporeal circulation or peripheral aorto-venous heart assistance, temporarily stopping the heart, surgically opening the heart, excising the deficient valve, and then implanting a prosthetic valve in its place. U.S. Pat. No. 4,106,129 to Carpentier describes a bioprosthetic heart valve with compliant orifice ring for surgical implantation. This procedure generally requires prolonged patient hospitalization, as well as extensive and often painful recovery. It also presents advanced complexities and significant costs.

[0004] To address the risks associated with open heart implantation, devices and methods for replacing a cardiac valve by a less invasive means have been contemplated. For example, French Patent Application No. 99 14462 illustrates a technique and a device for the ablation of a deficient heart valve by percutaneous route, with a peripheral valvular approach. International Application (PCT) Nos. WO 93/01768 and WO 97/28807, as well as U.S. Pat. No. 5,814,097 to Sterman et al., U.S. Pat. No. 5,370,685 to Stevens, and U.S. Pat. No. 5,545,214 to Stevens illustrate techniques that are not very invasive as well as instruments for implementation of these techniques.

[0005] U.S. Pat. No. 3,671,979 to Moulopoulos and U.S. Pat. No. 4,056,854 to Boretos describe a catheter-mounted artificial heart valve for implantation in close proximity to a defective heart valve. Both of these prostheses are temporary in nature and require continued connection to the catheter for subsequent repositioning or removal of the valve prosthesis, or for subsequent valve activation.

[0006] With regard to the positioning of a replacement heart valve, attaching this valve on a support with a structure in the form of a wire or network of wires, currently called a stent, has been proposed. This stent support can be contracted radially in such a way that it can be introduced into the body of the patient percutaneously by means of a catheter, and it can be deployed so as to be radially expanded once it is positioned at the desired target site. U.S. Pat. No. 3,657,744 to Ersek discloses a cylindrical, stent-supported, tri-leaflet, tissue, heart valve that can be delivered through a portion of the vasculature using an elongate tool. The stent is mounted onto the expansion tool prior to delivery to the target location where the stent and valve are expanded into place. More recently, U.S. Pat. No. 5,411,552 to Andersen also illustrates a technique of this type. In the Andersen patent, a stent-supported tissue valve is deliverable percutaneously to the native heart valve site for deployment using a balloon or other expanding device. Efforts have been made to develop a stent-supported valve that is self-expandable, using memory materials such as Nitinol.

[0007] The stent-supported systems designed for the positioning of a heart valve introduce uncertainties of varying degree with regard to minimizing migration from the target valve site. A cardiac valve that is not adequately anchored in place to resist the forces of the constantly changing vessel wall diameter, and turbulent blood flow therethrough, may dislodge itself, or otherwise become ineffective. In particular, the known stents do not appear to be suited to sites in which the cardiac wall widens on either proximally and/or distally of the valve annulus situs. Furthermore, the native cardiac ring remaining after ablation of the native valve can hinder the positioning of these stents. These known systems also in certain cases create problems related to the sealing quality of the replacement valve. In effect, the existing cardiac ring can have a surface that is to varying degrees irregular and calcified, which not only lessens the quality of the support of the stent against this ring but also acts as the source of leaks between the valve and this ring. Also, these systems can no longer be moved at all after deployment of the support, even if their position is not optimal. Furthermore, inflating a balloon on a stented valve as described by Andersen may traumatize the valve, especially if the valve is made from a fragile material as a living or former living tissue.

[0008] Also, the existing techniques are however considered not completely satisfactory and capable of being improved. In particular, some of these techniques have the problem of involving in any case putting the patient under extracorporeal circulation or peripheral aorto-venous heart assistance and temporary stopping of the heart; they are difficult to put into practice; they do not allow precise control of the diameter according to which the natural valve is cut, in view of the later calibration of the prosthetic valve; they lead to risks of diffusion of natural valve fragments, often calcified, into the organism, which can lead to an embolism, as well as to risks of perforation of the aortic or cardiac wall; they moreover induce risks of acute reflux of blood during ablation of the natural valve and risk of obstruction of blood flow during implantation of the device with a balloon expandable stent for example.

SUMMARY OF THE INVENTION

[0009] The object of the present invention is to transluminally provide a prosthetic valve assembly that includes features for preventing substantial migration of the prosthetic valve assembly once delivered to a desired location within a body. The present invention aims to remedy these

significant problems. Another objective of the invention is to provide a support at the time of positioning of the replacement valve that makes it possible to eliminate the problem caused by the native valve sheets, which are naturally calcified, thickened and indurated, or by the residues of the valve sheets after valve resection. Yet another objective of the invention is to provide a support making possible complete sealing of the replacement valve, even in case of an existing cardiac ring which has a surface which is to varying degrees irregular and/or to varying degrees calcified. Another objective of the invention is to have a device that can adapt itself to the local anatomy (i.e. varying diameters of the ring, the subannular zone, the sino-tubular junction) and maintain a known diameter of the valve prosthesis to optimize function and durability. The invention also has the objective of providing a support whose position can be adapted and/or corrected if necessary at the time of implantation.

[0010] The present invention is a prosthesis comprising a tissue valve supported on a self-expandable stent in the form of a wire or a plurality of wires that can be contracted radially in order to make possible the introduction of the support-valve assembly into the body of the patient by means of a catheter, and which can be deployed in order to allow this structure to engage the wall of the site where the valve is to be deployed. In one embodiment, the valve is supported entirely within a central, self-expandable, band. The prosthetic valve assembly also includes proximal and distal anchors. In one embodiment, the anchors comprise discrete self-expandable bands connected to the central band so that the entire assembly expands in unison into place to conform more naturally to the anatomy.

[0011] The valve can be made from a biological material, such as an animal or human valve or tissue, or from a synthetic material, such as a polymer, and includes an annulus, leaflets and commissure points. The valve is attached to the valve support band with, for example, a suture. The suture can be a biologically compatible thread, plastic, metal or adhesive, such as cyanoacrylate. In one embodiment, the valve support band is made from a single wire bent in a zigzag manner to form a cylinder. Alternatively, the valve support band can be made from a plurality of wires interwoven with one another. The wire can be made from stainless steel, silver, tantalum, gold, titanium, or any suitable tissue or biologically compatible plastic, such as ePTFE or Teflon. The valve support band may have a loop at its ends so that the valve support band can be attached to an upper anchor band at its upper end, and a lower anchor band at its lower end. The link can be made from, for example, stainless steel, silver, tantalum, gold, titanium, any suitable plastic material, or suture.

[0012] The prosthetic valve assembly is compressible about its center axis such that its diameter can be decreased from an expanded position to a compressed position. The prosthetic valve assembly may be loaded onto a catheter in its compressed position, and so held in place. Once loaded onto the catheter and secured in the compressed position, the prosthetic valve assembly can be transluminally delivered to a desired location within a body, such as a deficient valve within the heart. Once properly positioned within the body, the catheter can be manipulated to release the prosthetic valve assembly and permit it to into its expanded position. In one embodiment, the catheter includes adjustment hooks such that the prosthetic valve assembly may be partially released and expanded within the body and moved or otherwise adjusted to a final desired location. At the final desired location, the prosthetic valve assembly may be totally released from the catheter and expanded to its fully expanded position. Once the prosthetic valve assembly is fully released from the catheter and expanded, the catheter may be removed from the body.

[0013] Other embodiments are contemplated. In one such alternative embodiment, this structure comprises an axial valve support portion that has a structure in the form of a wire or in the form of a network of wires suitable for receiving the replacement valve mounted on it, and suitable for supporting the cardiac ring remaining after the removal of the deficient native valve. The embodiment may further comprise at least one axial wedging portion, that has a structure in the form of a wire or in the form of a network of wires that is distinct from the structure of said axial valve support portion, and of which at least a part has, when deployed a diameter greater or smaller than that of said deployed axial valve support portion, such that this axial wedging portion or anchor is suitable for supporting the wall bordering said existing cardiac ring. The embodiment preferably further comprises at least one wire for connecting the two portions, the wire or wires being connected at points to these portions in such a way as not to obstruct the deployment of said axial portions according to their respective diameters. The embodiment thus provides a support in the form of at least two axial portions that are individualized with respect to one another with regard to their structure, and that are connected in a localized manner by at least one wire; where this wire or these wires do not obstruct the variable deployment of the axial portion with the valve and of the axial wedging portion(s) or anchors. The anchors may be positioned distally or proximally.

[0014] The presence of a structure in the form of a wire or in the form of a network of wires in the axial valve support portion makes possible a perfect assembly of this valve with this structure, and the shape as well as the diameter of this axial portion can be adapted for supporting the existing cardiac ring under the best conditions. In particular, this axial valve support portion can have a radial force of expansion such that it pushes back ("impacts") the valve sheets that are naturally calcified or the residues of the valve sheets after valve resection onto or into the underlying tissues, so that these elements do not constitute a hindrance to the positioning of the replacement valve and also allow for a greater orifice area. This structure also makes it possible to support an optional anchoring means and/or optional sealing means for sealing the space between the existing cardiac ring and the replacement valve, as indicated below.

[0015] The configuration of each anchor portion can be adapted for supporting the cardiac wall situated at the approach to the existing cardiac ring under the best conditions. In particular, this anchor portion can have a tubular shape with a constant diameter greater than that of the axial valve support portion, or the form of a truncated cone whose diameter increases with distance from the axial valve support portion. By attaching at least one anchor portion to the axial valve support portion, the prosthetic valve assembly assumes a non-cylindrical or toroidal configuration. This non-cylindrical configuration provides an increased radial

expansion force and increased diameter at both ends of the prosthetic valve assembly that may tighten the fit between the valve assembly and surrounding tissue structures. The tighter fit from a non-cylindrical configuration can favorably increase the anchoring and sealing characteristics of the prosthesis. The axial valve support portion itself may be non-cylindrical as well.

[0016] Preferably, the tubular support has an axial valve support portion in the form of at least two parts, of which at least one is suitable for supporting the valve and of which at least another is suitable for pushing back the native valve sheets or the residues of the native valve sheets after valve resection, into or onto the adjacent tissue in order to make this region able to receive the tubular support. This axial valve support portion eliminates the problem generated by these valve or cardiac ring elements at the time of positioning of the replacement valve. The radial force of this axial valve support portion, by impacting all or part of the valvular tissue or in the wall or its vicinity in effect ensures a more regular surface more capable of receiving the valve support axis. It also ensures a better connection with the wall while reducing the risk of peri-prosthetic leakage. Furthermore, such a structure permits the valve to maintain a diameter within a preset range to ensure substantial coaptivity and avoid significant leakage.

[0017] The particular method of maintaining the valve diameter within a preset range described above relates to the general concept of controlling the expanded diameter of the prosthesis. The diameter attained by a portion of the prosthesis is a function of the radial inward forces and the radial expansion forces acting upon that portion of the prosthesis. A portion of the prosthesis will reach its final diameter when the net sum of these forces is equal to zero. Thus, controlling the diameter of the prosthesis can be addressed by addressing the radial expansion force, the radial inward forces, or a combination of both. Changes to the radial expansion force generally occur in a diameter-dependent manner and can occur extrinsically or intrinsically. Resisting further expansion can occur extrinsically by using structural restraints that oppose the intrinsic radial expansion force of the prosthesis, or intrinsically by changing the expansion force so that it does not expand beyond a preset diameter. The first way, referred to previously, relates to controlling expansion extrinsically to a preset diameter to ensure coaptivity. In one embodiment configured to control diameter, a maximum diameter of at least a portion of the support structure may be ensured by a radial restraint provided along at least a portion of circumference of the support structure. The radial restraint may comprise a wire, thread or cuff engaging the support structure. The restraint may be attached to the support structure by knots, sutures or adhesives, or may be integrally formed with the support structure. The radial restraints may also be integrally formed with the support structure during the manufacturing of the support structure. The configuration of the radial restraint would depend upon the restraining forces necessary and the particular stent structure used for the prosthesis. A radial restraint comprising a mechanical stop system is also contemplated. A mechanical stop system uses the inverse relationship between the circumference of the support structure and the length of the support structure. As the support structure radially expands, the longitudinal length of the support structure will generally contract or compress as the wires of the support structure having a generally longitudinal orientation change to a circumferential orientation during radial expansion. By limiting the distance by which the support structure can compress in a longitudinal direction, or the angle to which the support structure wires reorient, radial expansion in turn can be limited to a maximum diameter. The radial restraint may comprise a plurality of protrusions on the support structure where the protrusions abut or form a mechanical stop against another portion of the support structure when the support structure is expanded to the desired diameter.

[0018] In an embodiment configured to control the expanded diameter intrinsically for a portion of the support, the radial expansion force of the valve support may be configured to apply up to a preset diameter. This can be achieved by the use of the shape memory effect of certain metal alloys like nickel titanium or Nitinol. When Nitinol material is exposed to body heat, it will expand from a compressed diameter to its original diameter. As the Nitinol prosthesis expands, it will exert a radial expansion force that decreases as the prosthesis expands closer to its original diameter, reaching a zero radial expansion force when its original diameter is reached. Thus, use of a shape memory alloy such as Nitinol is one way to provide an intrinsic radial restraint. A non-shape memory material that is elastically deformed during compression will also exhibit diameter-related expansion forces when allowed to return to its original shape.

[0019] Although both shape memory and non-shape memory based material may provide diameter-dependent expansion forces that reach zero upon attaining their original shapes, the degree of force exerted can be further modified by altering the thickness of the wire or structure used to configure the support or prosthesis. The prosthesis may be configured with thicker wires to provide a greater expansion force to resist, for example, greater radial inward forces located at the native valve site, but the greater expansion force will still reduce to zero upon the prosthesis attaining its preset diameter. Changes to the wire thickness need not occur uniformly throughout a support or a prosthesis. Wire thickness can vary between different circumferences of a support or prosthesis, or between straight portions and bends of the wire structure.

[0020] The other way of controlling diameter previously mentioned is to alter or resist the radial inward or recoil forces acting upon the support or prosthesis. Recoil forces refer to any radially inward force acting upon the valve assembly that prevents the valve support from maintaining a desired expanded diameter. Recoil forces include but are not limited to radially inward forces exerted by the surrounding tissue and forces caused by elastic deformation of the valve support. Opposing or reducing recoil forces help to ensure deployment of the support structure to the desired diameter.

[0021] Means for substantially minimizing recoil are also contemplated. Such means may include a feature, such as a mechanical stop, integral with the support structure to limit recoil. By forming an interference fit between the mechanical stop and another portion of the support structure when the support structure is expanded to its preset diameter, the support structure can resist collapse to a smaller diameter and resist further expansion beyond the preset diameter. The interference fit may comprise an intercalating teeth configu-

ration or a latch mechanism. Alternatively, a separate stent may be applied to the lumen of the cardiac ring to further push aside the native valve leaflets or valve remnants by plastically deforming a portion of the prosthesis. This separate stent may be placed in addition to the support structure and may overlap at least a portion of the support structure. By overlapping a portion of the support structure, the separate stent can reduce any recoil force acting on the support structure. It is also contemplated that this separate stent might be applied to the native lumen before the introduction of the valve prosthesis described herein. Another alternative is to plastically deform the valve assembly diameter beyond its yield point so that the prosthesis does not return to its previous diameter.

[0022] At portions of the prosthesis where the control of the expansion force against surrounding tissue is desired, the various methods for controlling diameter can be adapted to provide the desired control of expansion force. Portions of the prosthesis may include areas used for anchoring and sealing such as the axial wedging portions previously described.

[0023] Specifically, in order to support the valve, the axial valve support portion can have a part in the form of an undulating wire with large-amplitude undulations, and a part in the form of an undulating wire with small-amplitude undulations, adjacent to said part with large amplitude undulations, having a relatively greater radial force in order to make it possible to push said valvular tissue against or into the wall of the passage. Preferably, the support according to one embodiment of the present invention has two axial wedging portions, one connected to an axial end of said valve support portion and the other to the other axial end of this same valve support portion. These two axial wedging portions thus make it possible to wedge the support on both sides of the existing cardiac ring, and consequently make possible complete wedging of the support in two opposite directions with respect to the treated site. If necessary, for example, in the case in which the passage with the valve has an aneurysm, the support according to the invention has: an axial holding portion, suitable for supporting in the deployed state the wall of the passage, and connecting wires such as the aforementioned connecting wires, connecting said axial valve support portion and said axial holding portion, these wires having a length such that the axial holding portion is situated after implantation a distance away from the axial valve support portion. This distance allows said axial holding portion to rest against a region of the wall of the passage not related to a possible defect which may be present at the approach to the valve, particularly an aneurysm. The length of the connecting wires can also be calculated in order to prevent the axial holding portion from coming into contact with the ostia of the coronary arteries. The aforementioned axial portions (valve support, wedging, holding portions) can have a structure in the form of an undulating wire, in zigzag form, or preferably a structure in diamond-shaped mesh form, the mesh parts being juxtaposed in the direction of the circumference of these portions. This last structure allows a suitable radial force making it possible to ensure complete resting of said portions against the wall that receives them.

[0024] As previously mentioned, the support according to the invention can be produced from a metal that can be plastically deformed. The instrument for positioning of the support then includes a balloon which has an axial portion with a predetermined diameter, adapted for realizing the deployment of said axial valve support portion, and at least one axial portion shaped so as to have, in the inflated state, a greater cross section than that of the passage to be treated, in such a way as to produce the expansion of the axial wedging portion placed on it until this axial wedging portion encounters the wall which it is intended to engage. The support according to this embodiment of the present invention can also be produced from a material that can be elastically deformed or even a material with shape memory, such as Nitinol, which can be contracted radially at a temperature different from that of the body of the patient and which regains its original shape when its temperature approaches or reaches that of the body of the patient.

[0025] Alternatively, the support may be made from a shape memory material that can be plastically deformed, or may be partially made from a shape memory material and partially made from a material that can be plastically deformed. With this embodiment, the support can be brought, by shape memory or plastic deformation, from a state of contraction to a stable intermediate state of deployment between the state of contraction and the state of total deployment, and then by plastic deformation or shape memory respectively, from said intermediate state of deployment to said state of total deployment. In said intermediate state of deployment, the support is preferably configured such that it remains mobile with respect to the site to be treated. The support may thus be brought to the site to be treated and then deployed to its intermediate state; its position can then possibly be adapted and/or corrected, and then the support be brought to its state of total deployment. One example of a shape memory material that can be plastically deformed may be a nickel-titanium alloy of the type called "martensitic Nitinol" that can undergo plastic deformation by means of a balloon. By using a balloon to expand and stress the alloy beyond its yield point, plastic deformation can occur. Plastic deformation by a balloon of a portion of the prosthesis that has already undergone self-expansion can also be used to compensate for any recoil that occurs.

[0026] Advantageously, the support according to the invention has some anchoring means suitable for insertion into the wall of the site to be treated, and is shaped in such a way as to be mobile between an inactive position, in which it does not obstruct the introduction of the support into the body of the patient, and an active position, in which it is inserted into the wall of the site to be treated. Substantially complete immobilization of the support at the site is thus obtained. In particular, this anchoring means can be in the form of needles and can be mounted on the support between retracted positions and radially projected positions. Advantageously, the axial valve support portion has, at the site of its exterior surface, a sealing means shaped in such a way as to absorb the surface irregularities that might exist at or near the existing cardiac ring. This sealing means can consist of a peripheral shell made from a compressible material such as polyester or tissue identical to the valve or a peripheral shell delimiting a chamber and having a radially expandable structure, this chamber being capable of receiving an inflating fluid suitable for solidifying after a predetermined delay following the introduction into said chamber. This sealing means can also include a material that can be applied between the existing cardiac ring and the axial valve support

portion, this material being capable of solidifying after a predetermined delay following this application. Specifically, in this case, this material is capable of heat activation, for example, by means of a laser, through the balloon, or capable of activation by emission of light of predetermined frequency, for example, by means of an ultraviolet laser, through the balloon. Said sealing means can also be present in the form of an inflatable insert with a spool-shaped cross section in the inflated state, which can be inserted between the existing cardiac ring and the axial valve support portion, Said spool shape allows this insert to conform to the best extent possible to the adjacent irregular structures and to provide a better seal.

[0027] In one embodiment of the invention, a drug-eluting component is contemplated. This component comprises a surface coating or matrix bonding to at least a portion of support structure. Drug elution is well known to those in the art. Potential drugs may include but are not limited to antibiotics, cellular anti-proliferative and anti-thrombogenic drugs.

[0028] An assembly and method for removing the native valve is also contemplated. In particular, the invention has the objective of providing a device that gives complete satisfaction with regard to the exeresis and replacement of the valve, while allowing one to operate without opening of the thorax, stopping of the heart and/or opening of the heart, and preventing any diffusion into the circulatory system of fragments of the removed valve. In one embodiment, the assembly comprises: (a) an elongated support element; (b) a first set of elongated blades arranged around the circumference of said elongated element and connected in a pivoting manner to the elongated element at the site of their proximal longitudinal ends, each blade having a sharp edge at the site of its distal longitudinal end and configured to pivot with respect to the elongated element between a folded up (retracted) position, in which they are near the wall of the elongated element in such a way that they do not stand in the way of the introduction and sliding of the device in the body channel in which the valve is located, in particular in the aorta, and an opened out (protracted) position, in which these blades are spread out in the form of a corolla in such a way that their sharp edges are placed in extension of one another and thus constitute a sharp circular edge; (c) a second set of blades arranged consecutively to said first series of blades in the distal direction; the blades of this second set have a structure identical to that of the blades of said first set, wherein the blades of this second series are connected to the elongated element by their distal longitudinal ends and wherein each has a sharp edge at the site of its proximal longitudinal end; (d) means making it possible to bring the blades of said first and second set from their retracted position to their protracted position; (e) means for permitting axial movement of the sets of blades axially relative to one another between a spaced position in which one set of blades can be placed axially on one side of the natural valve while the other set of blades is placed axially on the other side of this valve, and a proximate position in which the sharp circular edges of the two sets of blades may be brought into mutual contact for excising the natural valve.

[0029] A method of using this assembly comprises the steps of introducing the assembly percutaneously into said body channel and delivering the assembly to a position where the first and second sets of blades are spaced on opposite sides of the natural valve using the means of identification. The method may further comprise putting in place a system of peripheral aorto-venous heart assistance, extracorporeal circulation or a blood pump through the center of the delivery system for pumping blood, in the case of an aortic valve replacement, from the left ventricle (proximal to the aortic valve) to the aorta (distal to the aortic valve) in order to facilitate the flow of the blood, for the purpose of preventing stagnation of the blood in the heart. One embodiment of a blood flow pump is described further below. After the assembly is positioned in place, the method further comprises spreading the blades of the two sets of blades out; then bringing the two sets closer together to excise the valve. The configuration of these blades makes it possible to execute this cutting in a single operation, minimizing the generation of fragments that can be diffused into the circulatory system. This configuration moreover makes possible precise control of the diameter according to which the natural valve is cut, in view of later calibration of the prosthetic valve. The blades may then be retracted for placement of the prosthetic valve.

[0030] The prosthetic valve may be deployed discretely from the assembly, in which case the method may comprise removing the assembly and then separately deploying the prosthetic valve. Preferably however, the assembly comprises a proximal prosthetic valve having an expandable support structure that may occupy a contracted position near the wall of said elongated element for transmission through the body channel, and an expanded position to replace the natural cardiac valve.

[0031] After excising the natural valve, the method further comprises sliding the assembly axially in the distal direction in order to bring the prosthetic valve to the desired site in the channel, and then expanding the prosthetic valve support into place. The assembly may then be withdrawn, recovering the excised natural valve.

[0032] Preferably, the elongated support element is a tubular catheter permitting blood to flow through it during the excision of the natural valve. The cross section of the channel of this catheter can be sufficient to allow the blood to flow through this channel with or without the help of a pump. Continued blood flow during the excision procedure may limit or eliminate the need for placing the patient under extracorporeal circulation or peripheral aorto-venous heart assistance. The catheter has a lateral distal opening in order to allow the blood to rejoin the body channel, for example the ascending aorta, this opening being arranged in such a way that the length of catheter passed through the blood is as short as possible. Alternatively, the catheter may have a small diameter to facilitate the introduction and delivery of the assembly in the body channel, but a small diameter might require the provision of peripheral circulation by an external assistance system such as an extracorporeal circulation system or-peripheral aorto-venous heart assistance.

[0033] Preferably, the assembly for excising the native valve includes a distal inflatable balloon, placed at the site of the exterior surface of said elongated element; wherein the balloon is configured so as to occupy a deflated position, in which it has a cross section such that it does not stand hinder introduction and advancement of the assembly within the body channel, and an expanded position. The balloon may be inflated after the positioning of the sets of blades on

both sides of the natural valve in order to prevent reflux of the blood during the ablation of the natural valve. If the elongated element is a catheter, this balloon moreover makes it possible to cause blood to flow only through the catheter. Once the prosthetic valve is positioned, the balloon is deflated to re-establish the blood flow through the body channel.

[0034] The assembly for excising the native valve may optionally include a distal filter made of flexible material placed on the exterior surface of the elongated element. The filter is configured so that it can occupy a retracted position or a contracted position. This filter serves to capture possible fragments generated by the excision of the natural valve, for removal from the blood circulation. The assembly may include means for moving the sets of blades in the axial direction relative to the balloon and/or from said filter.

[0035] The balloon and optional filter may be separate from the assembly, being mounted on an elongated support element specific to them. In case of operation on a mitral valve, this balloon or filter may be introduced into the aorta by a peripheral artery route, and the assembly is itself introduced into the heart by the peripheral venous system, up to the right atrium and then into the left atrium through the interatrial septum, up to the site of the mitral valve. The prosthetic valve can advantageously have a frame made of a material with a shape memory, particularly a nickel-titanium alloy known as "Nitinol." This same valve can have valve leaflets made of biological material (preserved animal or human valves) or synthetic material such as a polymer. When replacing an aortic valve the assembly may be alternatively introduced in a retrograde manner through a peripheral artery (femoral artery) or through a venous approach and transseptally (antegrade).

[0036] One embodiment of a system for deploying a prosthetic valve may comprise a blood pump insertable into the lumen of a catheter to facilitate blood flow across the native valve and implantation sites during the implantation procedure. When the catheter is positioned across the implantation site, a proximal opening of the delivery catheter is on one side of the implantation site and the lateral distal opening is on another side of the implantation site. By inserting the blood pump into the catheter lumen between the proximal and lateral distal openings, blood flow across the native valve and implantation sites is maintained during the procedure. One embodiment of the blood pump comprises a rotating impeller attached to a reversible motor by a shaft. When the impeller is rotated, blood flow can be created in either direction along the longitudinal axis of the catheter between the proximal and lateral distal openings to provide blood flow across the implantation site. The pump may be used during the native valve excision step if so carried out.

[0037] In one application of the present invention, the prosthetic valve may be implanted by first passing a guidewire inserted peripherally, for instance, through a vein access; transseptally from the right atrium to the left atrium and then snaring the distal end of the guidewire and externalizing the distal end out of the body through the arterial circulation. This placement of the guidewire provides access to the implantation site from both venous and arterial routes. By providing venous access to the native valve, massive valvular regurgitation during the implantation procedure may be avoided by first implanting the replacement valve and then radially pushing aside the native valve leaflets through the venous access route.

[0038] The above embodiments and methods of use are explained in more detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] **FIG. 1** is a cross-sectional side view of one embodiment of an assembly of the present invention for removing and replacing a native heart valve percutaneously;

[0040] **FIG. 2** is a cross-section axial view of the assembly of **FIG. 1** taken at line II-II, shown in a closed condition;

[0041] **FIG. 3** is a cross-section axial view of the assembly of **FIG. 1** taken at line II-II, shown in an opened condition;

[0042] **FIG. 4** is a perspective schematic view of one embodiment of a prosthetic valve of the present invention;

[0043] FIGS. **5** to **9** are schematic views of the assembly of the present invention positioned in a heart, at the site of the valve that is to be treated, during the various successive operations by means of which this valve is cut out and the prosthetic valve shown in **FIG. 4** deployed;

[0044] **FIG. 10** is a schematic view of the prosthetic valve shown of **FIG. 4** shown in a deployed state;

[0045] **FIG. 11** is a schematic view of an alternative embodiment of the assembly of the present invention shown treating a mitral valve;

[0046] **FIG. 12** is a cross-sectional view of a section of a blade used in excising the native valve.

[0047] **FIG. 13** is a schematic view of one embodiment of the support structure of the prosthesis assembly of the present invention;

[0048] **FIG. 14** is a cross-sectional view of the support of **FIG. 13** showing a heart valve supported by the central portion of the support;

[0049] **FIG. 15** is an end view of the support of **FIGS. 13 and 14** in the deployed state;

[0050] **FIG. 16** is an end view of the support of **FIGS. 13 and 14** in the contracted state;

[0051] **FIG. 17** is a schematic view of a heart with an embodiment of the present inventive prosthesis shown deployed in place;

[0052] **FIG. 18** is a schematic view of an alternative embodiment of the present invention;

[0053] **FIG. 19** is schematic view of an alternative embodiment of the present invention;

[0054] **FIG. 20** is a detail view of a part of the support structure of one embodiment of the present invention;

[0055] **FIG. 21** is a schematic view of the support of **FIG. 19** shown in a deployed state;

[0056] **FIG. 22** is schematic view of an alternative embodiment of the present invention;

[0057] **FIG. 23** is a detail view of the support of **FIG. 22** shown in the contracted state;

[0058] **FIG. 24** is a detail view of the support of **FIG. 23** taken along line **23-23**;

[0059] **FIG. 25** is a detail view of the support of **FIG. 22** shown in the expanded state;

[0060] **FIG. 26** is a detail view of the support of **FIG. 25** taken along line **25-25**;

[0061] **FIG. 27** is a schematic view of an alternative embodiment of the present invention;

[0062] **FIG. 28** is a detailed cross section view of the support of **FIG. 27**;

[0063] **FIG. 29** is a partial schematic view in longitudinal section of the support of the present invention and of a calcified cardiac ring;

[0064] **FIG. 30** is a schematic view of an alternative to the support of **FIG. 29**;

[0065] **FIG. 31** is a schematic view of an alternative to the support of **FIG. 29**;

[0066] **FIGS. 32 and 33** are schematic views of an alternative to the support of **FIG. 29**;

[0067] **FIG. 34** is a schematic cross-sectional view of a balloon corresponding to the support structure of FIGS. **19** to **21**;

[0068] **FIG. 35** is a schematic longitudinal sectional view of an alternative embodiment of the balloon of **FIG. 34**;

[0069] **FIG. 36** is a schematic view of a heart with an embodiment of the present inventive prosthesis shown deployed in place;

[0070] **FIG. 37** is a perspective view of one embodiment of a prosthetic valve assembly of the present invention;

[0071] **FIG. 38** is a side view of the prosthetic valve assembly of **FIG. 37**;

[0072] **FIG. 39** is a perspective view of one embodiment of the prosthetic valve assembly of **FIG. 37**;

[0073] **FIG. 40** is a perspective view of an alternative embodiment of the prosthetic valve assembly with a sheath around the valve;

[0074] **FIG. 41A** is a perspective view of a distal portion of a catheter assembly for use in deploying the prosthetic valve assembly described herein;

[0075] **FIG. 41B** is a perspective view of a proximal portion of the catheter assembly of **FIG. 41A**;

[0076] **FIG. 42** is a perspective view of the distal portion of the catheter assembly of **FIG. 41A**;

[0077] **FIGS. 43 through 45** are perspective views of the catheter assembly of **FIG. 41A** showing deployment of a prosthesis assembly in sequence;

[0078] **FIGS. 46 and 47** are perspective views of the catheter assembly of **FIG. 41A** showing deployment of an alternative prosthesis assembly;

[0079] **FIG. 48** is a perspective view of the alternative prosthesis assembly shown in **FIGS. 46 and 47**.

[0080] **FIG. 49** is a perspective view of an alternative embodiment of the prosthetic valve assembly of **FIG. 37** showing a distal anchor;

[0081] **FIG. 50** is side view of an impeller and impeller housing of one embodiment of the blood pump;

[0082] **FIG. 51** is a side view of a catheter with catheter openings that allow blood flow by the impeller;

[0083] **FIG. 52** is a side view of the catheter with the impeller in place and blood flow depicted by arrows;

[0084] **FIG. 53** depicts another embodiment of the invention with a separate blood pump catheter relative to the prosthesis delivery system;

[0085] **FIG. 54** illustrates the embodiment shown in **FIG. 16** with the blood pump in place and blood flow shown by arrows;

[0086] **FIG. 55** depicts one embodiment of the present invention comprising loop elements released from a delivery catheter after withdrawal of an outer sheath;

[0087] **FIGS. 56A and 56B** represent one embodiment of the radial restraint comprising a wire interwoven into the support structure;

[0088] **FIG. 57** depicts another embodiment of the invention wherein two radial restraints of different size are attached to different portions of the support structure;

[0089] **FIG. 58** represents one embodiment of the radial restraint comprising a cuff-type restraint;

[0090] **FIG. 59** is a schematic view of a wire bend with a symmetrically reduced diameter;

[0091] **FIG. 60** is a schematic view of an alternative embodiment of a wire bend with an asymmetrically reduced diameter;

[0092] **FIG. 61** is a schematic view of one embodiment of the implantation procedure for the prosthetic valve where the distal end of a transseptally placed guidewire has been externalized from the arterial circulation;

[0093] **FIG. 62** is a schematic view of a balloon catheter passed over the guidewire of **FIG. 61** to dilate the native valve;

[0094] **FIG. 63** is a schematic view showing the deployment of a prosthetic valve by an arterial approach over the guidewire of **FIG. 62**;

[0095] **FIG. 64** is a schematic view showing a balloon catheter passed over the guidewire of **FIG. 63** from a venous approach and placed opposite the stented native valve for additional ablation and/or securing of the lower portion of the stent;

[0096] **FIG. 65** is a schematic view showing how the stent of **FIG. 64** remains attached to the delivery system by braces to allow full positioning of the stent;

[0097] **FIG. 66** depicts a schematic view of another embodiment of the implantation procedure for the prosthetic valve where a guidewire is inserted into the axillary artery and passed to the left ventricle;

[0098] **FIG. 67** depicts a schematic view of a blood pump passed over the guidewire of **FIG. 66**;

[0099] **FIG. 68** depicts a schematic view of a valve prosthesis passed over the blood pump of **FIG. 67**;

[0100] **FIGS. 69 and 70** depict schematic views of the deployment and attachment of the prosthesis of **FIG. 68** to the vessel wall.

[0101] **FIG. 71** is a photograph of a valve assembly with radial restraints integrally formed by laser cutting;

[0102] **FIGS. 72A through 72C** are schematic views of a portion of a valve assembly with different radial restraints formed by laser cutting;

[0103] **FIGS. 73A through 73E** are schematic views of another embodiment of a laser cut anti-recoil feature, in various states of expansion;

[0104] **FIGS. 74A and 74B** are schematic views of an angular mechanical stop for controlling diameter; and

[0105] **FIGS. 75A and 75B** are schematic views of an angular mechanical stop with a latch for resisting recoil.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0106] Reference is now made to the figures wherein like parts are designated with like numerals throughout. FIGS. **1** to **3** represent a device **1** for replacing a heart valve by a percutaneous route. This device comprises a tubular catheter **2** formed from three tubes **5**, **6**, **7** engaged one inside the other and on which there are placed, from the proximal end to the distal end (considered with respect to the flow of blood, that is to say from right to left in **FIG. 1**), a prosthetic valve **10**, two series of blades **11**, **12**, a balloon **13** and a filter **14**. The three tubes **5**, **6**, **7** are mounted so that they can slide one inside the other. The interior tube **5** delimits a passage **15**, the cross section of which is large enough to allow blood to flow through it. At the proximal end, the intermediate tube **6** forms a bell housing **6***a* delimiting, with the interior tube **5**, an annular cavity **17** in which the prosthetic valve **10** is contained in the furled condition.

[0107] **FIG. 4** shows that this valve **10** comprises an armature **20** and valve leaflets **21** mounted so that they are functionally mobile on this armature **20**. The armature comprises a collection of wires **22**, **23**, **24** made of shape memory material, particularly of nickel-titanium alloy known by the name of "NITINOL;" namely, (i) a proximal end wire **22** which, when the valve **10** is in the deployed state, has a roughly circular shape; (ii) a distal end wire **23** forming three corrugations in the axial direction, these corrugations being distributed uniformly around the circumference of the valve **10**, and (iii) an intermediate wire **24** forming longitudinal corrugations between the wires **22** and **23**, this wire **24** being connected to the latter ones via the ends of each of these corrugations. The valve leaflets **21** for their part are made of biological material (preserved human or animal valve leaflets) or of synthetic material, such as a polymer. The armature **20** may, when its material is cooled, be radially contracted so that the valve **10** can enter the cavity **17**. When this material is heated to body temperature, this armature **20** returns to its original shape, depicted in **FIG. 4**, in which it has a diameter matched to that of a bodily vessel, particularly the aorta, in which the native valve that is to be treated lies. This diameter of the armature **20** is such that the valve **10** bears against the wall of the bodily vessel and is immobilized in the axial direction with respect to that vessel.

[0108] Each series of blades **11**, **12** comprises metal elongate blades **30** and an inflatable balloon **31** situated between the catheter **2** and these blades **30**. The blades **30** have a curved profile and are arranged on the circumference of the catheter **2**, as shown in **FIGS. 2, 3** and **3**A. The blades **30** of the proximal series **11** are connected pivotably to the tube **6** by their proximal ends and comprise a cutting distal edge **30***a*, while the blades **30** of the distal series **12** are connected pivotably to the exterior tube **7** by their distal ends and comprise a cutting proximal edge **30***b*. The connection between the blades **30** and the respective tubes **6** and **7** is achieved by welding the ends of the blades **30** together to form a ring, this ring being fixed axially to the corresponding tube **6**, **7** by crimping this ring onto this tube **6**, **7**, the pivoting of the blades **30** being achieved by simple elastic deformation of these blades **30**. This pivoting can take place between a position in which the blades **30** are furled, radially internally with respect to the catheter **2** and shown in **FIGS. 1 and 2**, and a position in which these blades **30** are unfurled, radially externally with respect to this catheter **2** and shown in **FIG. 3**. In the furled position, the blades **30** lie close to the wall of the tube **6** and partially overlap each other so that they do not impede the introduction and the sliding of the device **1** into and in the bodily vessel in which the native valve that is to be treated lies; in said unfurled position, the blades **30** are deployed in a corolla so that their cutting edges **30***a*, **30***b* are placed in the continuation of one another and thus constitute a circular cutting edge visible in **FIG. 3**.

[0109] Each balloon **31**, placed between the tube **3** and the blades **30**, may be inflated from the end of the catheter **2** which emerges from the patient, via a passage **32** formed in the tube **6**. It thus, when inflated, allows the blades **30** to be brought from their furled position into their unfurled position, and performs the reverse effect when deflated. The axial sliding of the tube **6** with respect to the tube **7** allows the series of blades **11**, **12** to be moved axially toward one another, between a spaced-apart position shown in **FIG. 1**, and a close-together position. In the former of these positions, one series of blades **11** may be placed axially on one side of the native valve while the other series of blades **12** is placed axially on the other side of this valve, whereas in the latter of these positions, the circular cutting edges of these two series of blades **11**, **12** are brought into mutual contact and thus cut through the native valve in such a way as to detach it from said bodily vessel. The tubes **5** to **7** further comprise marks (not visible in the figures) in barium sulfate allowing the axial position of the device **1** with respect to the native valve to be identified percutaneously so that each of the two series of blades **11**, **12** can be placed on one axial side of this valve. These tubes **5** to **7** also comprise lateral distal openings (not depicted) to allow the blood to reach the bodily vessel, these openings being formed in such a way that the length of catheter **2** through which the blood flows is as short as possible, that is to say immediately after the filter **14**, in the distal direction.

[0110] The balloon **13** is placed on the exterior face of the tube **7**, distally with respect to the series **12**. This balloon **13** has an annular shape and is shaped to be able to occupy a furled position in which it has a cross section such that it

does not impede the introduction and sliding of the device **1** into and in said bodily vessel, and an unfurled position, in which it occupies all of the space between the exterior face of the tube **7** and the wall of said bodily vessel and, via a peripheral edge **13***a* which it comprises, bears against this wall.

[**0111**] The filter **14** is placed distally with respect to the balloon **13**, on the tube **7**, to which it is axially fixed. This filter **14** is made of flexible material, for example polyester netting, and is shaped to be able to occupy a furled position in which it has a cross section such that it does not impede the introduction and sliding of the device **1** into and in said bodily vessel, and an unfurled position in which it occupies all of the space between the exterior face of the catheter **2** and the wall of this vessel and, via a peripheral edge **14***a* which it comprises, bears against this wall.

[**0112**] An inflatable balloon **35** is placed between the tube **7** and the filter **14** so as, depending on whether it is inflated or deflated, to bring the filter **14** into its respective unfurled and furled positions. In practice, as shown by FIGS. **5** to **9**, the device **1** is introduced into said bodily vessel **50** by a percutaneous route and is slid along inside this vessel **50** until each of the series **11**, **12** of blades is placed on one side of the native valve **55** that is to be treated (**FIG. 5**). This position is identified using the aforementioned marks. When the device is in this position, the proximal part of the catheter **2** is situated in the heart, preferably in the left ventricle, while the aforementioned distal lateral openings are placed in a peripheral arterial vessel, preferably in the ascending aorta. The balloons **13** and **35** are inflated in such a way as to cause blood to flow only through the passage **15** and prevent blood reflux during the ablation of the valve **55**. A peripheral perfusion system is set in place to facilitate this flow, as further described below in connection with **FIGS. 50 through 52**. The blades **30** of the two series **11**, **12** are then deployed (**FIG. 6**) by inflating the balloons **31**, then these two series **11**, **12** are moved closer together by sliding the tube **6** with respect to the tube **7**, until the valve **55** is cut through (**FIG. 7**). The blades **30** are then returned to their furled position by deflating the balloons **31** while at the same time remaining in their close-together position, which allows the cut-out valve **55** to be held between them. The device **1** is then slid axially in the distal direction so as to bring the bell housing **6***a* to the appropriate position in the vessel **50** (**FIG. 8**), after which the valve **10** is deployed by sliding the tube **6** with respect to the tube **5** (**FIG. 9**). The balloons **13** and **35** are deflated then the device **1** is withdrawn and the cut-out valve **55** is recovered (**FIG. 10**).

[**0113**] **FIG. 11** shows a second embodiment of the device **1**, allowing operation on a mitral valve **56**. The same reference numerals are used to denote the same elements or parts as the aforementioned, as long as these elements or parts are identical or similar in both embodiments. In this case, the tubular catheter is replaced by a support wire **2**, on which one of the series of blades is mounted and by a tube engaged over and able to slide along this wire, on which tube the other series of blades is mounted; the passages for inflating the balloons **31** run along this support wire and this tube; the balloon **13** and the filter **14** are separate from the device **1** and are introduced into the aorta via a peripheral arterial route, by means of a support wire **40** along which the passages for inflating the balloons **13** and **35** run. The device **1**, devoid of balloon **13** and the filter **14**, is for its part introduced into the heart through the peripheral venous system, as far as the right atrium then into the left atrium through the inter-auricular septum, as far as the valve **56**. For the remainder, the device **1** operates in the same way as was mentioned earlier. The invention thus provides a device for replacing a heart valve by a percutaneous route, making it possible to overcome the drawbacks of the prior techniques. Indeed the device **1** is entirely satisfactory as regards the cutting-away of the valve **55**, **56**, making it possible to operate without stopping the heart and making it possible, by virtue of the filter **14**, to prevent any dispersion of valve fragments **55**, **56** into the circulatory system.

[**0114**] The above device may comprise a fourth tube, engaged on and able to slide along the tube **7**, this fourth tube comprising the balloon and the filter mounted on it and allowing said series of blades to be moved in the axial direction independently of said balloon and/or of said filter; the blades may be straight as depicted in the drawing or may be curved toward the axis of the device at their end which has the cutting edge, so as to eliminate any risk of lesion in the wall of the bodily vessel, as shown in **FIG. 12**; the filter **14** may be of the self-expanding type and normally kept in the contracted position by a sliding tube, which covers it, making the balloon **35** unnecessary.

[**0115**] FIGS. **13** to **16** represent tubular support **101** for positioning, by percutaneous route, of replacement heart valve **102**. The support structure **101** includes median portion **103**, which contains valve **102**, two extreme wedging portions **104** and wires **105** for connecting these portions **103** and **104**. Median portion **103** also includes peripheral shell **106** provided with anchoring needles **107** and shell **108** made of compressible material. As is particularly apparent from **FIG. 12**, each of portions **103** and **104** is formed with an undulating wire, and wires **105** connect pointwise the ends of the undulations of portion **103** to the end of an adjacent wave of portion **104**. Portions **104**, seen in expanded form, have lengths greater than the length of portion **103**, so that when the ends of the wires respectively forming portions **103** and **104** are connected in order to form the tubular support structure **101**, the diameter of portion **103** is smaller than the diameter of portions **104**.

[**0116**] The diameter of portion **103** is such that portion **103** can, as shown by **FIG. 17**, support cardiac ring **110** that remains after removal of the deficient native valve, while portions **104** support walls **111** bordering ring **110**. These respective diameters are preferably such that said supporting operations take place with slight radial restraint of ring **110** and walls **111**. Portion **103** presents in the deployed state a constant diameter. Portions **104** can have a constant diameter in the form of a truncated cone whose diameter increases away from portion **103**. The entire support structure **101** can be made from a material with shape memory, such as the nickel-titanium alloy known as "Nitinol." This material allows the structure to be contracted radially, as shown in **FIG. 16**, at a temperature different from that of the body of the patient and to regain the original shape shown in **FIGS. 14 and 15** when its temperature approaches or reaches that of the body of the patient. The entire support structure **101** can also be made from a material that can be expanded using a balloon, such as from medical stainless steel (steel **316** L). Valve **102** can be made of biological or synthetic tissue. It is connected to portion **103** by sutures or by any other appropriate means of attachment. It can also be

molded on portion **103**. Shell **106** may be made of "Nitinol." It is connected to the undulations of portion **103** at mid-amplitude, and has needles **107** at the site of its regions connected to these undulations. Needles **107** consist of strands of metallic wire pointed at their free ends, which project radially towards the exterior of shell **106**.

[**0117**] This shell can take on the undulating form that can be seen in **FIG. 16** in the contracted state of support **101** and the circular form which can be seen in **FIG. 4** in the deployed state of this support **101**. In its undulating form, shell **106** forms undulations **106***a* projecting radially on the outside of support **101**, beyond needles **107**, so that these needles **107**, in the retracted position, do not obstruct the introduction of support **101** in a catheter or, once support **101** has been introduced into the heart using this catheter, do not obstruct the deployment out of this support **1**. The return of shell **106** to its circular form brings needles **107** to a position of deployment, allowing them to be inserted in ring **110** in order to complete the anchoring of support **101**. Shell **108** is attached on shell **106**. Its compressible material allows it to absorb the surface irregularities that might exist at or near ring **110** and thus to ensure complete sealing of valve **102**.

[**0118**] **FIG. 18** shows a support structure **101** having a single portion **104** connected to portion **103** by wires **105**. This portion **104** is formed by two undulating wires **114** connected together by wires **115**. **FIG. 19** shows a support structure **101** that has portion **103** and portion **104** connected by connecting wires **105**. These portions **103** and **104** have diamond-shaped mesh structures, these mesh parts being juxtaposed in the direction of the circumference of these portions and connected together at the site of two of their opposite angles in the direction of the circumference of these portions **103** and **104**. Wires **105** are connected to these structures at the site of the region of junction of two consecutive mesh parts. These mesh parts also have anchoring hooks **107** extending through them from one of their angles situated in the longitudinal direction of support **101**.

[**0119**] **FIG. 20** illustrates, in an enlarged scale, the structure of this portion **104** and of a part of wires **105**, as cut, for example, with a laser from a cylinder of stainless steel, and after bending of sharp ends **107***a* of hooks **107**. These hooks, in a profile view, can have the shape as shown in FIGS. **24** or **26**. The structure represented in **FIG. 19** also has axial holding portion **120**, which has a structure identical to that of portion **104** but with a coarser mesh size, and three wires **105** of significant length connecting this portion **120** to portion **103**. These wires **105**, on the side of portion **120**, have a single link **105***a* and on the side of portion **103**, a double link **105***b*. Their number corresponds to the three junctions formed by the three valves of valve **102**, which facilitates mounting of valve **102** on support **101** thus formed. The support according to **FIG. 19** is intended to be used, as appears in **FIG. 21**, when the body passage with the valve to be replaced, in particular the aorta, has a variation in diameter at the approach to the valve. The length of wires **105** connecting portions **103** and **120** is provided so that after implantation, portion **120** is situated in a non-dilated region of said body passage, and this portion **120** is provided so as to engage the wall of the passage.

[**0120**] **FIG. 22** shows a structure similar to that of **FIG. 19** but unexpanded, except that the three wires **105** have a single wire structure but have an undulating wire **121** ensuring additional support near portion **103**. This wire **121** is designed to support valve **102** with three valve leaflets. FIGS. **23** to **26** show an embodiment variant of the structure of portions **103**, **104** or **120**, when this structure is equipped with hooks **107**. In this case, the structure has a zigzagged form, and each hook **107** has two arms **107***b*; each of these arms **107***b* is connected to the other arm **107***b* at one end and to an arm of structure **101** at its other end. The region of junction of the two arms **107***b* has bent hooking pin **107***a*.

[**0121**] **FIG. 27** shows portion **103** that has two undulating wires **125**, **126** extending in the vicinity of one another and secondary undulating wire **127**. As represented in **FIG. 28**, wires **125**, **126** can be used to execute the insertion of valve **102** made of biological material between them and the attachment of this valve **102** to them by means of sutures **127**. **FIG. 29** shows a part of support **101** according to FIGS. **13** to **17** and the way in which the compressible material constituting shell **108** can absorb the surface irregularities possibly existing at or near ring **110**, which result from calcifications. **FIG. 30** shows support **101** whose shell **106** has no compressible shell. A material can then be applied, by means of an appropriate cannula (not represented), between ring **110** and this shell **106**, this material being able to solidify after a predetermined delay following application.

[**0122**] **FIG. 31** shows support **101** whose shell **106** has a cross section in the form of a broken line, delimiting, on the exterior radial side, a lower shoulder. Housed in the step formed by this shoulder and the adjacent circumferential wall is peripheral shell **108** which can be inflated by means of a catheter (not represented). This shell **108** delimits a chamber and has a radially expandable structure, such that it has in cross section, in the inflated state, two widened ends projecting on both sides of shell **106**. This chamber can receive an inflating fluid that can solidify in a predetermined delay following its introduction into said chamber. Once this material has solidified, the inflating catheter is cut off.

[**0123**] **FIGS. 32 and 33** show support **101** whose shell **106** receives inflatable insert **108** which has a spool-shaped cross section in the inflated state; this insert **108** can be inflated by means of catheter **129**. Insert **108** is positioned in the uninflated state (**FIG. 32**) at the sites in which a space exists between shell **106** and existing cardiac ring **110**. Its spool shape allows this insert (cf. **FIG. 33**) to conform as much as possible to the adjacent irregular structures and to ensure a better seal.

[**0124**] **FIG. 34** shows balloon **130** making it possible to deploy support **101** according to FIGS. **19** to **21**. This balloon **130** has cylindrical portion **131** whose diameter in the inflated state makes possible the expansion of holding portion **120**, a cylindrical portion **132** of lesser diameter, suitable for producing the expansion of portion **103**, and portion **133** in the form of a truncated cone, makes possible the expansion of portion **104**. As shown by **FIG. 35**, portion **132** can be limited to what is strictly necessary for deploying portion **103**, which makes it possible to produce balloon **130** in two parts instead of a single part, thus limiting the volume of this balloon **130**.

[**0125**] **FIG. 36** shows support **101** whose median portion **103** is in two parts **103***a*, **103***b*. Part **103***a* is made of undulating wire with large-amplitude undulations, in order to support valve **102**, and part **103***b*, adjacent to said part

103*a* and connected to it by bridges **135**, is made of undulating wire with small-amplitude undulations. Due to its structure, this part **103***b* presents a relatively high radial force of expansion and is intended to be placed opposite ring **110** in order to push back the native valve sheets which are naturally calcified, thickened and indurated, or the residues of the valve sheets after valve resection against or into the wall of the passage. This axial portion **103***a*, **103***b* thus eliminates the problem induced by these sheets or residual sheets at the time of positioning of valve **102**.

[**0126**] It is apparent from the preceding that one embodiment of the invention provides a tubular support for positioning, by percutaneous route, of a replacement heart valve, which provides, due to its portions **103** and **104**, complete certitude as to its maintenance of position after implantation. This support also makes possible a complete sealing of the replacement valve, even in case of a cardiac ring with a surface that is to varying degrees irregular and/or calcified, and its position can be adapted and/or corrected as necessary at the time of implantation.

[**0127**] Referring to **FIGS. 37 and 38**, the present invention also comprises an alternative prosthetic valve assembly **310**, which further comprises a prosthetic valve **312**, a valve support band **314**, distal anchor **316**, and a proximal anchor **318**. Valve **312** can be made from a biological material, such as one originating from an animal or human, or from a synthetic material, such as a polymer. Depending upon the native valve to be replaced, the prosthetic valve **312** comprises an annulus **322**, a plurality of leaflets **324** and a plurality of commissure points **326**. The leaflets **324** permit the flow of blood through the valve **312** in only one direction. In the preferred embodiment, the valve annulus **322** and the commissure points **326** are all entirely supported within the central support band **314**. Valve **312** is attached to the valve support band **314** with a plurality of sutures **328**, which can be a biologically compatible thread. The valve could also be supported on band **314** with adhesive, such as cyanoacrylate.

[**0128**] In one embodiment, valve **312** can be attached to, or may integral with, a sleeve or sheath **313**. The sheath is secured to the valve support band **314** such that the outer surface of the sheath is substantially in contact with the inner surface of the valve support band **314**. In such embodiment, the sheath can be attached to the valve support band **314** with sutures **328**. **FIG. 40** is a schematic of the concept of this alternative embodiment. If desired, the sheath **313** can be secured to the outside of valve support band **314** (not shown).

[**0129**] Referring to **FIGS. 37 and 38**, in one embodiment, valve support band **314** is made from a single wire **342** configured in a zigzag manner to form a cylinder. Alternatively, valve support band **314** can be made from a plurality of wires **342** attached to one another. In either case, the band may comprise one or more tiers, each of which may comprise one or more wires arranged in a zigzag manner, for structural stability or manufacturing ease, or as anatomical constraints may dictate. If desired, even where the central valve support **314** is manufactured having more than one tier, the entire valve support **314** may comprise a single wire. Wire **342** can be made from, for example, stainless steel, silver, tantalum, gold, titanium or any suitable plastic material. Valve support band **314** may comprise a plurality of loops **344** at opposing ends to permit attachment to valve support band **314** of anchors **316** and/or **318** with a link. Loops **344** can be formed by twisting or bending the wire **342** into a circular shape. Alternatively, valve support band **314** and loops **344** can be formed from a single wire **342** bent in a zigzag manner, and twisted or bent into a circular shape at each bend. The links can be made from, for example, stainless steel, silver, tantalum, gold, titanium, any suitable plastic material, solder, thread, or suture. The ends of wire **342** can be joined together by any suitable method, including welding, gluing or crimping.

[**0130**] Still referring to **FIGS. 37 and 38**, in one embodiment, distal anchor **316** and proximal anchor **318** each comprise a discrete expandable band made from one or more wires **342** bent in a zigzag manner similar to the central band. Distal anchor band **316** and proximal anchor band **318** may comprise a plurality of loops **344** located at an end of wire **342** so that distal anchor band **316** and proximal anchor band **318** can each be attached to valve support band **314** with a link. Loop **344** can be formed by twisting or bending the wire **342** into a circular shape. As desired, distal and/or proximal anchors **316**, **318** may comprise one or more tiers, as explained before with the valve support **314**. Likewise, each anchor may comprise one or more wires, regardless of the number of tiers. As explained above in regard to other embodiments, the distal anchor may be attached to the central valve support band **314** directly, as in **FIG. 37**, or spaced distally from the distal end of the valve support **314**, as shown above schematically in **FIGS. 18, 19, 21** and **22**. In the later instance, one or more struts may be used to link the distal anchor band to the valve support band, as described above.

[**0131**] Distal anchor band **316** has a first end **350** attached to the central valve band **314**, and a second end **352**. Similarly, proximal anchor band **318** has first attached end **354** and a second end **356**. The unattached ends **352**, **356** of the anchors **316**, **318**, respectively are free to expand in a flared manner to conform to the local anatomy. In such embodiment, the distal and proximal anchor bands **316**, **318** are configured to exert sufficient radial force against the inside wall of a vessel in which it can be inserted. Applying such radial forces provides mechanical fixation of the prosthetic valve assembly **310**, reducing migration of the prosthetic valve assembly **310** once deployed. It is contemplated, however, that the radial forces exerted by the valve support **314** may be sufficient to resist more than a minimal amount of migration, thus avoiding the need for any type of anchor.

[**0132**] In an alternative embodiment, distal and proximal anchors may comprise a fixation device, including barbs, hooks, or pins (not shown). Such devices may alternatively or in addition be placed on the valve support **314**. If so desired, the prosthetic valve assembly **310** may comprise an adhesive on the exterior thereof to adhere to the internal anatomical lumen.

[**0133**] Prosthetic valve assembly **310** is compressible about its center axis such that its diameter may be decreased from an expanded position to a compressed position. When placed into the compressed position, valve assembly **310** may be loaded onto a catheter and transluminally delivered to a desired location within a body, such as a blood vessel, or a defective, native heart valve. Once properly positioned within the body the valve assembly **310** can be deployed

from the compressed position to the expanded position. **FIG. 39** is a schematic of one embodiment of the prosthetic valve assembly described with both distal and proximal anchor bands **316**, **318** while **FIG. 49** is a schematic showing only a distal anchor **316**.

[**0134**] In the preferred embodiment, the prosthetic valve assembly **310** is made of self-expanding material, such as Nitinol. In an alternative embodiment, the valve assembly **310** requires active expansion to deploy it into place. Active expansion may be provided by an expansion device such as a balloon.

[**0135**] As referred to above in association with other embodiments, the prosthetic valve assembly of the present invention is intended to be percutaneously inserted and deployed using a catheter assembly. Referring to **FIG. 41A**, the catheter assembly **510** comprises an outer sheath **512**, an elongate pusher tube **514**, and a central tube **518**, each of which are concentrically aligned and permit relative movement with respect to each other. At a distal end of the pusher tube **514** is a pusher tip **520** and one or more deployment hooks **522** for retaining the prosthesis assembly (not shown). The pusher tip **520** is sufficiently large so that a contracted prosthesis assembly engages the pusher tip **520** in a frictional fit arrangement. Advancement of the pusher tube **514** (within the outer sheath **512**) in a distal direction serves to advance the prosthesis relative to the outer sheath **512** for deployment purposes.

[**0136**] At a distal end of the central tube **518** is an atraumatic tip **524** for facilitating the advancement of the catheter assembly **510** through the patient's skin and vasculature. The central tube **518** comprises a central lumen (shown in phantom) that can accommodate a guide wire **528**. In one embodiment, the central lumen is sufficiently large to accommodate a guide wire **528** that is **0.038** inch in diameter. The guide wire can slide through the total length of the catheter form tip to handle ('over the wire' catheter) or the outer sheath **512** can be conformed so as to allow for the guide wire to leave the catheter before reaching its proximal end ('rapid exchange' catheter). The space between the pusher tube **514** and the outer sheath **512** forms a space within which a prosthetic valve assembly may be mounted.

[**0137**] Hooks **522** on the distal end of the pusher tube **514** may be configured in any desired arrangement, depending upon the specific features of the prosthetic assembly. With regard to the prosthesis assembly of **FIGS. 37 and 38**, the hooks **522** preferably comprise an L-shaped arrangement to retain the prosthesis assembly axially, but not radially. With a self-expanding assembly, as the prosthesis assembly is advanced distally beyond the distal end of the outer sheath **512**, the exposed portions of the prosthesis assembly expand while the hooks **522** still retain the portion of the prosthesis still housed within the outer sheath **512**. When the entire prosthesis assembly is advanced beyond the distal end of the outer sheath, the entire prosthesis assembly is permitted to expand, releasing the assembly from the hooks. **FIGS. 42 through 45** show the distal end of one embodiment of the catheter assembly, three of which show sequenced deployment of a valve prosthesis.

[**0138**] **FIG. 48** shows an alternative embodiment of the valve prosthesis, where loop elements extend axially from one end of the prosthesis and are retained by the hooks **522** on pusher tube **514** during deployment. **FIGS. 46 and 47** show a catheter assembly used for deploying the alternative prosthesis assembly of **FIG. 48**. By adding loop elements to the prosthesis, the prosthesis may be positioned with its support and anchors fully expanded in place while permitting axial adjustment into final placement before releasing the prosthesis entirely from the catheter. Referring to **FIG. 55**, an alternative embodiment of a self-expanding valve prosthesis and delivery system comprises loop elements **694** on prosthetic assembly **310** retained by disks **696** on pusher tube **514** by outer sheath **512**. When outer sheath **512** is pulled back to expose disks **696**, self-expanding loop elements **694** are then released from pusher tube **514**.

[**0139**] **FIG. 41B** shows the proximal end of the catheter assembly **510** that, to a greater extent, has many conventional features. At the distal end of the pusher tube **514** is a plunger **530** for advancing and retreating the pusher tube **514** as deployment of the prosthesis assembly is desired. As desired, valves and flush ports proximal and distal to the valve prosthesis may be provided to permit effective and safe utilization of the catheter assembly **510** to deploy a prosthesis assembly.

[**0140**] In one embodiment, prosthetic valve assembly **310** (not shown) is mounted onto catheter **510** so that the valve assembly **310** may be delivered to a desired location inside of a body. In such embodiment, prosthetic valve assembly **310** is placed around pusher tip **520** and compressed radially around the tip **520**. The distal end of prosthetic valve assembly **310** is positioned on the hooks **522**. While in the compressed position, outer sheath **512** is slid toward the atraumatic tip **524** until it substantially covers prosthetic valve assembly **310**.

[**0141**] To deliver prosthetic valve assembly **310** to a desired location within the body, a guide wire **528** is inserted into a suitable lumen of the body, such as the femoral artery or vein to the right atrium, then to the left atrium through a transseptal approach, and maneuvered, utilizing conventional techniques, until the distal end of the guide wire **528** reaches the desired location. The catheter assembly **510** is inserted into the body over the guide wire **528** to the desired position. Atraumatic tip **524** facilitates advancement of the catheter assembly **510** into the body. Once the desired location is reached, the outer sheath **512** is retracted permitting the valve prosthesis to be released from within the outer sheath **512**, and expand to conform to the anatomy. In this partially released state, the position of prosthetic valve **310** may be axially adjusted by moving catheter assembly **510** in the proximal or distal direction.

[**0142**] It is apparent that the invention advantageously contemplates a prosthesis that may have a non-cylindrical shape, as shown in several earlier described embodiments including but not limited to FIGS. **21**, **37-40**, **49** and **59**. This non-cylindrical shape results from controlling the diameters at some portions of prosthetic valve assembly **310**. Referring to **FIG. 56A**, yet another non-cylindrical prosthesis is shown. Central support band **314** comprises a diameter-restrained portion of valve assembly **310** attached to distal and proximal anchors **316**, **318**, that comprise discrete self-expandable bands capable of expanding to a flared or frusta-conical configuration. Anchors **316**, **318** further accentuate the non-cylindrical shape of central support band **314**. **FIG. 56A** shows one embodiment of the invention for limiting the diameter of portions of the valve assembly **310**

from excessive expansion, whereby valve assembly **310** further comprises a radial restraint **690** to limit the diameter of central support band **314**. Radial restraint, as used herein, shall mean any feature or process for providing a desired diameter or range of diameters, including but not limited to the selection of materials or configurations for valve assembly **310** such that it does not expand beyond a preset diameter. Controlling radial expansion to a preset diameter at central support band **314** helps maintain the coaptivity of valve **312** and also preserves the patency of the coronary ostia by preventing central support band **314** from fully expanding to the lumen or chamber wall to cause occlusion. Restraint **690** may be sufficiently flexible such that restraint **690** may contract radially with valve assembly **310**, yet in the expanded state resists stretching beyond a set limit by the radial expansion forces exerted by a self-expanding valve assembly **310** or from a balloon catheter applied to valve assembly **310**. Referring to **FIG. 56A and 56B**, restraint **690** may take any of a variety of forms, including wires **700** of a specified length that join portions of central support band **314**. Threads may also be used for radial restraint **690**. The slack or bends in the wires allow a limited radial expansion to a maximum diameter. Once the slack is eliminated or the bends are straightened, further radial expansion is resisted by tension created in wires **700**. These wires may be soldered, welded or interwoven to valve assembly **310**. By changing the length of wire joining portions of valve assembly **310**, radial restraints of different maximum diameters are created. For example, by using short wires to form the radial restraint, the valve support structure may expand a shorter distance before tension forms in the short wires. If longer wires are used, the support structure may expand farther before tension develops in the longer wires.

[**0143**] **FIG. 57** depicts central support band **314** with a radial restraint **700** of a smaller diameter and another portion of the same valve assembly **310** with longer lengths of wire **701** and allowing a larger maximum diameter. The portion of valve assembly **310** with the larger diameter can be advantageously used to allow greater dilation around cardiac ring **110** and native valve sheets. The degree of resistance to expansion or recollapse can be altered by changing the diameter of the radial restraint or by changing the configuration of the restraint. For example, a cross-linked radial restraint will have a greater resistance to both expansion and recollapse. Referring to **FIG. 58**, restraint **690** may alternatively comprise a cuff **691** encompassing a circumference of central support band **314** that resists expansion of central support band **314** beyond the circumference formed by cuff **691**. Cuff **691** may be made of ePTFE or any other biocompatible and flexible polymer or material as is known to those skilled in the art. Cuff **691** may be attached to valve assembly **310** by sutures **692** or adhesives.

[**0144**] **FIG. 71** illustrates one embodiment of the invention where radial restraints are integrally formed as part of valve assembly **310** by using a laser cutting manufacturing process, herein incorporated by reference. **FIG. 72A** depicts a schematic view of a laser-cut portion of valve assembly **310** in the unexpanded state with several radial restraints **706, 708, 710**. Each end of radial restraints **706, 708, 710** is integrally formed and attached to valve assembly **310**. An integrally formed radial restraint may be stronger and may have a lower failure rate compared to radial restraints that are sutured, welded or soldered to valve assembly **310**. **FIG. 72B** depicts a shorter radial restraint **706** along one circumference of valve assembly **310**. **FIG. 72C** depicts another portion of valve assembly **310** with a longer radial restraint **708** and a cross-linked radial restraint **710** positioned along the same circumference. Thus, the segments of a radial restraint along a given circumference need not have the same characteristics or size.

[**0145**] Another embodiment of the radial restraint comprises at least one protrusion extending from valve assembly **310** to provide a mechanical stop arrangement. The mechanical stop arrangement restricts radial expansion of valve assembly **310** by using the inverse relationship between the circumference of valve assembly **310** and the length of valve assembly **310**. As valve assembly **310** radially expands, the longitudinal length of valve assembly **310** may contract or compress as the diameter of valve assembly **310** increases, depending upon the particular structure or configuration used for valve assembly **310**. For example, **FIGS. 37, 38, 56**A, **57** and **71** depict embodiments of the invention wherein valve assembly **310** comprises a diamond-shaped mesh. The segments of the mesh have a generally longitudinal alignment that reorient to a more circumferential alignment during radial expansion of valve assembly **310**. By limiting the distance to which valve assembly **310** can compress in a longitudinal direction, or by restricting the amount of angular reorientation of the wires of valve assembly **310**, radial expansion in turn may be controlled to a pre-set diameter. **FIG. 74A** shows one embodiment of the mechanical stop arrangement comprising an angular stop **730** and an abutting surface **732** on the wire structure of valve assembly **310**. A plurality of stops **730** and abutting surfaces **732** may be used along a circumference of valve assembly **310** to limit expansion to a preset diameter. Angular stop **730** may be located between two adjoining portions of valve assembly **310** forming an angle that reduces with radial expansion. As shown in **FIGS. 74B**, as valve assembly **310** radially expands, angular stop **730** will come in closer proximity to surface **732** and eventually abut against surface **732** to prevent further diameter expansion of valve assembly **310**. The angular size **734** of stop **730** can be changed to provide different expansion limits. The radial size **736** of stop **730** can also be changed to alter the strength of stop **730**. One skilled in the art will understand that many other configurations may be used for valve assembly **310** besides a diamond-shape configuration. For example, **FIGS. 15 and 16** depict support **101** with an undulating wire stent configuration that exhibits minimal longitudinal shortening when expanding. The mechanical stop arrangements described above may be adapted by those skilled in the art to the undulating wire stent configuration, or any other stent configuration, for controlling the diameter of the support structure or valve assembly **310**.

[**0146**] The particular method of maintaining the valve diameter within a preset range described previously relates to the general concept of controlling the expanded diameter of the prosthesis. The diameter attained by a portion of the prosthesis is a function of the radial inward forces and the radial expansion forces acting upon that portion of the prosthesis. A portion of the prosthesis will reach its final diameter when the net sum of these forces is equal to zero. Thus, controlling the diameter of the prosthesis can be addressed by changing the radial expansion force, changing the radial inward forces, or a combination of both. Changes to the radial expansion force generally occur in a diameter-related manner and can occur extrinsically or intrinsically.

Radial restraint **690**, cuff **691** and mechanical stop **730** of **FIGS. 56A, 58** and **74A**, respectively, are examples of extrinsic radial restraints that can limit or resist diameter changes of prosthetic valve assembly **310** once a preset diameter is reached.

[**0147**] Other ways to control diameter may act intrinsically by controlling the expansion force so that it does not expand beyond a preset diameter. This can be achieved by the use of the shape memory effect of certain metal alloys like Nitinol. As previously mentioned, when a Nitinol prosthesis is exposed to body heat, it will expand from a compressed diameter to its original diameter. As the Nitinol prosthesis expands, it will exert a radial expansion force that decreases as the prosthesis expands closer to its original diameter, reaching a zero radial expansion force when its original diameter is reached. Thus, use of a shape memory alloy such as Nitinol is one way to provide an intrinsic radial restraint. A non-shape memory material that is elastically deformed during compression will exhibit similar diameter-dependent expansion forces when returning to its original shape.

[**0148**] The other way of controlling diameter mentioned previously is to alter the radial inward or recoil forces acting upon the support or prosthesis. Recoil forces refer to any radially inward force acting upon the valve assembly that prevents the valve support from maintaining a desired expanded diameter. Recoil forces include but are not limited to radially inward forces exerted by the surrounding tissue and forces caused by elastic deformation of prosthetic valve assembly **310**. Countering or reducing recoil forces help to ensure deployment of prosthetic valve assembly **3,10** to the desired diameter or diameter range, particularly at the native valve. For example, when the prosthetic valve assembly **310** of **FIGS. 37, 38, 56A, 57** and **58** is deployed, some recoil or diameter reduction may occur that can prevent portions of valve assembly **310** from achieving it pre-set or desired diameter. This recoil can be reduced by applying an expansion force, such as with a balloon, that stresses the material of valve assembly **310** beyond its yield point to cause plastic or permanent deformation, rather than elastic or transient deformation. Similarly, balloon expansion can be used to further expand a self-expanded portion of valve assembly **310** where radially inward anatomical forces have reduced the desired diameter of that portion. Balloon expansion of a self-expanded portion of valve assembly **310** beyond its yield point provides plastic deformation to a larger diameter.

[**0149**] In addition to the use of a balloon catheter to deform valve assembly **310** beyond its yield point, other means for reducing recoil are contemplated. In the preferred embodiment of the invention, a separate stent may be expanded against cardiac ring **110** in addition or in place of valve assembly **310**. The separate stent may further push back the native valve sheets or residues of the resected valve and reduce the recoil force of these structures on valve assembly **310**. If the separate stent is deployed against cardiac ring **110** prior to deployment of valve assembly **310**, a higher radial force of expansion is exerted against ring **110** without adversely affecting the restrained radial force of expansion desired for the central support band **314** supporting valve **312**. Alternatively, the separate stent may be deployed after valve assembly **310** and advantageously used to reduce the recoil of valve assembly **310** caused by the elastic deformation of the material used to form valve assembly **310**. The separate stent may be self-expanding or balloon-expandable, or a combination thereof.

[**0150**] Another means for addressing recoil involves providing the radial restraint and mechanical stop arrangements previously described with an additional feature that forms an interference fit when the valve assembly **310** is at its preset diameter. By forming an interference fit, the radial restraint or mechanical stop will resist both further expansion and recollapse from recoil. **FIGS. 73A through 73E** depict an embodiment of a radial restraint with a recoil-resistant configuration integrally formed with valve assembly **310**. In this embodiment, each segment of the radial restraint comprises a pair of protrusions **712** having a proximal end **714** and a distal end **716**. Proximal end **714** is integrally formed and attached to valve assembly **310** while distal end **716** is unattached. Each pair of protrusions **712** is configured so that distal end **716** of one protrusion **712** is in proximity to the proximal end **714** of other protrusion **712** in the unexpanded state, and where distal ends **716** come close together as valve assembly **310** radially expands. Distal ends **716** comprise a plurality of teeth **718** for providing an interference fit between distal ends **716** upon contact with each other. The interference fit that is formed will resist both further radial expansion and collapse of valve assembly **310**. As mentioned earlier, collapse may result from the inherent elastic properties of the materials used for valve assembly **310** or from radially inward forces exerted by the tissue surrounding valve assembly **310**. The interference fit may be provided over a range of expansion, as depicted in **FIGS. 72B and 72C** from the self-expanded state through the extra-expanded state. This allows the inference fit to act even when a self-expanded valve assembly **310** is further expanded by a balloon catheter to an extra-expanded state as the expansion diameter is further adjusted. The lengths of protrusions **712** will determine the amount of radial restraint provided. Shorter protrusions **712** have distal ends **716** that contact each other after a shorter distance of radial expansion, while longer protrusions **712** will form an interference fit after a longer distance.

[**0151**] **FIGS. 75A and 75B** depict another embodiment of a radial restraint with a recoil resistant feature. Angular stop **730** from **FIGS. 74A and 74B** is provided with a notch **736** that forms an interference fit with a latch **738** protruding from valve assembly **310** adjacent to surface **732**. As valve assembly **310** expands, angular stop **730** will eventually abut against to surface **732** to prevent further expansion. Latch **738** will also move closer to notch **736** as valve assembly **310** expands. When the preset diameter is reached, latch **738** forms an interference fit with notch **736** that resists collapse to a smaller diameter. It is contemplated that a balloon catheter may be used to expand valve assembly **310** to the desired diameter and to engage latch **738** to notch **736**.

[**0152**] Although both shape memory and non-shape memory based prostheses provide diameter-dependent expansion forces that reach zero upon attaining their original shapes, the degree of force exerted can be further modified by altering the thickness of the wire or structure used to configure the support or prosthesis. A prosthesis can be configured with thicker wires to provide a greater expansion force to resist, for example, greater radial inward forces located at the native valve site, but the greater expansion force will still reduce to zero upon the prosthesis attaining its preset diameter. Changes to wire thickness need not occur

uniformly throughout a support or prosthesis. Wire thickness can vary between different circumferences of a support or prosthesis, or between straight portions and bends of the wire structure. As illustrated in **FIG. 59**, the decreased diameter **702** may be generally symmetrical about the longitudinal axis of the wire. Alternatively, as in **FIG. 60**, the decreased diameter **704** may be asymmetrical, where the diameter reduction is greater along the lesser curvature of the wire bend or undulation relative to the longitudinal axis of the wire. At portions of the prosthesis where the exertion of a particular expansion force against surrounding tissue has importance over the actual diameter attained by that portion of the prosthesis, the various methods for controlling diameter can be adapted to provide the desired expansion force. These portions of the prosthesis may include areas used for anchoring and sealing such as the axial wedging portions or anchors previously described.

[0153] Referring to **FIG. 61**, a method for deploying the preferred embodiment of the invention using the separate stent is provided. The method of deployment comprises a guidewire **640** inserted via a venous approach **642** and passed from the right **644** to left atrium **646** through a known transseptal approach, herein incorporated by reference. After transseptal puncture, guidewire **640** is further directed from left atrium **646** past the mitral valve **648** to the left ventricle **650** and through the aortic valve **652**. An introducer (not shown) is inserted via an arterial approach and a snare (not shown), such as the Amplatz GOOSE NECK® snare (Microvena, Minn.), is inserted through the introducer to grasp the distal end of guidewire **640** and externalize guidewire **640** out of the body through the introducer. With both ends of guidewire **640** external to the body, access to the implantation site is available from both the venous **642** and arterial approaches **654**. In **FIG. 62**, aortic valve **652** is pre-dilated by a balloon catheter **656** using a well-known valvuloplasty procedure, herein incorporated by reference. The prosthesis is then implanted as previously described by passing the delivery system from either the venous or arterial approaches. As illustrated in **FIG. 63**, the prosthesis **658** may be implanted using arterial approach **654** with prosthetic valve **658** implanted above the level of native valve **652**. As shown in **FIG. 64**, a balloon catheter **660** may be passed by venous approach **642** for further displacement of native valve **652** and/or to further secure the lower stent **662** to the annulus. Hooks **664**, shown in **FIG. 65**, connecting the delivery catheter to prosthetic valve **658** allow full control of prosthetic valve **658** positioning until the operator chooses to fully release and implant prosthetic valve **658**. A separate stent may then be implanted by venous approach **642** at the valvular ring to further push back the native valve or valve remnants and reduce recoil forces from these structures. Passing balloon **660** by the venous approach **642** avoids interference with superiorly located prosthetic valve **658**. Implantation of replacement valve **658** by arterial approach **654** prior to the ablation of the native valve **652** or valve remnants by venous approach **642** may reduce the risks associated with massive aortic regurgitation when native valve **652** is pushed back prior to implantation of replacement valve **658**. Reducing the risks of massive aortic regurgitation may provide the operator with additional time to position replacement valve **658**.

[0154] It is further contemplated that in the preferred embodiment of the invention, valve assembly **310** also comprises a drug-eluting component well known in the art and herein incorporated by reference. The drug-eluting component may be a surface coating or a matrix system bonded to various portions of valve assembly **310**, including but not limited to central support band **314**, anchors **316318**, valve **312**, loop elements **352** or wires **342**. The surface coating or matrix system may have a diffusion-type, erosive-type or reservoir-based drug release mechanism. Drugs comprising the drug-eluting component may include antibiotics, cellular anti-proliferative and/or anti-thrombogenic drugs. Drugs, as used herein, include but are not limited to any type of biologically therapeutic molecule. Particular drugs may include but are not limited to actinomycin-D, batimistat, c-myc antisense, dexamethasone, heparin, paclitaxel, taxanes, sirolimus, tacrolimus and everolimus.

[0155] As previously mentioned, one embodiment of the system for implanting the prosthesis and/or excising the native valve leaflets contemplates maintaining blood flow across the native valve site during the excision and implantation procedure. By maintaining blood flow across the native valve, use of extracorporeal circulation or peripheral aorto-venous heart assistance and their side effects may be reduced or avoided. Major side effects of extracorporeal circulation and peripheral aorto-venous heart assistance include neurological deficits, increased bleeding and massive air emboli. **FIGS. 50 through 52** depict one embodiment of the invention for maintaining blood perfusion during the procedure. This embodiment comprises a blood pump **600** and an opening **602** positioned in the wall of tubular catheter **2** of the excision system. When the tubular catheter **2** is positioned at the excision site, blood pump **600** allows continued blood flow across the excision site that would otherwise be interrupted during the excision procedure. Blood pump **600** may comprise a motor, a shaft and an impeller. Blood pump **600** is insertable through passage **15** of tubular catheter **2**. The motor is connected to a shaft **604** that in turn is coupled to an impeller **606**. The motor is capable of rotating shaft **604**, resulting in the rotation of impeller **606**. Impeller **606** comprises a proximal end **608**, a distal end **610** and a plurality of fins **612** angled along the longitudinal axis of impeller **606**, such that when impeller **606** is rotated in one direction, fins **612** are capable of moving blood from a proximal to distal direction. When impeller **606** is rotated in the other direction, fins **612** are capable of moving blood in a distal to proximal direction. The ability to rotate impeller **606** in either direction allows but is not limited to the use of the blood pump in both anterograde and retrograde approaches to a heart valve. The blood pump is positioned generally about catheter opening **602**. The blood pump has an external diameter of about 4-mm and the passage of the catheter has a 4-mm internal diameter. Catheter opening **602** has a longitudinal length of about 4-mm. Catheter opening **602** may comprise a plurality of openings located along a circumference of tubular catheter **2**. To reduce interruption of blood flow through tubular catheter **2** during the implantation portion of the procedure, catheter opening **602** should preferably be about 30 mm from the tip of catheter **2** or distal to the bell housing **6***a*. This positioning of catheter opening **602** reduces the risk of occlusion of catheter opening **602** by the replacement valve.

[0156] **FIG. 50** depicts an optional feature of blood pump **600** further comprising an impeller housing **614** having at least one proximal housing opening **616** and at least one distal housing opening **618**. Housing **614** protects passage **15** of tubular catheter **2** from potential damage by rotating

impeller **600**. Proximal **616** and distal housing openings **618** provide inflow and outflow of blood from the impeller, depending on the rotation direction of impeller **600**.

[**0157**] To reduce interruption of blood flow through catheter **2** during the implantation portion of the procedure, catheter opening **602** should preferably be at least a distance of about 30 mm from the distal tip of the catheter or about distal to the bell housing **6***a* to avoid occlusion of catheter opening **602** by the replacement valve.

[**0158**] **FIGS. 53 and 54** depict an alternative embodiment, where blood pump **620** is located in a second catheter **622** in the prosthesis delivery system. Once blood pump **620** and second catheter **622** are in position, the prosthesis delivery system **624** is slid over the separate catheter **622** to position the prosthesis for implantation, while avoiding blockage of blood flow in separate catheter **622**. In this embodiment, the diameter of the delivery system is preferably about 8 mm.

[**0159**] One method of using the blood flow pump during the implantation of the prosthesis is now described. This procedure may be performed under fluoroscopy and/or transesophageal echocardiography. **FIG. 66** shows vascular access made through the axillary artery **666**. A guidewire **668** is inserted past the aortic valve **670** and into the left ventricle **672**. In **FIG. 67**, a blood pump **674** is inserted into a hollow catheter passed **676** over guidewire **668** inside the aorta **678** and pushed into left ventricle **672**. Blood pump **674** is started to ensure a steady and sufficient blood flow of about 2.5 L/min from left ventricle **672** downstream during the valve replacement. **FIG. 68** depicts valve prosthesis **680**, retained on the delivery system **682** and positioned by sliding over blood pump catheter **676**. Prosthesis **680** is positioned generally about the valve annulus **684** and the coronary ostia **686**, with the assistance of radiographic markers. As shown in **FIGS. 69 and 70**, the sheath **688** overlying prosthesis **680** is pulled back and prosthesis **680** is deployed as previously described Catheter hooks **690** connecting the delivery catheter to the prosthetic valve allow full control of prosthetic valve positioning until the operator chooses to fully release and implant the prosthetic valve. Optional anchoring hooks, described previously, may be deployed generally about he annulus, the ventricle and the ascending aorta. Deployment of the anchoring hooks may be enhanced by radial expansion of a balloon catheter that further engages the hooks into the surrounding structures. Blood pump **674** is stopped and blood pump catheter **676** is removed. Other configurations may be adapted for replacing a valve at other site will be familiar to those skilled in the art.

[**0160**] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. For all of the embodiments described above, the steps of the methods need not be performed sequentially. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising:

a valve having a plurality of resilient leaflets;

a valve support configured to be collapsible for transluminal delivery and comprising a first and a second portion, said first portion expandable to contact the anatomical annulus of the native valve when the assembly is properly positioned, said second portion supporting the base and the commissure points of the valve; and

a radial restraint for controlling a diameter of the second portion.

2. The valve assembly of claim 1, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter.

3. The valve assembly of claim 1, wherein the radial restraint is capable of substantially resisting collapse below a preset diameter.

4. The valve assembly of claim 1, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter.

5. The valve assembly of claim 1, wherein the radial restraint comprises a wire.

6. The valve assembly of claim 1, wherein the radial restraint comprises a thread.

7. The valve assembly of claim 1, wherein the radial restraint comprises a mechanical stop.

8. The valve assembly of claim 1, wherein the radial restraint comprises material from which at least a portion of the valve support is made so that the second portion does not expand beyond a preset diameter.

9. The valve assembly of claim 8, wherein the material comprise shape memory material.

10. The valve assembly of claim 1, wherein the radial restraint comprises a cuff.

11. The valve assembly of claim 1, wherein the radial restraint comprises a stent configured to cooperate with the valve support so as to substantially preclude recoil.

12. The valve assembly of claim 1, further comprising a drug-eluting component.

13. The valve assembly of claim 1, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment.

14. The valve assembly of claim 1, wherein the valve support comprises at least one wire.

15. The valve assembly of claim 14, wherein the valve support comprises a single length of wire.

16. The valve assembly of claim 14, wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force.

17. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support permitting attachment thereto of the base and the commissures of the valve, and an anchor for engaging the lumen wall when expanded for preventing substantial migration of the valve assembly when positioned in place;

collapsing the valve support to fit within a distally positioned sheath on a catheter;

inserting a guidewire into a vascular access site;

externalizing at least a portion of the guidewire through a second vascular access site;

advancing the catheter over the guidewire to the deficient native valve;

deploying the valve assembly; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

18. The method of claim 17, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the first vascular access site.

19. The method of claim 17, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the second vascular access site.

20. The method of claim 17, further comprising the step of advancing a blood pump across the deficient native valve.

21. The method of claim 20, wherein the step of advancing the catheter comprises advancing the catheter over the blood pump.

22. The method of claim 20, wherein the step of advancing the blood pump comprises inserting the blood pump across the first vascular access site.

23. The method of claim 20, wherein the step of advancing the blood pump comprises inserting the blood pump across the second vascular access site.

24. The method of claim 18, further comprising the steps of:

advancing a stent from the second vascular access site to the deficient valve;

deploying the stent to substantially preclude any portion of the native valve from obstructing blood flow.

25. The method of claim 17, wherein the valve support and anchor are self-expanding.

26. The method of claim 25, further comprising the step of restraining self-expansion of the valve support to a preset diameter by at least one radial restraint

27. The method of claim 17, wherein the valve assembly further comprises loop elements for releasably attaching the anchor to the catheter.

28. The method of claim 17, wherein the catheter comprises a filter for catching emboli or valve fragments.

29. The method of claim 17, wherein the catheter comprises an over-the-wire catheter.

30. The method of claim 17, wherein the catheter comprises a rapid exchange catheter.

31. A prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve, the valve assembly comprising an axial valve support portion configured to support a prosthetic valve having at least one leaflet and to prevent substantial interference with the positioning and/or operation of the prosthetic valve by any residual components of the native valve, including calcified native components, said support portion comprising at least one radial restraint at a first section of said support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic valve leaflets and to prevent significant regurgitation.

32. The valve assembly of claim 31, wherein the radial restraint is configured to reduce recoil.

33. The valve assembly of claim 31, wherein the radial restraint comprises a mechanical stop.

34. The valve assembly of claim 31, wherein the support portion further comprises a second section configured to expand in situ for pushing the residual native valve components against the native annulus and surrounding tissue.

35. The valve assembly of claim 34, wherein the second section is configured to expand to a diameter different from that of the first section.

36. The valve assembly of claim 34, wherein said second section is configured to be expanded by a balloon catheter.

37. The valve assembly of claim 36, wherein said second section is configured to be expanded beyond its yield point in situ.

38. The valve assembly of claim 31, further comprising a stent configured to expand in situ for pushing against the residual native valve components.

39. The valve assembly of claim 38, wherein the stent is self-expanding.

40. The valve assembly of claim 38, wherein the stent is configured to be expanded by a balloon catheter.

41. The valve assembly of claim 31, further comprising a stent configured to reduce the recoil of the support portion following self-expansion of the support portion.

42. The valve assembly of claim 38, wherein the stent is configured to reside within the valve support portion when deployed.

43. The valve assembly of claim 38, wherein the stent is configured to reside outside the valve support portion when deployed.

44. The valve assembly of claim 31, further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration.

45. The valve assembly of claim 31, wherein said radial restraint comprises a wire.

46. The valve assembly of claim 31, wherein said radial restraint comprises a thread.

47. The valve assembly of claim 31, wherein said radial restraint comprises a cuff.

48. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support comprising a first valve support section permitting attachment thereto of the base and the commissures of the valve, and a second valve support section configured to expand in situ to push the residual native valve components against the native annulus and surrounding tissue;

collapsing the valve support to fit within a distally positioned sheath on a catheter;

inserting a guidewire into a vascular access site;

externalizing at least a portion of the guidewire through a second vascular access site;

advancing the catheter over the guidewire to the deficient native valve;

deploying the valve assembly; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

49. The method of claim 48, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the first vascular access site.

50. The method of claim 48, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the second vascular access site.

51. The method of claim 48, further comprising the step of advancing a blood pump across the deficient native valve.

52. The method of claim 51, wherein the step of advancing the catheter comprises advancing the catheter over the blood pump.

53. The method of claim 51, wherein the step of advancing the blood pump comprises inserting the blood pump across the first vascular access site.

54. The method of claim 51, wherein the step of advancing the blood pump comprises inserting the blood pump across the second vascular access site.

55. The method of claim 48, further comprising the steps of:

advancing a stent from the second vascular access site to the deficient valve;

deploying the stent to substantially preclude any portion of the native valve from obstructing blood flow.

56. The method of claim 48, wherein the valve support is self-expanding.

57. The method of claim 56, further comprising the step of restraining self-expansion of a portion of the valve support to a preset diameter by at least one radial restraint

58. The method of claim 49, wherein the valve assembly further comprises loop elements for releasably attaching the anchor to the catheter.

59. The method of claim 48, wherein the catheter comprises a filter for catching emboli or valve fragments.

60. The method of claim 48, wherein the catheter comprises an over-the-wire catheter.

61. The method of claim 48, wherein the catheter comprises a rapid exchange catheter.

62. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support permitting attachment thereto of the base and the commissures of the valve, and a radial restraint controlling a diameter of at least a portion of the valve assembly;

collapsing the valve support to fit within a distally positioned sheath on a catheter;

inserting a guidewire into a vascular access site;

externalizing at least a portion of the guidewire through a second vascular access site;

advancing the catheter over the guidewire to the deficient native valve;

deploying the valve assembly; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

63. The method of claim 62, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the first vascular access site.

64. The method of claim 62, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the second vascular access site.

65. The method of claim 62, further comprising the step of advancing a blood pump across the deficient native valve.

66. The method of claim 65, wherein the step of advancing the catheter comprises advancing the catheter over the blood pump.

67. The method of claim 65, wherein the step of advancing the blood pump comprises inserting the blood pump across the first vascular access site.

68. The method of claim 65, wherein the step of advancing the blood pump comprises inserting the blood pump across the second vascular access site.

69. The method of claim 64, further comprising the steps of:

advancing a stent from the second vascular access site to the deficient valve;

deploying the stent to substantially preclude any portion of the native valve from obstructing blood flow.

70. The method of claim 62, wherein the valve support is self-expanding.

71. The method of claim 62, wherein the valve assembly further comprises loop elements for releasably attaching the anchor to the catheter.

72. The method of claim 62, wherein the catheter comprises a filter for catching emboli or valve fragments.

73. The method of claim 62, wherein the catheter comprises an over-the-wire catheter.

74. The method of claim 62, wherein the catheter comprises a rapid exchange catheter.

75. A prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve, the valve assembly comprising a non-cylindrical valve support and at least one anchor.

76. A method of replacing a deficient heart valve comprising the steps of:

delivering to a target native valve site a valve prosthesis comprising a first portion and a second portion, the first portion limited in its expansion diameter when compared to the second portion;

delivering a perfusion pump to the desired target site to pump blood through the target site during application of the valve prosthesis; and

deploying the valve prosthesis while pumping blood through the target site.

77. The method of claim 76, wherein the valve prosthesis further comprises a radial restraint.

78. The method of claim 76, wherein the valve prosthesis further comprises an anchor.

* * * * *

US005855601A

United States Patent [19]

Bessler et al.

[11] **Patent Number: 5,855,601**

[45] **Date of Patent: Jan. 5, 1999**

[54] **ARTIFICIAL HEART VALVE AND METHOD AND DEVICE FOR IMPLANTING THE SAME**

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[73] Assignee: **The Trustees of Columbia University in the City of New York**, New York, N.Y.

[21] Appl. No.: **668,376**

[22] Filed: **Jun. 21, 1996**

[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/900

[58] **Field of Search** 623/2, 1, 900

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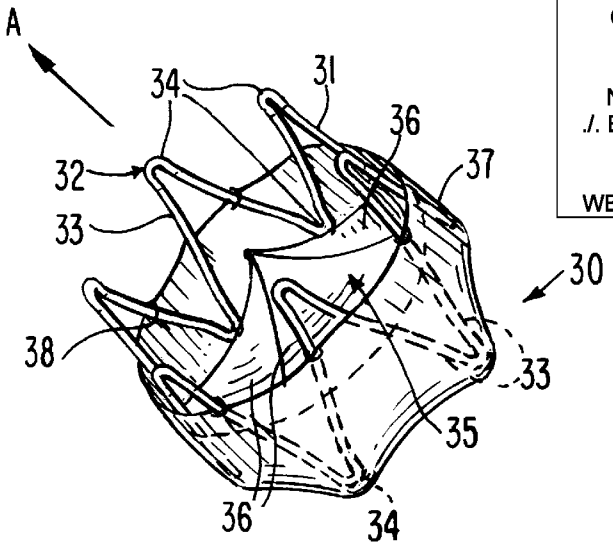
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Primary Examiner—Michael J. Milano
Assistant Examiner—Tram A. Nguyen
Attorney, Agent, or Firm—Cowan, Liebowitz & Latman, P.C.; William H. Dippert

[57] **ABSTRACT**

An artificial heart valve comprises a relatively rigid stent member having a first cylindrical shape and a flexible valve disposed in the stent member, the stent member being self-expandable to a second cylindrical shape and collapsible to its first cylindrical shape. The valve comprises a circular portion comprising a plurality of leaflets extending from the periphery of the circular portion towards the center thereof, the leaflets being configured to allow for flow of blood through the valve in one direction only. The diameter of the circular portion is substantially the same as the inside diameter of the stent member when the stent member is in its second cylindrical shape, the valve member being attached to the stent member.

20 Claims, 8 Drawing Sheets



WBH16
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

FIG. 1

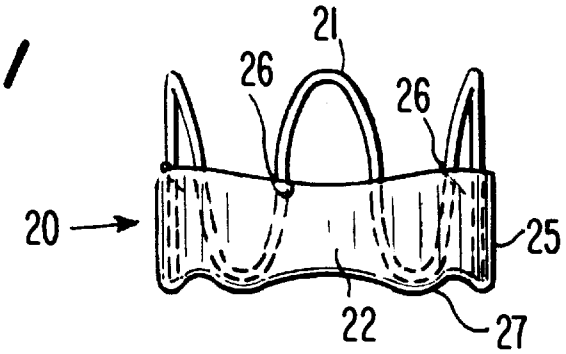


FIG. 2

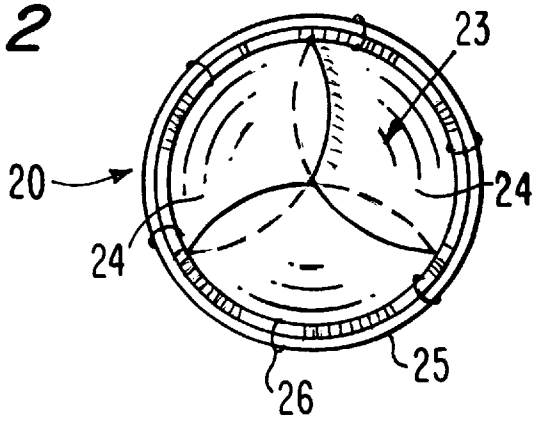


FIG. 3

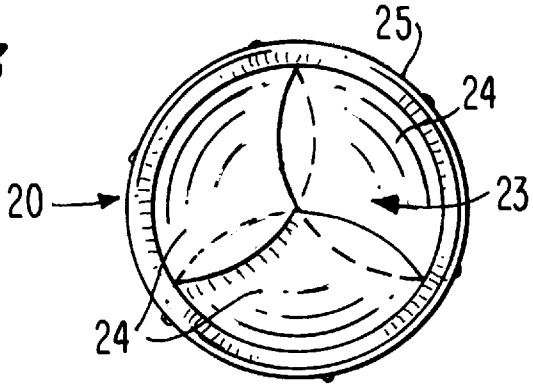


FIG. 4

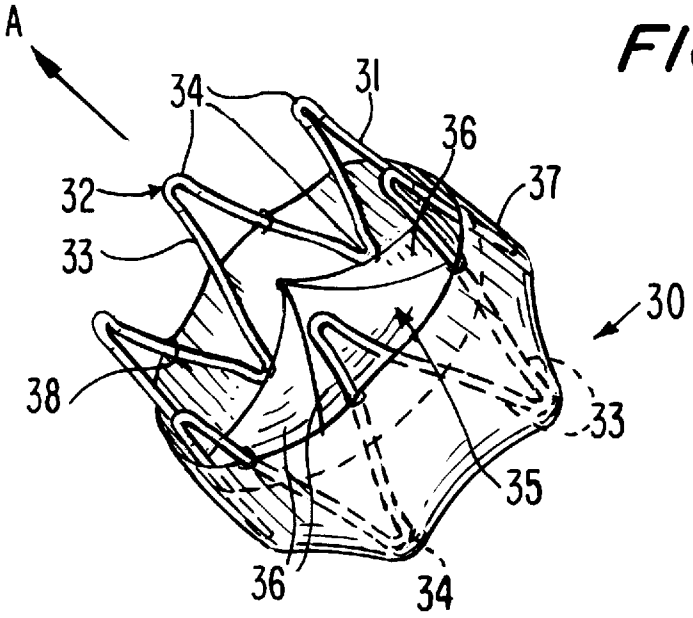


FIG. 5

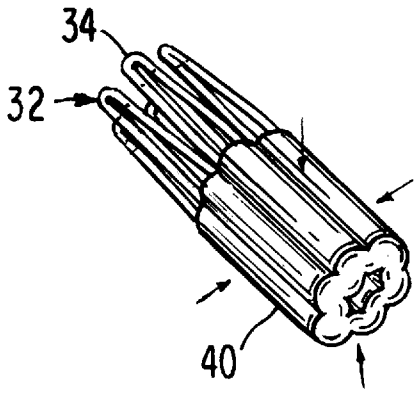


FIG. 6

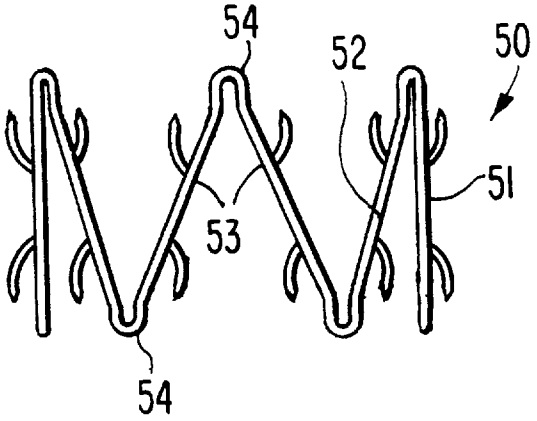
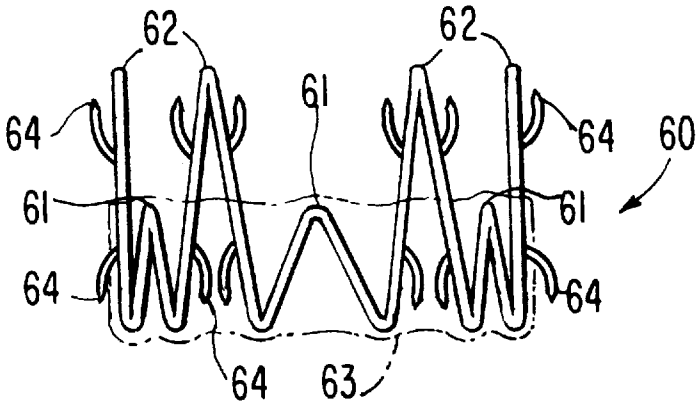


FIG. 7



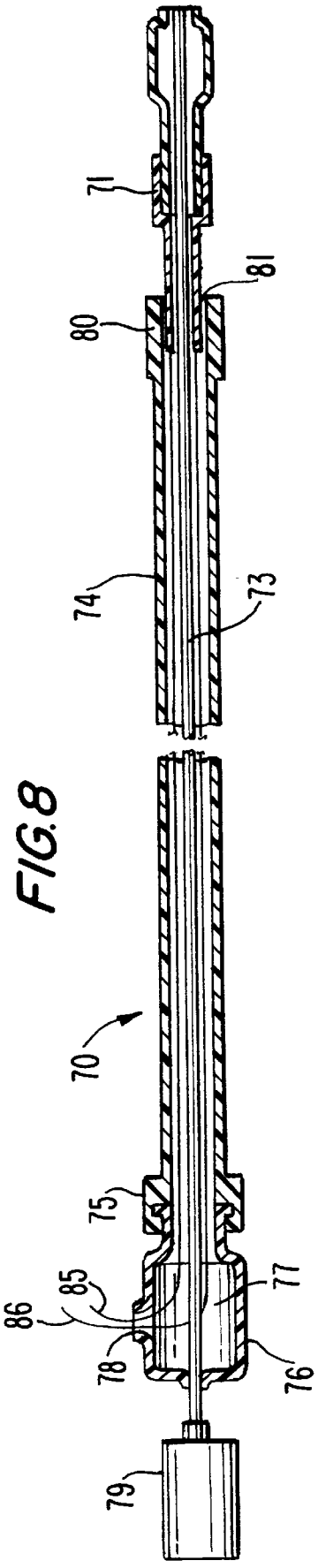


FIG. 8

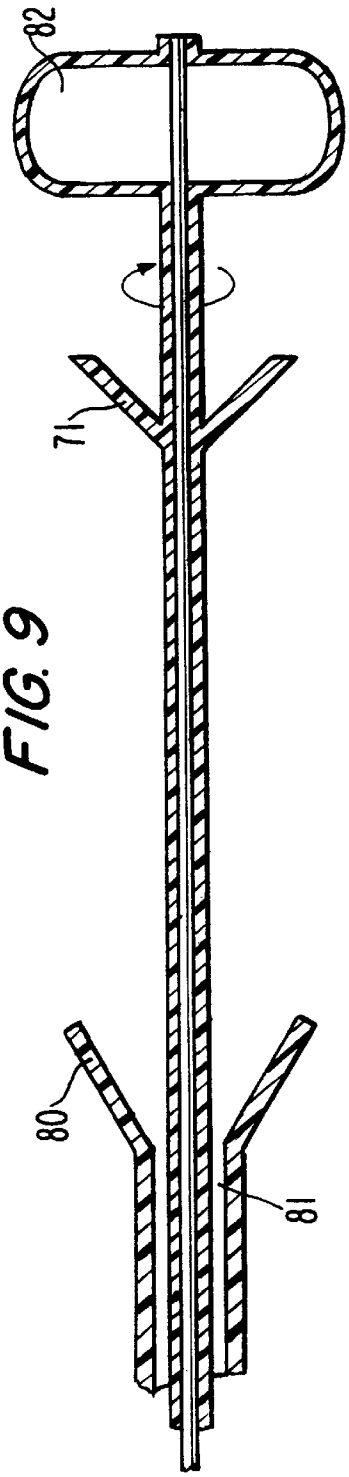


FIG. 9

FIG. 10

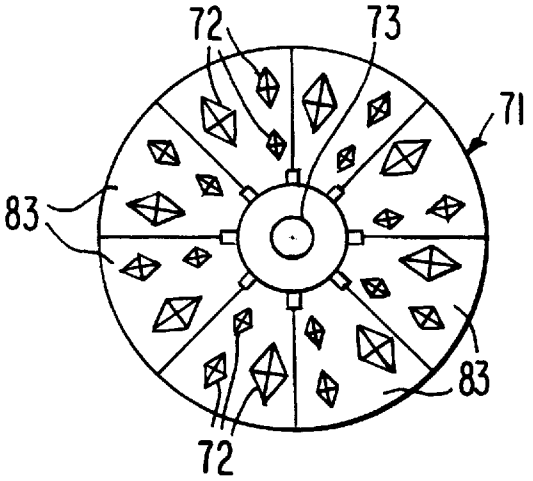
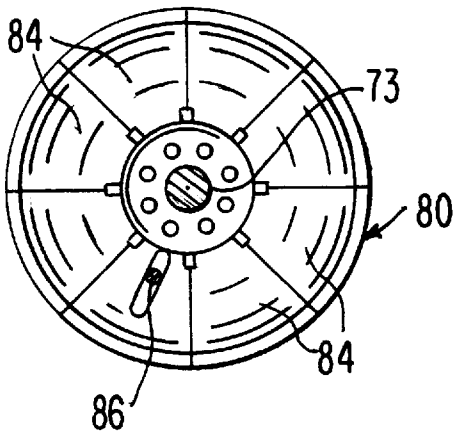


FIG. 11



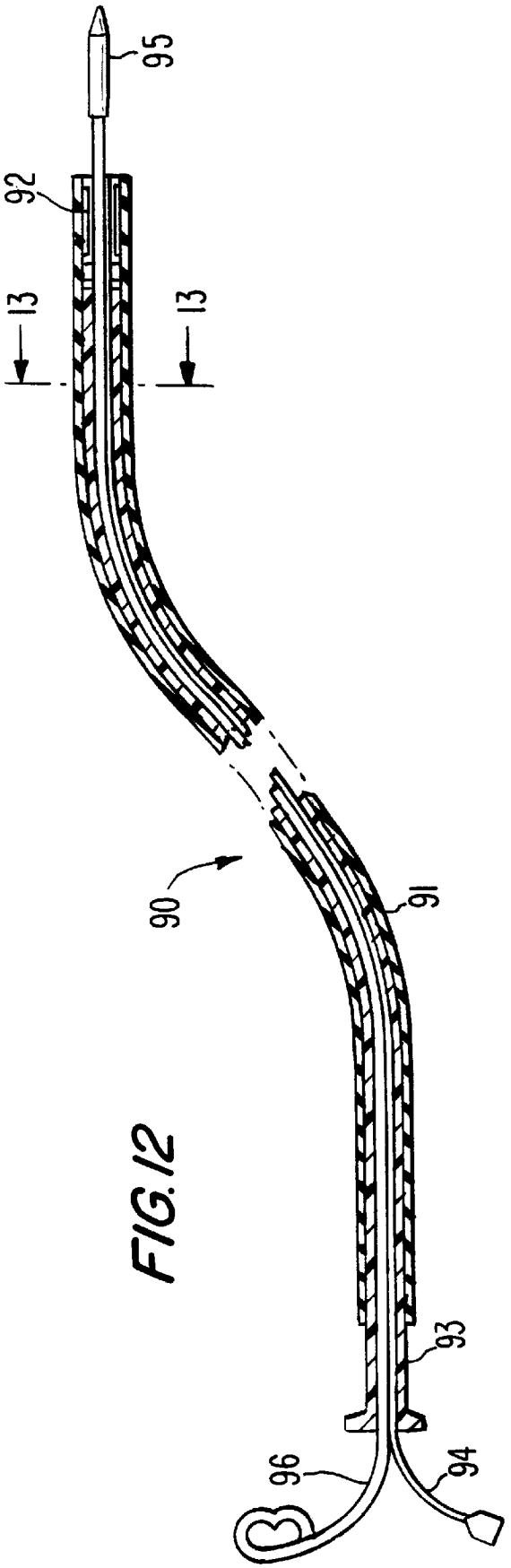


FIG. 12

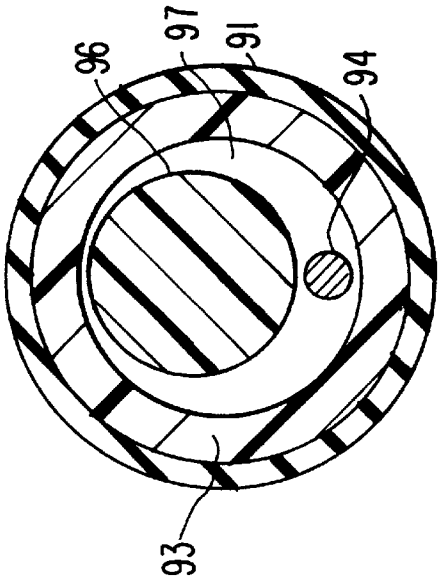
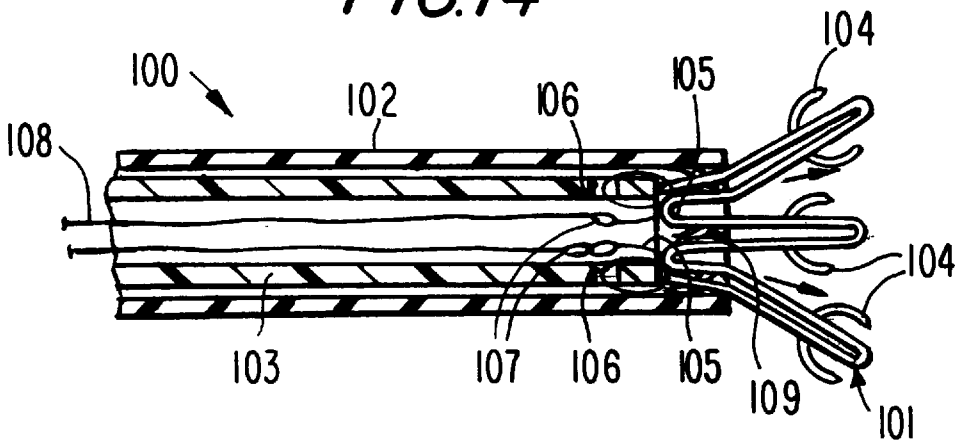


FIG. 13

FIG.14


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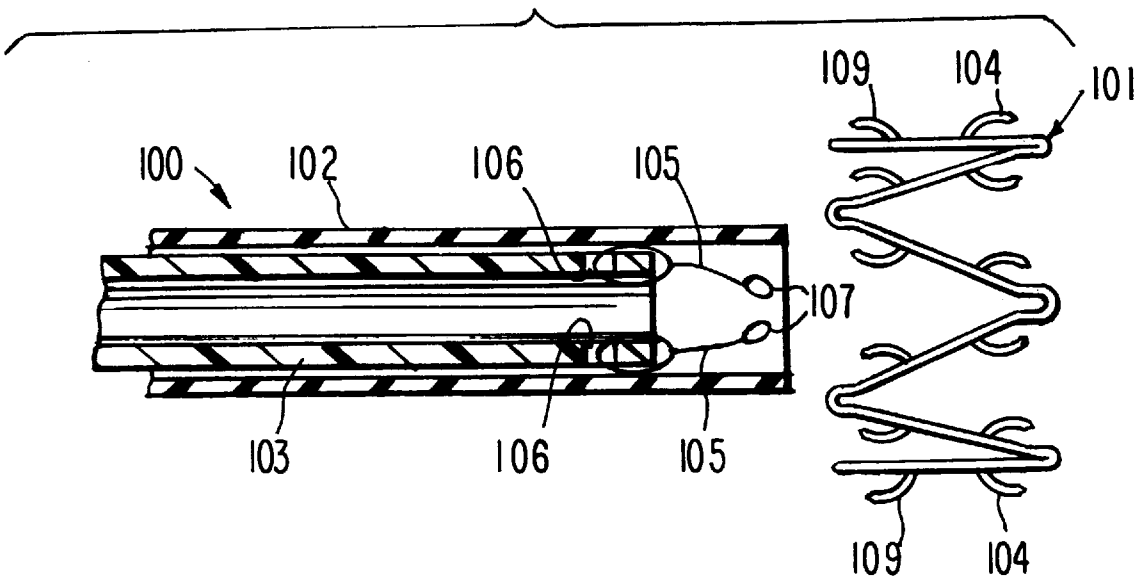
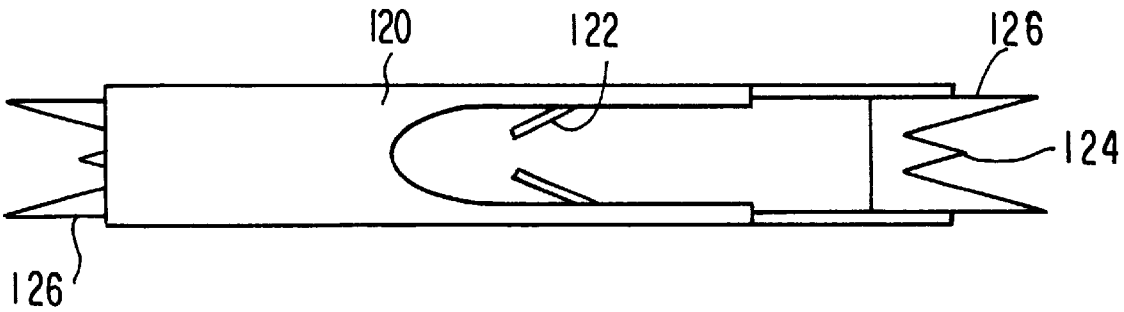

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FIG.15

FIG.16



ARTIFICIAL HEART VALVE AND METHOD AND DEVICE FOR IMPLANTING THE SAME

FIELD OF THE INVENTION

The present invention relates to novel artificial heart valves. More particularly, the present invention relates to novel heart valves that are especially adapted for placement using minimally invasive surgical techniques and to the method and device useful for such placement.

BACKGROUND OF THE INVENTION

Over the past several years a number of less invasive or minimally invasive surgical techniques have been developed. Examples of such techniques are various endoscopic or laparoscopic procedures, angioplasty procedures, atherectomy procedures, and the like. While the instruments and devices used in these minimally invasive procedures are complex and hence relatively expensive, the procedures are gaining more and more acceptance. It is believed the reasons for this acceptance are the reduced risk to the patient, as the patient often doesn't have to undergo general anesthesia or the time under general anesthesia is greatly reduced. Perhaps, more importantly, the recovery time required after a minimally invasive procedure is much less, thus greatly reducing hospital costs.

One of the more invasive procedures being performed today is open heart surgery. Such procedures require the use of general anesthesia, sternotomy, use of extracoporeal by-pass, recovery in an intensive care unit, and a stay of at least a few days in the hospital. Although such procedures carry a low mortality rate, they are quite expensive.

Currently in the United States approximately 100,000 defective heart valves are replaced annually, at an approximate cost of $30–50,000 per procedure, and thus it would be desirable if heart valves could be replaced using minimally invasive techniques. It would be especially advantageous if a defective heart valve could be removed via an endovascular procedure, that is, a procedure where the invasion into the body is through a blood vessel such as the femoral artery. The procedure is then carried out percutaneously and transluminally using the vascular system to convey appropriate devices to the position in the body wherein it is desired to carry out the desired procedure. An example of such a procedure would be angioplasty, wherein a catheter carrying a small balloon at its distal end is manipulated through the body's vessels to a point where there is a blockage in a vessel. The balloon is expanded to create an opening in the blockage, and then the balloon is deflated and the catheter and balloon are removed from the vessel.

Endovascular procedures have substantial benefits both from the standpoint of health and safety as well as cost. Such procedures require minimal invasion of the human body, and there is consequently considerable reduction and in some instances even elimination, of the use of a general anesthesia and much shorter hospital stays.

In the last few years a number of atherectomy devices have been developed. These are endovascular devices used to remove plaque and other abnormal deposits from vessels. Representative examples of such devices are those disclosed in U.S. Pat. Nos. 4,445,509, 4,646,736, and 4,990,134.

A number of minimally invasive techniques for replacing heart valves have been developed. Such techniques have been reported in an article by H. R. Andersen et al., entitled "Transluminal Implantation of Artificial Heart Valves", *European Heart Journal* (1992), Vol. 13, pp. 704–708; in an article by L. L. Knudsen et al., entitled "Catheter-Implanted Prosthetic Heart Valves", *The International Journal of Artificial Organs,* Vol. 16, No. 5 (1993), pp. 253–262; and in an article by D. Pavcnik et al., entitled "Development and Initial Experimental Evaluation of a Prosthetic Aortic Valve for Trans-Catheter Placement", *Radiology* (1992), Vol. 183, pp. 151–154. While the devices and techniques reported are clearly experimental, it appears that each of them suffers from one or more of the following problems: (1) secure placement of the heart valve; (2) durability of the heart valve; (3) ease of placement; (4) thrombogenicity, (5) leakage or regurgitation of blood, (6) excessive pressure gradient across the valve, and (7) size of the device and delivery system, as well as other similar problems. In addition, none of the above described devices or methods deals with the presence of a diseased or defective native valve.

An endovascular valve replacement procedure is described in Stevens, U.S. Pat. No. 5,370,685. While it cannot be discerned whether the procedure disclosed will work, it is evident that the replacement valve is structurally limited and will have the disadvantages associated with the problems discussed above.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide endovascular procedures and devices for the percutaneous and transluminal replacement of diseased or defective heart valves.

It is also an object of the present invention to provide a heart valve that can be relatively easily placed and secured in position.

It is a further object of the present invention to provide a valve that is relatively non-thrombogenic and eliminates undesirable leakage.

It is a still further object of the present invention to provide a method and device for the simple placement and securement of the new and improved heart valve in the desired position in a patient.

It is likewise an object of the present invention to provide a method and device for implanting an artificial heart valve using minimally invasive techniques especially endovascular techniques.

It is an even further object of the present invention to provide a method and device for the percutaneous and transluminal removal of a defective heart valve.

It is additionally a further object of the present invention to provide for the minimally invasive or endovascular placement of heart valves while preventing embolization.

These and other objects of the invention will become more apparent in the discussion below.

SUMMARY OF THE INVENTION

The invention herein encompasses methods and devices for the endovascular removal and replacement of diseased or defective heart valves. The invention includes a new heart valve which may be implanted percutaneously and transluminally, which heart valve comprises a stent member and a valve means. The stent member is self-expanding and has within it valve means that permit flow in only one direction. Preferably the stent member has barbs which anchor the expanded stent member at a desired site. A cutting mechanism is used to remove the diseased or defective heart valve, and then the replacement valve is inserted percutaneously to the site, where it is released in a controlled fashion from the distal end of a catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front, partially cross-sectional view of an artificial heart valve of the present invention;

FIG. **2** is a top view of the artificial heart valve depicted in FIG. **1**;

FIG. **3** is a bottom view of the artificial heart valve depicted in FIG. **1**;

FIG. **4** is a perspective, partially cross-sectional view of an artificial heart valve of the invention in an expanded configuration;

FIG. **5** is a perspective view of an artificial heart valve of the invention in a collapsed or constrained configuration;

FIG. **6** is an expanded front view of a segment of one type of stent member that may be used in the artificial heart valves of the invention;

FIG. **7** is a front, partially cross-sectional view of another embodiment of an artificial heart valve of the invention;

FIG. **8** is a partially cross-sectional view of a device according to the invention for removing a defective or diseased heart valve;

FIG. **9** is an enlarged, cross-sectional view of the distal end of the device shown in FIG. **8**;

FIG. **10** is a view taken along line **10—10** of FIG. **9**;

FIG. **11** is a view taken along line **11—11** of FIG. **9**;

FIG. **12** is a cross-sectional view of a device of the invention for the percutaneous and transluminal implantation of a heart valve;

FIG. **13** is an enlarged, cross-sectional view taken along line **13—13** of FIG. **12**;

FIG. **14** is an enlarged, cross-sectional view of the distal end of the device depicted in FIG. **12** showing the heart valve of the invention in a partially ejected state;

FIG. **15** is an enlarged, cross-sectional view of the distal end of the device depicted in FIG. **12** showing the heart valve fully ejected from the device; and

FIG. **16** is a partially cross-sectional view of an artificial heart valve according to the invention useful for venous insufficiency.

DETAILED DESCRIPTION OF THE INVENTION

The present invention includes methods and devices for implanting a heart valve percutaneously and transluminally. The artificial heart valves of the invention, which are capable of exhibiting a variable diameter between a compressed or collapsed position and an expanded position, comprise (1) a relatively rigid stent member and (2) a flexible valve means. The stent member is self-expanding and has a first cylindrical shape in its compressed or collapsed configuration and a second, larger cylindrical shape in its expanded configuration. The flexible valve means comprises a generally arcuate center portion and, preferably, a peripheral upstanding cuff portion. The flexible valve means is disposed within the cylindrical stent member with the arcuate portion transverse of and at some acute angle relative to the stent walls. The diameter of the arcuate portion is substantially the same as the inside diameter of the stent member in its initial expanded configuration. The peripheral upstanding cuff portion is disposed substantially parallel to the walls of the stent member.

The arcuate portion of the valve means contains at least one slit to form leaflets which open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the arcuate portion of the valve means contains a plurality of leaflets and most preferably three leaflets.

The cuff portion of the valve means is attached to the stent member and may extend partly or wholly around the outer perimeter of the stent member. In some of the preferred embodiments of the artificial heart valve of the invention, the cuff portion of the valve means extends on only one side of the circular portion of the stent member. The flexible valve means preferably comprises porcine pericardium configured with three leaflets.

Preferably the stent member carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve in a desired position. More preferably the barbs are disposed in two spaced-apart, circular configurations with the barbs in one circle extending in an upstream direction and the barbs in the other circle extending in a downstream direction. It is especially preferable that the barbs on the inflow side of the valve point in the direction of flow and the barbs on the outflow side point in the direction opposite to flow. It is preferred that the stent be formed of titanium alloy wire or other flexible, relatively rigid, physiologically acceptable material arranged in a closed zig-zag configuration. Such a configured stent member will readily collapse and expand as pressure is applied and released, respectively.

The invention includes methods and devices for the percutaneous and transluminal removal of the diseased or defective heart valve and the percutaneous and transluminal implantation of the new heart valve described above. The defective heart valve is removed by a suitable modality, such as, for example, laser, ultrasound, mechanical, or other suitable forms of delivery of energy, or phacoemulsion, including, but not limited to, laser lithotripsy, mechanical lithotripsy, electrohydraulic lithotripsy, and laser or mechanical ablation. For example, the valve can be ground or cut into fine particles or pieces and the particles are gathered and removed. The device for grinding or cutting the defective heart valve and removing the debris can include a rotating cutting tool mounted on the end of a flexible drive shaft. The drive shaft is surrounded over most of its length by a guiding catheter. The cutting tool, which is inserted into a vessel of the patient and guided to the location of the defective heart valve, may comprise cutting blades disposed at its distal end. The blades are configured such that the debris that is created by the cutting action is thrown or ejected proximal of the distal end. Disposed close to the cutting blades and proximal thereof is a collecting member which preferably has a concave shape and is expandable to occlude the aorta as well as to catch debris. If desired the collecting member may be perforated so that suction may be used to aid in the removal of the ground debris.

The system for implanting the above described artificial heart valve percutaneously and transluminally includes a flexible catheter which may be inserted into a vessel of the patient and moved within that vessel. The distal end of the catheter, which is hollow and carries the artificial heart valve of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the artificial heart valve. The catheter has a pusher member disposed within the catheter lumen and extending from the proximal end of the catheter to the hollow section at the distal end of the catheter. Once the distal end of the catheter is positioned as desired, the pusher mechanism is activated and the distal portion of the artificial heart valve is pushed out of the catheter and the stent member partially expands. In this position the stent member is restrained so that it doesn't pop

out and is held for controlled release, with the potential that the artificial heart valve can be recovered if there is a problem with the positioning or the like. The catheter is them retracted slightly and the artificial heart valve is completely pushed out of the catheter and released from the catheter to allow the stent member to fully expand. If the stent member includes two circles of barbs on its outer surface as previously described, the first push and retraction will set one circle of barbs in adjacent tissue and the second push and release of the artificial heart valve will set the other circle of barbs in adjacent tissue and securely fix the artificial heart valve in place when the valve is released from the catheter. Alternatively, or in combination with the above, the heart valve could be positioned over a guidewire.

The invention can perhaps be better appreciated by reference to the drawings. An artificial heart valve according to the present invention is set forth in FIGS. **1** to **3**. The artificial heart valve **20** is comprised of a stent member **21** and a flexible valve means **22**. In this embodiment the stent member **21** is comprised of stainless steel wire in a sine wave-like configuration as shown in FIG. **1**. The center portion **23** of valve member **22** is generally arcuate in shape and comprises three leaflets **24** as shown, although it is understood that there could be from 2 to 4 leaflets. A cuff portion **25** extends from the periphery of the circular portion **27** along the outside of the stent member **21** and is attached to the stent member **21** by a plurality of sutures **26**.

FIG. **4** is a perspective view of another embodiment of an artificial heart valve **30** of the invention. The heart valve **30** has a generally circular shape with the walls **31** of the cylinder being formed by the stent member **32**. The stent member **32** is a wire formed in a closed zig-zag configuration. The member has an endless series of straight sections **33** joined by bends **34**. The valve member **35** is flexible and includes a plurality of leaflets **36**.

The leaflet portion of the valve member **35** extends across or transverse of the cylindrical stent. The leaflets **36** are the actual valve and allow for one-way flow of blood. Extending from the periphery of the leaflet portion is a cuff portion **37**. The cuff portion **37** extends adjacent the stent walls **31** in the direction of the arrow A. The cuff portion is attached to the stent by sutures **38**.

The configuration of the stent member **32** and the flexible, resilient material of construction allows the valve to collapse into a relatively small cylinder **40** as seen in FIG. **5**. The artificial heart valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member **32** will cause the artificial heart valve to take its expanded configuration, as seen in FIG. **4**.

An enlarged view of a preferred embodiment of a stent member for use in the artificial heart valve of the invention is depicted in FIG. **6**. The stent member **50** includes a length of wire **51** formed in a closed zig-zag configuration. The wire can be a single piece, stamped or extruded, or it could be formed by welding the free ends together as at **52**. The straight sections **53** of the stent are joined by bends **54**. The stent is readily compressible to a small cylindrical shape and resiliently self-expandable to the shape shown in FIG. **6**.

Another embodiment of the artificial heart valve of the present invention is depicted in FIG. **7**. In this embodiment the heart valve **60** has a modified sine wave configuration. As seen in the drawing every other wave **61** has approximately 0.50–0.75 the amplitude of adjacent waves **62**. The flexible valve member **63** is disposed at the crown or top of the smaller waves. The larger waves carry a plurality of barbs **64** for holding the valve in place once it has been appropriately positioned.

The stent members of the artificial heart valves of the present invention may be made from Elgiloy alloy, titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials. The configuration may be the zig-zag configuration shown or a sine wave configuration, mesh configuration or a similar configuration which will allow the stent to be readily collapsible and self-expandable. When a zig-zag or sine wave configured stent member is used, the diameter of the wire from which the stent is made should be from about 0.010 to 0.035 inches, preferably from about 0.012 to 0.025 inches. The diameter of the stent member will be from about 1.5 to 3.5 cm, preferably from about 1.75 to 3.00 cm, and the length of the stent member will be from about 1.0 to 10 cm, preferably from about 1.1 to 5 cm.

The valve member is flexible, compressible, host-compatible, and non-thrombogenic. The valve can be, for example, a glutaraldehyde fixed porcine aortic valve which has three cusps that open distally to permit unidirectional blood flow. The valve can also be fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts. The optimal material will be synthetic such that it is manufactured from non-biological materials, non-thrombogenic, flexible such that it can be transported through the vasculature, biocompatible and very durable such that it can withstand a permanent fixation at the valve site. Biocompatible materials such as polytetrafluoroethylene, polyester and the like may be used.

In FIGS. **8** through **11** there is shown a device for the percutaneous and transluminal removal of a diseased or defective heart valve. The device **70** includes a cutting tool **71** disposed at the distal end of the device **70**. As shown in FIG. **10** cutting tool **71** has a plurality of abrasive surfaces **72** on its outer surface for cutting or grinding away the defective heart valve. Abrasive surfaces **72** comprise diamond chips, small metal blades, or other similar abrading means that would be effective to safely remove the defective heart valve. The cutting tool **71** is rotated by a flexible transluminal drive shaft **73**, which is preferably contained along substantially its entire length in a flexible catheter **74** made of physiologically acceptable plastic material. At the proximal end of the catheter **74** remote from the cutting tool **71** there is a catheter connector **75** to connect the catheter **74** to a drive shaft bearing block **76**. The bearing block includes a central cavity **77** and a port **78**. The proximal end of the drive shaft **73** is connected to and through a prime mover or motor **79** for rotation of drive shaft **73** and cutting tool **71**.

As is more clearly shown in FIG. **9**, disposed just proximal of the cutting tool **71** is a collecting member **80** for collecting debris generated by the cutting or grinding away of the defective heart valve. The collecting member is circular, preferably with a concave shape for directing debris toward the annular space **81** between drive shaft **73** and catheter **74**. Suction may be applied to the port **78** in bearing block **76** to assist in removal of debris from the operative site. Collecting member **80** preferably expands due to an inflatable component to cause the outward radial portion of collecting member **80** to abut the inner surface of the appropriate vessel. Thus, all or part of collecting member **80** could be inflatable either in a single inflatable member or a series of inflatable members. Catheter **74** would contain one or more inflation lumens, not shown, in fluid communication with the one or more parts of collecting member **80** to be inflated.

It is preferred that the cutting tool **71** have an initial, relatively small diameter configuration and then a larger configuration as drive shaft **73** and cutting tool **71** are rotated. Alternatively, cutting tool **71** could be mechanically connected to a mechanical rod extending to the proximal end of catheter **74** to cause cutting tool **71** to expand prior to contact with the defective heart valve.

Suction may be applied to the port **78** in the bearing block **76** to assist in the removal of debris from the operative site. Distal protective balloon **82** which is inflated through a lumen in catheter **86** within drive shaft **73**, is inflated to a diameter slightly larger than the extended diameter of cutting tool **71**.

It is preferred that both the cutting tool **71** and the collecting member **80** be expandable. In the embodiment shown the cutting tool **71** comprises a plurality of leaves **83** and the collecting member basin **80** also comprises a plurality of leaves **84**. In both instances the leaves may be mechanically contracted so as to overlap adjacent leaves and reduce the diameter of the respective unit. This will allow both units to be collapsed while being inserted in the vessel and guided to the operative site. The cutting **71** tool is then rotated at a relatively high speed of 3000 to 4000 rpm to grind away the defective valve. The resultant debris is collected in the collecting member **80** and removed from the site with the aid of suction.

The device set forth in FIGS. **12** and **13** represents a novel device for implanting the artificial heart valves of the present invention. The device **90** comprises a flexible catheter **91** for percutaneous and transluminal delivery of the heart valve to the desired site. A heart valve **92** of the invention is carried, in its collapsed state, at the distal end of the catheter **91** where the catheter walls maintain the valve **92** in its collapsed state. Disposed within the catheter **91** is a hollow flexible pusher member **93**, which is movable longitudinally with respect to the catheter **91**. A guidewire **94** having a blunt end **95** is disposed through a lumen **97** of the pusher member **93** and is used to guide the distal end of the catheter **91** to the desired site. Means **96** is also disposed through lumen **97** of the pusher member **93** for holding the valve **92** in place and allowing release of the valve **92** when desired, as will be more fully described in conjunction with FIGS. **14** and **15**.

In FIG. **14** there is shown an implanting device **100** of the present invention with a heart valve **101** partially ejected, and FIG. **15** shows the device **100** with the heart valve **101** fully ejected. In FIG. **14** the catheter **102** has been brought to the appropriate site and the guide wire removed proximally. The pusher member **103** has been moved forward longitudinally of the catheter **102** to eject approximately one-half of the heart valve **101** from the distal end of the catheter **102**. As seen in the drawing the distal end of the valve **101** is expanded and a slight pull of the entire unit will set the first circle of barbs **104** in the vessel wall. The heart valve **101** is held in place within the delivery catheter by a pair of threads or sutures **105**. The sutures are looped through an opening **106** in the pusher member **103** and then passed about a portion of the heart valve **101** as shown. The other end of the suture **105** contains a loop **107**. A tension thread **108** is passed through the suture loops and down through the center of the pusher member **103** to the proximal end of the catheter **102**. As seen in FIG. **15** the heart valve **101** has been completely ejected from the catheter **102**. The tension thread **108** has been removed and the pusher member **103** longitudinally retracted. The looped sutures have been disengaged from the heart valve **101** and the second circle of barbs **109** set in the vessel wall and the valve implanted.

Before the invention herein is used, the patient is studied to determine the architecture of the patient's heart. Useful techniques include fluoroscopy, transesophageal echocardiography, MRI, and angiography. The results of this study will enable the physician to determine the appropriate sized cutting tool and heart valve to employ.

To use Applicant's invention, a guidewire is inserted percutaneously and transluminally using standard vascular or angiography techniques. The distal end of the guidewire is manipulated to extend through and across the defective heart valve. Then a catheter corresponding to catheter **74** is advanced distally through the femoral artery to a point proximal to the defective heart valve, between the origin of the coronary artery and the origin of the right subclavian artery. The position of the distal end of catheter **74** can be monitored by observation of radiopaque markers. Collector member **80** is preferably inflated and occludes the aorta at a point between the origin of the coronary artery and the right subclavian artery. Next, balloon **87** and cutting tool **71** are advanced through catheter **74** so that the cutting tool **71** and uninflated balloon **87** are distal to the defective heart valve. Optionally an additional step, such as balloon dilatation or atherectomy, may be required to provide a passageway through the heart valve.

A catheter is placed into the coronary sinus via a transjugular puncture. This catheter is used for infusion of blood or cardioplegia solution during the portion of the procedure when the aorta is occluded. The absence of valves in the cardiac venous system allows retrograde flow so that there will be an effluence of fluid from the coronary arteries. This flow of fluid is desired to prevent embolization of material into the coronary arteries during the procedure.

Once the cutting tool **71** is in place, the balloon **82** is inflated and flexible shaft **73** is rotated. Once cutting tool **71** has reached the appropriate rotation speed, cutting tool **71** is pulled proximally to remove the defective heart valve. Balloon **87** and cutting tool **71** are spaced apart so that inflated balloon **87** will be stopped by the perimeter, unremoved portion of the defective heart valve, which will signal the physician that the valve has been removed, as well as protect the heart and aorta from damage from the valve removal device. Also, the spacing is such that the cutting tool will not contact collecting member **80**. Once it is determined that the defective heart valve has been removed, cutting tool **71** is slowed or stopped altogether and balloon **87** is deflated. Cutting tool **71** and deflated balloon **87** are pulled proximally through catheter **74**. Then, a catheter containing an artificial heart valve is inserted and the artificial heart valve is placed as described above.

The valve removal devices and the valve implantation devices of the present invention may be made from any of the materials presently being used commercially to make catheters or angioplasty devices. Examples of such materials include polyvinylchloride, polyethylene, polypropylene, polyurethane, and co-polymers thereof.

In addition, it is within the scope of the invention that the artificial valves described herein can be used to replace or supplement venous valves. Such valves could be delivered percutaneously and transluminally after, or in the absence of, removal of natural venous valves. The artificial valves described above could be used, preferably where the barbs on the outer surface of the stent member are either deleted or reduced, such as one circle of barbs being eliminated. Also, the stent member of a venous valve useful herein could comprise a natural, preserved vein segment with a natural venous valve. One or both ends of the vein segment would

comprise self-expandable metal stents that would cause the ends of the segment to remain in position.

As shown in FIG. **16**, an artificial venous valve device can comprise a natural vein segment **120** with valve **122**, which has a stent **124** at one or both ends of the segment **120**. The ends of the segment are secured to the outer surface **126** of stents **124** by suture or other suitable means. Each stent **124** may also contain barbs (not shown), as described above. Such a valve device can be deployed using any one of several possible delivery systems, including the delivery systems described above.

While preferred embodiments of the invention have been illustrated and described, it should be understood that variations will be apparent to those skilled in the art. Accordingly, the invention is not to be limited to the specific embodiments shown and described, but includes all embodiments encompassed within the scope of the following claims.

What is claimed is:

1. An artificial heart valve comprising

a self-expanding, cylindrical stent member having first and second ends and an outer surface, and

a valve member comprising one-way valve means arranged within the stent and a cuff portion extending on said outer surface to a point between the first and second ends,

wherein the cuff portion is configured to position the valve snugly and sealingly at a valve site; and

wherein the stent member has a plurality of barbs extending from the outer surface of the stent member to engage the natural tissue of the heart to hold the valve in place after implantation.

2. The artificial valve of claim **1**, wherein the valve means comprises a plurality of leaflets.

3. The artificial valve of claim **1**, wherein the cuff portion extends in the downstream direction.

4. The artificial valve of claim **1**, wherein the barbs are disposed in a pair of spaced apart concentric circles.

5. The artificial valve of claim **4**, wherein the barbs of one circle are all extending in the same direction and the barbs of the other circle all extending in the opposite direction.

6. The artificial valve of claim **1**, wherein the stent member is comprised of a suitable flexible, resilient, biocompatible material.

7. The artificial valve of claim **6**, wherein the material is Elgiloy alloy or nitinol.

8. The artificial valve of claim **1**, wherein the stent member comprises a closed zig-zag configuration having an endless series of straight sections and a plurality of bends joining said straight sections.

9. The artificial valve of claim **8**, wherein the straight sections of said stent member are all substantially the same length.

10. The artificial valve of claim **2** wherein the valve member has three leaflets.

11. The artificial valve of claim **10**, wherein the valve member is made of porcine pericardium or a suitable polymeric material.

12. The artificial valve of claim **1**, wherein the valve member is attached to the stent member with a plurality of sutures or other attachment means.

13. An artificial heart valve comprising a relatively rigid stent member and a flexible valve means disposed in said stent member, said stent member comprising a wire formed into a closed zig-zag configuration having an endless series of straight sections and a plurality of bends connecting said straight sections, said stent member having a first collapsed cylindrical shape and being self-expandable to a second expanded cylindrical shape, said stent member having a plurality of barbs extending from its outer surface, said valve member comprising a circular portion, said circular portion having a plurality of leaflets extending from the periphery of said circular portion towards the center thereof, said leaflets allowing for flow of blood through the valve in one direction only, the diameter of said circular portion being substantially the same as the inside diameter of said stent member when said stent member is in its expanded cylindrical shape, said valve member having a cuff portion extending from the periphery of said circular portion, said cuff portion being disposed downstream of said valve member and substantially parallel to the cylindrical surface of said stent member and said cuff portion being attached to said stent member with a plurality of sutures.

14. The artificial valve of claim **13**, wherein the stent member is a titanium alloy and the valve means has three leaflets and is made of porcine pericardium.

15. The artificial valve of claim **13**, wherein the barbs are disposed in a pair of spaced apart concentric circles.

16. The artificial valve of claim **15**, wherein the barbs of one circle are all extending in the same direction and the barbs of the other circle all extending in the opposite direction.

17. A method of implanting an artificial heart valve, which method comprises

providing a transluminal catheter having proximal and distal ends, wherein the distal end carries in a collapsed cylindrical shape a valve comprising a self-expanding, cylindrical stent member having first and second ends and an outer surface, and a valve member comprising one-way valve means arranged within the stent and a cuff portion extending on said outer surface to a point between the first and second ends, wherein the cuff portion is configured to position the valve snugly and sealingly at a valve site; and, wherein the stent member has a plurality of barbs extending from the outer surface of the stent member to engage the natural tissue of the heart to hold the valve in place after implantation,

positioning the distal end of said catheter at a desired location for placement of said valve,

moving the leading half of said valve out of the distal end of the catheter to allow the leading half of said valve to expand, and

retracting the catheter slightly to remove the trailing half of said valve from the hollow end of said catheter to allow the valve to completely expand to place the heart valve in the desired location.

18. The method of claim **17**, wherein the valve has a pair of spaced apart concentric circles of barbs extending from the outer surface of said heart valve, one circle of barbs is set when the leading half of the heart valve is moved out of the distal end of said catheter means and the second circle of barbs is set when the trailing half of said heart valve is removed from the distal end of said catheter means.

19. An artificial venous valve comprising

a tubular valve segment containing venous valve means and having distal ends,

at least one self-expanding, cylindrical stent member at a valve segment distal end, having first and second ends and an outer surface, and

a cuff portion extending on the outer surface of each stent to a point between the respective first and second ends,

wherein each cuff portion is configured to position the respective stent snugly and sealingly at a site; and

wherein the stent member has a plurality of barbs extending from the outer surface of the stent member to engage the natural tissue of the site to hold the valve in place after implantation.

20. In an artificial valve for placement in a corporeal duct or vessel wherein said valve comprises a self-expanding stent member and a valve member arranged within the stent member, the improvement wherein a cuff portion extends on the outer surface of said stent member and said cuff member causes said stent member to snugly position itself to the inner surface of the corporeal duct or vessel, wherein the stent member has a plurality of barbs extending from the outer surface of the stent member to engage the natural tissue of the corporeal duct or vessel to hold the valve in place after implantation.

* * * * *

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(54) **GRAFT HAVING REGION FOR BIOLOGICAL SEAL FORMATION**

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(21) Appl. No.: **09/998,961**

(22) Filed: **Oct. 31, 2001**

Related U.S. Application Data

(63) Non-provisional of provisional application No. 60/244,489, filed on Oct. 31, 2000.

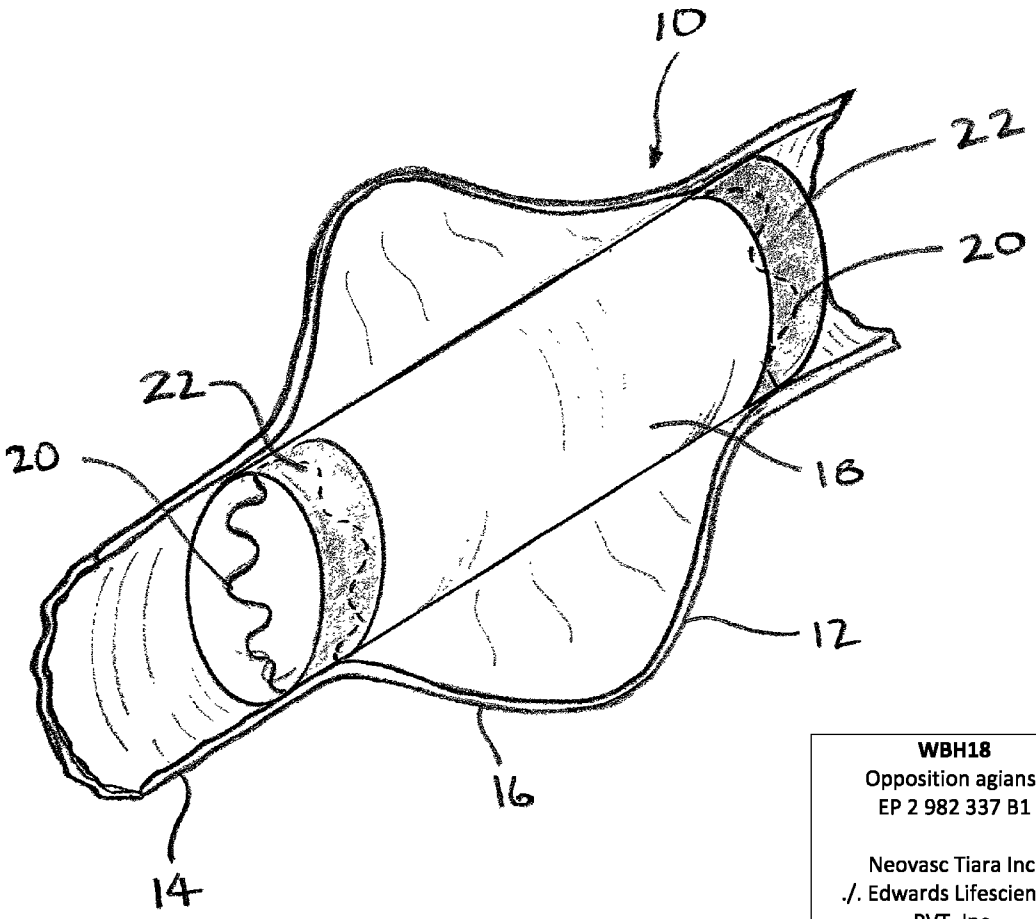
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(57) **ABSTRACT**

A graft compatible with living animal tissue is disclosed. The graft has attachment regions with means for promoting growth of living animal tissue across the attachment regions to form a biological seal between the graft and the tissue. The means for promoting growth include locating pores in the attachment regions sized to favor growth of the tissue, increasing the surface area of the attachment regions by forming filamentary loops extending from the attachment regions, forming the attachment regions from textured filaments, forming the attachment regions from materials which elicit a healing reaction in living animal tissue or coating the attachment regions with a compound such as thrombin or collagen which promotes healing of the tissue.



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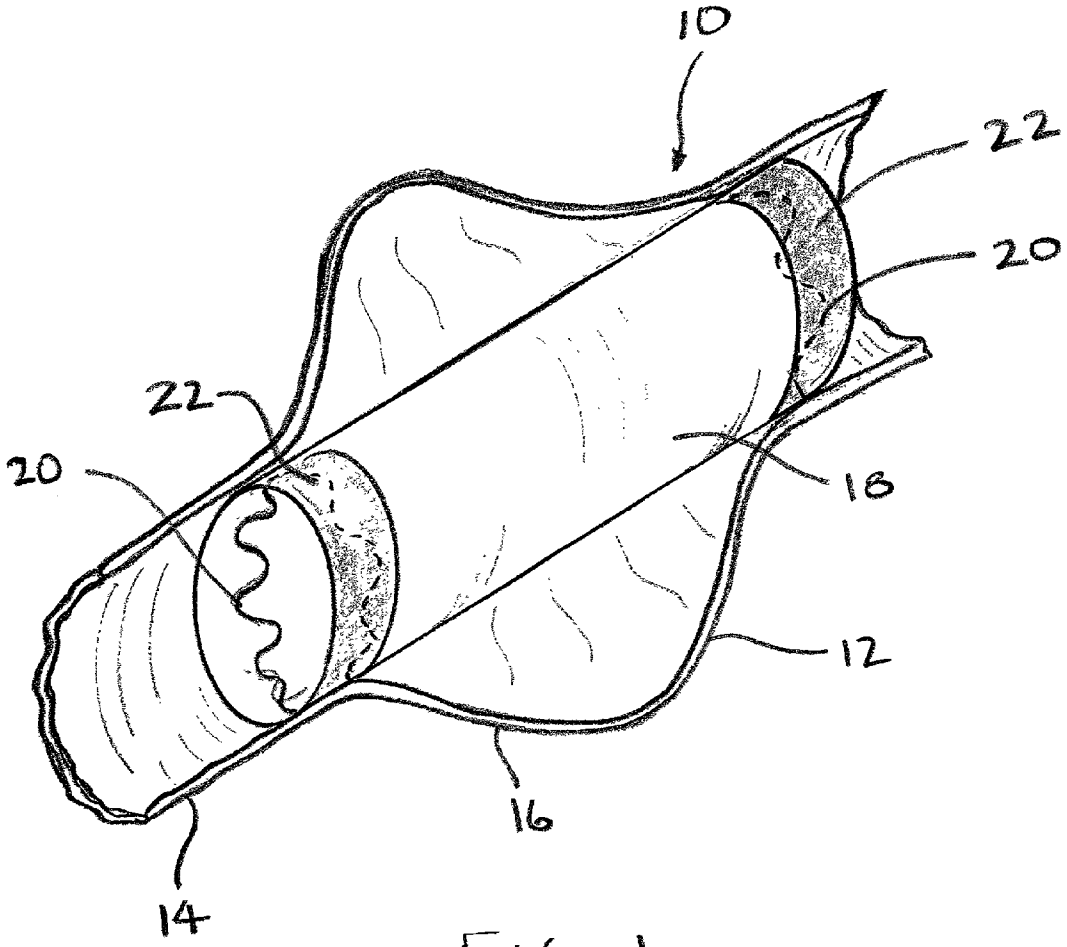


FIG 1

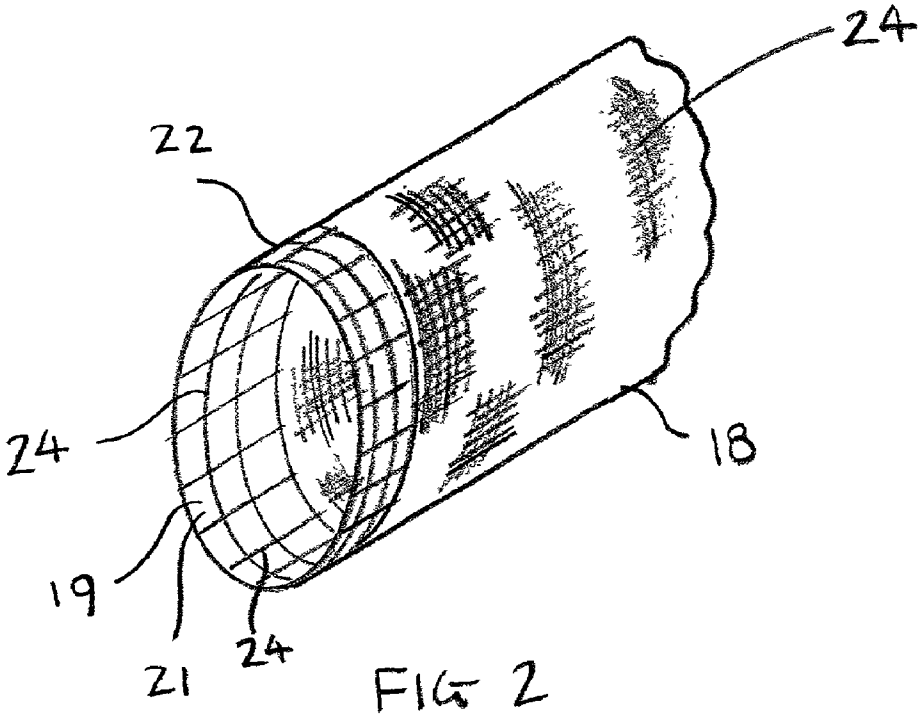


FIG 2

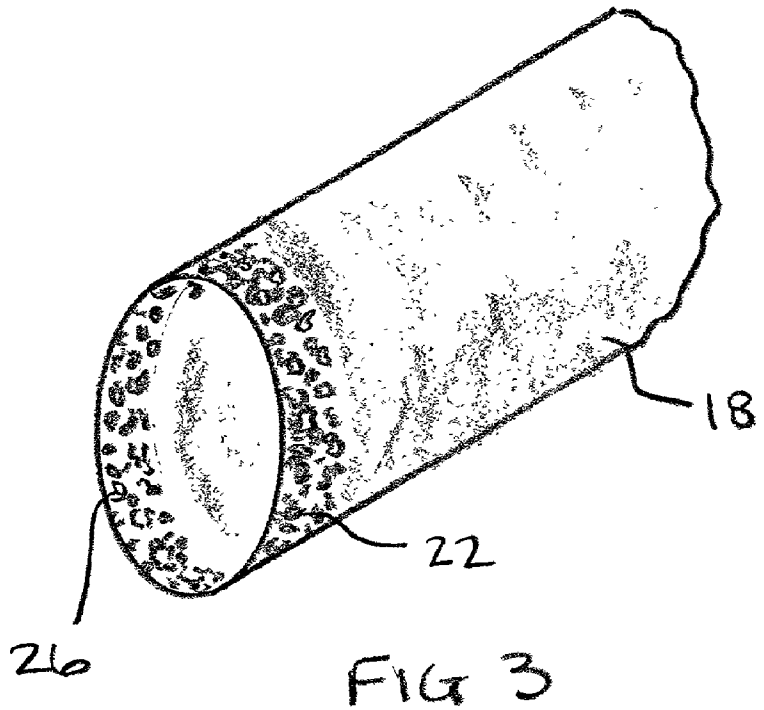


FIG 3

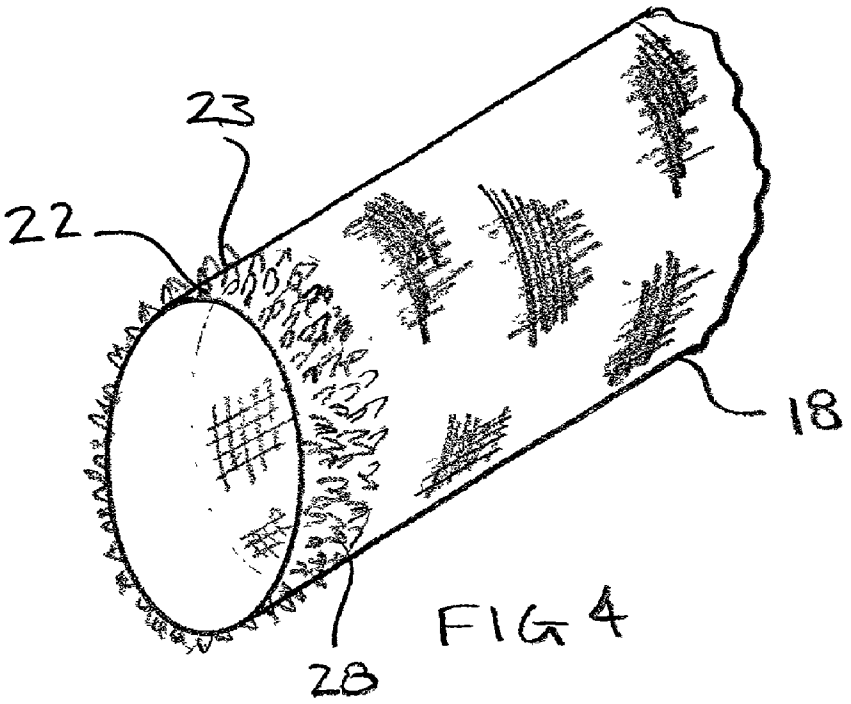


FIG 4

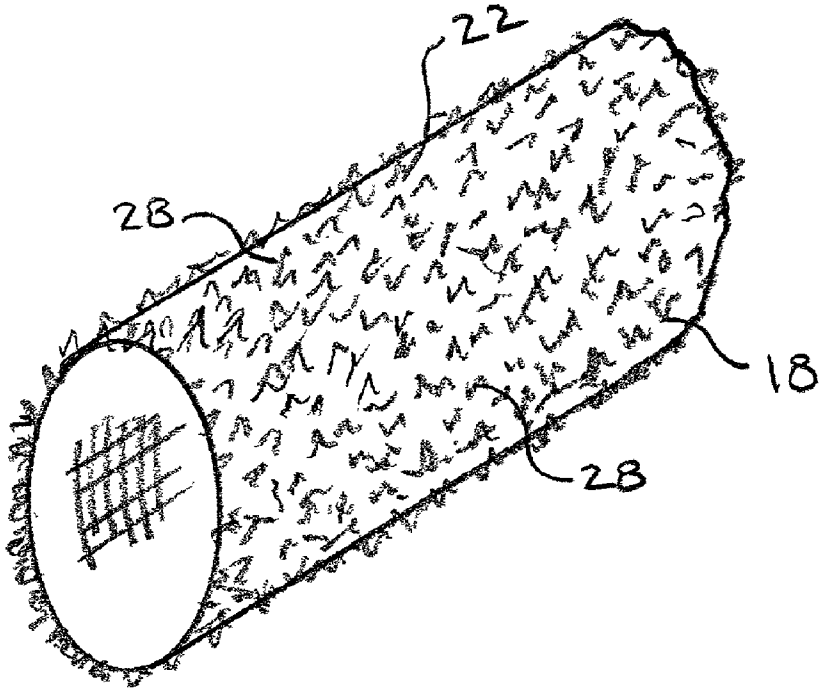


FIG 5

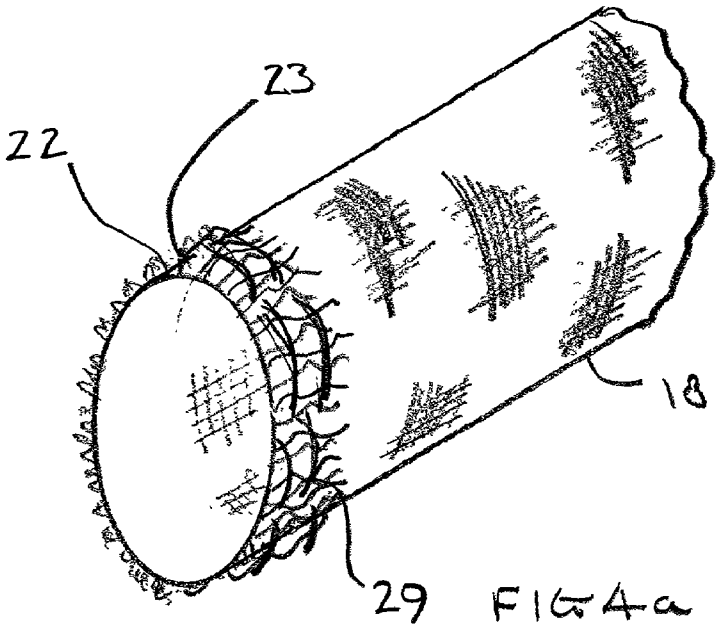


FIG 4a

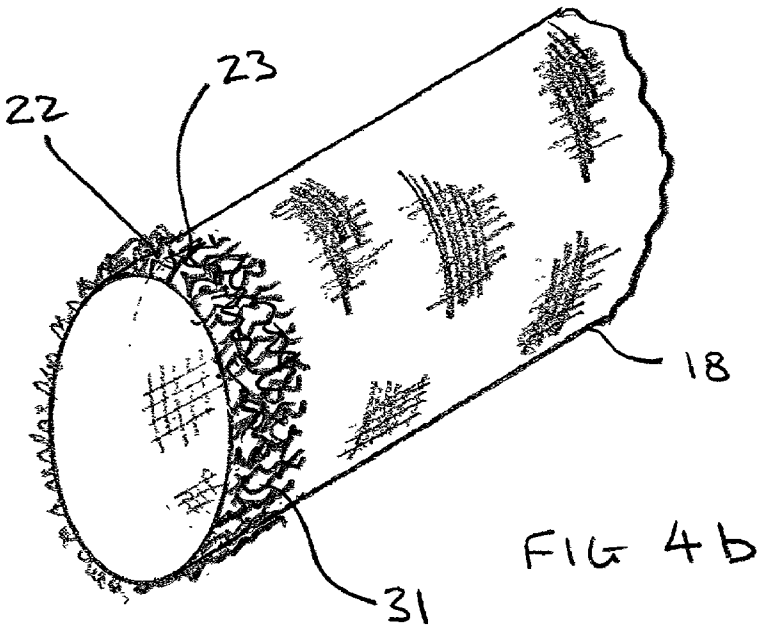


FIG 4b

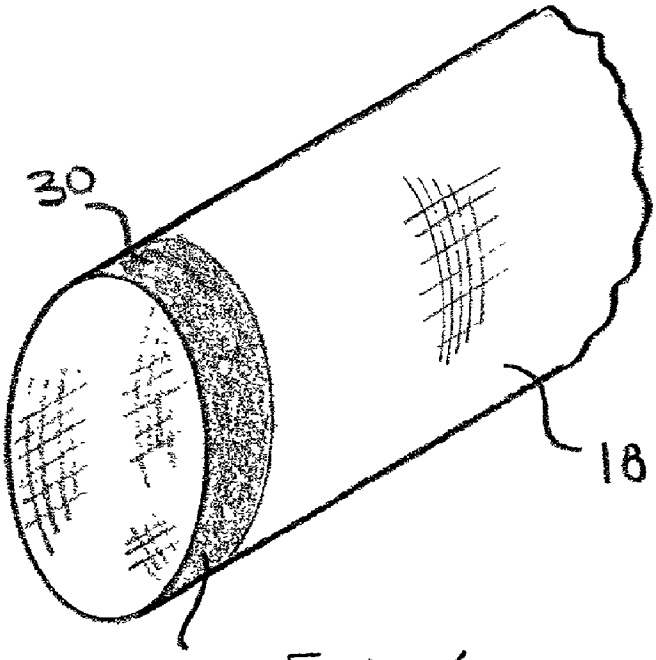


FIG 6

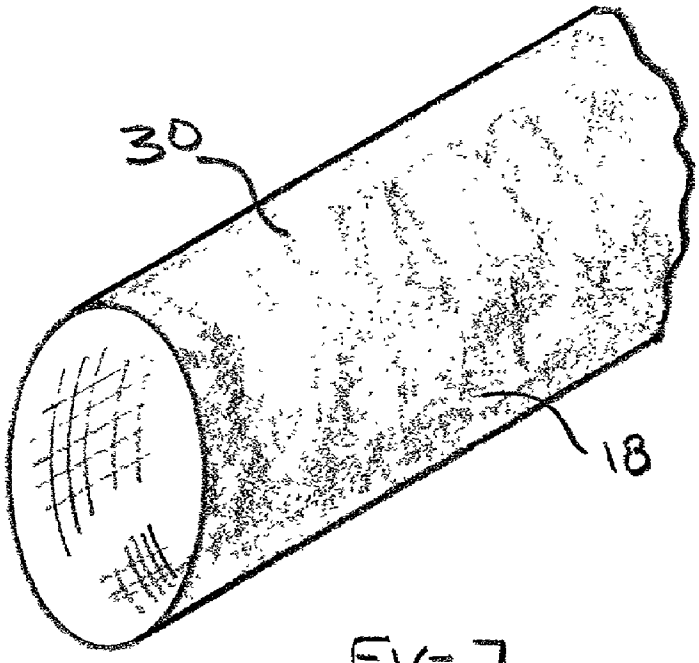


FIG 7

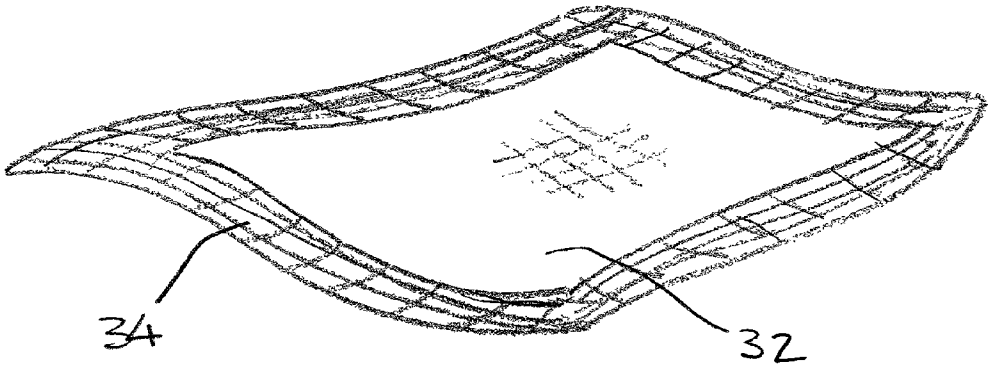


FIG 8

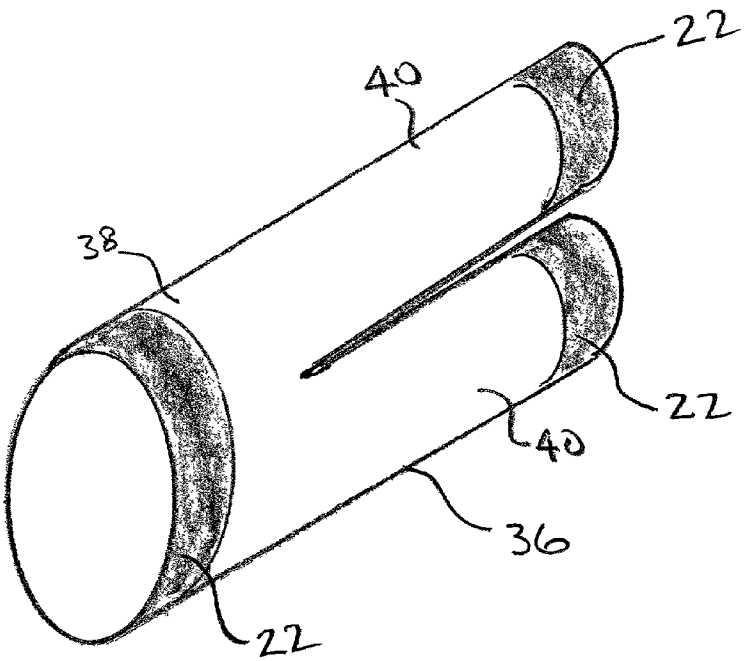


FIG 9

GRAFT HAVING REGION FOR BIOLOGICAL SEAL FORMATION

RELATED APPLICATION

[0001] This application is based on and claims priority of U.S. Provisional Application No. 60/244,489, filed Oct. 31, 2000.

FIELD OF THE INVENTION

[0002] This invention relates to grafts compatible with living animal tissue and having regions which encourage the growth of the tissue across the regions to form a biological seal and attachment between the graft and the tissue.

BACKGROUND OF THE INVENTION

[0003] Grafts are widely used as human implants to treat and correct various disorders, such as a vascular aneurysm, in which the graft replaces a weakened portion of an artery or to repair a hernia, wherein a mesh is used to repair an abnormal opening in the wall of the abdomen through which a portion of the intestine protrudes. Grafts may also find further use in various anastomosis procedures wherein two vessels in the body are joined. Vascular anastomoses include, for example, the arteriovenous shunt, in which an artery is connected to a vein to provide access to the circulatory system for hemodialysis. An ileorectal anastomosis is used to treat ulcerative colitis and involves connecting the ileum to the rectum after a total colectomy. Intestinal anastomoses, such as the Rouxen-Y anastomosis, establish a connection between the intestine and another organ or vessel, such as the stomach or esophagus.

[0004] The use of grafts involves attaching and often sealing the graft to the tissue of an organ or vessel. This is presently accomplished by means of stents which support the graft and force it against the tissue;

[0005] hooks which are attached to the graft and anchor the graft to the tissue; and sutures wherein the graft is sewn directly to the vessel or tissue. A drawback of these methods of attachment is that they cause trauma to the tissue and damage to the graft which results in leaks occurring at the points of attachment. This is especially problematic in vascular grafts which must withstand repeated pressure pulsations as blood is pumped by the heart. Sutures and hooks tend to cause endoleaks in the connected vessels, which take time to heal and cause major complications if they do not heal and form a proper hemostatic seal.

[0006] There is clearly a need for a graft which can be attached to human or other living animal tissue with less trauma and which will readily form a seal between the graft and the tissue which reduces or eliminates leakage at the attachment.

SUMMARY AND OBJECTS OF THE INVENTION

[0007] The invention concerns a graft compatible with living animal tissue. The graft comprises a thin flexible biocompatible substrate having an attachment region engageable with the living animal tissue for attachment of the substrate to the tissue. The attachment region has means for promoting growth of the living animal tissue across the attachment region to sealingly attach the substrate to the tissue.

[0008] In one embodiment of the graft, the growth promoting means comprises a plurality of pores extending throughout the attachment region. The pores are sized to promote growth of the living animal tissue within the pores and thereby across the attachment region. Preferably, the substrate comprises a plurality of interlaced filamentary members, the pores being defined by interstices formed between the filamentary members.

[0009] In another embodiment of a graft according to the invention, the substrate comprises an elastic, substantially impermeable, non-woven membrane and the growth promoting means again comprises a plurality of pores extending throughout the attachment region, the pores being sized to promote growth of the living animal tissue within the pores and thereby across the attachment region. The pores may be formed by penetrating the substrate or expanding the substrate at the proper rate to produce pores of the desired size.

[0010] The growth promoting means may also comprise a textured surface positioned at the attachment region, the textured surface having an increased surface area favoring growth of the living animal tissue across the attachment region.

[0011] In another embodiment, the growth promoting means comprises a coating which promotes healing of living animal tissue applied to the attachment region. Such coatings may comprise thrombin, collagen or silicone. This embodiment may be combined with all of the embodiments of the invention to further increase their effectiveness.

[0012] In yet another embodiment of the invention, the substrate comprises a plurality of interlaced first filamentary members formed of a first material, and the attachment region comprises a plurality of interlaced second filamentary members formed of a second material different from the first material. The second material has a characteristic eliciting a healing response from living animal tissue. Examples of such material include nylon, polyethylene and polypropylene.

[0013] In all of the embodiments, the substrate may be formed in any of a number of practical shapes and preferably comprises an elongated tube having attachment regions positioned at each end.

[0014] It is an object of the invention to provide a graft having means for sealingly attaching the graft to living animal tissue while avoiding trauma to the tissue and damage to the graft.

[0015] It is another object of the invention to provide a graft having pores sized to promote growth of living animal tissue and form an attachment between the graft and the tissue.

[0016] It is yet another object of the invention to provide a graft having attachment regions with increased surface area to promote growth of living animal tissue and form an attachment between the graft and the tissue and form an attachment between the graft and the tissue.

[0017] It is again another object of the invention to provide a graft having attachment regions formed by providing a coating which promotes healing of living animal tissue to form an attachment between the tissue and the graft.

[0018] It is still another object of the invention to provide a graft having an attachment region comprising a material which elicits a healing response from living animal tissue.

[0019] These and other objects and advantages will become apparent upon consideration of the following drawings and detailed description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] **FIG. 1** shows a partial sectional perspective view of a graft according to the invention;

[0021] FIGS. **2-7** each show a partial perspective view of a respective embodiment of a graft according to the invention; and

[0022] **FIGS. 8 and 9** show each a perspective view of yet other embodiments of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] By way of example, **FIG. 1** shows a vascular stent graft **10** typically used to treat a vascular aneurysm **12** in an artery **14**. (It is understood that the invention is not limited to use with vascular stent grafts but may be applied to any type of graft.) Aneurysm **12** comprises a region of artery **14** wherein the wall **16** is weakened and dilated. Rupture of an aneurysm can be fatal, and treatment consists of replacing the weakened region of the vessel with the stent graft **10**. The stent graft may be implanted by means of a catheter or by more invasive surgical techniques.

[0024] Stent graft **10** comprises a thin, flexible, biocompatible substrate **18**, preferably tubular and having stents **20** located at either end. Stents **20** are spring-like supports which hold the graft open and allow the ends to be sealingly attached to the wall **16** of the artery to either side of aneurysm **12**.

[0025] At each end of substrate **18** are attachment regions **22** engageable with the living tissue of the artery, the attachment regions having means for promoting growth of the tissue across the attachment region to form a biological attachment and a seal between the graft **10** and the tissue comprising the artery wall **16**. The means for promoting growth of the tissue across regions **22** have several embodiments, described in detail below.

Porous Regions of Higher Permeability

[0026] In one embodiment, illustrated in **FIGS. 2 and 3**, the means for promoting growth of living animal tissue across regions **22** to form the attachment and seal between the graft and the artery comprise relatively narrow bands which have higher permeability than the remaining portion of the graft. The example vascular graft should have a permeability over most of its length no greater than about 300 $cc/cm^2/min$ so that it is substantially impermeable and, thus, hemostatic. However, the average pore size associated with this level of permeability is too small and substantially prevents ingrowth of living animal tissue into the graft. Regions **22** are formed which have substantially higher permeability and, consequently, a larger average pore size, so as to accommodate and encourage tissue ingrowth to form a biological seal and attachment. For the vascular graft, a permeability of about 1000 $cc/cm^2/min$ for the regions **22** should provide the relatively larger pore sizes which promote substantial tissue ingrowth. Because the substrate **18** between the attachment regions **22** must remain substantially hemostatic, however, the attachment regions **22** of higher permeability are confined to relatively narrow bands preferably between about ⅛ inch and about ¼ inch in length along the substrate. This length should provide adequate attachment and sealing of the graft to the artery without resulting in unacceptable levels of leakage.

[0027] As illustrated in **FIG. 2**, substrate **18** may be formed of interlaced filamentary members **24** and may be woven, knitted or braided. The term "filamentary member" as used herein is a generic term for a continuous strand or strands of fibers, yarns, filaments or material in a form suitable for knitting, weaving, braiding or otherwise intertwining or interlacing to form a fabric. Various forms of filamentary members include monofilaments, filaments twisted together, filaments laid together without twist, as well as other configurations.

[0028] For woven grafts, the regions **22** of higher permeability may be formed by changing the density of the weave in these regions, i.e., weaving fewer filamentary members per unit area. For example, regions **22** may be woven with fewer fill yarns per inch, for example, 60 fill yarns per inch, while the remaining length of the graft is woven at 90 fill yarns per inch to maintain hemostatic integrity. Modern looms can readily be programmed to automatically produce tubular sleeves having regions of varying lengths with varying weave density for the manufacture of the graft according to the invention. As shown in **FIG. 2**, pores **19** providing the increased permeability are defined by interstices **21** formed between the filamentary members **24**. Filamentary members comprising polyester are preferred for many grafts due to this material's compatibility with living animal tissue and history of success in human implants. Other materials such as polypropylene, polyethylene and polytetrafluoroethylene are also feasible.

[0029] Knitted grafts having regions of varying permeability are also readily manufacturable on modern knitting machines by selectively changing the density of the stitch to include fewer or more loops per unit length as desired to control the permeability and pore size of the graft. Such machines can be programmed to automatically vary the stitch density as a function of graft length by varying the tension under which the yarn is knitted and how much yarn is used per unit length of the graft to produce the regions **22** of higher permeability along with hemostatic regions having relatively high mesh density and consequent low permeability.

[0030] As shown in **FIG. 3**, for substrates **18** comprising elastic, non-woven, continuous membranes formed of polymers such as expanded polytetrafluoroethylene and polyurethane, regions **22** of higher permeability are preferably formed by creating or enlarging pores **26** in narrow bands around the graft. The pores may be formed by mechanically piercing the membrane, etching with chemicals or ablating with a laser.

[0031] In a preferred embodiment, a membrane of expanded polytetrafluoroethylene (ePTFE) is used to form the graft substrate **18**. As is well known, when polytetrafluoroethylene is heated and stretched quickly to form ePTFE, the heat and the stretching cause the surface to break up and form pores. The pore size can be controlled by the rate at which the polytetrafluoroethylene is stretched. For vascular grafts, the average preferred pore size in the ePTFE membrane over areas other than the attachment regions is about

10 to about 40 microns. This size allows nutrients to pass through the membrane, while ensuring that the graft is hemostatic, but such pores are too small to allow cell ingrowth for sealing and attaching the graft to the vessel. Migration of ePTFE grafts is of particular concern since it is difficult to induce anything to adhere to ePTFE. By including regions **22** of ePTFE comprising pores **26** having relatively greater size than the remaining portion of the graft, areas are created in the graft which will promote the ingrowth of living animal tissue to attach and seal the vessel to the graft via a biological attachment. Pores having an average size between about 100 to about 200 microns in diameter are preferred for the regions **22** and are formed by stretching the regions more rapidly than the adjacent regions of smaller pore size when forming the ePTFE.

Regions of Increased Surface Area

[**0032**] As shown in **FIG. 4, a** means for promoting growth of living animal tissue across attachment regions **22** to attach and seal the graft to the vessel also includes creating a textured surface **23** having increased surface area. The increased surface area preferably comprises loops **28** which extend outwardly from the substrate **18**. The loops may be relatively fine and form a layer of fuzz similar to velour or they may comprise coarser loops, such as found in terry cloth, as well as relatively large loops which are easily visually discernable. The areas of increased surface area comprising regions **22** provide a region which promotes the ingrowth of living animal tissue for attaching and sealing the vessel to the graft.

[**0033**] The loops may be formed in woven or knitted grafts in either the warp or fill directions by well known techniques, such as overfeeding the filamentary members at low tension. Overfeeding pushes more of each filamentary member into the graft and causes the loops to extend outwardly from the substrate. The graft may be formed automatically on a programmable loom or knitting machine by adjusting the tension and overfeeding the filamentary members to produce attachment regions of a predetermined length and then increasing the tension and ceasing overfeeding to produce regions of less bulk and lower surface area. Other methods of forming loops to increase the surface area include adding extra filamentary members in either or both the warp and fill directions to form the regions **22**. As shown in **FIG. 4***a,* floats **29**, which are warp or fill filamentary members which are not interwoven over the regions **22** but ride on the surface of the fabric, may also be used to selectively create textured surface **23** which encourages tissue ingrowth. As shown in **FIG. 4***b,* the textured surface **23** having increased surface area may also be formed over region **22** by weaving or knitting textured filamentary members **31** under varying tension, using low tension where the fabric is to be bulkier and have a higher surface area and high tension to stretch the yarns and remove the bulk and reduce the surface area available for attachment to the living animal tissue.

[**0034**] The density of the loops is controlled by limiting the number of filamentary members used to form the loops. For example, for a vascular graft having 300 warp yarns, 60 of the yarns may be used to form the loops. The 60 loop yarns are preferably evenly spaced circumferentially around the graft and will provide adequate surface area for tissue ingrowth without adding too much bulk to the graft. (Bulky grafts cannot be implanted by means of a catheter, and too much bulk is to be avoided for catheter delivered grafts.) The density of the loops may be increased or decreased by increasing or decreasing the percentage of loop forming yarns in the graft or by adding more or fewer overfed yarns to form the loop yarns. If fill yarns are to form the regions of increased surface area, the loop density is similarly controlled by the number of fill yarns overfed under low tension or added to the fabric comprising the substrate.

[**0035**] One advantage with using increased surface area to form the regions to promote living animal tissue ingrowth is that the hemostatic properties of the graft are maintained throughout the entire length of the graft, i.e., there are no regions of high permeability which may leak initially after the graft is implanted and require time to heal. This characteristic allows the regions **22** to be extended to cover the length of the graft so that the entire graft becomes a substrate for the ingrowth of tissue as shown in **FIG. 5**. Such a graft would be useful in the treatment of aneurysms, which sometimes shrink after a graft has been implanted to relieve the pressure. As the aneurysm shrinks, the endothelial cells lining the artery wall contact the graft and will be encouraged to grow into it due to the presence of the loops **28** extending from the substrate **18**.

Coating Graft with a Bioactive Substance

[**0036**] Yet another means of promoting living animal tissue ingrowth with a graft is by coating the graft with bioactive substances which cause aggressive healing or blood clotting response when they are in contact with living animal tissue or blood. Examples of such substances are thrombin, collagen and silicone. As shown in **FIG. 6**, the bioactive substance may be applied as a coating **30** to selected regions **22** of the substrate **18** or over the entire surface of the substrate (see **FIG. 7**) by various methods such as painting, dipping and spraying. The filamentary members themselves could also be coated or impregnated with the substance prior to weaving, knitting or braiding.

[**0037**] While the bioactive substance alone may be used to effect the attachment and seal of the graft to the tissue, it is preferred to use it in combination with the above described embodiments by coating the regions of higher permeability or textured surfaces having increased surface area with the bioactive substance to promote rapid initial tissue ingrowth at these locations. This should shorten the time required for the graft to join to the tissue and reduce the incidence of leakage for vascular grafts.

Include Materials Which Encourage Healing and Clotting

[**0038**] Materials such as nylon, polypropylene and polyethylene elicit a natural healing response when in contact with living animal tissue and, thus, provide yet another means for promoting tissue growth in attachment regions of a graft. The tissue forms around the material to encapsulate and isolate it from the body. By selectively positioning such material in the graft, tissue will be encouraged to attach and seal itself to the graft in these regions. To further promote tissue ingrowth, the material may be woven or knitted having higher permeability or with loops providing greater surface area for the attachment of the cells. **FIG. 8** shows an example of a flat mesh graft **32** used to repair hernias. The

graft **32** may comprise PTFE filaments interlaced with nylon in perimeteral regions **34** which will elicit the healing reaction of the tissue and promote more rapid ingrowth of tissue into the graft **32** at the perimeter **34**.

[**0039**] **FIG. 9** shows yet another example of a graft according to the invention, the graft being a bifurcated sleeve **36** for the treatment of abdominal aortic aneurysms. Such aneurysms occur in the abdominal aorta between the renal and iliac arteries and require a bifurcate graft to accommodate the branching of the aorta into the iliac arteries. Regions **22** which form the attachment and seal between the graft and the arteries are positioned at the end of the main tube **38** and each of the branch tubes **40**. In the example of **FIG. 9**, no particular embodiment of the regions **22** is specified. As with any of the grafts described, the regions could comprise any of the aforementioned embodiments such as regions of higher permeability, increased surface area, bioactive coatings or materials which encourage healing. The various regions **22** need not all be the same type of region, the graft **36** could employ a combination of the aforementioned embodiments in the regions **22** as necessary to effect the attachment.

[**0040**] Grafts having regions which promote the ingrowth of living animal tissue and the formation of biological attachments and seals promise to improve the treatment of various disorders by reducing the trauma to the tissue occasioned by the implanting of the graft, reducing the amount of endoleakage at the graft and shortening the healing time required.

What is claimed is:

1. A graft compatible with living animal tissue, said graft comprising a thin flexible substrate having an attachment region biocompatible with said tissue, said attachment region being engageable with said living animal tissue for attachment of said substrate thereto, said attachment region having means for promoting growth of said living animal tissue across said attachment region to sealingly attach said substrate to said tissue.

2. A graft according to claim 1, wherein said growth promoting means comprises a plurality of pores extending throughout said attachment region, said pores being sized to promote growth of said living animal tissue within said pores and thereby across said attachment region.

3. A graft according to claim 2, wherein said substrate comprises a plurality of interlaced filamentary members, said pores being defined by interstices formed between said filamentary members.

4. A graft according to claim 3, wherein said substrate comprises an elongated tube, one of said attachment regions being positioned at each end of said tube.

5. A graft according to claim 4, wherein said tube is a bifurcated tube.

6. A graft according to claim 4, wherein said filamentary members are interlaced by weaving, said filamentary members comprising said attachment regions being woven with fewer filamentary members per unit area than said filamentary members comprising a portion of said tube between said attachment regions, thereby providing relatively larger interstices over said attachment regions and forming said pores adapted to promote growth of said living animal tissue across said attachment regions, said portion of said tube between said attachment regions having interstices sized relatively smaller, thereby making said portion between said attachment regions substantially impermeable to fluids allowing said tube to act as a fluid conduit.

7. A graft according to claim 6, wherein said pores extending throughout said attachment regions are sized to provide a permeability of about 1000 cc/cm2/min for promoting growth of said living animal tissue across said attachment regions, said portion of said tube between said attachment regions having a permeability of about 300 cc/cm2/min and being substantially fluid impermeable.

8. A graft according to claim 6, wherein said filamentary members comprising said attachment region have a coating which promotes healing of living animal tissue.

9. A graft according to claim 8, wherein said coating is selected from the group consisting of thrombin, collagen and silicone.

10. A graft according to claim 1, wherein said substrate comprises an elastic, non-woven membrane and said growth promoting means comprises a plurality of pores extending throughout said attachment region, said pores being sized to promote growth of said living animal tissue within said pores and thereby across said attachment region.

11. A graft according to claim 10, wherein said pores are formed by piercing said membrane throughout said attachment region.

12. A graft according to claim 11, wherein said membrane comprises an elongated tube, one of said attachment regions being positioned at each end of said tube.

13. A graft according to claim 12, wherein said pores have an average size between about 100 microns and about 200 microns in diameter.

14. A graft according to claim 12, wherein said membrane comprising said attachment regions has a coating which promotes healing of living animal tissue.

15. A graft according to claim 14, wherein said coating is selected from the group consisting of thrombin, collagen and silicone.

16. A graft according to claim 2, wherein said substrate comprises a thin flexible membrane of expanded polytetrafluoroethylene, said membrane being expanded in said attachment region at an expansion rate adapted to form said pores sized to promote growth of said living animal tissue across said attachment region.

17. A graft according to claim 16, wherein said membrane comprises an elongated tube, one of said attachment regions being positioned at each end of said tube, said membrane between said attachment regions being formed by expanding said polytetrafluoroethylene at a second expansion rate relatively lower than said first named expansion rate thereby yielding a substantially impermeable tube between said attachment regions.

18. A graft according to claim 17, wherein said membrane comprising said attachment regions has a coating which promotes healing of living animal tissue.

19. A graft according to claim 18, wherein said coating is selected from the group consisting of thrombin, collagen and silicone.

20. A graft according to claim 17, wherein said pores in said attachment region have an average size between about 100 microns to about 200 microns in diameter.

21. A graft according to claim 1, wherein said growth promoting means comprises a textured surface positioned at said attachment region, said textured surface having an

increased surface area favoring growth of said living animal tissue across said attachment region.

22. A graft according to claim 21, wherein said textured surface comprises a plurality of loops extending outwardly from said substrate, said loops providing said increased surface area favoring growth of said living animal tissue.

23. A graft according to claim 22, wherein said substrate comprises a plurality of interlaced filamentary members, said filamentary members being overfed during interlacing at least in said attachment region to form said loops extending outwardly to form said textured surface.

24. A graft according to claim 22, wherein said substrate comprises a plurality of filamentary members interlaced by weaving and said loops comprise floats positioned at least in said attachment region and extending outwardly to form said textured surface.

25. A graft according to claim 21, wherein said substrate comprises a plurality of interlaced filamentary members, said filamentary members being textured filamentary members at least in said attachment region, said textured filamentary members having increased bulk providing said increased surface area favoring growth of said living animal tissue.

26. A graft according to claim 21, wherein said textured surface comprising said attachment region has a coating which promotes healing of living animal tissue.

27. A graft according to claim 26, wherein said coating is selected from the group consisting of thrombin, collagen and silicone.

28. A graft according to claim 1, wherein said attachment region comprises a surface having a coating which promotes healing of living animal tissue.

29. A graft according to claim 28, wherein said coating is selected from the group consisting of thrombin, collagen and silicone.

30. A graft according to claim 1, wherein said substrate comprises a plurality of interlaced first filamentary members formed of a first material, said attachment region comprising a plurality of interlaced second filamentary members formed of a second material different from said first material, said second material having a characteristic eliciting a healing response from living animal tissue.

31. A graft according to claim **30**, wherein said second material is selected from among the group consisting of nylon, polypropylene and polyethylene.

* * * * *

PATENT ASSIGNMENT

Electronic Version v1.1
Stylesheet Version v1.1

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT

CONVEYING PARTY DATA

Name	Execution Date
Assaf Bash	04/30/2007
Netanel Benichou	05/01/2007
Benjamin Spenser	05/01/2007

RECEIVING PARTY DATA

Name:	Edwards Lifesciences Corporation
Street Address:	One Edwards Way
Internal Address:	Legal Department
City:	Irvine
State/Country:	CALIFORNIA
Postal Code:	92614

PROPERTY NUMBERS Total: 1

Property Type	Number
Application Number:	10883575

CORRESPONDENCE DATA

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Annex 3
Opposition against
EP 2 982 337 B1

Neovasc Tiara, Inc.
./. Edwards Lifesciences
PVT, Inc.

WBH-Ref.: 272.0046OP

ATTORNEY DOCKET NUMBER:	PVI-5800
NAME OF SUBMITTER:	David L. Hauser

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Total Attachments: 3
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source=Doc070516as2#page1.tif
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Whereas, we have invented certain new and useful improvements entitled PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

X for which an application for a United States Letters Patent was filed on June 30, 2004 Application Number 10/883,575.

__ for which an application for a United States Letters Patent is filed herewith.

Now therefore, in consideration of one dollar ($1.00) and other good and valuable consideration, the receipt and sufficiency whereof are hereby acknowledged, we hereby convey, transfer and assign to EDWARDS LIFESCIENCES PVT, INC. (hereinafter referred to as "assignee"), a corporation of Delaware, having a principal place of business at One Edwards Way, Irvine, California, its successors, legal representatives and assigns, the entire right, title and interest throughout the world in the above-mentioned invention or improvements, in the above-mentioned application for United States Letters Patent, and any and all other applications for United States Letters Patent and applications in any other countries which we may file, either solely or jointly with others, on said invention or improvements, including any divisional, continuation and continuation-in-part applications, and in any and all Letters Patent of the United States or of any other country which may be obtained on any of said applications, and in any reissue, reexam or extension thereof.

We hereby authorize and request the Commissioner of Patents to issue said Letters Patent to said EDWARDS LIFESCIENCES PVT, INC.

We hereby authorize and request the attorneys of record in said application to insert in this Assignment the date and serial number of said application when officially known.

We warrant ourselves to be the owners of the interest herein assigned and to have the right to make this assignment; and further warrant that there are no outstanding prior assignments, licenses, or other rights in the interest herein assigned.

For said consideration we hereby agree, upon the request and at the expense of said assignee, its successors, legal representatives and assigns, to execute any and all divisional, continuation, and C-I-P applications for said invention or improvements, and any necessary oath or supplemental oath or affidavit relating thereto, and any application for the reissue, reexam or extension of any Letters Patent that may be granted upon said application that said assignee, its successors, legal representatives and assigns may deem necessary or expedient. For said consideration we further agree, upon the request of said assignee, its successors, legal representatives and assigns, in the event of said application or any division, continuation, or C-I-P thereof, or Letters Patent issued thereon, or any reexam, reissue or application for the reissue thereof becoming involved in interference, to cooperate to the best of our ability with said assignee, its successors, legal representatives and assigns in the matters of preparing and executing the preliminary statement and giving and producing evidence in support thereof. We further agree to perform, upon such request, any and all affirmative acts to obtain Letters Patent, and vest all rights therein hereby conveyed in said assignee, its successors, legal representatives and assigns whereby said Letters Patent will be held and enjoyed by said assignee, its successors, legal representatives and assigns to the end of the term for which said Letters Patent may be granted as fully and entirely as the same would have been held and enjoyed by us if this assignment and sale had not been made, including the right to enforce said patent and to sue for and recover damages and all other remedies arising out of any and all past, present and future infringement or violation of said Letters Patent, and for said considerations we hereby also assign to said assignee, its successors, legal representatives and assigns the entire rights, title and interest in said invention or improvements for any and all foreign countries and the right of priority for patent and utility model applications in all countries arising under any applicable international convention for the protection of industrial property and/or any internal priority legislation of such countries, and we further agree upon the request of said assignee, its successors, legal representatives and assigns to execute any

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and all documents that shall be required to be executed in connection with any and all applications for foreign Letters Patent therefor, including the prosecution thereof, and to execute any and all documents necessary to invest title in said foreign applications and patents in said assignee.

Witness my hand:

Date 01, May, 07

Signature: N. Benichou

Typed Name: Netanel Benichou

5/1/07
Witness Signature Date

Witness my hand:

Date_____

Signature: _____

Typed Name: _____

_____ _____
Witness Signature Date

Dated: 4/30/07

Signature: X _____

Typed Name: Assaf Bash

State of California, County of Orange

On 4/30/07 before me, Melissa A Sanchez, Notary Public, personally appeared ASSAF BASH, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument and acknowledged to me that he/~~she~~ executed the same in his/~~her~~ authorized capacity, and that by his/~~her~~ signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

_____ (Seal)
Signature of Notary

MELISSA A. SANCHEZ
Commission # 1488783
Notary Public - California
Orange County
My Comm. Expires May 10, 2008

5228v1

and all documents that shall be required to be executed in connection with any and all applications for foreign Letters Patent therefor, including the prosecution thereof, and to execute any and all documents necessary to invest title in said foreign applications and patents in said assignee.

Witness my hand:

Date 01, May, 07

Signature: N. Benichou

Typed Name: Netanel Benichou

Witness Signature 5/1/07 Date

Witness my hand:

Date 1 May 2007

Signature:

Typed Name: BENJAMIN SPENSER

Witness Signature 01 May 2007 Date

Dated: 4/30/07

Signature: X

Typed Name: Assaf Bash

State of California, County of Orange

On 4/30/07 before me, Melissa A Sanchez, Notary Public, personally appeared ASSAF BASH, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument and acknowledged to me that he/~~she~~ executed the same in his/~~her~~ authorized capacity, and that by his/~~her~~ signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature of Notary (Seal)

MELISSA A. SANCHEZ
Commission # 1488783
Notary Public - California
Orange County
My Comm. Expires May 10, 2008

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European Patent Office
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CONSOLIDATED LIST - KONSOLIDIERTE LISTE - LISTE RÉCAPITULATIVE

P: Edwards Lifesciences PVT, Inc.
1: Abbott Cardiovascular Systems, Inc.
2: Neovasc Tiara Inc.

EPO	CITATIONS-ENTGEGENHALTUNGEN-CITATIONS	P	1	2
P1	US 10/883,575		E1a	
A1	EP 2 982 337 A1		E1c	
B1	EP 2 982 337 B1		E1d	
D1	US 5,258,023 A		D1	WBH1
D2	FR 2 337 543		D2	WBH2
D2a	US 4,106,129		D2a	
D3	WO 00/64380 A1		D3	WBH3
D4	FR 2 815 844 A1		D4	WBH4
D5	EP 2 537 487 A1		D5	WBH5
D5a	US 2005/0137688		D5a	
D5b	US 2005/0137698		D5b	WBH11
D6	WO 01/56512 A1		D6	
D7	US 6,454,799 B1		D7	WBH7
D8	US 2003/0153974 A1		D8	WBH9
D9	DE 26 13 575 A1		D9	
D10	WO 03/053287 A1		D10	WBH17
D11	US 6,729,356 B1		D11	
D12	US 2004/0082989 A1		D12	
D13	Moazami et al.; Transluminal Aortic Valve Placement (9/10 1996)		D13	
D14	WO 03/039613 A1		D14	
D15	WO 2006/005015 A2		E1b	
D16	US 5,554,184 A			WBH6
D17	US 6,638,257 B2			WBH8
D18	WO 2006/089236 A1			WBH10
D19	WO 2004/082527 A2			WBH12
D20	WO 01/54625 A1			WBH13
D21	WO 01/76510 A2			WBH14

EPO	CITATIONS-ENTGEGENHALTUNGEN-CITATIONS	P	1	2
D22	US 2004/0210304 A1			WBH15
D23	US 5,855,601 A			WBH16
D24	US 2002/0052649 A1			WBH18
D25	Patent Assignment			Annex 3

WBH Wachenhausen
Patentanwälte

FACTS & ARGUMENTS

On behalf of the Neovasc Tiara Inc., 13562 Maycrest Way #5138 of Richmond, BC V6V 2J7, Canada, it is requested to revoke European Patent EP 2 982 337 B1 (in the following referred to as "opposed patent") in its entirety on the grounds of Art. 100(a) EPC, Art. 100(b) EPC and Art. 100(c) EPC. The opposed patent was granted to Edwards Lifesciences PVT, Inc., One Edwards Way, Irvine, CA 92614 (US) and is entitled "Paravalvular leak Detection, sealing, and prevention".

As an auxiliary measure, if the Patent in its entirety is not revoked on the basis of the written proceedings, oral proceedings are requested.

The opposition grounds will be substantiated in the following. The below arguments are made without prejudice to the right to adapt and supplement them in the course of the Opposition Proceedings.

1 Introduction

The opposed patent relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses (see paragraph [0001]).

The opposed patent is a first generation divisional application from the parent application with the application number EP 05769359.0 of 30 June 2005 and claims the priority of the US patent application filed on June 30, 2004 with application number US 10/883,575.

During prosecution, 5 prior art documents were cited:

WBH1	US 5,258,023 A
WBH2	FR 2 337 543 A1
WBH3	WO 00/64380 A1
WBH4	FR 2 815 844 A1
WBH5	EP 2 537 487 A1

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The Applicant further cited the following documents in the opposed patent:

WBH6	US 5,554,184 A
WBH7	US 6,454,799 B1
WBH8	US 6,638,257 B2
WBH9	US 2003/0153974 A

In addition to the prior art documents already known from the prosecution phase, it is referred to the following documents:

WBH10	WO 2006/089236 A1
WBH11	US 2005/0137698 A1
WBH12	WO 2004/082527 A2
WBH13	WO 01/54625 A1
WBH14	WO 01/76510 A2
WBH15	US 2004/0210304 A1
WBH16	US 5,855,601 A
WBH17	WO 03/053287 A1
WBH18	US 2002/0052649 A1

2 Construction of Claim 1

The opposed patent comprises one independent device Claim 1 followed by dependent Claims 2 to 9.

Independent device Claim 1 can be structured as follows:

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

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1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

For ease of reference, the feature analysis is submitted along with this opposition brief as

Annex 2.

3 Added matter (Art. 100(c) EPC)

Applicant filed the present divisional application with a new set of claims and with the claims of the parent application as filed included as clauses at the end of the description. Applicant did not provide any kind of basis where the subject-matter of the new claims is disclosed in the parent application as filed. It appears as if Claim 1 of the opposed patent is based on Claim 27 of the parent application as filed. However, as derivable from the below marked-up version, in which Claim 1 of the opposed patent is compared to Claim 27 of the parent application as filed, Applicant has significantly amended and shifted the claims' subject-matter during prosecution of this divisional application.

Marked-up claim 1

1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

1.1 a substantially cylindrical stent structure (252) configured for radial expansion;

1.2 a valvular structure (254) ~~providing a flexible conduit~~ having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

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1.3 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted ~~for expansion~~ after deployment to fill gaps between the prosthetic valve and the body channel,

1.4 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Among other amendments, Applicant has

a) deleted that the compressible material is adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel

b) added that the compressible material includes a plurality of fibers extending outward from the outer surface

c) deleted that the valvular structure provides a flexible conduit

d) added that the layer of compressible material forms a sleeve.

As outlined below, at least each of the amendments a)-d) add matter to the application as filed, contravening either Art. 76 EPC, Art. 123(2) EPC or both.

3.1 Amendment a): deletion of adaptation of compressible material for expansion after deployment

In Claim 27 of the parent application as filed, it is claimed that the compressible material is "*adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel*". Likewise, paragraph [0055] of the description of the parent application as filed states that the compressible material "*is configured to expand into the gaps*". The same applies to paragraph [00145] of the description of the parent application *mutatis mutandis*, stating in lines 22 to 23 that the "*compressible material expands after deployment at a treatment side. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.*"

The parent application as filed only provides support for a prosthetic valve, which comprises a compressible material adapted for expansion after

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deployment (of the cylindrical stent structure) to fill gaps between the prosthetic valve and the body channel. In other words, the parent application as filed only provides support for embodiments in which the compressible material expands to fill gaps between the prosthetic valve and the native anatomy, said expansion occurring after deployment of the prosthetic valve from the delivery device. This implies that the parent application as filed does not provide any kind of basis for a prosthetic valve with an expandable stent structure and a compressible material, the compressible material being pressed into gaps between the valve prosthesis and the native anatomy via the stent structure during deployment of the stent structure, for example.

Thus, by conducting amendment a), Applicant has deleted a feature from independent Claim 27 of the parent application, which is outlined as being essential in the parent application as filed. This constitutes a breach of Art. 123(2) EPC (see *Case Law of the Boards of Appeal, 9th edition, II-E-1.4.3*).

Furthermore, we stress that the underlying idea of Art. 123(2) EPC is that an Applicant should not be allowed to improve his/her position by adding subject-matter not disclosed in the application as filed, which would give him/her an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application (see G1/93, *Case Law of the Boards of Appeal, 9th edition, II-E-1.1*). The public may not be confronted with an extent of protection, which could not have been established by a skilled person having studied the whole content of the technical disclosure of the originally filed patent application (see e.g. T157/90 and T187/91).

As outlined in detail above, the parent application as originally filed does not provide support for a prosthetic valve having a stent, a valvular structure and a generic compressible material adapted to fill gaps between the prosthesis and the native tissue but only for such a valve prosthesis having a compressible material adapted to expand after deployment to fill said gaps between the prosthetic valve and the body channel. The latter has already been claimed in Claim 27 of the parent application as filed and the entire disclosure of the parent application does not teach any alternative. Applicant thus extended the scope

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of protection to an extent not justified by the overall disclosure damaging the legal security of third parties.

The subject-matter of Claim 1 of the opposed patent therefore contravenes the requirements of Art. 76 EPC.

3.2 Amendment b): addition that the compressible material includes a plurality of fibers extending outward from the outer surface

During prosecution, Applicant specified that the compressible material includes a plurality of fibers extending outward from the outer surface. This feature finds basis in Claim 29 of the parent application as filed but only in combination with the feature that the prosthetic valve further comprises "*a tissue growth factor disposed along the compressible material*". According to paragraph [00145] of the description of the parent application as filed, the tissue growth factor is applied to "*the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps*". This additional sealing functionality is provided by the combination of the fibers and the tissue growth factor, which are therefore functionally interlinked.

Separating the fibers from the tissue growth factor constitutes an unallowable intermediate generalization, contravening the requirements of Art. 76 EPC.

3.3 Amendments c) and d): deletion that the valvular structure provides a flexible conduit and addition that the compressible material forms a sleeve

Amendments c) and d) constitute unallowable intermediate generalizations.

Firstly, we note that the parent application as filed only provides support for a valvular structure providing a flexible conduit having an inlet and an outlet but not for a valvular structure with an inlet and an outlet having an arbitrary shape. We refer to Fig. 22 of the parent application as filed showing an elongated valvular structure in the form of a conduit. No other type of configuration of the valvular structure is disclosed in the parent application as filed.

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By deleting the feature that the valvular structure provides a flexible conduit, Applicant extended the scope of protection to an extent not justified by the overall disclosure. Amendment b) therefore contravenes the requirements of Art. 76 EPC.

Secondly, we note that the addition of the feature that the compressible material forms a sleeve constitutes an unallowable intermediate generalization. Specifically, a sleeve is only mentioned in paragraph [00145] of the parent application as filed. However, this paragraph states that the compressible material "*may extend entirely around the stent structure, such as in the form of a sleeve*". In contrast, Claim 1 of the opposed patent requires the layer of compressible material to form a sleeve.

The *Merriam Webster* dictionary defines a "*sleeve*" as "*a tubular part … designed to fit over another part*". The purpose of the sleeve is to protect the other part, i.e. the part over which it is fitted. Accordingly, a compressible material forming a sleeve of a stent structure is required to engage with the stent structure to provide covering and protection functionalities. In contrast, a compressible material in the form of a sleeve may be provided spaced apart from the stent structure, for example.

It is not directly and unambiguously derivable from the parent application that the compressible material actually forms a sleeve – that it exhibits a configuration and is adapted to the remaining parts of the prosthesis so as to provide covering and protection functionalities. In contrast, the parent application as filed merely provides support for a compressible material extending around the stent structure in the form of a sleeve but not of a compressible material which actually forms a sleeve.

Claim 1 of the opposed patent therefore contravenes the requirements of Art. 76 EPC. For the sake of completeness, we note that amending Claim 1 by specifying that the compressible material is extending around the stent in the form of a sleeve to overcome the Art. 76 EPC objection, Proprietor would broaden the scope of protection contravening the stipulations of Art. 123(3) EPC.

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3.4 Lack of basis of other parts of the disclosure

Furthermore, the subject-matter of dependent Claims 2, 3, 4 and 9 is not directly and unambiguously derivable from the parent application as filed. In detail:

- Claim 2: It is not directly and unambiguously derivable from the parent application that the sleeve may surround an inflow end of the stent structure. In fact, the term "inflow" is not used at any point in the parent application as filed. Likewise, it is not directly and unambiguously derivable from Fig. 22 of the parent application as filed that the sleeve surrounds the inflow end since the inflow of the stent structure is not visible in Fig. 22.

- Claim 3: The feature that the compressible material exhibits a thickness ranging from 1 to 5 mm is only mentioned in paragraph [00145] of the parent application. However, it is only disclosed in combination with the compressible material being formed of polyethylene terephthalate (PET). There is no teaching in the entire parent application of a compressible material having a thickness ranging from about 1 to 5 mm that is formed from any other type of material. Claim 3 of the opposed patent therefore constitutes an unallowable intermediate generalization.

- Claim 4 of the opposed patent specifies that the compressible material comprises a cloth or fabric. This feature is also only mentioned in paragraph [00145] of the parent application as filed. However, said paragraph only discloses that the compressible material resembles a cloth or fabric having small fibers extending from the surface of the material. Claim 4 of the opposed patent thus constitutes an unallowable intermediate generalization since it only requires the compressible material to comprise a cloth of fabric while the parent application as filed requires the compressible material to resemble a cloth of fabric having small fibers.

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- Claim 8 of the opposed patent specifies the compressible material to be configured to expand into gaps. However, said claim does not specify at what point in time the compressible material is configured to expand into gaps during the delivery process of the prosthetic valve. As outlined in detail under section 3.1 above, the parent application as filed merely provides basis for a compressible material being adapted for expansion after deployment to fill gaps. As the specification of the point in time for the expansion of the compressible material is lacking in Claim 8 of the opposed patent, it constitutes an unallowable intermediate generalization which contravenes Art. 76 EPC.

- Claim 9 specifies the compressible material to be configured to adjust to the shape of the cavity existing between the valve and the wall of the body vessel upon stent opening. It appears as if the subject-matter of Claim 9 is ought to be directed to an embodiment in which the compressible material is passively introduced into gaps between the prosthetic valve in the body channel via the radially expanding stent structure. We have outlined in detail under section 3.1 above that such an embodiment does not find any kind of basis in the parent application as filed. Claim 9 of the opposed patent therefore contravenes the requirements of Art. 76 EPC.

Finally, we note that the parent application was filed with a provisional set of drawings while the opposed patent was filed with a substituted set of formal drawings. The provisional drawings originally filed with the parent application and the substituted formal drawings originally filed with this divisional application deviate in multiple aspects, thereby adding subject-matter against the stipulations of Art. 76 EPC.

Specifically, as derivable from a comparison of Fig. 22 of the provisional drawings of the parent application and Fig. 22 of the substituted formal drawings of this divisional application illustrated side-by-side below, the compressible material (256, Fig. 22) of the substituted formal drawing exhibits a plurality of components, which appear to be the claimed fibes. Said components are not depicted in Fig. 22 of the provisional drawings. Instead, the compressible

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material of Fig. 22 of the provisional drawings exhibits a continuous and uniform planar outer surface. Accordingly, Fig. 22 of the opposed patent as originally filed provides the skilled person with additional information not derivable from Fig. 22 of the parent application as filed. Similar objections apply to Fig. 2B, Fig. 3, Figs. 5C and D, Figs. 8C and D, Fig. 10E, Figs. 11C and D, Figs. 13A and B, Fig. 15A, Fig. 16A, Fig. 17B, Fig. 19D, Fig. 20A as well as Figs. 20E and 20G.

Also because of these reasons, the subject-matter of the opposed patent contravenes the requirements of Art. 76 EPC.

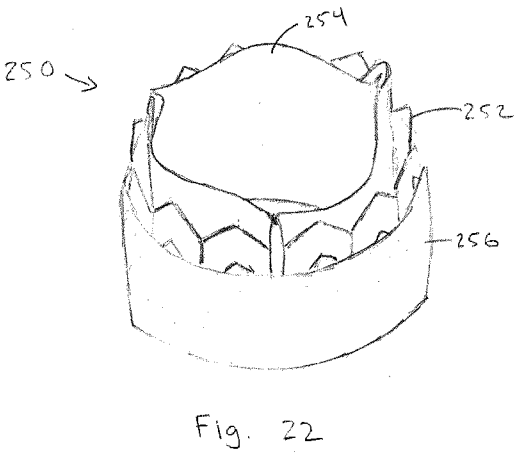


Fig 22 as filed of parent

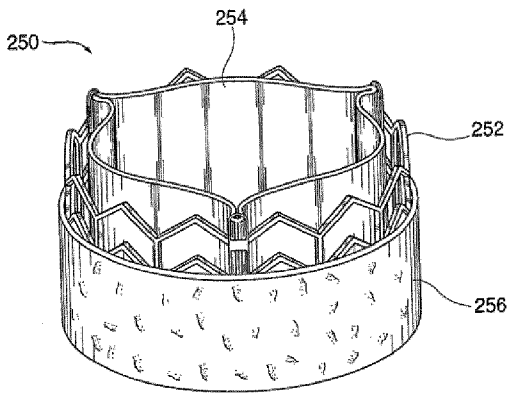


Fig. 22 as filed of divisional

4 Insufficiency (Art. 100(b) EPC)

Claim 1 of the opposed patent requires the compressible material to be adapted after deployment to fill gaps between the prosthetic valve and the body channel (feature 1.3). According to paragraph [0064] of the opposed patent, "*the compressible material creates a mechanical seal that prevents paravalvular leakage*". The skilled person therefore takes from feature 1.3 that the compressible material is compressed against the tissue of the native anatomy. At the same time, feature 1.4 of Claim 1 of the opposed patent requires the compressible material to comprise fibers extending outward from the outer surface.

The skilled person is provided with contradictory teaching. The compressible material and therefore also the fibers are supposed to be compressed against

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the native anatomy, implying that the fibers are bent to not extend outward from the outer surface. However, in contradiction with this teaching of feature 1.3, feature 1.4 requires the fibers to extend outward the outer surface.

Neither the disclosure of the opposed patent nor the common general knowledge provides the skilled person with any kind of teaching on how this contradictory teaching can be resolved and the invention can be put into practice over the whole area claimed without undue burden and without requiring inventive activity.

Due to the above, the opposed patent does not fulfil the requirements of Art. 83 EPC.

5 Lack of patentability (Art. 100(a) EPC)

The opposed patent lacks novelty over several prior art documents not considered during prosecution – inter alia since the priority of the opposed patent is not validly claimed. In addition, also some of the prior art documents cited during prosecution are prejudicial to novelty of the opposed patent. Besides, the opposed patent lacks an inventive step.

5.1 Priority not validly claimed

The opposed patent does not validly claim the priority due to formal reasons and due to the subject-matter of the claims of the opposed patent not being directly and unambiguously derivable from the priority application.

5.1.1 Priority claim invalid due to formal reasons

Pursuant to Art. 87(1) EPC, a right of priority originates in the Applicant of a first application. However, pursuant to the same provision, the right of priority may also be invoked by the "successor in title" of the person who has filed the first application. It is generally accepted that the right of priority is transferable. However, according to well established case law of the Boards of Appeal, the transfer must have occurred before the filing date of the subsequent application

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(see e.g. T 1201/14). The Boards of Appeal confirmed in T 577/11 that a succession in title that occurred after the filing date of the subsequent application was not sufficient to comply with the requirements of Art. 87(1) EPC.

The priority application of the opposed patent, US 10/883,575 filed on June 30, 2004, was filed with the Inventors as Applicant. The latter already becomes evident from the matter of fact that all US patent applications prior to the American Invents Act (AIA) in 2011 had to be filed with the Inventors as Applicant. The filing date of the opposed patent is of course the filing date of the PCT application with the publication number WO 2006/005015 from which the opposed patent's parent derives. WO 2006/005015 was filed on June 30, 2005 in the name of Edwards Lifesciences PVT, Inc. In view of the above outlined requirements, for the priority to be validly claimed, the right to priority must have been validly transferred to the Applicant of the opposed patent, i.e. Edwards Lifesciences PVT, Inc., prior to the filing date of the opposed patent.

This is not the case. As derivable from the attached assignment, which we enclose as

Annex 3,

the right to priority was only transferred from the Inventors to the predecessor in title, the proprietor of the opposed patent, in April/May 2007 and, thus, after filing of the opposed patent.

In view of the above, the opposed patent does not validly claim the priority since the Applicant/Proprietor of the opposed patent was not entitled to the priority right at the time of filing of the opposed patent.

5.1.2 Subject matter of Claim 1 not disclosed in priority application

Furthermore, we note that the subject-matter of Claim 1 of the opposed patent is not directly and unambiguously derivable from the priority document (US 10/883,575). We note that Art. 87(1) EPC stipulates that the subject-matter of a claim is only entitled to priority in respect of "the same invention" as was

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disclosed in the previous application. The Enlarged Board of Appeal has decided in the landmark decisions G 3/93 and G 2/98 that for assessing the "same invention" requirement, the "Gold standard" disclosure test must be applied. The latter implies that priority of a claim is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the priority application as a whole. This has been confirmed by the decisions of the Enlarged Board of Appeal G 1/03, G 2/03, G 2/10 and G 1/16.

The subject-matter of Claim 1 of the opposed patent relates to a prosthetic valve with a cylindrical stent structure, a valvular structure with three leaflets and a layer of compressible material having a plurality of fibers adapted to fill gaps between the prosthetic valve and a body channel. The compressible material is disposed on an outer surface of the stent structure and extends entirely around the stent structure. Only the embodiment of Fig. 22 of the opposed patent, which is described in paragraphs [0063] to [0064], relates to such a prosthetic valve having a stent, a valvular structure with three leaflets and a layer of compressible material extending around the outer surface of the stent structure. However, the configuration illustrated in Fig. 22 and described in the above listed passages of the description is missing in the priority document. In fact, if any, the priority document only shows configurations according to Figs. 1 to 19 of the opposed patent. A compressible material being provided on the outer surface of the stent, in particular a compressible material comprising a plurality of fibers, is not disclosed in the priority document whatsoever. Likewise, the priority document does not disclose a valvular structure having three leaflets.

In view of the above, for the subject-matter of the claims of the opposed patent, the priority is not validly claimed since it is not directly and unambiguously derivable from the priority document.

5.2 Lack of novelty over WO 2006/089236 A1 (WBH10)

WBH10 was filed on February 18, 2006 and validly claims a priority of February 18, 2005. Since the opposed patent does not validly claim the priority (see 5.1.1 and 5.1.2 above) and WBH10 validly entered the EP regional phase,

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WBH10 constitutes prior art according to Art. 54(3) EPC in line with Rule 165 EPC.

WBH10 relates to an apparatus (10, Fig. 4) having an expandable support member (40, Fig. 4) – a stent – and a prosthetic valve (page 5, lines 23 to 25). According to page 22, lines 8 to 11, the apparatus may be delivered "with a percutaneous approach". Furthermore, according to page 5, lines 25 to 28, the support member "*has a known stent configuration that allows it to be collapsed and expanded*" and may be made from "*shape memory materials such as Nitinol*". Accordingly, WBH10 discloses features **1** and **1.1**. Features 1 and 1.1 are also directly and unambiguously derivable from the priority document of WBH10 (see page 8, lines 1 to 6, page 14, lines 4 to 8 and Fig. 2).

Furthermore, as described on page 21, line 13 to page 22, line 7, the apparatus may comprise "a tri-leaflet" prosthetic valve (12b, Fig. 12 illustrated below) having an inlet and an outlet, which may be made of a biological material (page 21, line 23) and/or a biocompatible material (page 21, line 26), both of which constituting a pliant material. According to page 21, lines 14 to 15, the apparatus of Fig. 12 is, besides having such a "tri-leaflet" configuration, constructed as the apparatus of Figs. 2 to 8. According to page 8, lines 6 to 8, the prosthetic valve is secured "*by sutures or other suitable means*" within the support member (40, Fig. 4). Accordingly, WBH10 also discloses feature **1.2**. Feature 1.2 is also directly and unambiguously derivable from the priority document of WBH10 (see page 13, line 16 to page 14, line 2, page 10, lines 13 to 21, Fig. 7).

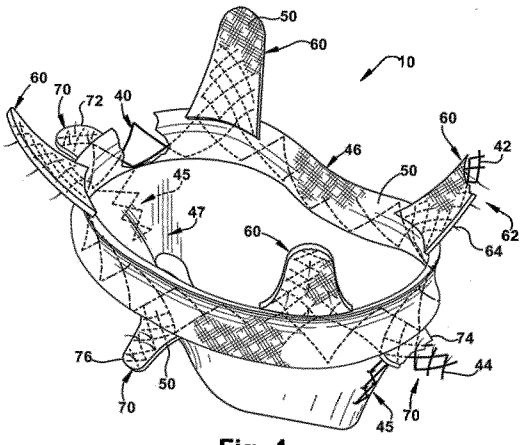


Fig. 4

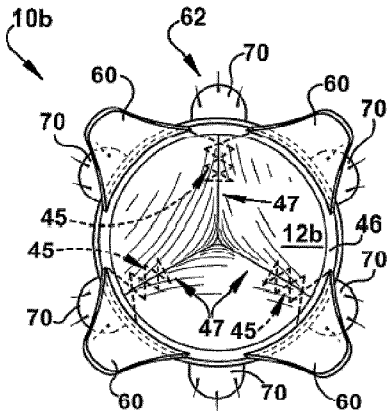


Fig. 12

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Finally, we note that the device of WBH10 may include a layer of biocompatible material (50, Fig. 4), which can cover the outside surface of the support member (40, Fig. 4) (see page 6, lines 10 to 12) and which may be attached around the entire circumference of the support member (40, Fig. 4) (see page 6, lines 12 to 13). The layer (50, Fig. 4) may be "*a synthetic such as Dacron, Gore-Tex, woven velour, polyurethane, polytetrafluorethylene (PTFE), or heparin-coated fabric. Alternatively, the layer 50 may be a biological material such as bovine or equine pericardium, peritoneal tissue, an allograft, a homograft, patient graft, or a cell-seeded tissue*" (see page 6, lines 5 to 9). Accordingly, the layer (50, Fig. 4) is suitable to fill gaps between the prosthetic valve in the body channel and comprises a plurality of fibers (e.g. when being made from woven velour), therefore constituting a compressible material according to features **1.3** and **1.4**. Features 1.3 and 1.4 are also directly and unambiguously derivable from the priority document (see page 8, line 13 to page 9, line 2).

In view of the above, the subject-matter of Claim 1 of the opposed patent is not novel over WBH10.

5.3 Lack of novelty over US 2005/0137698 A1 (WBH11)

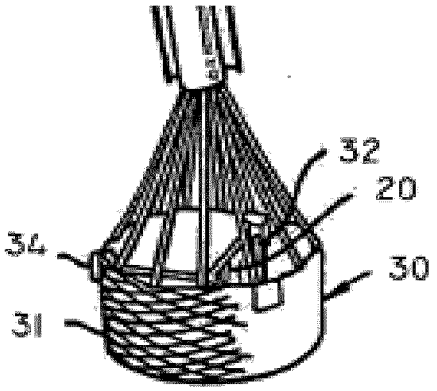
WBH11 is a US patent application published on June 23, 2005 and, thus, prior to the filing date of the opposed patent. Since the opposed patent does not validly claim the priority (see 5.1.1 and 5.1.2), WBH11 constitutes prior art according to Art. 54(2) EPC.

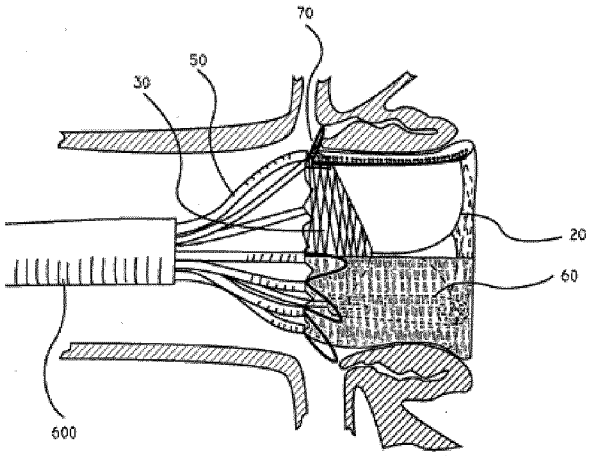
WBH11 relates to a prosthetic valve for percutaneous implantation in a body channel (see paragraph [0002]), which includes an expandable anchor and a replacement valve (see paragraph [0013]). The anchor (30, Fig. 1B illustrated below) may be self-collapsing and/or self-expanding and may be made out of a shape memory material, such as Nitinol as described in paragraph [0036]. The replacement valve (20, Fig. 1B illustrated below) can be composed of "a metal, a synthetic material and/or may be derived from animal tissue" as described in the last three lines of paragraph [0035]. Furthermore, as shown in Fig. 1B and as described in paragraph [0035], the replacement valve (20, Fig. 1B) comprises

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three commissure attachments secured at three posts of the anchor. The matter of fact that the replacement valve comprises three commissure attachments implies to that it also comprises three leaflets as a commissure attachment is provided at the interface of two leaflets. Accordingly, WBH11 discloses features **1, 1.1** and **1.2**.

Furthermore, as described in paragraph [0071] of WBH11, anchor (30, Fig. 8C illustrated below) may be "*externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric*."





As described in paragraph [0073] of WBH11, seal (60, Fig. 8C) can be bunched up and create pleats, which "*pleats can then fill pockets thereby improving the paravalvular seal*". Accordingly, we note that seal (60, Fig. 8C) of WBH11 constitutes a compressible material adapted to fill gaps between the prosthetic valve and the body channel. Therefore, feature **1.3** is disclosed in WBH11. Finally, we note that a seal composed of a fabric comprises a plurality of fibers, some of which also always extending outward from the outer surface. Accordingly, WBH11 also discloses feature **1.4**.

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In view of the above, the subject-matter of Claim 1 also lacks novelty over WBH11.

5.4 Lack of novelty over WO 2004/082527 A2 (WBH12)

WBH12 is an International patent application published on September 30, 2004 and constitutes prior art according to Art. 54(2) EPC since the opposed patent does not validly claim its priority.

WBH12 discloses a prosthetic heart valve that can be implanted in a minimally invasive manner (see paragraph [0014]) comprising a support frame (50, Fig. 5 illustrated below), which may be "*elastic*", e.g. manufactured from a Nitinol alloy (see paragraph [0066]). The valve comprising three flexible leaflets is attached within the support frame (see paragraph [0057]). Accordingly, WBH13 discloses features **1, 1.1** and **1.2**.

Fig. 3A

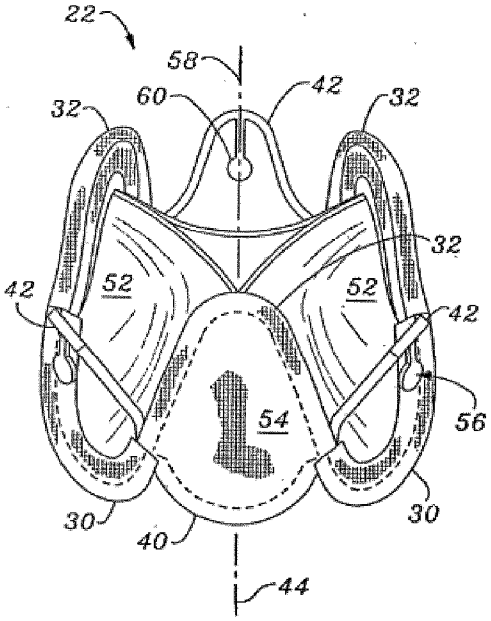
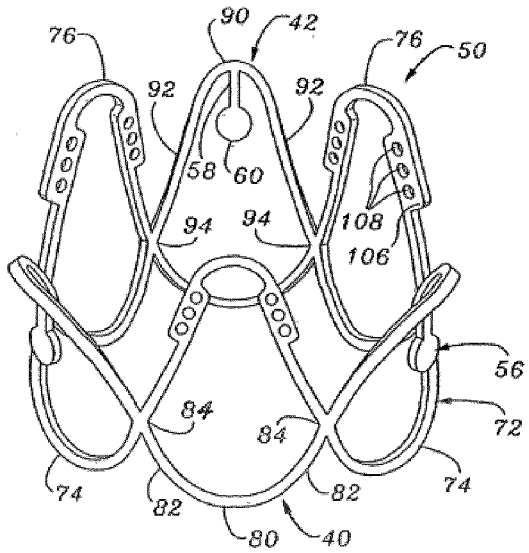


Fig. 5



In addition, the prosthetic heart valve comprises an exterior layer of a fabric, e.g. polyethylene terephthalate providing "*a matrix into which surrounding tissue can grow to help anchor the valve in place*" (see paragraph [0056]). The same

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paragraph states that the exterior layer of fabric covers the entire support frame. As the fabric made from polyethylene terephthalate exhibits a matrix-like structure, it must comprise fibers, some of which extending outward from the outer surface. Thus, WBH13 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH12.

5.5 Lack of novelty over WO 01/54625 A1 (WBH13)

WBH13 is an International patent application published on August 02, 2001 and, thus, constitutes prior art according to Art. 54(2) EPC.

WBH13 discloses a prosthetic valve for percutaneous implantation in a body channel (see Claims 1, 26 and 34) having a self-expanding stent (see Claim 2) (20, Fig. 15 illustrated below) and a valve, which may exhibit three leaflets (column 5, lines 9 to 12). Accordingly, WBH13 discloses features **1, 1.1** and **1.2**.

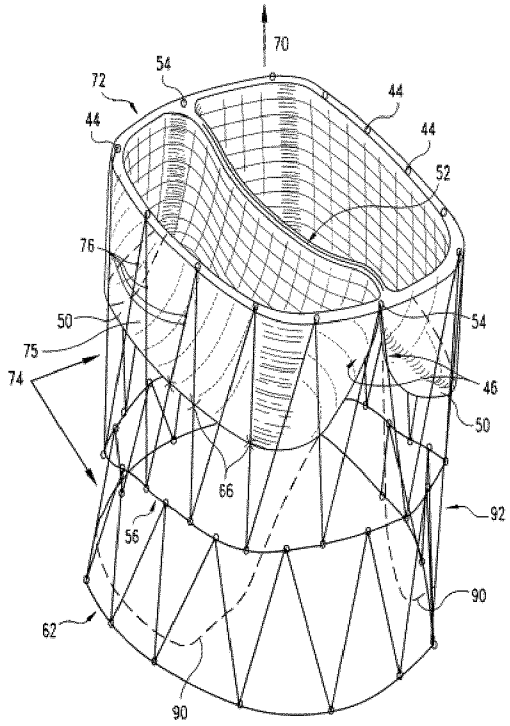


Fig. 15

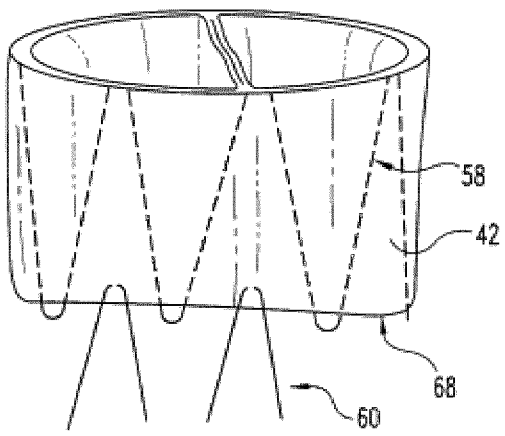


Fig. 13A

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Furthermore, as described in the last paragraph on page 7, excess material of the valve material "*can be kept outside the stent, which will later become a potential fold-over 42*". As described in the third paragraph on page 15, "*the external surface of the frame can be covered with a sheath that is not necessarily the same material as the valve 41. For example, while the valve can be a naturally occurring material, the outer sheath can be synthetic material such as described herein. The sheath, therefore, can be the fold-over of the valve material, another type of naturally occurring material, or a synthetic material. Accordingly, the sheath may partially or totally cover the frame*". The second paragraph of page 8 provides examples of the type of material from which the sheath may be manufactured and explicitly names PET, PP, PTFE or any polymer or derivative thereof as well as Gore-Tex, Dacron or other any synthetic material. As described in lines 6 to 11 of page 17, the fold-over or sheath may include "*barbs, hooks, adhesives, notches, a textured surface, or any other treated surface that facilitates relative affixation of the device in its location*". Accordingly, WBH13 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH13.

5.6 Lack of novelty over WO 01/76510 (WBH14)

WBH14 is an International patent application published on October 18, 2001 and, thus, constitutes prior art according to Art. 54(2) EPC.

WBH14 discloses a prosthetic valve for percutaneous implantation in a body channel (see title and Claims 35 to 39) comprising a substantially cylindrical stent structure for radial expansion (flexible tubular member 42 and support stent 24, Fig. 1, page 7, lines 26 to 28). Furthermore, as derivable from Fig. 2 of WBH14 illustrated below, the prosthetic valve comprises a valvular structure being formed of a pliant material and forming three valve leaflets (82, Fig. 2 illustrated below, page 11, lines 4 to 6).

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In addition, we note that the heart valve may comprise a fabric section (34, Fig. 2 illustrated below), which may be "*a woven polyester, such as polyethylene terephthalate. Alternatively, the fabric section 34 may be formed of polytetrafluorethylene (PTFE), or other suitable biocompatible sheet material*" (see page 8, line 30 to page 9, line 1). As described on page 8, lines 21 to 23, the fabric section may be formed as a tube extending entirely around the stent structure. As described on page 12, lines 8 to 9, the fabric section (34, Fig. 2 illustrated below) is compressible to be compressed against the host annulus. Accordingly, WBH14 also discloses feature **1.3**. We also note that feature **1.4** is disclosed by WBH14 since the fabric section may be formed from a woven polyester, therefore exhibiting fibers, which inevitably extend outward from the outer surface.

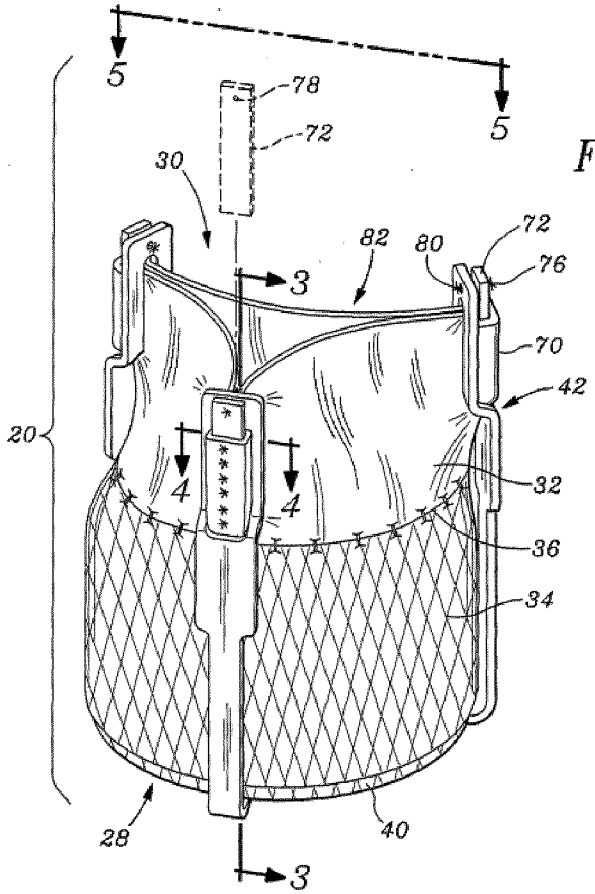


Fig. 2

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH14.

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5.7 Lack of novelty over US 2004/0210304 A1 (WBH15)

WBH15 is a US patent application published on October 21, 2004 and constitutes prior art according to Art. 54(2) EPC since the opposed patent does not validly claim its priority.

WBH15 discloses a device for replacing a heart valve by a percutaneous route (see paragraph [0106]) which comprises a support structure (101, Fig. 14 illustrated below) containing a valve (102, Fig. 14 illustrated below) (see paragraph [0115]). As described in paragraph [0116], the support structure can be made from a material with shape memory characteristics, such as Nitinol. The valve (102, Fig. 14) is provided inside of the support structure and may be connected to the support structure by sutures or other appropriate means of attachment (see paragraph [0116]). Thus, WBH14 discloses features **1, 1.1** and **1.2.**

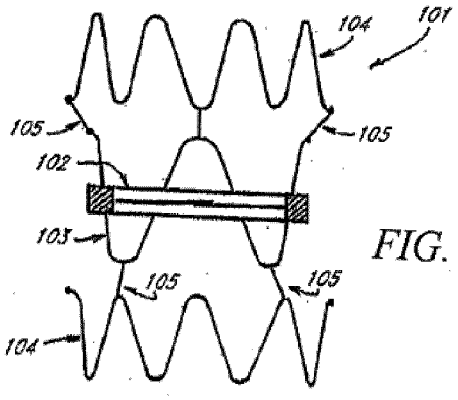
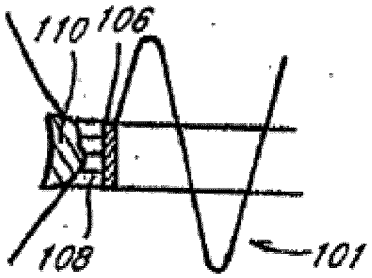


FIG. 14

FIG. 29



As described in paragraph [0115], the support structure (101, Fig. 14) comprises a shell (108, Fig. 29 illustrated above) made from a compressible material. As described in paragraph [0121] under reference to Fig. 29 illustrated above, the compressible material (108, Fig. 29) "*can absorb the surface irregularities possibly existing at or near ring 110, which results from calcifications*". Paragraph [0026] of WBH15 discloses that the sealing means "*can consist of a peripheral shell made from a compressible material such as polyester or tissue … This sealing means can also include a material that can be applied between the existing cardiac ring and the axial valve support portion, this material being*

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capable of solidifying after a predetermined delay following this application.". Thus, WBH15 also discloses features **1.3** and **1.4.**

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH15.

5.8 Lack of novelty over US 5,855,601 (WBH16)

WBH16 was published on January 5, 1999 and, thus, constitutes prior art according to Art. 54(2) EPC. WBH16 relates to a heart valve prosthesis, which may be implanted percutaneously comprising a stent member and a valve means (see column 2, lines 55 to 60). According to column 3, lines 52 to 55, "*the stent member is self-expanding and has a first cylindrical shape in its compressed or collapsed configuration and a second, larger cylindrical shape in its expanded configuration*". According to column 3, lines 55 to 57 and column 4, lines 1 to 3, the valve means is flexible and may contain three leaflets (stent member 32, valve member 35 with leaflets 36 and cuff portion 37, Fig. 4 illustrated below).

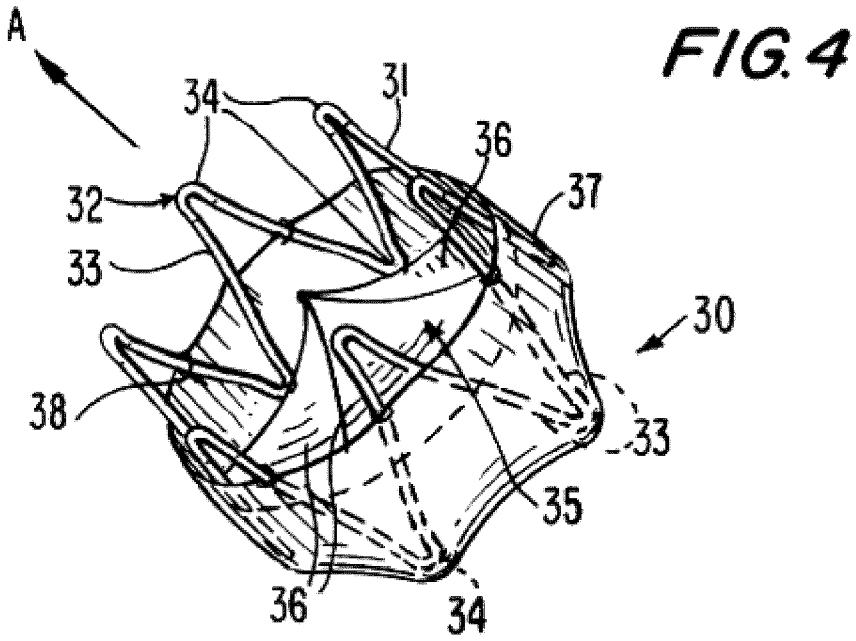


FIG. 4

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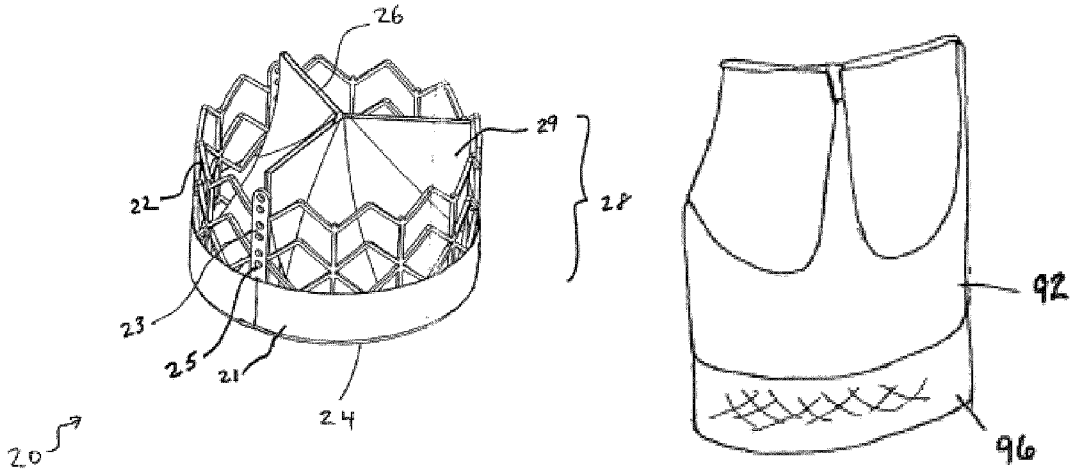
Furthermore, as described in column 4, lines 4 to 6, the valve means further comprises a cuff portion, which may extend wholly around the outer perimeter of the stent member. According to Claim 1 of WBH16, the cuff portion is configured "*to position the valve snugly and sealingly at a valve side*". As described in column 6, lines 19 to 31, the "*valve member is flexible, compressible, host-compatible, and non-thrombogenic*", wherein biocompatible materials "*such as polytetrafluorethylene, polyester and the like may be used*". Accordingly, the cuff portion, which constitutes part of the valve member, is compressible and adapted to fill gaps between the prosthetic valve and the body channel and comprises fibers extending outward. Therefore, WBH16 also discloses features **1.3** and **1.4**.

In view of the above, the subject-matter of Claim 1 of the opposed patent also lacks novelty over WBH16.

5.9 Lack of novelty over US 2003/0153974 A1 (WBH9)

WBH9 is a US patent application published on August 14, 2003 and, thus, constitutes prior art according to Art. 54(2) EPC. WBH9 is cited in paragraph [0009] of the opposed patent. As explicitly stated in paragraph [0009] of the opposed patent, WBH9 discloses a prosthetic device suitable for implantation in body ducts, the device comprising a support stent "*of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radially forces from within by means of a deployment device to a deployed state in the target location*". The support stent comprises a "*valve assembly comprising a flexible conduit having an inlet and an outlet, made of pliant material attached to the support stent*". Accordingly, WBH9 discloses features **1, 1.1** and **1.2.**

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In paragraph [0010] of the opposed patent, it is stated that WBH9 does not address leaks that can occur around the implanted valve. This is not correct. According to paragraph [0112] of WBH9, the valve assembly may exhibit "*a rolled sleeve, which enhances the sealing of the device at the valve inlet*". This rolled sleeve is indicated with reference sign 24 in Fig. 1 and reference sign 96 in Fig. 8A, both figures being illustrated side-by-side above. As described in paragraph [0118] of WBH9, the sleeve may be made from PET, therefore constituting a compressible material in line with feature **1.4**. Furthermore, we note that the PET sleeve comprises fibers, some of which extending outward from the outer surface. Thus, WBH9 also discloses feature **1.5**.

In view of the above, the subject-matter of Claim 1 of the opposed patent is also not novel over WBH9.

5.10 Lack of inventive step starting from WBH9/WBH12-WBH16 in combination with WO 03/053287 A1 (WBH17) or US 2002/0052649 A1 (WBH18)

Should the Opposition Division, for any reason, be of the opinion that one of documents WBH9 and WBH12-WBH16 does not disclose feature 1.4, i.e. that the compressible material includes a plurality of fibers extending outward from the outer surface, we note that the subject-matter of Claim 1 of the opposed patent lacks an inventive step over WBH9 or either one of documents WBH12-WBH16 in combination with either WBH17 or WBH18.

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The technical effect of feature 1.4 is derivable from paragraphs [0011], [0025] and [0064] of the opposed patent and is directed to the mitigation of paravalvular leakage.

Starting from either one of WBH9 and WBH12-WBH16, the objective technical problem is thus the mitigation of paravalvular leakage.

WBH17 was published on July 3, 2003 and WBH18 on May 2, 2002. Therefore, both documents constitute prior art according to Art. 54(2) EPC. When being confronted with the above technical problem, the skilled person learns from both documents that providing fibers extending outward from the outer surface of the stent structure mitigates paravalvular leakage.

For WBH17, we refer to column 1, lines 18-20 already stating that it "*is known that tufts of fibrous material may be placed on grafts to enhance blood clotting*". Furthermore, we refer to Fig. 4 of WBH17 illustrated below showing a stent graft comprising a "*band of fibrous material 25 provided by brushing or similar means to raise fibres 26 from the material of the graft 1*" (see column 6, lines 7-8). As described in lines 23.26 of column 5, this provides the technical effect that leakage around the device is prohibited.

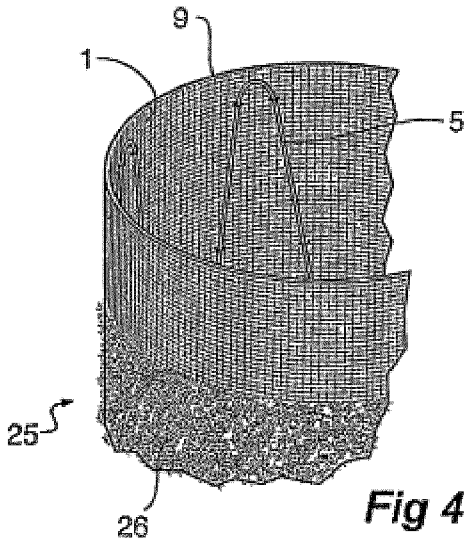


Fig 4

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For WBH18, we refer to Fig. 4a illustrated below showing a stent graft comprising a tissue engaging region 22 with a "*textured surface 23 having increased surface area. The increased surface area preferably comprises loops 28 which extend outward from the substrate 18*" (see paragraph [0032]). According to the last two lines of paragraph [0032] of WBH18, this enhances sealing.

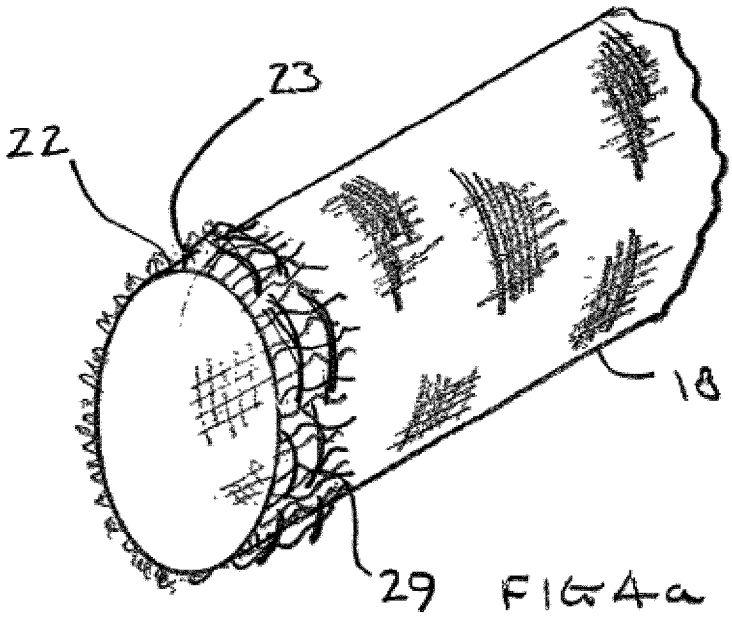


FIG 4a

When being confronted with the above stated objective technical problem of mitigating paravalvular leakage, the skilled person would thus provide fibers according to feature 1.4 to the valve prostheses of WBH9/WBH12-WBH16, therefore arriving at the subject-matter of Claim 1 of the opposed patent without inventive activity.

Therefore, the subject-matter of Claim 1 of the opposed patent also lacks an inventive step over WBH9 or either one of documents WBH12-WBH16 in combination with WBH17 or WBH18.

5.11 Lack of patentability of dependent claims

Also the dependent claims lack novelty and/or inventive step as outlined in the following:

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- dependent Claim 2: not novel over WBH10 (see Fig. 4), WBH11 Fig. (see Fig. 8C), WBH12 (see Fig. 3a), WBH13 (see Fig. 13A), WBH14 (see Fig. 2), WBH16 (see Fig. 4), WBH9 (see 1).
- dependent Claim 3: not novel over WBH10-WBH16 and WBH9. We note that the burden of proof that the prior art does not exhibit parameter lies with Proprietor. No benefit of doubt can be accorded if the Proprietor does not provide respective evidence support (see T 1764/06).
- dependent Claim 4: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above).
- dependent Claims 5 and 6: not novel over at least WBH10 (see page 15, last paragraph), WBH13 (see page 19, line 27) and anticipated by WBH1 (see column 5, line 60).
- dependent Claim 7: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above) – all of the fibers must be curved since they collectively form a tube-shaped covering.
- dependent Claim 8: not novel over at least WBH15 (see paragraph [0026] – "sealing means ... in the form of an inflatable insert").
- dependent Claim 9: not novel over WBH10-WBH16 (see argumentation under 5.2-5.8 above) and WBH9 (see argumentation under 5.9 above) – all of the coverings are suitable to be adjusted in shape to cavities existing between the valve and the wall of the body vessel.

Consequently, the request for revocation of the patent in its entirety is justified at least due to the facts and arguments presented above.

-electronically signed-

Thorsten Haslinde
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WBH Wachenhausen Patentanwälte PartG mbB
Association 786

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Enclosures

WBH1 US 5,258,023 A

WBH2 FR 2 337 543 A1

WBH3 WO 00/64380 A1

WBH4 FR 2 815 844 A1

WBH5 EP 2 537 487 A1

WBH6 US 5,554,184 A

WBH7 US 6,454,799 B1

WBH8 US 6,638,257 B2

WBH9 US 2003/0153974 A

WBH10 WO 2006/089236 A1

WBH11 US 2005/0137698 A1

WBH12 WO 2004/082527 A2

WBH13 WO 01/54625 A1

WBH14 WO 01/76510

WBH15 US 2004/0210304 A1

WBH16 US 5,855,601

WBH17: WO 03/053287 A1

WBH18: US 2002/0052649 A1

Annex 2: Feature analysis Claim 1

Annex 3: Assignment

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Europäisches Patentamt
European Patent Office
Office européen des brevets

Notice of opposition to a European patent

I. Patent opposed

Patent No.	EP2982337
Application No.	EP15180327.7
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	26 August 2020
Title of the invention	PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

II. Proprietor of the patent

first named in the patent specification	Edwards Lifesciences PVT, Inc.
Opponent's or representative's reference	272.0046OP

III. Opponent

Name	Neovasc Tiara Inc.
Address:	13562 Maycrest Way Suite 5138 Richmond British Columbia V6V 2J7 Canada
State of residence or of principal place of business	Canada
Multiple opponents (see additional sheet)	☐

IV. Authorisation

1. Representative

	WBH Wachenhausen Patentanwälte PartG mbB	
Association No.:	786	
Address of place of business	Müllerstraße 40 80469 Munich Germany	
Telephone/Fax	+49 (0)89 9545370 30	+49 (0)89 9545370 31
E-mail:	office@wachenhausen.com	

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Additional representative(s) on additional sheet/see authorisation ☐

Authorisation(s)

is/are enclosed ☐

has/have been registered under No. ☐

V. Opposition is filed against

the patent as a whole ☒

claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

- it is not new (Art. 52(1); Art. 54 EPC) ☒
- it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒
- patentability is excluded on other grounds, namely articles ☐

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☒

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☒

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on an attached document ☒

VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.

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IX. Evidence presented

WBH1	Patent document	US5,258,023 (A) , 02.11.1993 original file name: WBH1_US5258023A.pdf attached as: Published-Evidence-1.pdf
WBH10	Patent document	WO2006/089236 (A1) , 24.08.2006 original file name: WBH10_WO2006089236A1.pdf attached as: Published-Evidence-10.pdf
WBH11	Patent document	US2005/0137698 (A1) , 23.06.2005 original file name: WBH11_US20050137698A1.pdf attached as: Published-Evidence-11.pdf
WBH12	Patent document	WO2004/082527 (A2) , 30.09.2004 original file name: WBH12_WO2004082527A2.pdf attached as: Published-Evidence-12.pdf
WBH13	Patent document	WO01/54625 (A1) , 02.08.2001 original file name: WBH13_WO01054625A1.pdf attached as: Published-Evidence-13.pdf
WBH14	Patent document	WO01/76510 (A2) , 18.10.2001 original file name: WBH14_WO01076510A2.pdf attached as: Published-Evidence-14.pdf
WBH15	Patent document	US2004/0210304 (A1) , 21.10.2004 original file name: WBH15_US20040210304A1.pdf attached as: Published-Evidence-15.pdf
WBH16	Patent document	US5,855,601 (A) , 05.01.1999 original file name: WBH16_US5855601A.pdf attached as: Published-Evidence-16.pdf
WBH17	Patent document	WO 03/053287 (A1) , 03.07.2003 original file name: WBH17_WO03053287A1.pdf attached as: Published-Evidence-17.pdf
WBH18	Patent document	US2002/0052649 (A1) , 02.05.2002 original file name: WBH18_US20020052649A1.pdf attached as: Published-Evidence-18.pdf
WBH2	Patent document	FR2337543 (A) , 05.08.1977 original file name: WBH2_FR2337543A1.pdf attached as: Published-Evidence-2.pdf
WBH3	Patent document	WO00/64380 (A1) , 02.11.2000 original file name: WBH3_WO0064380A1.pdf attached as: Published-Evidence-3.pdf
WBH4	Patent document	FR2815844 (A1) , 03.05.2002 original file name: WBH4_FR2815844A1.pdf attached as: Published-Evidence-4.pdf
WBH5	Patent document	EP2537487 (A1) , 26.12.2012 original file name: WBH5_EP2537487A1.pdf

		attached as: Published-Evidence-5.pdf
WBH6	Patent document	US5,554,184 (A) , 10.09.1996 original file name: WBH6_US5554184A.pdf attached as: Published-Evidence-6.pdf
WBH7	Patent document	US6,454,799 (B1) , 24.09.2002 original file name: WBH7_US6454799B1.pdf attached as: Published-Evidence-7.pdf
WBH8	Patent document	US6,638,257 (B2) , 28.10.2003 original file name: WBH8_US6638257B2.pdf attached as: Published-Evidence-8.pdf
WBH9	Patent document	US2003/0153974 (A1) , 14.08.2003 original file name: WBH9_US20030153974A1.pdf attached as: Published-Evidence-9.pdf

X. Payment

Method of payment: Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated in the fees section below.

Currency: EUR

Deposit account number: 28003089

Account holder: WBH Wachenhausen Patentanwälte PartG mbB

Refunds

Any refunds should be made to EPO deposit account: 28003089

Account holder: WBH Wachenhausen Patentanwälte PartG mbB

Fees

	Factor applied	Fee schedule	Amount to be paid
010 Opposition fee	1	815.00	815.00
Total:		EUR	815.00

	A Forms	Details:	System file name:
A-1	Form for notice of opposition		ep-oppo.pdf

	B Attached document files	Original file name:	System file name:
B-1	1. Facts and arguments	20210525_Annex 1_Facts and Arguments_272.0046OP.pdf	OPPO.pdf
B-2	1. Any annexes (other than citation) to an opposition letter - Annex 3_Assignment	Annex 3_Assignment.pdf	OTHER-2.pdf
B-3	2. Any annexes (other than citation) to an opposition letter - Annex 2_Feature Analysis	20210525_Annex 2_Feature Analysis_272.0046OP.pdf	OTHER-1.pdf

	C Attached evidence files	Original file name:	System file name:
C-1	1. Patent document	WBH3_WO0064380A1.pdf	Published-Evidence-3.pdf
C-2	2. Patent document	WBH4_FR2815844A1.pdf	Published-Evidence-4.pdf
C-3	3. Patent document	WBH5_EP2537487A1.pdf	Published-Evidence-5.pdf

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C-4	4. Patent document	WBH6_US5554184A.pdf	Published-Evidence-6.pdf
C-5	5. Patent document	WBH7_US6454799B1.pdf	Published-Evidence-7.pdf
C-6	6. Patent document	WBH8_US6638257B2.pdf	Published-Evidence-8.pdf
C-7	7. Patent document	WBH9_US20030153974A1.pdf	Published-Evidence-9.pdf
C-8	8. Patent document	WBH10_WO2006089236A1.pdf	Published-Evidence-10.pdf
C-9	9. Patent document	WBH11_US20050137698A1.pdf	Published-Evidence-11.pdf
C-10	10. Patent document	WBH12_WO2004082527A2.pdf	Published-Evidence-12.pdf
C-11	11. Patent document	WBH13_WO01054625A1.pdf	Published-Evidence-13.pdf
C-12	12. Patent document	WBH14_WO01076510A2.pdf	Published-Evidence-14.pdf
C-13	13. Patent document	WBH15_US20040210304A1.pdf	Published-Evidence-15.pdf
C-14	14. Patent document	WBH16_US5855601A.pdf	Published-Evidence-16.pdf
C-15	15. Patent document	WBH17_WO03053287A1.pdf	Published-Evidence-17.pdf
C-16	16. Patent document	WBH18_US20020052649A1.pdf	Published-Evidence-18.pdf
C-17	17. Patent document	WBH1_US5258023A.pdf	Published-Evidence-1.pdf
C-18	18. Patent document	WBH2_FR2337543A1.pdf	Published-Evidence-2.pdf

Signature of opponent or representative

Place	**Munich**
Date:	**26 May 2021**
Signed by:	**Thorsten Haslinde 53075**
Association:	**WBH Wachenhausen Patentanwälte PartG mbB**
Representative name:	**Thorsten Haslinde**
Capacity:	**(Representative)**

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Europäisches Patentamt
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Office européen des brevets

Acknowledgement of receipt

We hereby acknowledge receipt of the Notice of Opposition:

Submission number	9830327
Application number	EP15180327.7
Patent number	EP2982337
Date of receipt	25 May 2021
Your reference	255.0051G1
Opponent	Abbott Cardiovascular Systems, Inc.
Title	Paravalvular leak detection, sealing, and prevention

Documents submitted

package-data.xml	ep-opposition-data.xml
ep-oppo.pdf (6 p.)	OPPO.pdf\20210525_NtcOfOppo.pdf (40 p.)
Published-Evidence-1.pdf\D1_US000005258023A.pdf (19 p.)	Published-Evidence-2.pdf\D2_FR000002337543A1.pdf (16 p.)
Published-Evidence-3.pdf\D2a_US000004106129A.pdf (7 p.)	Published-Evidence-4.pdf\D3_WO002000064380A1.pdf (40 p.)
Published-Evidence-5.pdf\D4_FR000002815844A1.pdf (28 p.)	Published-Evidence-6.pdf\D5_EP000002537487A1.pdf (145 p.)
Published-Evidence-7.pdf\D5a_US020050137688A1.pdf (78 p.)	Published-Evidence-8.pdf\D5b_US020050137698A1.pdf (37 p.)
Published-Evidence-9.pdf\D6_WO002001056512A1.pdf (38 p.)	Published-Evidence-10.pdf\D7_US000006454799B1.pdf (20 p.)
Published-Evidence-11.pdf\D8_US020030153974A1.pdf (37 p.)	Published-Evidence-12.pdf\D9_DE000002613575A1.pdf (18 p.)
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Annex A1

Feature Analysis of independent claim 1

Independent claim 1 of the opposed patent as granted has been partitioned into the following features:

F1 A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

F2 a substantially cylindrical stent structure (252) configured for radial expansion,

F3 a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets,

F4 characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure,

F5 the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel,

F6 wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Basically, a stented valve with a layer of material on the outside of the stent is claimed. The material is compressible and includes fibers. Interestingly, these fibers extend from the outer surface of the stent structure outwardly.

According to paragraph [0064] of the description of the patent, it is intended to encourage coagulation of blood by means of the fibers to fill gaps between the stented valve and surrounding tissue. In consequence, it must be assumed that the fibers extend from the inner side of the layer of material, i.e. from the outer surface of the stent structure into the layer,

through the layer and further outwardly. However, there is contradicting disclosure in the patent.

In the following, it will be shown that the claim language is not supported by the description, that neither the original claims nor the original description may form basis for the claims of the opposed patent. The claimed subject-matter cannot be put into practice, and in as far as it can be understood, the subject-matter is known or at least not inventive.

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(54) **PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION**

ERKENNUNG, VERSCHLUSS UND PRÄVENTION VON PARAVALVULÄREN LECKS

DÉTECTION DE FUITE PARAVALVULAIRE, ÉTANCHÉITÉ ET PRÉVENTION

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly it relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses.

BACKGROUND OF THE INVENTION

[0002] Cardiac valve implantation is well known in the art. Less well addressed is how to detect possible leaks between the valve and surrounding blood vessel, how to seal such leaks, or how to design the valve such that it automatically seals the leaks.

[0003] Machiraju in U.S. Patent No 5,554,184, entitled "HEART VALVE ", describes a heart valve and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart, including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs.

[0004] Machiraju does not address leaks that can occur around the implanted valve.

[0005] Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE", describes expandable heart valves for minimally invasive valve replacement surgeries. In a first embodiment, an expandable preassembled heart valve includes a plastically-expandable annular base having a plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

[0006] Schreck also does not address leaks that can occur around the implanted valve.

[0007] Amplatz in U.S. Patent No. 6,638,257, entitled, "INTRAVASCULAR FLOW RESTRICTOR," describes an intravascular flow restrictor that comprises a braided tubular structure designed to be placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter, but when it is ejected from the delivery catheter, it assumes a substantially larger diameter disk shaped device having one or more longitudinal channels or passways therethrough.

[0008] Amplatz also does not address leaks that can occur around the implanted valve. In addition, Amplatz's braided structures are of a shape and size not appropriate for paravalvular leak detection and sealing. Their geometry is designed for the conditions of the transceptal hole and not appropriate for valve leakage.

[0009] Spenser et al. in U.S. Patent Application No. 20030153974, entitled "IMPLANTABLE PROSTHETIC VALVE", describe a prosthesis device suitable for implantation in body ducts. The device comprises a support stent bring comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent bring provided with a plurality of longitudinally rigid support beams of fixed length, and (2) a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet. When flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly to provide blockage to the reverse flow.

[0010] Spenser et al. also do not address leaks that can occur around the implanted valve.

[0011] With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use of newer percutaneous methods, some of which are described in the patents mentioned above. With both methods paravalvular leaks are a known side effect. One way to approach the leak problem is to identify the leak location and repair it. Another approach is to equip the prosthesis with means to prevent the leak ("self-sealing" prosthesis). Both these approaches are encompassed by the present invention.

[0012] Percutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation. In contrast, surgical placement involves a large chest surgical incision and requires general anesthesia, to expose a large portion of a patient's thoracic region.

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Percutaneous introduction is therefore considered safer and less invasive.

[0013] Percutaneous introduction of a leak detection and repair device or of a self-sealing valve resembles other known interventional cardiologic procedures. The percutaneous deployment procedure and device has an impact on several parameters of the product design, some of which are explained hereinafter.

[0014] In summary, the present invention provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

[0015] Further prior art arrangements are known from US 5258023, US 4106129, WO 00/64380 and FR 2815844.

SUMMARY OF THE INVENTION

[0016] In accordance with a preferred embodiment of the present invention, there is provided a prosthetic valve for percutaneous implantation in a body channel as recited by Claim 1.

[0017] The sleeve preferably surrounds an inflow end of the stent structure.

[0018] The compressible material may have a thickness ranging from 1 to 5mm.

[0019] The compressible material may comprise a cloth or fabric.

[0020] A tissue growth factor may be disposed along the compressible material. The growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

[0021] The fibers may be straight, curved or hook-shaped.

[0022] The compressible material is preferably configured to expand into the gaps.

[0023] The compressible material may be configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

BRIEF DESCRIPTION OF THE FIGURES

[0024] To better understand the present invention and appreciate its practical applications, the following Figures are provided and referenced hereafter. It should be noted that the Figures are given as examples only and in no way limit the scope of the invention as defined in the appended claims. Like components are denoted by like reference numerals.

Figure 1 illustrates an implanted valve with a cavity creating a paravalvular leak and a device comprising a soft guidewire with an inflatable balloon and designed to identify the exact location of the paravalvular leak.

Figures 2a and 2b depict a plurality of balloons on soft guidewires designed to identify paravalvular leaks around an implanted valve.

Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring designed to identify paravalvular leaks around an implanted valve.

Figures 4a to 4c depict the process of inserting a sealing stent over a guidewire to close a paravalvular leak.

Figures 5a to 5d depict several types of sealing stents

Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device assisted by anchors, which attach the device to the aortic wall (or annulus).

Figure 7 illustrates an anchoring apparatus for achieving sealing as shown in Figure 6, in this case by use of a screw, which is embedded into to the aortic wall (or annulus).

Figures 8a and 8b depict a leak repair done using a two-component biological glue.

Figures 9a to 9c depict a leak repair done, using an ultra-violet light-cured biological glue.

Figure 10 illustrates a catheter that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

Figures 11a to 11f illustrate a device and procedure for blocking a paravalvular leak using two connected sealing stents.

Figures 12 depicts a valve with a built-in inflatable portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

Figures 13a to 13d illustrate a valve having a flexible and self-expanding portion for blocking possible leaks around the stent.

Figures 14a to 14c illustrate a valve having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

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Figures 15a to 15c illustrate a valve having a plurality of flexible and expanding segments on its proximal side for blocking possible leaks around the stent.

Figures 16a and 16b illustrate a valve device comprising an additional portion for blocking possible leaks around the stent.

Figures 17a to 17e illustrate a valve device where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

Figures 18a to 18e illustrate a valve, constructed with additional sutures attached to the proximal side, allowing attachment of extra pieces of pericardium or artificial fabric for blocking paravalvular leaks.

Figures 19a to 19d depict a procedure comprising two stages: first, insertion of a stent that includes an outer sealing layer; and second, insertion of a prosthetic valve through the stent.

Figures 20a to 20g illustrate a valve, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

Figure 21 illustrates a valve device, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

Figure 22 illustrates a valve device, in accordance with an embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

DETAILED DESCRIPTION OF THE INVENTION

[0025] The present invention provides apparatuses for substantially reducing or effectively eliminating the deleterious effects of paravalvular leaks in prosthetic valves. More specifically, it enables locating, sealing, and preventing paravalvular leaks using both dedicated and integrated (with the valve) means.

[0026] While the present invention is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve, it can also be applied to other leakage problems such as in other blood vessels, a septum, or other body lumens. Similarly, while the prosthetic valve described herein is a tricuspid valve, it could be another type of valve as well.

[0027] A main aspect of the present invention are several novel designs for modifying percutaneous prosthetic valves to automatically seal paravalvular leaks when the valve is implanted.

[0028] Another main aspect of the present invention is a novel design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

[0029] Another main aspect of the present invention is the disclosure of several novel designs for modifying percutaneous prosthetic valves to enable sealing of paravalvular leaks after the valve is implanted.

[0030] Figure 1 illustrates a simple leak detector 27 of the present invention. Leak detector 27 detects a leak between general tricuspid implantable prosthesis valve 20 and the aortic annulus 22. Leak detector 27 will typically be used together with leak sealing devices, like those described later in this specification.

[0031] A cavity 24 exists between the perimeter of valve 20 and aortic annulus 22. The cavity could have any number of causes, including calcification or other irregularities in the aortic annulus 22 that prevent proper sealing between the valve 20 and the annulus 22. The cavity will cause regurgitation (leaking) during diastole, characterized by blood flowing 25 from the aorta into the left ventricle. Leak detector 27, is delivered through catheter 21 to a position above valve 20. Leak detector 27 comprises a soft guide wire 28 on which is mounted inflatable balloon 29, which is inflated after leak detector 27 has been passed through catheter 21. Guidewire 28 is soft enough that during diastole inflated balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

[0032] Figures 2a and 2b depict a multiple leak detector 228 that is similar to leak detector 27 of Figure 1 but which comprises a plurality of soft guidewires 31 rather than just the single guidewire 28 of detector 27. On each guidewire 31 is mounted a balloon 35. Figure 2b is a top view showing valve 20 during diastole. Two cavities 24 cause a flow of blood, which pulls the balloon 35 closest to each cavity 24 into that cavity while remaining balloons 35 stay stationary. At this point, cavity 24 locations can be determined and marked and the cavities repaired.

[0033] Figure 3 illustrates an annular-configured leak detector 229, which incorporates an adaptation that can be used to force wire(s) 40 of leak detector 27 or multiple-leak detector 228 (implementation shown) to remain close to aortic wall 45 rather than being allowed to drift to the center of the aorta. The advantage of this adaptation is that, in the case of detectors 27 and 228, if there is a central leak in valve 20, a balloon near the center of the aorta might be drawn into the central leak instead of to the paravalvular cavity, thereby indicating a false paravalvular leak. Spacing ring 40 is a compressible wire ring that pops open after catheter 21 delivery. Guidewire(s) 42 are distributively attached to the external edge of ring 40 and are thereby held by the ring against the aortic wall 45.

[0034] Figures 4a to 4c depict an implantable valve 49 deployed in the native aortic valve position, creating a cavity 24, which causes paravalvular regurgitation (leak) during diastole. In Figure 4a, guidewire 46, which can be

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a leak detection device like those shown in Figures 1, 2, and 3, is inserted through cavity 24. Balloon 33 is deflated. In Figure 4b, a balloon-expandable sealing stent (stent with an impermeable membrane that prevents the passage of fluids through the stent), is catheter-deployed over guidewire 46. Balloon 33 is inflated, causing balloon-expandable sealing stent 47 to be expanded, thereby sealing cavity 24 and stopping the paravalvular leak. Figure 4c shows a similar leak repair with the difference that a self-expanding sealing stent 48 is used, and therefore balloon inflation is not required. The sealing stents 47 and 48 are anchored by friction between themselves and the surrounding aortic annulus. Means for providing stronger anchoring for sealing stents are described later in this specification.

[0035] Figures 5a and 5b illustrate a balloon-expandable sealing stent (such as that used in Figure 4b).

The outer part 51 of the stent is made of a material that can be reshaped by plastic deformation. Sealing element 52, comprising an impermeable membrane, is connected to the inside wall of outer part 51 by spring hinge 53. The balloon-expandable sealing stent 47 is crimped on balloon 55. Once balloon 55 has reached cavity 24, the balloon is inflated, thereby expanding the sealing stent (Figure 5a). Balloon 33 is then deflated, whereupon (Figure 5b) sealing element 52 is forced by spring 53 to close and seal the lumen of the stent.

[0036] Figures 5c and 5d show a self-expanding sealing stent (such as that used in Figure 4c).

One way to implement the self-expanding sealing stent is to build stent framework 56 from a shape memory material such as nitinol 56 and cover it with a layer of impermeable material 58. The self-expanding sealing stent is catheter-delivered to the cavity, whereupon the stent opens, its shape adjusting to the shape of the cavity and its impermeable covering 58 sealing the cavity, to prevent the paravalvular regurgitation. To anchor the self-expanding sealing stent in place, hooks 59 can be included on framework 56. Hooks 59 are attached to framework 56 and extend through sealing material 58 and into the wall of the aortic annulus. The hooks are self-extending. One way to implement them is to make them from a shape memory material such as nitinol.

[0037] Figures 6a to 6d illustrate a technique for anchoring a sealing stent 66 (such as balloon-expandable sealing stent 47 or self-expanding sealing stent 48) into an open cavity 24, which is situated between aortic annulus 63 and prosthetic valve 20, and which creates paravalvular regurgitation. In Figure 6a, a guidewire 61 is led through cavity 24 by balloon 29 (this can be done with a device such as those disclosed in Figures 1 to 3). Guiding catheter 603 is fed over the guidewire, and the guidewire is removed. In Figure 6b an additional wire, anchoring wire 67, which terminates in anchoring apparatus 65, is inserted through catheter 63 to the anchoring location in cavity 24. Anchor 65 is a hook with one or more hook heads that can be compressed for delivery and will spring back to their original position when the delivery compression is removed (in other words, when the device emerges from the delivery catheter). Anchor 65 could be composed of flexible metal or a shape memory compound. Anchor 65 penetrates the aortic annulus at an approximately perpendicular angle due to the angled tip of guiding catheter 603. Figure 6c shows sealing stent 66 inserted via anchoring wire 67 and expanded to seal the cavity by one of the methods described in Figure 4 or 5. In the case shown in Figure 6c, a self expandable sealing stent as described in Figure 4 is shown. This method enables improved anchoring forces in comparison to friction alone, which is the sole anchoring shown Figures 4 and 5. Figure 6d shows the final step of the procedure, where the wire is detached from the anchor at detaching point 68.

[0038] Figure 7 depicts an apparatus that is similar to that illustrated in Figure 6, only here anchor 65 is implemented as a screw tip 69. The anchoring is accomplished by rotating anchoring wire 67, thereby threading tip 69 into aortic annulus 22.

[0039] Figures 8a to 8d demonstrate an apparatus for repairing a paravalvular leak by means of biological bi-component adhesive material (such as an epoxy resin), the components of which are in liquid form and turn to solid when mixed.

The leak is caused by an open cavity between valve 20 and annulus 22. A leak detector, such as those shown in Figures 1 to 3, is used to run guidewire 83 through cavity 24. A second guidewire 84 with a slide element 85 is slid over the first guide wire 83. Slide element 85 enables second guidewire 84 to slide over first guidewire 28 and can be a ring at the end of second wire 84. In Figure 8b, when slide element 85 and first guidewire 83 reach a point approximately midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

[0040] In Figure 8c one of the components of a biological bi-component adhesive material is injected via catheter 86, and the other component is injected via catheter 87. The liquid adhesive components meet at the catheter outlets at meeting point 75, mixing to create the adhesive blocking element 89, which repairs the paravalvular leak by closing cavity 24. Figure 8d depicts a top view of the final result of the repaired cavity showing that adhesive blocking element has been formed to seal cavity 24 between valve 20 and annulus 22.

[0041] Figure 9 illustrates another apparatus for blocking a leak by means of biological adhesive.

Again, two guidewires meet at meeting point 75, and catheters, in this case 91 and 93, are fed over the guidewires to meeting point 75. However, in this case the blocking adhesive material comprises one liquid component that is solidified by the presence of ultra-violet light or another radiation cure. The liquid adhesive material is inserted into cavity 24 at catheter meeting point 75 via catheter 91. Active wave 96 shining through light probe catheter 93 hardens the material, creating sealing block 95, which closes the leak caused by cavity 24.

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[0042] Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material.

Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to the desired location, inside cavity 24 between aorta 82 and prosthetic valve 81. Figure 10b is a cross-section of the catheter 100's multiple-lumen shaft. Lumens 102 and 103 provide means of approach for the separate components of the adhesive. Lumen 104 provides means for catheter to be fed over guidewire 28. Figure 10c shows a bi-component adhesive infusion chamber 100 in the form of a double syringe connected to the end of catheter 100 that is proximal to the medical operator. Figure 10d illustrates a mixing element 105 located at the distal end of catheter 100 (its location can be seen in Figure 10a). Mixing element 105 serves to mix the two adhesive components as they emerge from distal end of catheter 100 after being forced out of chamber 101, thereby ensuring that they will solidify and cure inside cavity 24. Figure 10e shows the adhesive components after they have been infused by chamber 101 via multiple-lumen catheter 100 and mixing element 105 into cavity 24 to form a plug. The cured adhesive fills the cavity and blocks the leak. Also shown in Figure 10e is an optional flexible mesh bag 106, which receives and holds the adhesive mix. The bag prevents possible migration of adhesive material during insertion and prevents the adhesive from passing through stent struts 108 in cases where such valve designs are present.

[0043] Figures 11a to 11f illustrate an apparatus for repairing a paravalvular leak.

Two self-expanding sealing stents 110 are connected by suture 112 and pushed into insertion catheter 111 (Figure 11b). At this stage, insertion into the catheter has reduced the stents' diameter, enabling them to enter a cavity 24 between a prosthetic valve and surrounding blood vessel. Figures 11c and 11d depict an implanted valve 115 where two large calcifications 116 create cavity 117, which causes regurgitation and must be repaired. (The calcification is just one example of a condition that creates a cavity that must be repaired. The cavity could equally have been caused by other factors).

[0044] Figure 11e depicts insertion catheter 111 inserted over guidewire 28 to a point where the distal (delivery) end of the catheter has passed through the bottom of cavity 117. A first sealing stent 110 is deployed below the bottom of cavity 117. Catheter 111 is withdrawn and suture 112 is partially retracted, pulling the first sealing stent 110 into the bottom of the cavity, where it lodges. With reference to Figure 11f, insertion catheter 111 is withdrawn until its distal end is near the top of cavity 24, whereupon a second sealing stent 110 is deployed. Suture 112 is further retracted, pulling the second stent into the top of the cavity, where it lodges. The final step of the procedure is to disconnect the proximal part of the suture at point 119.

[0045] Figure 12 depicts a valve adapted to seal paravalvular leaks.

Valve 121 is held in holder stent 124 with sealing element 120 attached circumferentially around stent 124's outer surface. When valve 121 is implanted, sealing element 120 is expanded to seal any peripheral paravalvular leaks. Several means can be used to implement expansion of sealing element 120. In the implementation shown in Figure 12, sealing element 120 is inflated by operator application of syringe 123, and it constitutes a balloon-like portion, made of a pliant physiologically acceptable polymeric material such as polyurethane. The inflation media can be saline solution, the patient's blood, or another physiologically acceptable fluid.

[0046] Alternatively, the sealing portion can be made of a material that, on contact with a fluid, soaks up the fluid and swells up. Once inserted into the body, the sealing portion comes into contact with the blood, causing it to swell and seal the cavity.

[0047] Figures 13a to 13d depict a valve adapted to seal paravalvular leaks.

[0048] Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing component 126 is comprised of a plurality of flaps 127 and expands to a larger diameter than the principal diameter of the stent 125, creating an extra sealing line to prevent paravalvular leaks. Figure 13b depicts a top view of valve 124. Sealing component 126 comprises a plurality of flaps 127 that, independent of one another, are connected to the valve stent 125. Each flap 127 is made of spring wire 131, which, after the valve is deployed, causes flap 127 to extend out. Flaps 127 are covered with impermeable sealing material 128. Flaps 127 are arranged such that they are substantially perpendicular to the longitudinal axis of stent 124 and overlap one another, ensuring a full seal.

[0049] Figure 13c shows stent-mounted valve 124 in its crimped configuration. Introducing sheath tube 130 holds stent 125 and sealing component 126 crimped on balloon 129. After deployment, flaps 127 of sealing component 126 open to their final diameter.

[0050] Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by mechanical attachment means 134, which can be a rivet, a screw, etc. Spring wire ring 131 can be folded into introducing sheath tube 130 shown in Figure 13c and, when released from tube 130, springs back to its shape as shown in Figure 13d.

[0051] Figure 14 illustrates a valve adapted to seal paravalvular leaks.

[0052] This design includes balloon-inflatable stent 140 (containing a prosthetic valve) and balloon-inflated sealing ring 145, which is similar to sealing component 126 of Figure 13, only here balloon-inflatable wire 145 is used instead of spring wire ring 131. Stent 140 is inflated using a double balloon. First balloon section 142 inflates stent 140 to the desired diameter, and then second balloon section 143 inflates sealing flaps 145 perpendicular to stent 140, creating a larger diameter and thus sealing any cavities around the stent.

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[0053] Figures 15a and 15b depict a valve adapted to seal paravalvular leaks.

The sealing ring comprises flexible sealing elements 150. Each sealing element 150 is independently spring-actuated. When the valve is crimped, sealing elements 150 fold, enabling valve to be reduced to a small diameter for insertion. When valve is expanded to its final diameter, sealing elements 150 open to a larger diameter 154 to seal cavities around the valve, preventing paravalvular leaks. Since each sealing element 150 is independent, sealing elements adjacent to native valve tissue 152 remain closed. These closed elements provide a further benefit of adding compressive forces that improve the anchoring of the valve.

[0054] Figures 16a to 16c depict a valve adapted to seal paravalvular leaks

Here the sealing ring 165 comprises at least one of a plurality of flexible, self-expanding sealing elements 165 connected to the outer surface of stent 160. Similar to Figure 15, when stent 160 is pressed against the native tissue, sealing element 165 will stay compressed against the wall. But where there is a gap between stent 160 and the surrounding tissue, sealing element 165 will expand and block any possible leak. With reference to Figure 16b, sealing element 165 is made of self-expanding mesh 166 covered with PET (polyethylene terephthalate) mesh 167 or other impermeable material.

[0055] Figures 17a to 17e depict a valve adapted to seal paravalvular leaks

wherein the sealing component is built into a ring 172 of the stent struts. In the figure the ring of struts 172 is located at the stent's inlet; however, the ring of struts can equally be implemented at another point along the stent. The modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

[0056] Figures 17c and 17d show front and side views of the geometrical restriction in modified strut 173 that causes the displacement of point 175, creating enlarged diameter 169. Figure 17c shows modified strut 173 before stent expansion and in line with the rest of the stent wall. Figure 17d shows modified strut 173 after stent expansion, which has caused modified strut 173 to rise up and out, creating the sealing ring. Figure 17e details the operation of the geometric restriction: when stent 170 is crimped, the strut legs are relatively close to each other 176, making strut height relatively large 177. After expansion, the strut legs are spaced further apart 176a, leading to displacement of point 175, and lessening of strut height 177a. The result of the movement of point 175 is shown in Figures 17c, 17d, and 17e. When the stent is crimped, as shown in Figure 17c and the left side of Figure 17e, point 175 is low. When the stent is expanded, as shown in the right side of Figure 17e, point 175 moves up, pulling the stent to the shape shown in 17d .

[0057] Figures 18a to 18e depict a valve adapted to include means for sealing paravalvular leaks.

In Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic aortic valve 175. At least one of a plurality of sutures 181 are connected to valve 180 at inlet end 187. The sutures spread back along the balloon's shaft 183 and continue back along the deployment path and out of the patient's body as shown in Figure 18b.

[0058] Inflating balloon 183, as shown in Figure 18c, anchors valve 185 in annulus 179 with sutures 181 arranged around it. In cases where paravalvular cavities 178 are present, it is possible to repair them assisted by sutures 181. Figure 18d shows a patch 189 made of pericardium (or other suitable patch material) inserted on sutures 181 and pushed to the leaking cavity by means of a pushing catheter 190. After the patch is in place, a knot or clip 191 is used to secure it, thereby repairing the leak (18e).

[0059] Figures 19a to 19d depict a valve adapted to include means for sealing paravalvular leaks.

First elastic sealing stent 195 is inserted in the desired location. Then, valve 196 is inserted into sealing stent 195. Figure 19a shows inserting catheter 191 with sealing stent 195 and valve 196 mounted on it. Sealing stent 195 and valve 196 can be either balloon inflated as shown in this figure, or self-expanding which would then require an introducing sheath.

[0060] Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the stented valve 196, which is mounted inside sealing stent 195, can be absolutely round. Sealing stent 195 is able to avoid leaks caused by cavities or irregularities caused by pieces of calcification as described earlier in this patent. The sealing component of sealing stent 195 can be self-expandable hydrophilic sponge 197 (Figure 19c) or other suitable material. Sealing stent 195 can include hooks 198 that open when the stent is inserted, improving the anchoring of the stent in the annulus as well as improving sealing around the stent by blocking blood (Figure 19d).

[0061] Figure 20a depicts a stented valve 201 having a valvular structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks.

A flexible sealing element 203 provides a sealing ring. The sealing element 203 may be formed of any material suitable for implantation in the human body, such as, for example, a sponge material. When the stented valve 201 is crimped to a smaller diameter, sealing element 203 is also crimped, thereby enabling valve to be easily advanced to a treatment site. For purposes of illustration, figure 20f illustrates sealing element 203 before crimping, while Figure 20g illustrates sealing element in a crimped condition. When the valve is expanded to its final diameter, sealing element 203 expands to its original size di-

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ameter by internal spring forces and/or by absorbing blood. Expansion of the sealing element seals cavities around the valve and thereby prevents paravalvular leaks. In addition to the mechanical effect of blocking cavities, blood protein preferably adheres to the sealing element, thereby causing coagulation for further leak prevention. Figures 20c and 20d provide cross-sectional views of preferred sealing elements. A tubular form 203a shown in figure 20c is configured to be crimped to a smaller size than a rod form 203b shown in figure 20d. Figure 20e illustrates the sealing element with additional fibers 206, which increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing. Figure 20e also illustrates a suture 207 as one preferred means for attachment to the valve body. Figure 20b is a perspective view illustrating
valve 210 having a sealing mechanism. In this variation, two sealing elements 204, 205 are provided along an exterior region.

[0062] Figure 21 depicts yet another stented valve 220 adapted to seal paravalvular leaks. A sealing element 223, which is preferably made of the same materials described above with respect to figures 20a through 20g, is attached to the stent in a non-linear sealing line. In preferred configurations, the line can be adjacent to the connection of a valvular structure 222 to the stent or according to the lines of the stent structure. In one feature, an improved crimped profile may be achieved using the illustrated attachment line.

[0063] Figure 22 depicts a stented valve 250 in accordance with the invention configured to reduce or prevent paravalvular leaks. The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254. The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration.

[0064] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material extends entirely around the stent structure in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. The compressible material 256 resembles a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps. Any suitable tissue growth factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

[0065] In yet another embodiment, a biocompatible hydrogel may be applied to the outside surface of a prosthetic valve. After deployment, the hydrogel absorbs fluids from the blood and expands to the fill the gaps between the valve and surrounding tissue (e.g., host annulus). In preferred methods, the hydrogel may be applied to the surface of the stented valve before deployment or may be applied after deployment.

[0066] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the scope of the appended claims.

Claims

1. A prosthetic valve (250) for percutaneous implantation in a body channel, comprising:

   a substantially cylindrical stent structure (252) configured for radial expansion;
   a valvular structure (254) having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;
   characterised by a layer of compressible material (256), which forms a sleeve disposed along an outer surface of the stent structure and extending entirely around the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

2. The prosthetic valve of Claim 1, wherein the sleeve surrounds an inflow end of the stent structure.

3. The prosthetic valve of Claim 1 or 2, wherein the compressible material has a thickness ranging from 1 to 5mm.

4. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

5. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

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6. The prosthetic valve as claimed in Claim 5, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

7. The prosthetic valve of any preceding claim, wherein the fibers are straight, curved or hook-shaped.

8. The prosthetic valve of any of the previous claims, wherein the compressible material is configured to expand into the gaps.

9. The prosthetic valve of any of the previous claims, wherein the compressible material is configured such that upon stent opening the shape of the compressible material adjusts to the shape of the cavity existing between the valve and the wall of the body vessel, where the valve is implanted, the cavities producing paravalvular leaks during diastole.

Patentansprüche

1. Klappenprothese (250) für die perkutane Implantation in einen Körperkanal, die Folgendes umfasst:

   eine im Wesentlichen zylindrische Stent-Struktur (252), die zur radialen Ausdehnung konfiguriert ist;
   eine klappenförmige Struktur (254), die einen Einlass und einen Auslass aufweist, wobei die klappenförmige Struktur aus einem biegsamen Material ausgebildet ist, das an der Stent-Struktur angebracht ist und drei Klappensegel ausbildet;
   gekennzeichnet durch eine Schicht aus komprimierbarem Material (256), das eine Hülse ausbildet, die entlang einer äußeren Oberfläche der Stent-Struktur angeordnet ist und sich vollständig um die Stent-Struktur erstreckt, wobei das komprimierbare Material geeignet ist, um nach dem Einsatz Lücken zwischen der Klappenprothese und dem Körperkanal auszufüllen, wobei das komprimierbare Material eine Vielzahl von Fasern einschließt, die sich nach außen von der äußeren Oberfläche erstrecken.

2. Klappenprothese nach Anspruch 1, wobei die Hülse ein Eintrittsende der Stent-Struktur umgibt.

3. Klappenprothese nach Anspruch 1 oder 2, wobei das komprimierbare Material eine Dicke im Bereich von 1 bis 5 mm aufweist.

4. Klappenprothese nach einem vorstehenden Anspruch, wobei das komprimierbare Material ein Tuch oder einen Stoff umfasst.

5. Klappenprothese nach einem vorstehenden Anspruch, die weiter einen Gewebewachstumsfaktor umfasst, der entlang des komprimierbaren Materials angeordnet ist.

6. Klappenprothese nach Anspruch 5, wobei der Wachstumsfaktor entlang der äußeren Oberfläche des komprimierbaren Materials aufgetragen ist oder das Material vor der Verwendung in dem Wachstumsfaktor getränkt oder darin getaucht wird.

7. Klappenprothese nach einem vorstehenden Anspruch, wobei die Fasern gerade, gebogen oder hakenförmig sind.

8. Klappenprothese nach einem der vorstehenden Ansprüche, wobei das komprimierbare Material zur Ausdehnung in die Lücken konfiguriert ist.

9. Klappenprothese nach einem der vorstehenden Ansprüche, wobei das komprimierbare Material derart konfiguriert ist, dass bei Öffnung des Stents sich die Form des komprimierbaren Materials an die Form des Hohlraums anpasst, der zwischen der Klappe und der Wand des Körpergefäßes vorliegt, wo die Klappe implantiert wird, wobei die Hohlräume paravalvuläre Lecks während der Diastole erzeugen.

Revendications

1. Valve prothétique (250) pour implantation percutanée dans un canal corporel, comprenant :

   une structure de stent sensiblement cylindrique (252) configurée pour dilatation radiale ;
   une structure valvulaire (254) ayant une admission et une sortie, la structure valvulaire formée d'un matériau pliable attaché à la structure de stent et formant trois feuillets de valve ;
   caractérisée par une couche de matériau compressible (256), qui forme une douille disposée le long d'une surface extérieure de la structure de stent et s'étendant entièrement autour de la structure de stent, le matériau compressible étant adapté pour remplir, après le déploiement, les espaces entre la valve prothétique et le canal corporel, où le matériau compressible comprend une pluralité de fibres s'étendant vers l'extérieur de la surface extérieure.

2. Valve prothétique selon la revendication 1, dans laquelle la douille entoure une extrémité de flux d'entrée de la structure de stent.

3. Valve prothétique selon la revendication 1 ou 2, dans laquelle le matériau compressible a une épaisseur allant de 1 à 5 mm.

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4. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle le matériau compressible comprend une étoffe ou un tissu.

5. Valve prothétique selon l'une quelconque des revendications précédentes, comprenant en outre un facteur de croissance tissulaire disposé le long du matériau compressible.

6. Valve prothétique selon la revendication 5, dans laquelle le facteur de croissance est appliqué le long de la surface extérieure du matériau compressible ou bien le matériau est imbibé de/ou trempé dans le facteur de croissance avant l'emploi.

7. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle les fibres sont droites, recourbées ou crochues.

8. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle le matériau compressible est configuré pour se dilater dans les espaces.

9. Valve prothétique selon l'une quelconque des revendications précédentes, dans laquelle le matériau compressible est configuré de telle sorte que lors de l'ouverture du stent la forme du matériau compressible s'ajuste à la forme de la cavité existante entre la valve et la paroi du vaisseau corporel, où la valve est implantée, les cavités produisant des fuites paravalvulaires durant la diastole.

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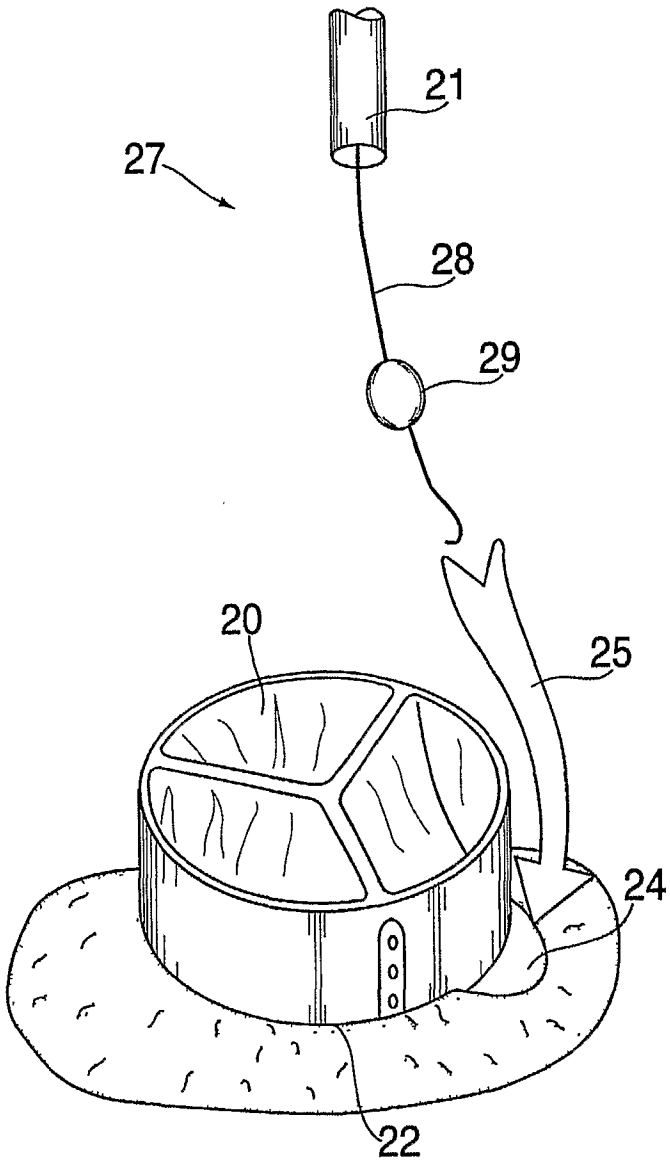


FIG. 1

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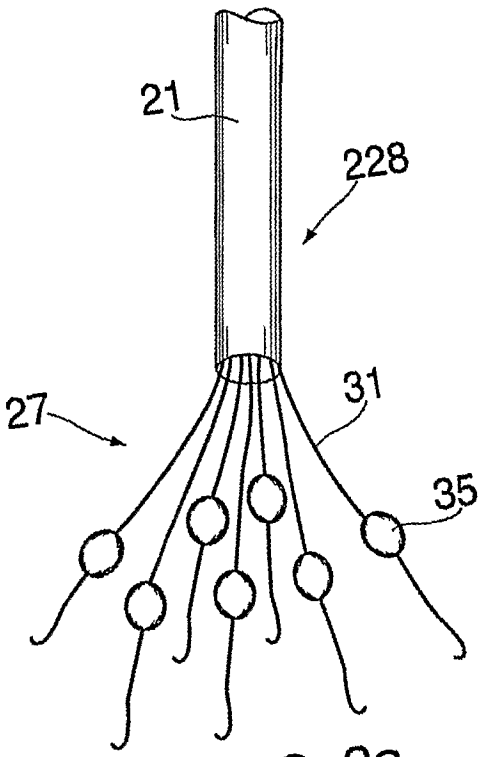


FIG. 2a

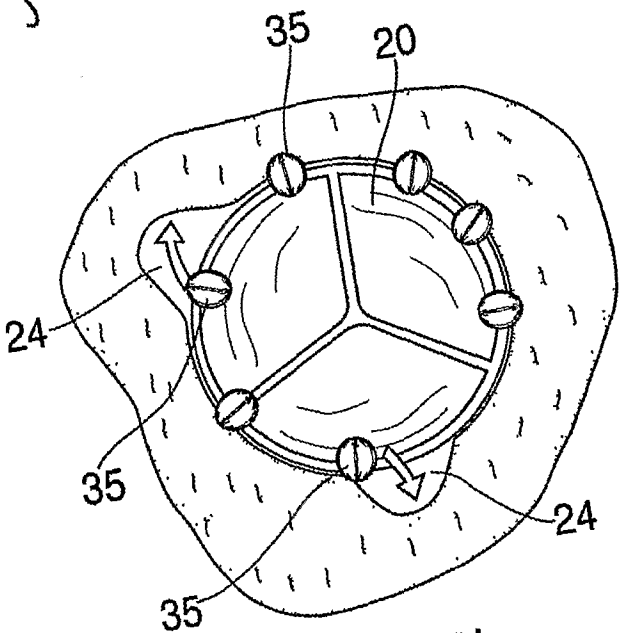


FIG. 2b

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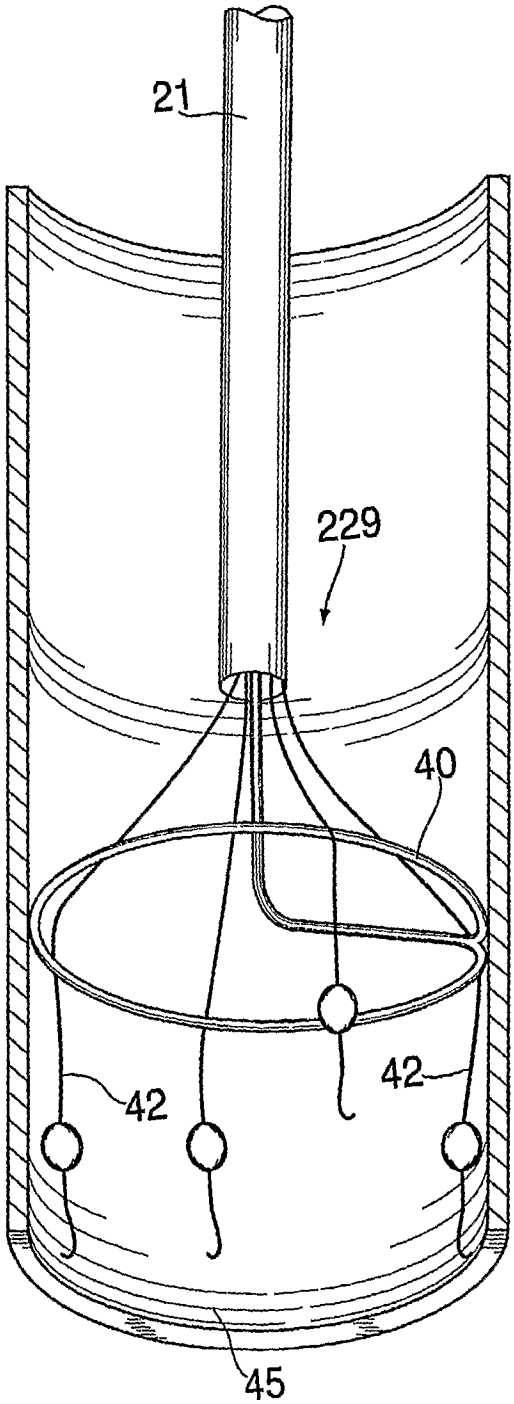


FIG. 3

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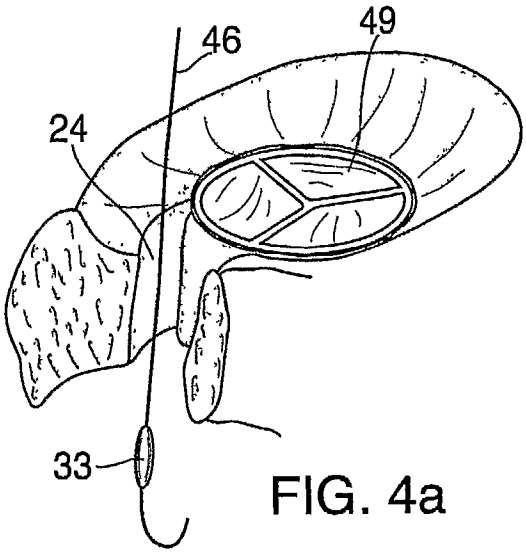


FIG. 4a

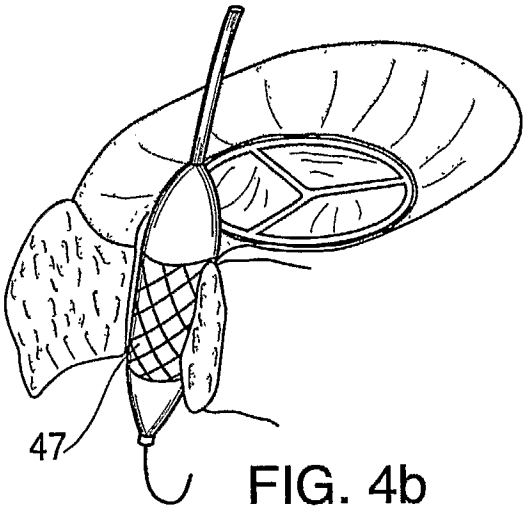


FIG. 4b

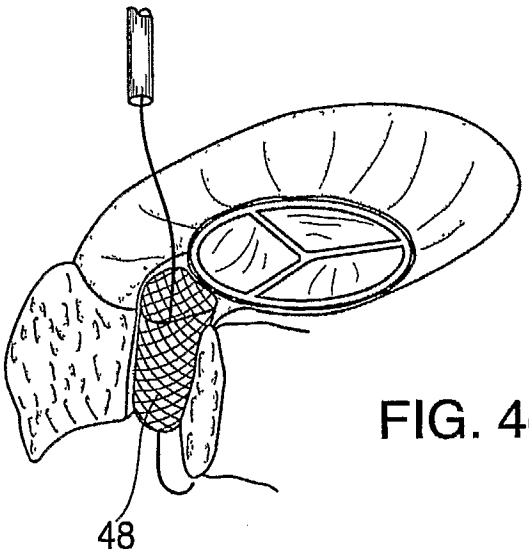


FIG. 4c

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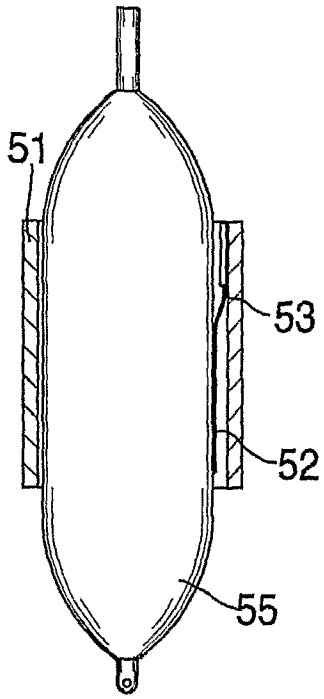


FIG. 5a

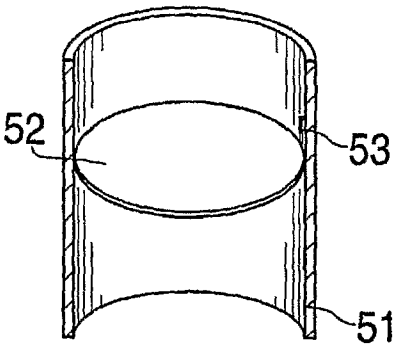


FIG. 5b

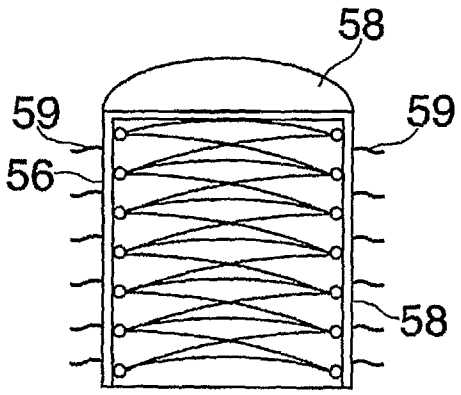


FIG. 5c

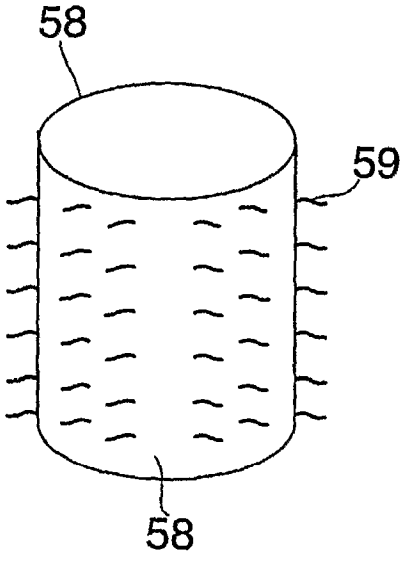


FIG. 5d

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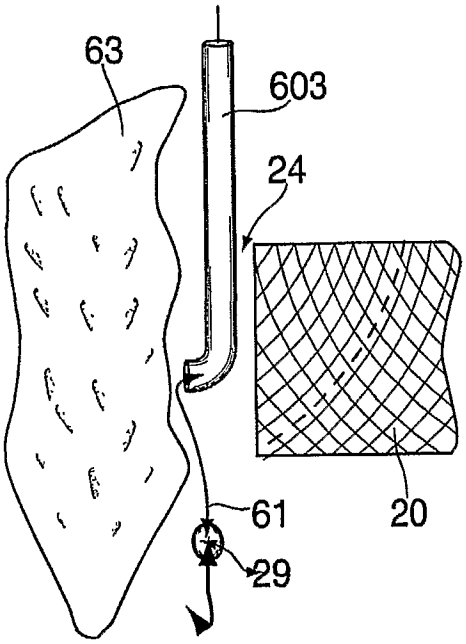


FIG. 6a

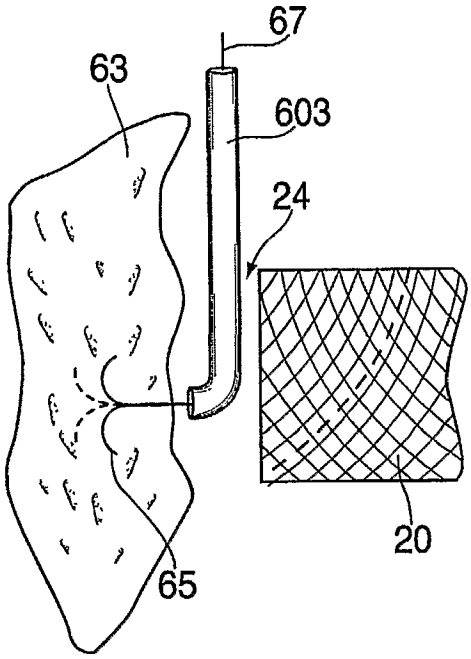


FIG. 6b

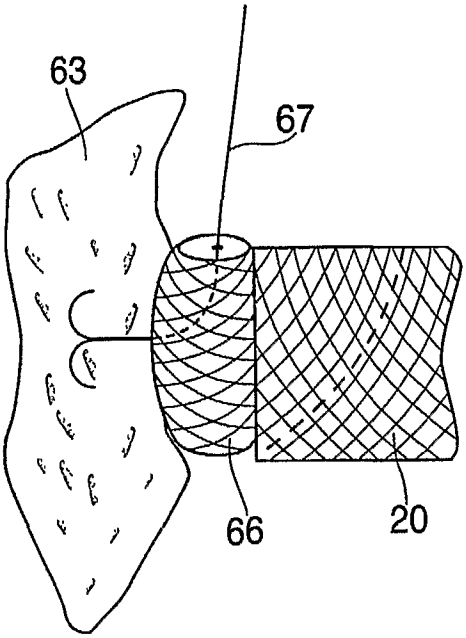


FIG. 6c

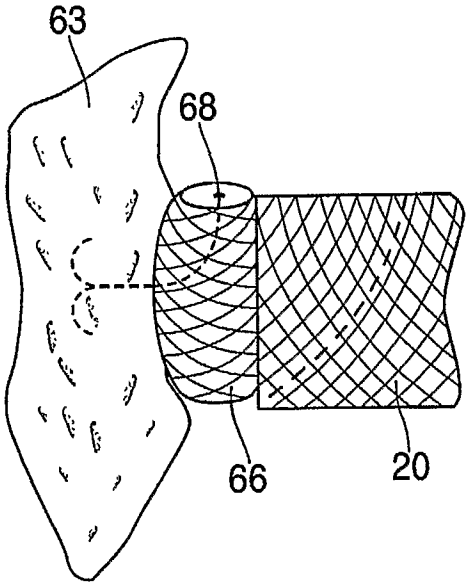


FIG. 6d

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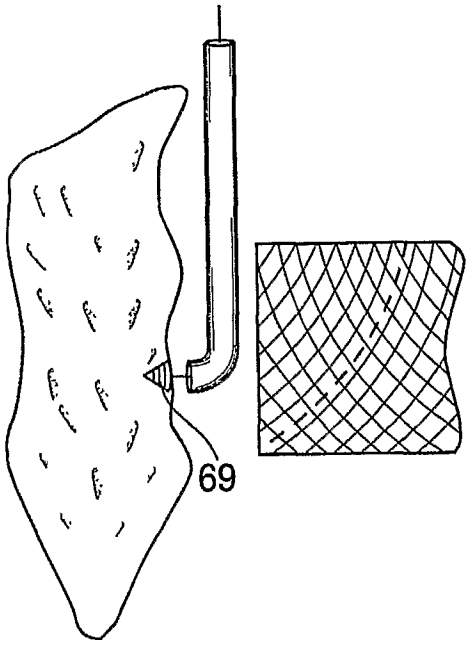


FIG. 7

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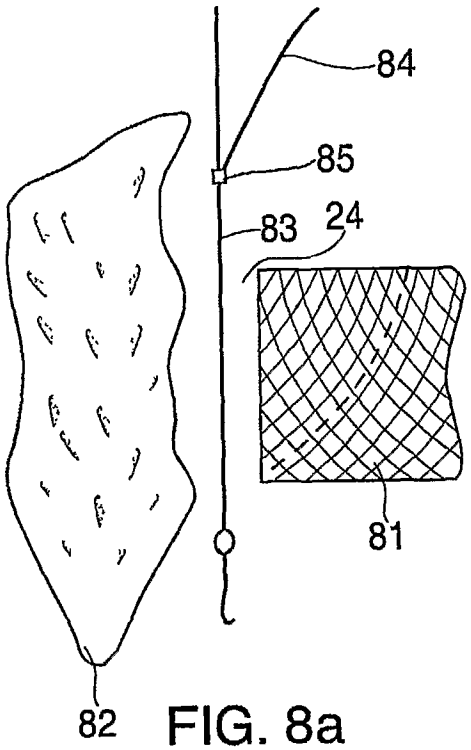


FIG. 8a

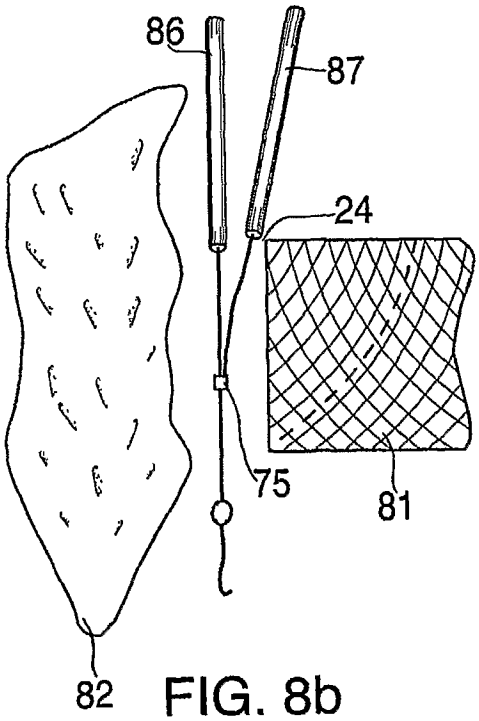


FIG. 8b

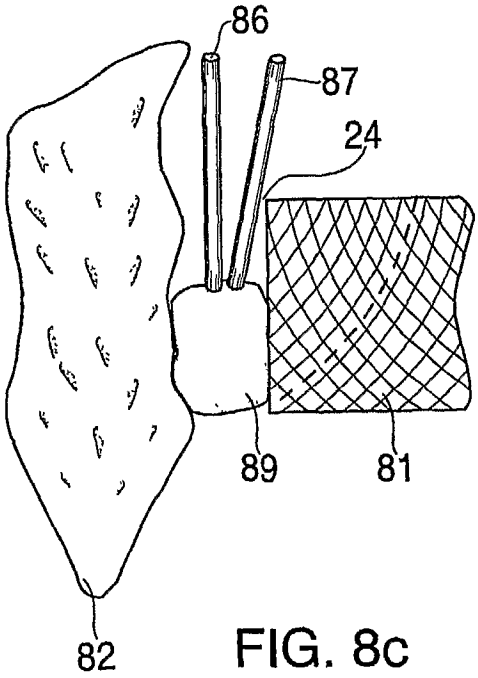


FIG. 8c

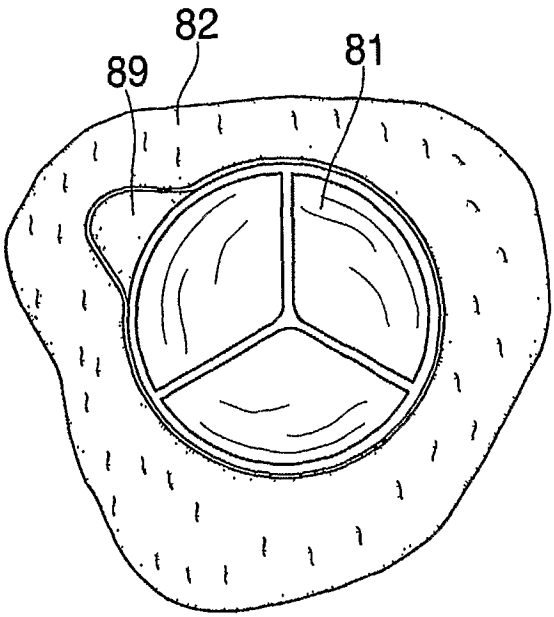


FIG. 8d

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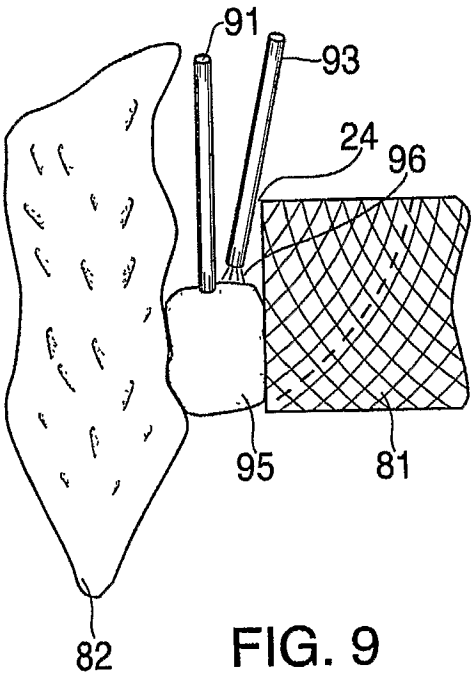


FIG. 9

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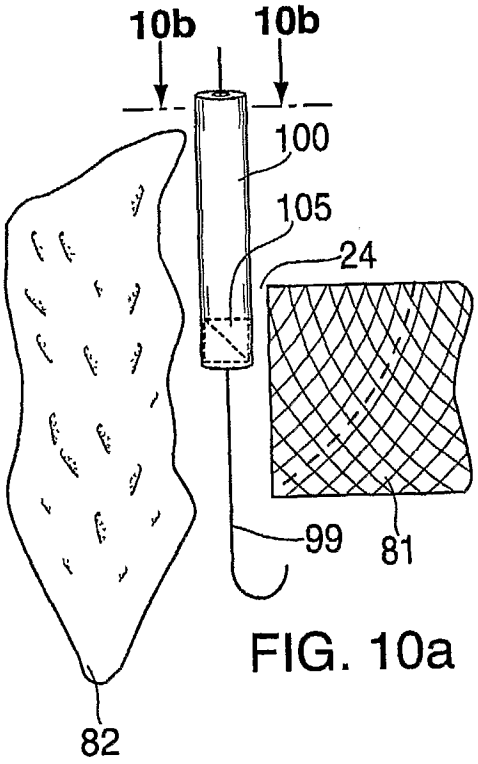


FIG. 10a

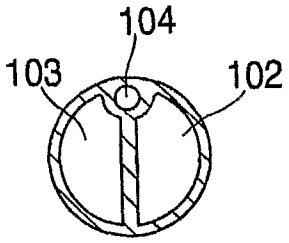


FIG. 10b

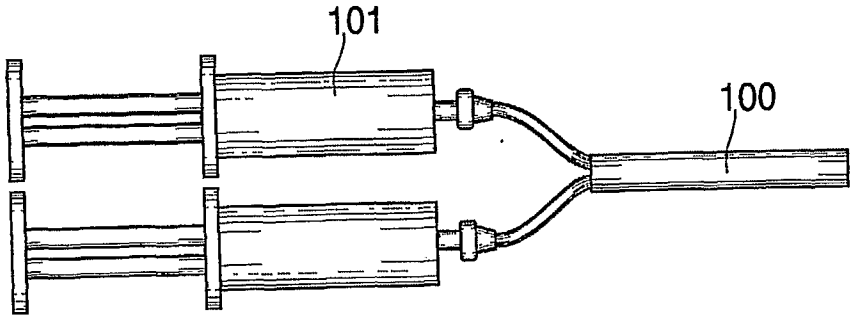


FIG. 10c

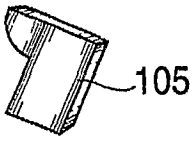


FIG. 10d

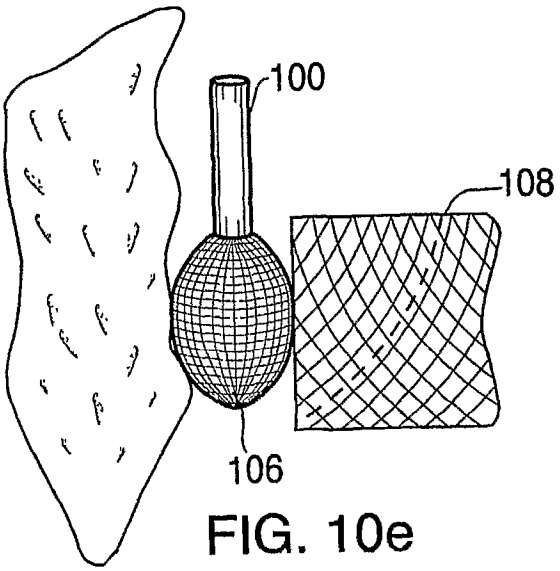


FIG. 10e

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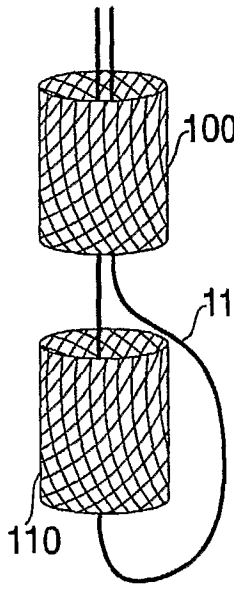


FIG. 11a

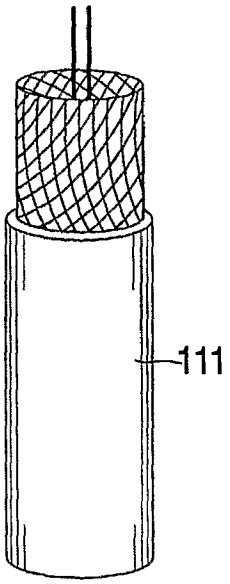


FIG. 11b

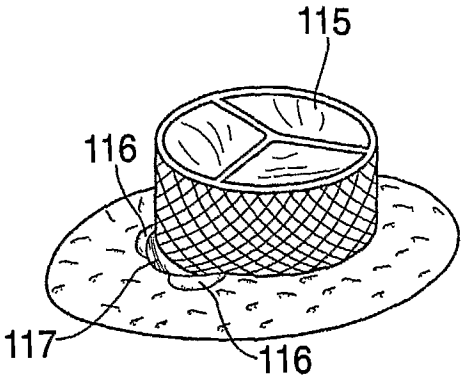


FIG. 11c

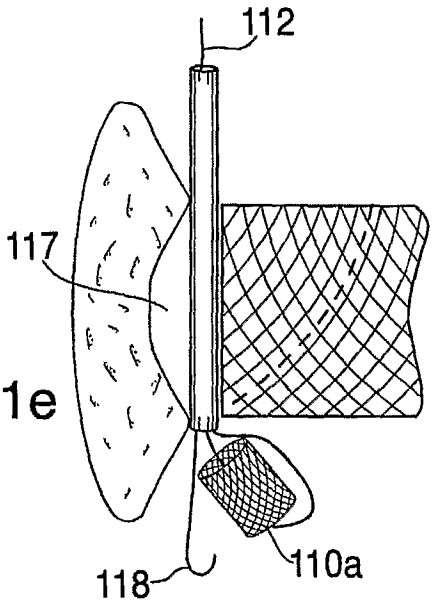


FIG. 11e

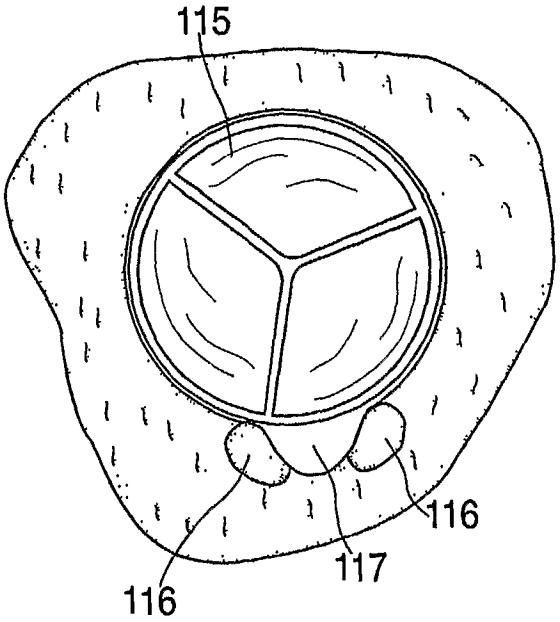


FIG. 11d

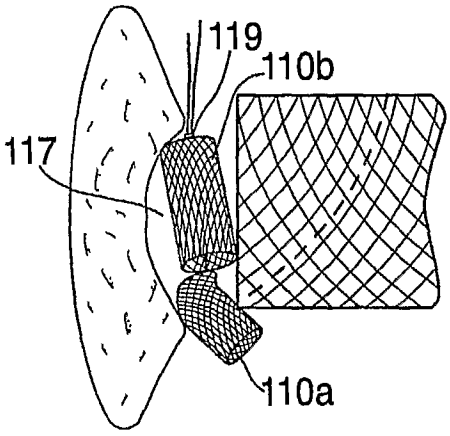


FIG. 11f

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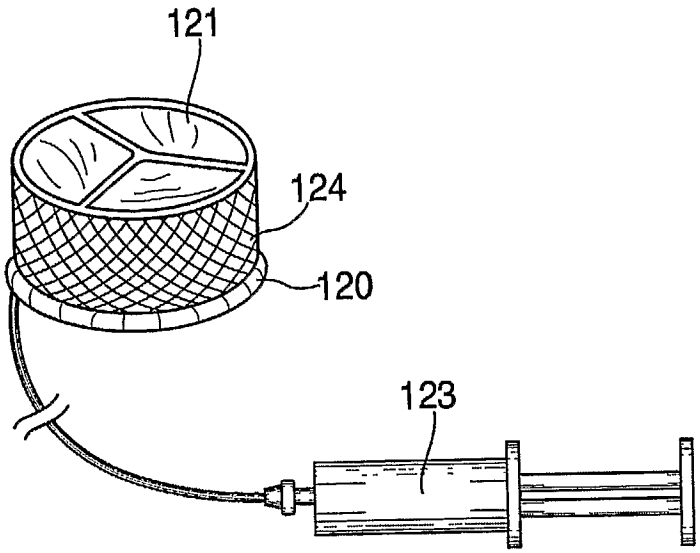


FIG. 12

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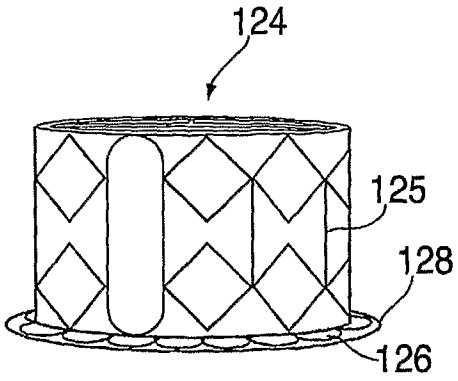


FIG. 13a

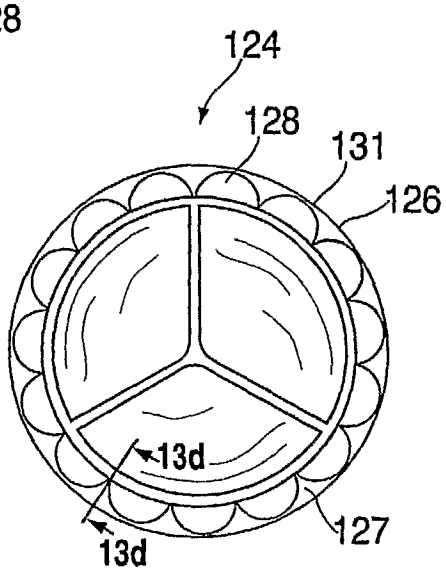


FIG. 13b

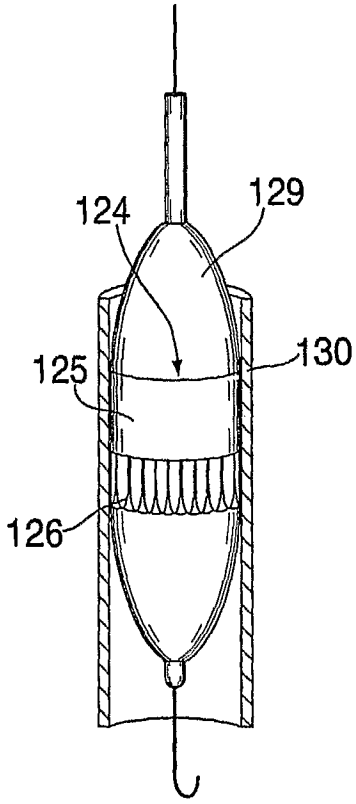


FIG. 13c

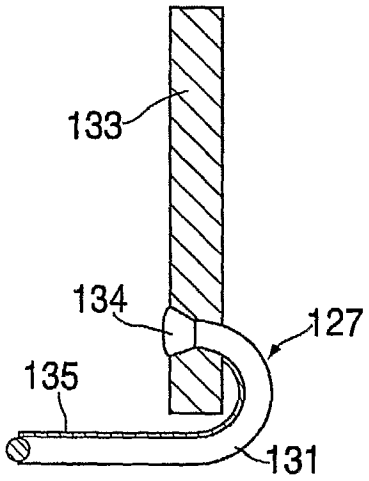


FIG. 13d

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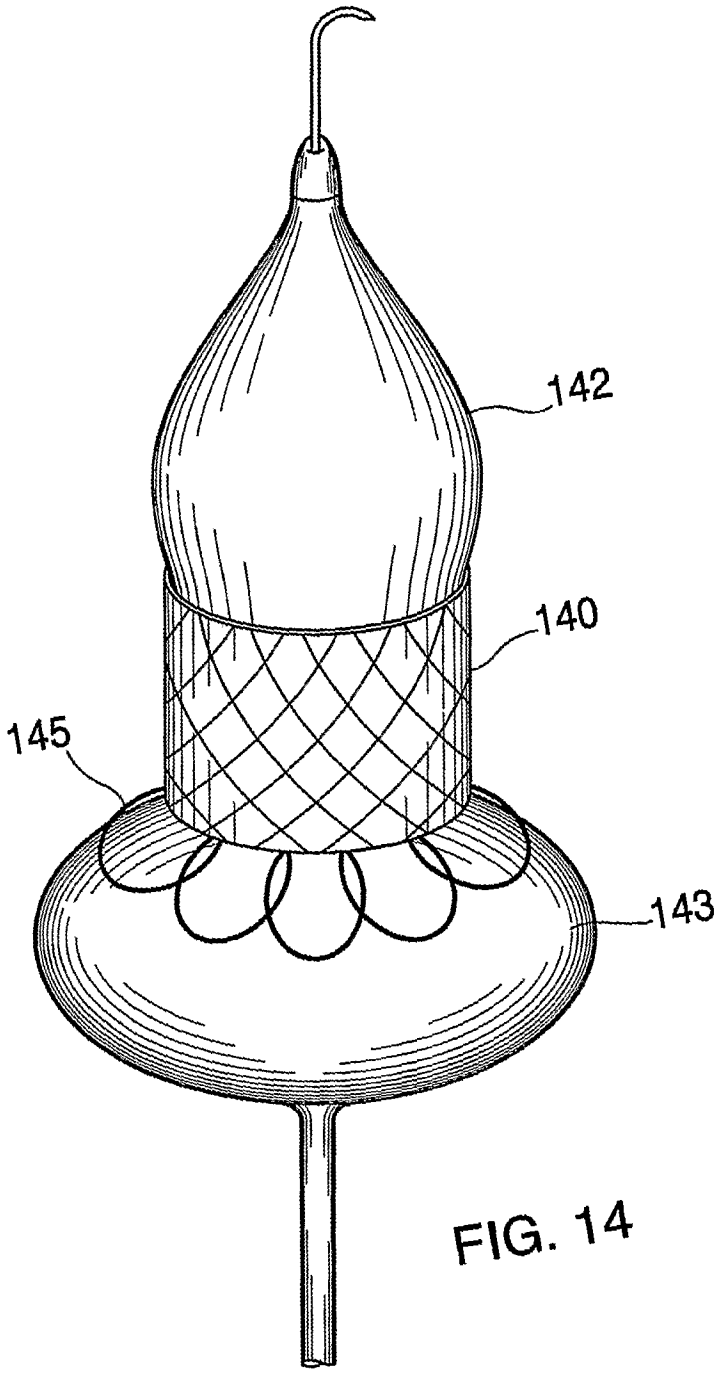


FIG. 14

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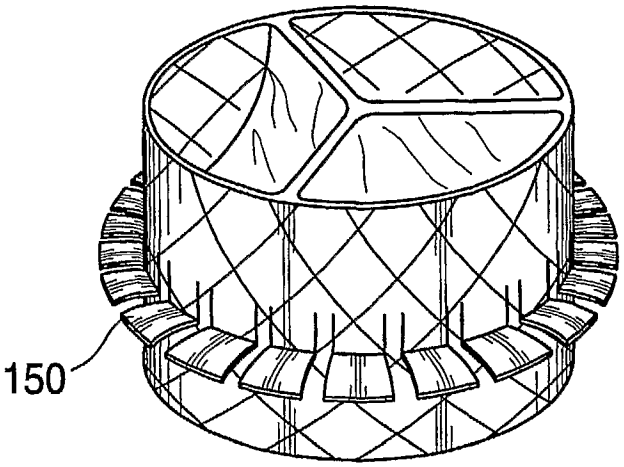


FIG. 15a

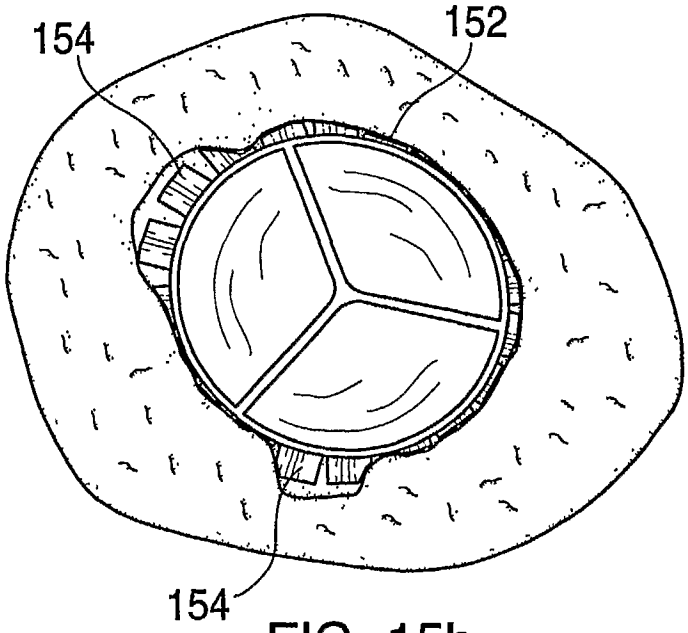


FIG. 15b

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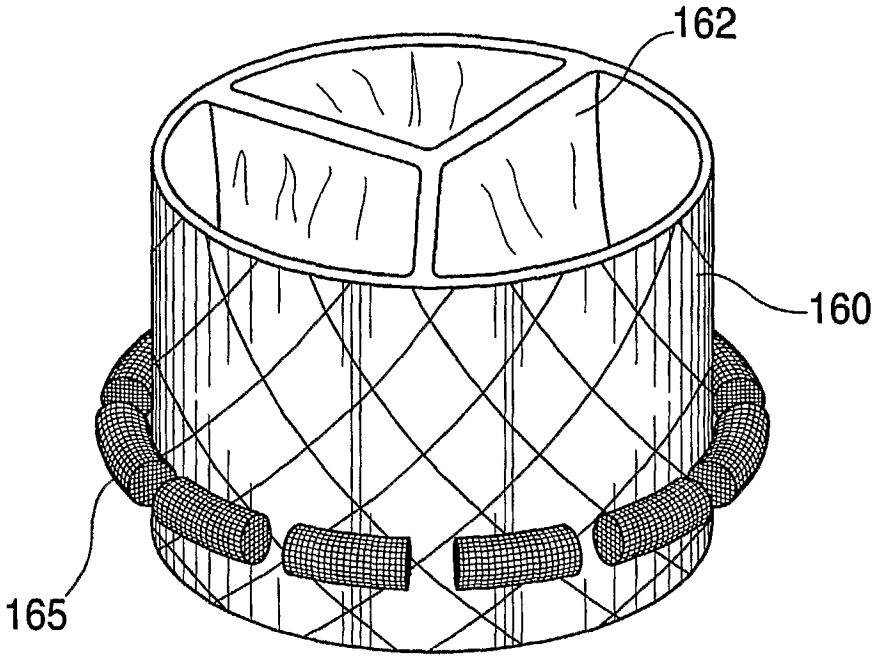


FIG. 16a

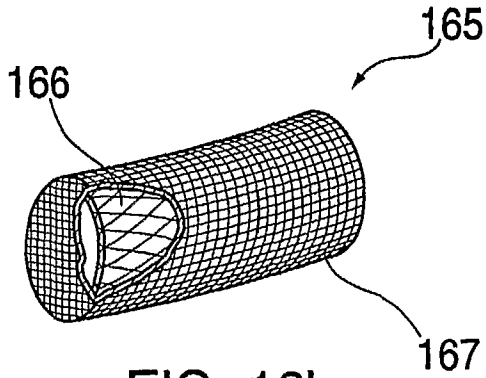


FIG. 16b

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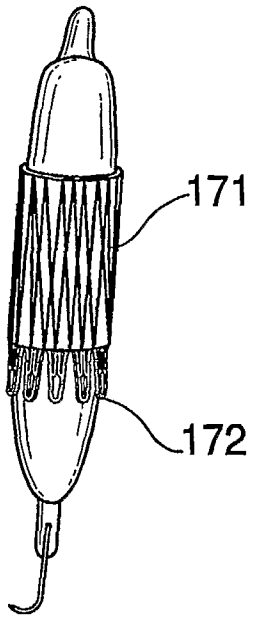


FIG. 17a

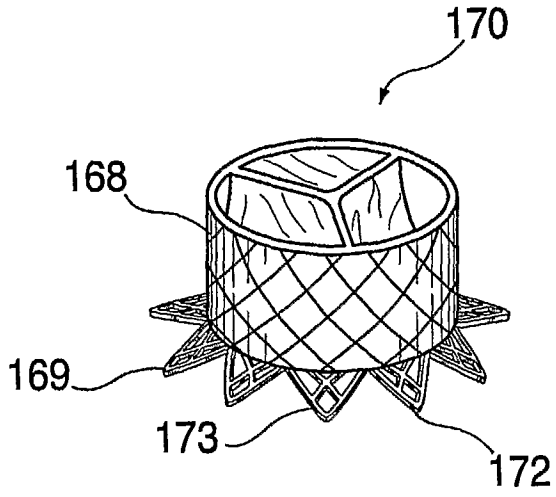


FIG. 17b

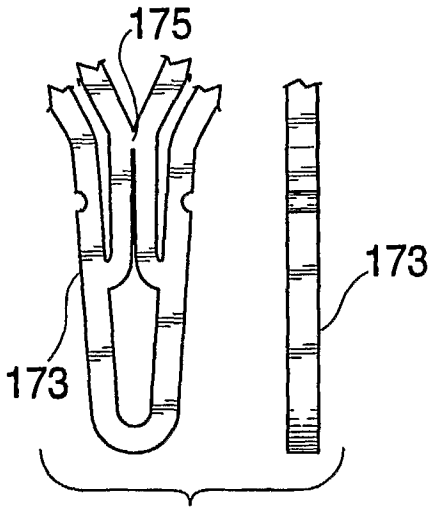


FIG. 17c

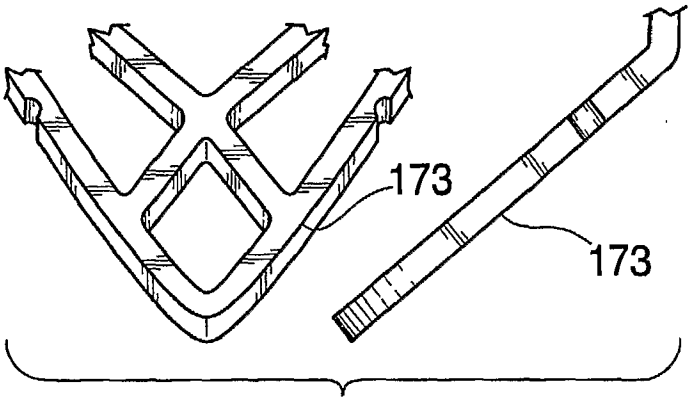


FIG. 17d

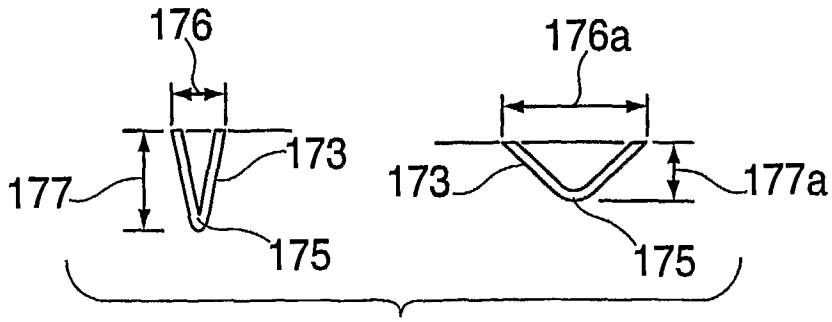


FIG. 17e

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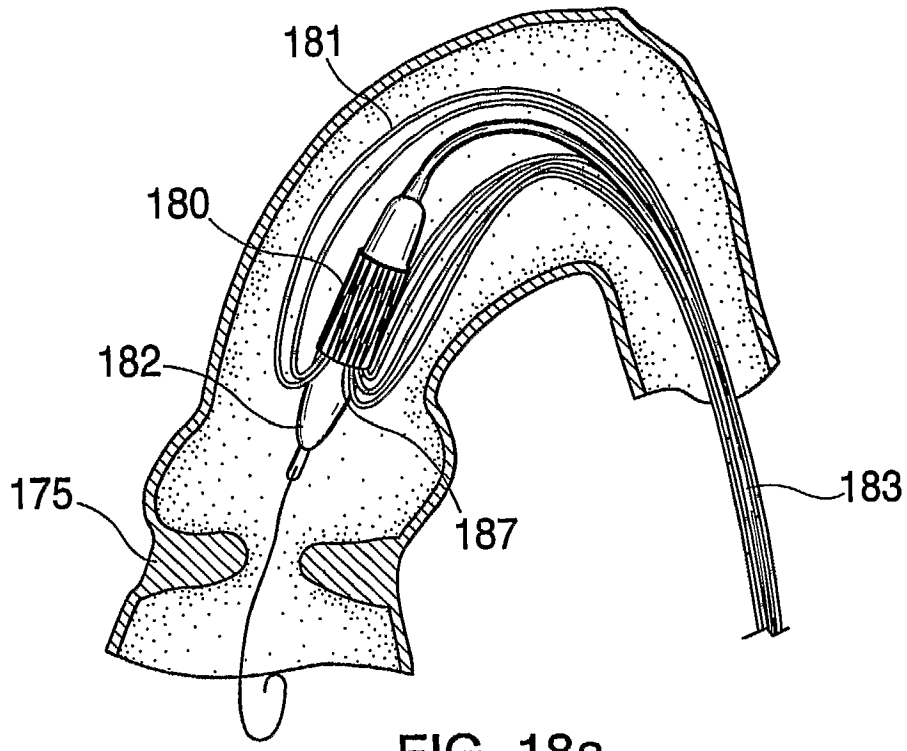


FIG. 18a

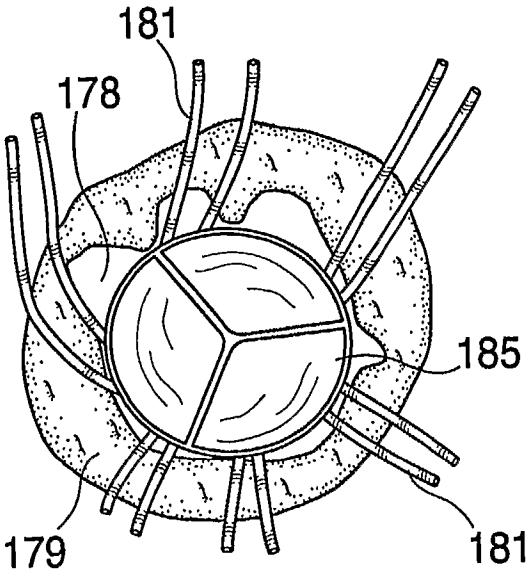


FIG. 18c

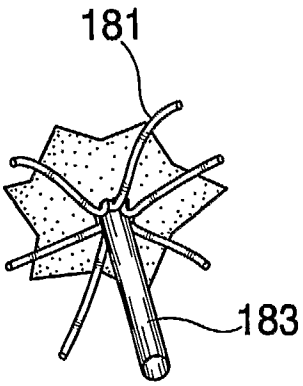


FIG. 18b

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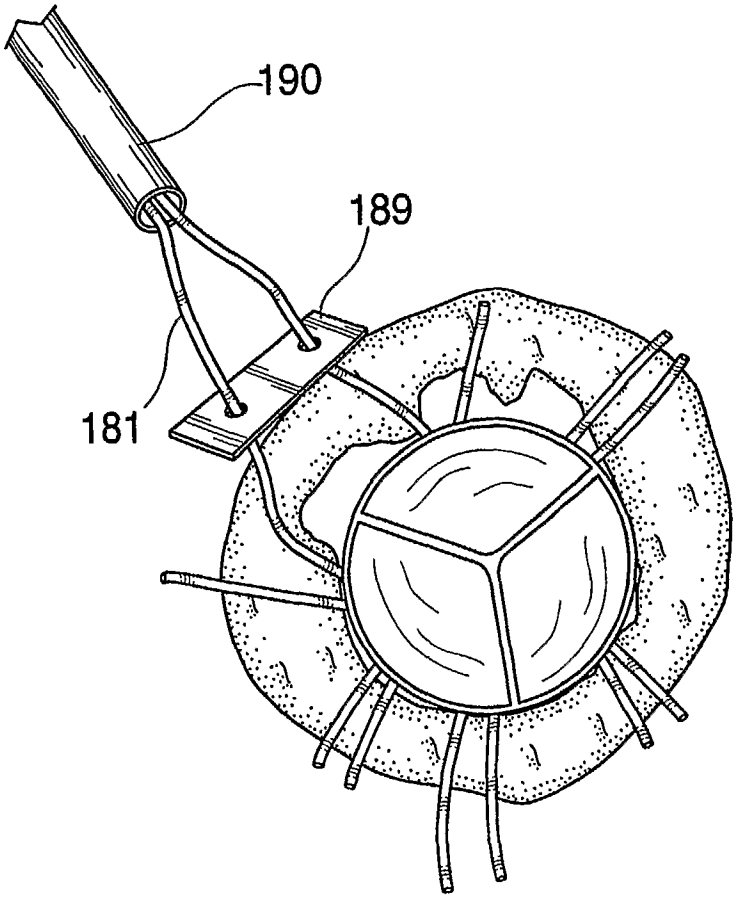


FIG. 18d

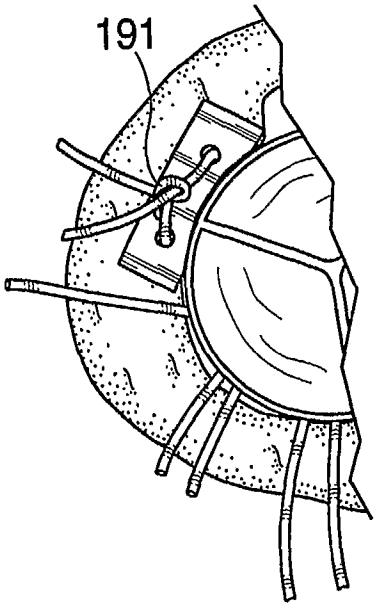


FIG. 18e

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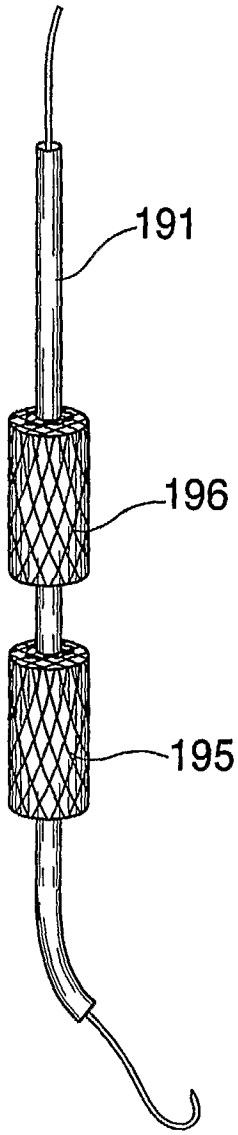


FIG. 19a

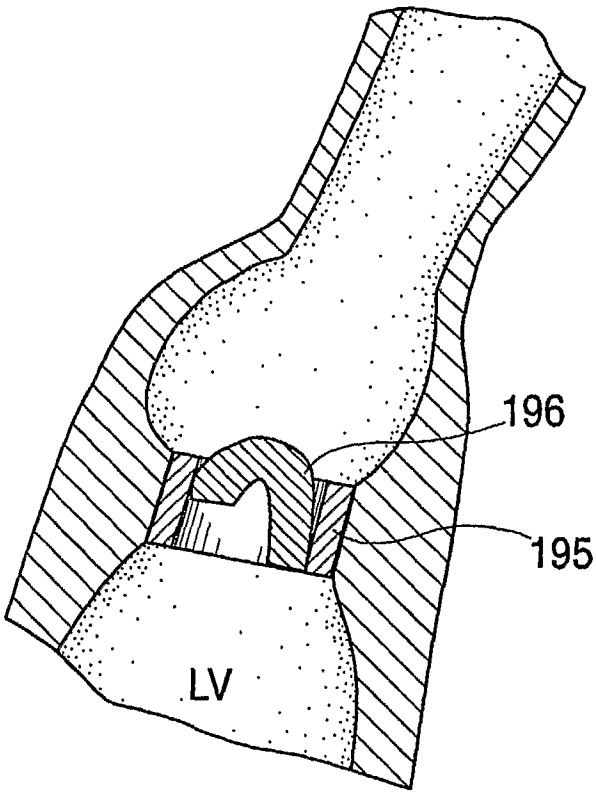


FIG. 19b

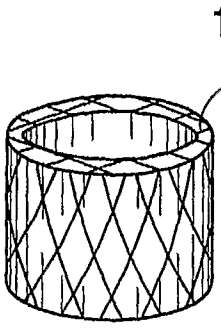


FIG. 19c

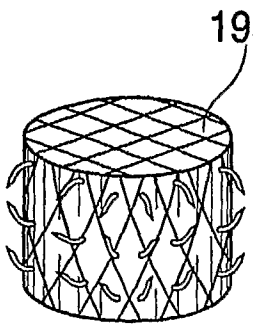


FIG. 19d

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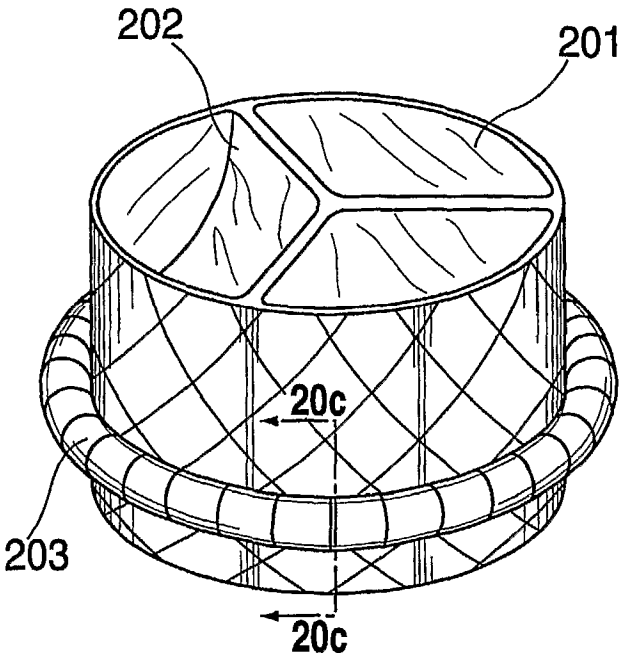


FIG. 20a

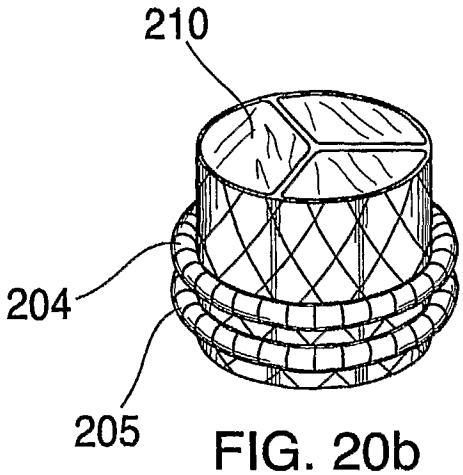


FIG. 20b

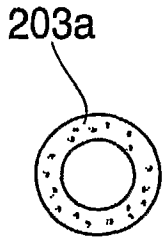


FIG. 20c

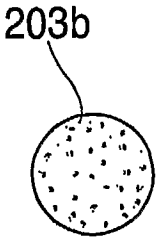


FIG. 20d

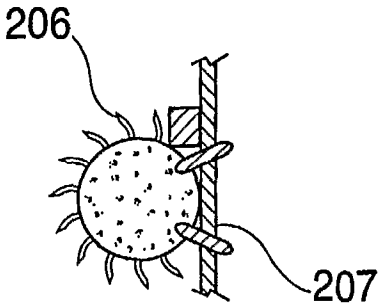


FIG. 20e

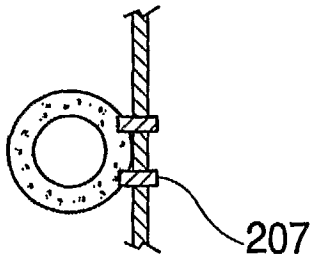


FIG. 20f



FIG. 20g

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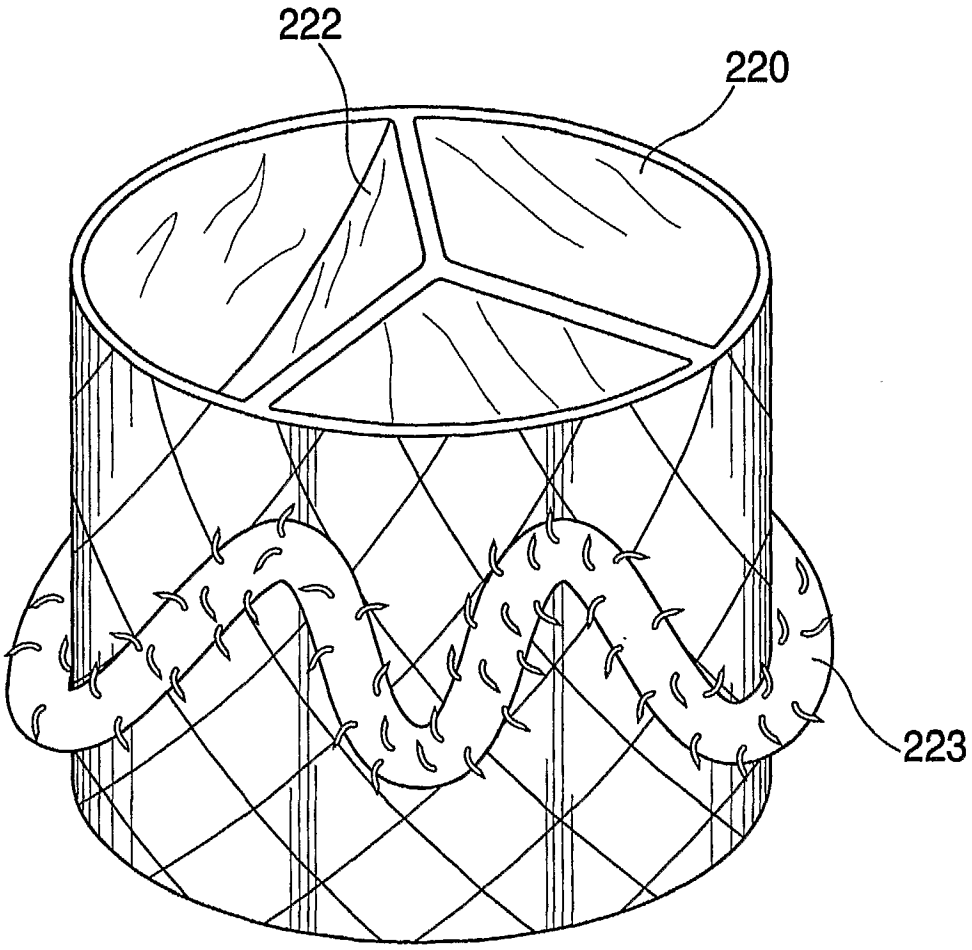


FIG. 21

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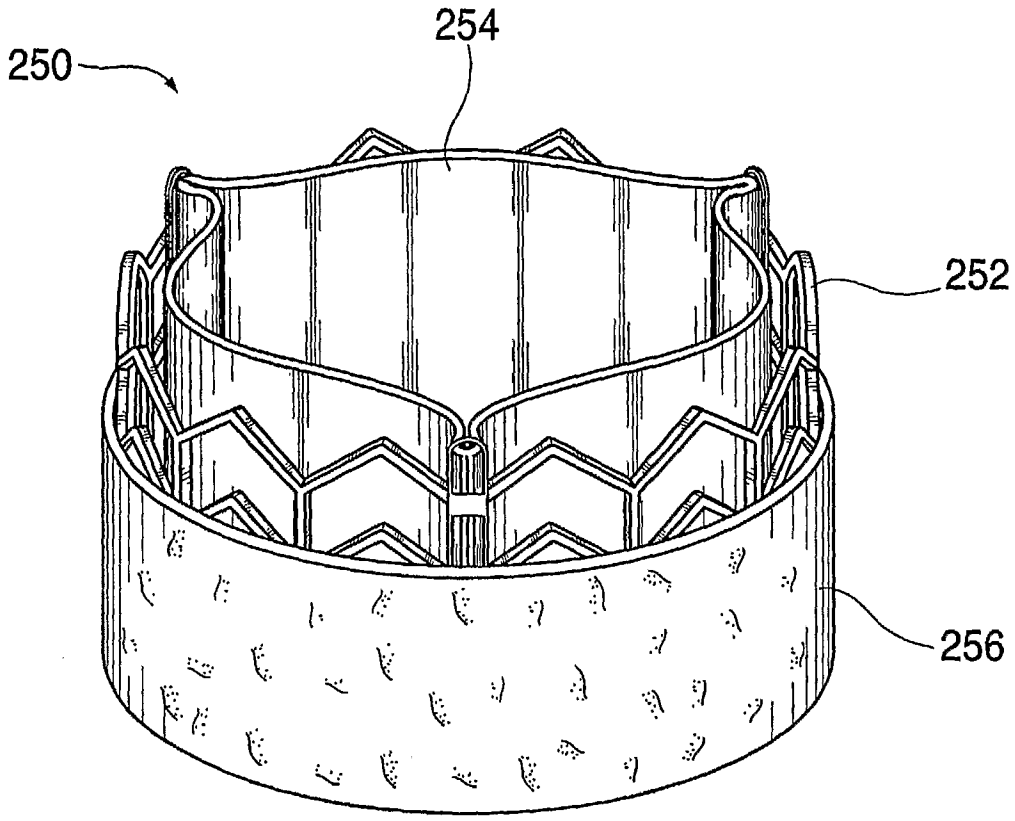


FIG. 22

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REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5554184 A **[0003]**
- US 6454799 B **[0005]**
- US 6638257 B **[0007]**
- US 20030153974 A **[0009]**
- US 5258023 A **[0015]**
- US 4106129 A **[0015]**
- WO 0064380 A **[0015]**
- FR 2815844 **[0015]**

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A61F 2/24 *(2006.01)*

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05769359.0 / 1 765 225

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Remarks:
This application was filed on 10-08-2015 as a divisional application to the application mentioned under INID code 62.

(54) PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

(57) The present invention provides a series of new percutaneous concepts of paravalvular repairs including identifying the leak location, several repair techniques and finally built-in means for leak prevention, built on percutaneous valves. A catheter-delivered device locates cavities occurring between a prosthetic valve (250) and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

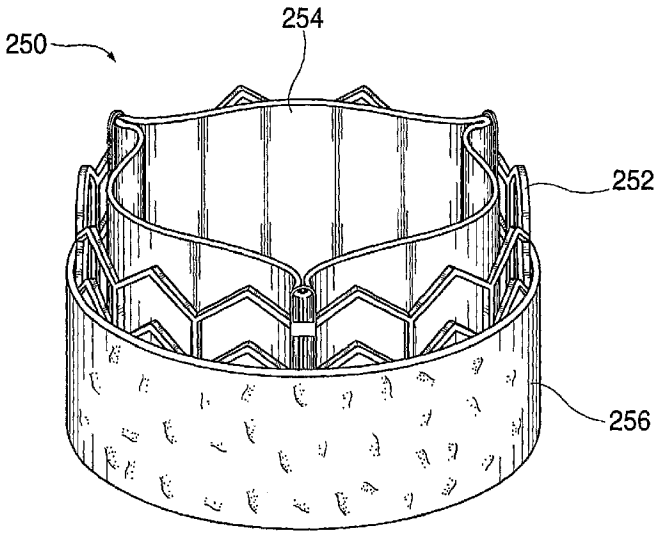


FIG. 22

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly it relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses.

BACKGROUND OF THE INVENTION

[0002] Cardiac valve implantation is well known in the art. Less well addressed is how to detect possible leaks between the valve and surrounding blood vessel, how to seal such leaks, or how to design the valve such that it automatically seals the leaks.

[0003] Machiraju in U.S. Patent No 5,554,184, entitled "HEART VALVE ", describes a heart valve and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart, including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs.

[0004] Machiraju does not address leaks that can occur around the implanted valve.

[0005] Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE", describes expandable heart valves for minimally invasive valve replacement surgeries. In a first embodiment, an expandable preassembled heart valve includes a plastically-expandable annular base having a plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

[0006] Schreck also does not address leaks that can occur around the implanted valve.

[0007] Amplatz in U.S. Patent No. 6,638,257, entitled, "INTRAVASCULAR FLOW RESTRICTOR," describes an intravascular flow restrictor that comprises a braided tubular structure designed to be placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter, but when it is ejected from the delivery catheter, it assumes a substantially larger diameter disk shaped device having one or more longitudinal channels or passways therethrough.

[0008] Amplatz also does not address leaks that can occur around the implanted valve. In addition, Amplatz's braided structures are of a shape and size not appropriate for paravalvular leak detection and sealing. Their geometry is designed for the conditions of the transceptal hole and not appropriate for valve leakage.

[0009] Spenser et al. in U.S. Patent Application No. 20030153974, entitled "IMPLANTABLE PROSTHETIC VALVE", describe a prosthesis device suitable for implantation in body ducts. The device comprises a support stent bring comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent bring provided with a plurality of longitudinally rigid support beams of fixed length, and (2) a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet. When flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly to provide blockage to the reverse flow.

[0010] Spenser et al. also do not address leaks that can occur around the implanted valve.

[0011] With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use of newer percutaneous methods, some of which are described in the patents mentioned above. With both methods paravalvular leaks are a known side effect. One way to approach the leak problem is to identify the leak location and repair it. Another approach is to equip the prosthesis with means to prevent the leak ("self-sealing" prosthesis). Both these approaches are encompassed by the present invention.

[0012] Percutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation. In contrast, surgical placement involves a large chest surgical incision and requires general anesthesia, to expose a large portion of a patient's thoracic region.

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Percutaneous introduction is therefore considered safer and less invasive.

[0013] Percutaneous introduction of a leak detection and repair device or of a self-sealing valve resembles other known interventional cardiologic procedures. The percutaneous deployment procedure and device has an impact on several parameters of the product design, some of which are explained hereinafter.

[0014] In summary, the present invention provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, a catheter-delivered device is provided for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0016] Furthermore, in accordance with another preferred embodiment of the present invention, a spacing element is provided to maintain the wires adjacent to the wall of the body vessel.

[0017] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The stent, which is delivered via a guidewire to the cavity and held in place in the cavity by friction, comprises a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

[0018] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is balloon-expandable and the membrane comprises a tab spring-hinged to the inside of the stent lumen and sized to occlude the lumen when closed. The tab is held open by the stent balloon during insertion and springs closed when the balloon is removed after the stent is expanded.

[0019] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

[0020] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is comprised of shape memory material.

[0021] Furthermore, in accordance with another preferred embodiment of the present invention, the material is nitinol.

[0022] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

[0023] Furthermore, in accordance with another preferred embodiment of the present invention, the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

[0024] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter delivery into the vessel wall, whereupon the hook extends out, anchoring the guidewire into the vessel wall.

[0025] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guidewire into the vessel wall.

[0026] Also provided in accordance with a preferred embodiment of the present invention, is a device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first guidewire and inserted such that the slidable coupling is moved to a desired point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the desired point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the desired point, a second component of the two-component adhesive inserted through the second catheter to the desired point, the two components thereby mixing to form a plug that seals the cavity.

[0027] Furthermore, in accordance with another preferred embodiment of the present invention, the device is adapted to apply an adhesive with more than two components.

[0028] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, and the catheter terminates in a mixer that forces the components to mix when they exit the catheter in the cavity, thereby creating the plug that seals the cavity.

[0029] Furthermore, in accordance with another preferred embodiment of the present invention, instead of

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two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive to create the plug in the cavity.

[0030] Also provided in accordance with a preferred embodiment of the present invention is a catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The assembly is delivered via guidewire to the cavity and comprises two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane. One stent of the assembly is inserted underneath the cavity and the other stent is inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

[0031] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0032] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a balloon.

[0033] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0034] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprises a balloon under the tabs. The tabs are folded down on the deflated balloon during catheter delivery, and, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

[0035] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0036] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0037] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0038] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

[0039] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body. Patches can be pushed down the sutures and attached to the point where the suture is attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0040] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed. The elastic stent seals any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0041] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for locating cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

inserting a balloon mounted on a flexible wire next to the valve,

wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0042] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

inserting an impermeable stent into the cavity,

whereby the stent seals the cavity.

[0043] There is thus also provided in accordance with

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a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

inserting a first guidewire into the cavity;

running a loop attached to a second guidewire over the first guidewire to a point inside the cavity;

injecting one component of a two-component adhesive through a catheter over the first guidewire to the cavity; and

injecting the second component of the two-component adhesive through a catheter over the second guidewire to the cavity,

wherein the components combine to create an adhesive plug that seals the cavity.

[0044] Furthermore, in accordance with another preferred embodiment of the present invention, instead of the first adhesive component, a radiation-cured adhesive is injected and instead of the second adhesive component a radiation source is applied, thereby creating the adhesive plug.

[0045] Furthermore, in accordance with another preferred embodiment of the present invention, only one guidewire is used and the two components are inserted via separate lumens within a single catheter over the guidewire.

[0046] In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps. Furthermore, fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage. In one variation, a tissue growth factor may be disposed on the material to encourage tissue growth between the material and the surrounding tissue.

[0047] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for providing integrated sealing capability in an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

providing an expandable elastic ring around the outside of the valve; and

expanding the ring,

wherein the ring seals any cavities.

[0048] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

inserting a sealing stent at the distal end of the cavity; and

inserting a second sealing stent attached to the first stent into the cavity.

BRIEF DESCRIPTION OF THE FIGURES

[0049] To better understand the present invention and appreciate its practical applications, the following Figures are provided and referenced hereafter. It should be noted that the Figures are given as examples only and in no way limit the scope of the invention as defined in the appended claims. Like components are denoted by like reference numerals.

Figure 1 illustrates an implanted valve with a cavity creating a paravalvular leak and a device, in accordance with a preferred embodiment of the present invention, comprising a soft guidewire with an inflatable balloon and designed to identify the exact location of the paravalvular leak.

Figures 2a and 2b depict a plurality of balloons on soft guidewires, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

Figures 4a to 4c depict the process, in accordance with another preferred embodiment of the present invention, of inserting a sealing stent over a guidewire to close a paravalvular leak.

Figures 5a to 5d depict several types of sealing stents, in accordance with another preferred embodiment of the present invention.

Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device, in accordance with another preferred embodiment of the present invention, assisted by anchors, which attach the device to the aortic wall (or annulus).

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Figure 7 illustrates an anchoring apparatus, in accordance with another preferred embodiment of the present invention, for achieving sealing as shown in Figure 6, in this case by use of a screw, which is embedded into to the aortic wall (or annulus).

Figures 8a and 8b depict a leak repair done, in accordance with another preferred embodiment of the present invention, using a two-component biological glue.

Figures 9a to 9c depict a leak repair done, in accordance with another preferred embodiment of the present invention, using an ultra-violet light-cured biological glue.

Figure 10 illustrates a catheter, in accordance with another preferred embodiment of the present invention, that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

Figures 11a to 11f illustrate a device and procedure, in accordance with another preferred embodiment of the present invention, for blocking a paravalvular leak using two connected sealing stents.

Figures 12 depicts a valve, in accordance with another preferred embodiment of the present invention, with a built-in inflatable portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

Figures 13a to 13d illustrate a valve, in accordance with another preferred embodiment of the present invention, having a flexible and self-expanding portion for blocking possible leaks around the stent.

Figures 14a to 14c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

Figures 15a to 15c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a plurality of flexible and expanding segments on its proximal side for blocking possible leaks around the stent.

Figures 16a and 16b illustrate a valve device, in accordance with another preferred embodiment of the present invention, comprising an additional portion for blocking possible leaks around the stent.

Figures 17a to 17e illustrate a valve device, in accordance with another preferred embodiment of the present invention, where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

Figures 18a to 18e illustrate a valve, in accordance with another preferred embodiment of the present invention, constructed with additional sutures attached to the proximal side, allowing attachment of extra pieces of pericardium or artificial fabric for blocking paravalvular leaks.

Figures 19a to 19d depict a procedure, in accordance with another preferred embodiment of the present invention, the procedure comprising two stages: first, insertion of a stent that includes an outer sealing layer; and second, insertion of a prosthetic valve through the stent.

Figures 20a to 20g illustrate a valve, in accordance with another preferred embodiment of the present invention, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

Figure 21 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

DETAILED DESCRIPTION OF THE INVENTION

[0050] The present invention provides methods and apparatuses for substantially reducing or effectively eliminating the deleterious effects of paravalvular leaks in prosthetic valves. More specifically, it enables locating, sealing, and preventing paravalvular leaks using both dedicated and integrated (with the valve) means.

[0051] While the present invention is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve, it can also be applied to other leakage problems such as in other blood vessels, a septum, or other body lumens. Similarly, while the prosthetic valve described herein is a tricuspid valve, it could be another type of valve as well.

[0052] A main aspect of the present invention is the introduction of several novel designs and methods for locating paravalvular leaks in prosthetic valves.

[0053] Another main aspect of the present invention are several novel designs for sealing paravalvular leaks detected in prosthetic valves.

[0054] Another main aspect of the present invention are several novel designs for modifying percutaneous prosthetic valves to automatically seal paravalvular leaks

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when the valve is implanted.

[0055] Another main aspect of the present invention is a novel design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

[0056] Another main aspect of the present invention is the disclosure of several novel designs for modifying percutaneous prosthetic valves to enable sealing of paravalvular leaks after the valve is implanted.

[0057] For locating paravalvular leaks, the present invention provides several designs comprising catheter-delivered balloons mounted on flexible guidewires. The balloons are delivered to a point near the valve. When regurgitation (leaking) occurs during diastole, the balloons are drawn into the leak-producing cavities occurring between the valve and the wall of the blood vessel, thereby providing a means to deliver means for sealing the leak.

[0058] For sealing paravalvular leaks, the present invention provides several designs including sealing stents, and multi-component and radiation-cured adhesive compounds.

[0059] Sealing stents are crimped stents that are delivered to the leak location, expanded, and anchored in place. The stents are designed to block flow, thereby sealing the leak. Several innovations are provided for these operations.

[0060] Delivery of the sealing stent is via a guidewire that is anchored in the wall of the blood vessel at the leak location. The anchoring means can be a hook, for example a multi-headed hook composed of a shape memory alloy, such as nickel titanium (also known as nitinol), which is crimped at low temperature for delivery. The anchoring means expands back to its original shape due to the higher temperature of the blood vessel wall at its deployment point, thereby anchoring itself into the blood vessel wall.

[0061] Another anchoring means is for the guidewire to be terminated in a screw, which can be threaded into the blood vessel wall.

[0062] Once delivered to the leak location via the guidewire, the sealed stent is expanded. This can be done by another agent, such as a balloon, or by making the stent self-expanding. In the case of balloon inflation, the stent is crimped around the deflated balloon prior to insertion in the delivery catheter. Upon delivery the balloon is inflated, thereby expanding the stent, and then the balloons can be deflated and withdrawn. In the case of the self-expanding stent, the stent is preferably built from a shape memory alloy, such as nickel titanium (also known as nitinol), which can be crimped at low temperature for delivery, expanding back to its original shape due to the higher body temperature at the deployment site. Alternatively the self-expanding stent can be a metallic stent comprised of a physiologically acceptable metal such as stainless steel or an alloy such as nitinol, which is compressed or wound on a delivery, catheter or device. When the stent is released from the delivery catheter or device, it expands.

[0063] The sealing stent is held in place by friction. Additional holding force can be obtained by adding hooks around the perimeter of the stent, such as self-expanding hooks made of shape memory alloy.

[0064] The expanded stent includes an internal element that seals the stent's own lumen, preventing flow through the stent and thereby sealing the cavity causing the leak. Examples of internal sealing elements include a spring-hinged flap inside the stent lumen that opens upon stent expansion or, in the case of the self-expanding stent, a membrane covering one or both openings of the stent.

[0065] In some cases, it may be preferred to use two sealing stents. In this embodiment, the two stents are connected in series by a suture. The delivery catheter is extended through the top of the cavity and out the bottom of the cavity to deploy one of the sealing stents and then, together with the stents' guide wire, retracted. This pulls the deployed stent back until it catches in the bottom of the cavity. The catheter is further retracted, and the second stent is deployed into the cavity. The catheter is further retracted and the second stent is pulled back, catching it (from the bottom) in the top of the cavity.

[0066] An alternative sealing element to the sealing stent is a biological adhesive compound that can be delivered to the cavity via catheterization. In such a case, two catheters are brought to the leak location. The catheters are used in one of the following ways: to deliver two adhesive components that, when mixed, harden to form an adhesive sealing plug, or to deliver a radiation-cured adhesive and the cure source, for example an ultra-violet light source, to produce an adhesive sealing plug.

[0067] In both sealing element designs there is a need to bring the distal catheter ends in close proximity to one another, for proper mixing or curing, at the leak point. This is accomplished as follows: a first catheter is used to insert the leak detector guidewire mentioned above. A second guidewire is fitted with a loop, and the loop is run over the first guidewire until it reaches the leak location. The respective cathethers are then slid over their guidewires to meet at the leak location, thereby providing egress for applying the bi-component adhesive or radiation-cured adhesive.

[0068] Another delivery design for a bi-component adhesive utilizes a single catheter run over the leak detection guidewire. The catheter has three lumens: one to track the guidewire and one for each adhesive component. A mixing means at the distal end of the catheter mixes the components at the leak location to form the sealing plug.

[0069] In other embodiments of the present invention, leak sealing means are integrated into the valve as an impermeable ring that, when the valve is implanted, adaptively seals any gaps between the valve and the surrounding lumen.

[0070] In one embodiment of such a self-sealing valve, the ring is deflated for delivery and then inflated for seal-

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ing.

[0071] In another self-sealing valve embodiment, the ring is a sponge-like material that is compressed for delivery and then expands for sealing.

[0072] In another self-sealing valve embodiment, the ring comprises a set of flaps that are closed for delivery and are opened either by balloon inflation, by the geometry of their connection to the valve, or by spring-action.

[0073] In another self-sealing valve embodiment, the ring comprises a set of self-expanding tubes.

[0074] In another self-sealing valve embodiment, the ring comprises struts of the valve's stent that are geometrically constrained to bend and enlarge their final diameter in respect to the main stent geometry when expanded from the crimped form

[0075] In another embodiment where sealing means are built into the valve, a set of filament pairs are attached around the valve and feed back to the delivery catheter ingress. When a paravalvular leak is detected, impermeable patches of a material such as pericardium are threaded onto the local filament pair and pushed down to the leak location where they are tied off in place.

[0076] In another embodiment of the present invention, a sealing stent is first inserted into the lumen, and then the valve is inserted inside the sealing stent.

[0077] The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different types of devices are discussed with reference to the drawings. Note that the drawings are only given for the purpose of understanding the present invention and presenting some preferred embodiments of the present invention. The drawings are not meant to limit the scope of the present invention as defined in the appended claims.

[0078] Figure 1 illustrates a simple leak detector 27 in accordance with a preferred embodiment of the present invention. Leak detector 27 detects a leak between general tricuspid implantable prosthesis valve 20 and the aortic annulus 22. Leak detector 27 will typically be used together with leak sealing devices, like those described later in this specification.

[0079] A cavity 24 exists between the perimeter of valve 20 and aortic annulus 22. The cavity could have any number of causes, including calcification or other irregularities in the aortic annulus 22 that prevent proper sealing between the valve 20 and the annulus 22. The cavity will cause regurgitation (leaking) during diastole, characterized by blood flowing 25 from the aorta into the left ventricle. Leak detector 27, is delivered through catheter 21 to a position above valve 20. Leak detector 27 comprises a soft guide wire 28 on which is mounted inflatable balloon 29, which is inflated after leak detector 27 has been passed through catheter 21. Guidewire 28 is soft enough that during diastole inflated balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

[0080] Figures 2a and 2b depict a multiple leak detector 228 that is similar to leak detector 27 of Figure 1 but which comprises a plurality of soft guidewires 31 rather than just the single guidewire 28 of detector 27. On each guidewire 31 is mounted a balloon 35. Figure 2b is a top view showing valve 20 during diastole. Two cavities 24 cause a flow of blood, which pulls the balloon 35 closest to each cavity 24 into that cavity while remaining balloons 35 stay stationary. At this point, cavity 24 locations can be determined and marked and the cavities repaired.

[0081] Figure 3 illustrates an annular-configured leak detector 229, which incorporates an adaptation that can be used to force wire(s) 40 of leak detector 27 or multiple-leak detector 228 (implementation shown) to remain close to aortic wall 45 rather than being allowed to drift to the center of the aorta. The advantage of this adaptation is that, in the case of detectors 27 and 228, if there is a central leak in valve 20, a balloon near the center of the aorta might be drawn into the central leak instead of to the paravalvular cavity, thereby indicating a false paravalvular leak. Spacing ring 40 is a compressible wire ring that pops open after catheter 21 delivery. Guidewire(s) 42 are distributively attached to the external edge of ring 40 and are thereby held by the ring against the aortic wall 45.

[0082] Figures 4a to 4c depict an implantable valve 49 deployed in the native aortic valve position, creating a cavity 24, which causes paravalvular regurgitation (leak) during diastole. In Figure 4a, guidewire 46, which can be a leak detection device like those shown in Figures 1, 2, and 3, is inserted through cavity 24. Balloon 33 is deflated. In Figure 4b, a balloon-expandable sealing stent (stent with an impermeable membrane that prevents the passage of fluids through the stent), is catheter-deployed over guidewire 46. Balloon 33 is inflated, causing balloon-expandable sealing stent 47 to be expanded, thereby sealing cavity 24 and stopping the paravalvular leak. Figure 4c shows a similar leak repair with the difference that a self-expanding sealing stent 48 is used, and therefore balloon inflation is not required. The sealing stents 47 and 48 are anchored by friction between themselves and the surrounding aortic annulus. Means for providing stronger anchoring for sealing stents are described later in this specification.

[0083] Figures 5a and 5b illustrate an embodiment of a balloon-expandable sealing stent (such as that used in Figure 4b) in accordance with another preferred embodiment of the present invention. The outer part 51 of the stent is made of a material that can be reshaped by plastic deformation. Sealing element 52, comprising an impermeable membrane, is connected to the inside wall of outer part 51 by spring hinge 53. The balloon-expandable sealing stent 47 is crimped on balloon 55. Once balloon 55 has reached cavity 24, the balloon is inflated, thereby expanding the sealing stent (Figure 5a). Balloon 33 is then deflated, whereupon (Figure 5b) sealing element 52 is forced by spring 53 to close and seal the lumen of the stent.

[0084] Figures 5c and 5d show a self-expanding sealing stent (such as that used in Figure 4c) in accordance

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with another preferred embodiment of the present invention. One way to implement the self-expanding sealing stent is to build stent framework 56 from a shape memory material such as nitinol 56 and cover it with a layer of impermeable material 58. The self-expanding sealing stent is catheter-delivered to the cavity, whereupon the stent opens, its shape adjusting to the shape of the cavity and its impermeable covering 58 sealing the cavity, to prevent the paravalvular regurgitation. To anchor the self-expanding sealing stent in place, hooks 59 can be included on framework 56. Hooks 59 are attached to framework 56 and extend through sealing material 58 and into the wall of the aortic annulus. The hooks are self-extending. One way to implement them is to make them from a shape memory material such as nitinol.

[0085] Figures 6a to 6d illustrate a technique for anchoring a sealing stent 66 (such as balloon-expandable sealing stent 47 or self-expanding sealing stent 48) into an open cavity 24, which is situated between aortic annulus 63 and prosthetic valve 20, and which creates paravalvular regurgitation. In Figure 6a, a guidewire 61 is led through cavity 24 by balloon 29 (this can be done with a device such as those disclosed in Figures 1 to 3). Guiding catheter 603 is fed over the guidewire, and the guidewire is removed. In Figure 6b an additional wire, anchoring wire 67, which terminates in anchoring apparatus 65, is inserted through catheter 63 to the anchoring location in cavity 24. Anchor 65 is a hook with one or more hook heads that can be compressed for delivery and will spring back to their original position when the delivery compression is removed (in other words, when the device emerges from the delivery catheter). Anchor 65 could be composed of flexible metal or a shape memory compound. Anchor 65 penetrates the aortic annulus at an approximately perpendicular angle due to the angled tip of guiding catheter 603. Figure 6c shows sealing stent 66 inserted via anchoring wire 67 and expanded to seal the cavity by one of the methods described in Figure 4 or 5. In the case shown in Figure 6c, a self expandable sealing stent as described in Figure 4 is shown. This method enables improved anchoring forces in comparison to friction alone, which is the sole anchoring for the embodiments shown Figures 4 and 5. Figure 6d shows the final step of the procedure, where the wire is detached from the anchor at detaching point 68.

[0086] Figure 7 depicts an apparatus that is similar to that illustrated in Figure 6, only here anchor 65 is implemented as a screw tip 69. The anchoring is accomplished by rotating anchoring wire 67, thereby threading tip 69 into aortic annulus 22.

[0087] Figures 8a to 8d demonstrate an apparatus for repairing a paravalvular leak by means of biological bi-component adhesive material (such as an epoxy resin), the components of which are in liquid form and turn to solid when mixed, in accordance with another preferred embodiment of the present invention. The leak is caused by an open cavity between valve 20 and annulus 22. A leak detector, such as those shown in Figures 1 to 3, is used to run guidewire 83 through cavity 24. A second guidewire 84 with a slide element 85 is slid over the first guide wire 83. Slide element 85 enables second guidewire 84 to slide over first guidewire 28 and can be a ring at the end of second wire 84. In Figure 8b, when slide element 85 and first guidewire 83 reach a point approximately midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

[0088] In Figure 8c one of the components of a biological bi-component adhesive material is injected via catheter 86, and the other component is injected via catheter 87. The liquid adhesive components meet at the catheter outlets at meeting point 75, mixing to create the adhesive blocking element 89, which repairs the paravalvular leak by closing cavity 24. Figure 8d depicts a top view of the final result of the repaired cavity showing that adhesive blocking element has been formed to seal cavity 24 between valve 20 and annulus 22.

[0089] Figure 9 illustrates another apparatus for blocking a leak by means of biological adhesive in accordance with another preferred embodiment of the present invention. Again, two guidewires meet at meeting point 75, and catheters, in this case 91 and 93, are fed over the guidewires to meeting point 75. However, in this case the blocking adhesive material comprises one liquid component that is solidified by the presence of ultra-violet light or another radiation cure. The liquid adhesive material is inserted into cavity 24 at catheter meeting point 75 via catheter 91. Active wave 96 shining through light probe catheter 93 hardens the material, creating sealing block 95, which closes the leak caused by cavity 24.

[0090] Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material in accordance with another preferred embodiment of the present invention. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to the desired location, inside cavity 24 between aorta 82 and prosthetic valve 81. Figure 10b is a cross-section of the catheter 100's multiple-lumen shaft. Lumens 102 and 103 provide means of approach for the separate components of the adhesive. Lumen 104 provides means for catheter to be fed over guidewire 28. Figure 10c shows a bi-component adhesive infusion chamber 100 in the form of a double syringe connected to the end of catheter 100 that is proximal to the medical operator. Figure 10d illustrates a mixing element 105 located at the distal end of catheter 100 (its location can be seen in Figure 10a). Mixing element 105 serves to mix the two adhesive components as they emerge from distal end of catheter 100 after being forced out of chamber 101, thereby ensuring that they will solidify and cure inside cavity 24. Figure 10e shows the adhesive components after they have been infused by chamber 101 via multiple-lumen catheter 100 and mixing element 105 into cavity 24 to form a plug. The cured adhesive fills the cavity and blocks the leak. Also shown in Figure 10e is an optional flexible mesh bag 106, which receives and

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holds the adhesive mix. The bag prevents possible migration of adhesive material during insertion and prevents the adhesive from passing through stent struts 108 in cases where such valve designs are present.

[0091] Figures 11a to 11f illustrate an apparatus for repairing a paravalvular leak in accordance with another preferred embodiment of the present invention. Two self-expanding sealing stents 110 are connected by suture 112 and pushed into insertion catheter 111 (Figure 11b). At this stage, insertion into the catheter has reduced the stents' diameter, enabling them to enter a cavity 24 between a prosthetic valve and surrounding blood vessel. Figures 11 c and 11d depict an implanted valve 115 where two large calcifications 116 create cavity 117, which causes regurgitation and must be repaired. (The calcification is just one example of a condition that creates a cavity that must be repaired. The cavity could equally have been caused by other factors, the cause is not determinant for the embodiment.) Figure 11e depicts insertion catheter 111 inserted over guidewire 28 to a point where the distal (delivery) end of the catheter has passed through the bottom of cavity 117. A first sealing stent 110 is deployed below the bottom of cavity 117. Catheter 111 is withdrawn and suture 112 is partially retracted, pulling the first sealing stent 110 into the bottom of the cavity, where it lodges. With reference to Figure 11f, insertion catheter 111 is withdrawn until its distal end is near the top of cavity 24, whereupon a second sealing stent 110 is deployed. Suture 112 is further retracted, pulling the second stent into the top of the cavity, where it lodges. The final step of the procedure is to disconnect the proximal part of the suture at point 119.

[0092] Figure 12 depicts a valve adapted to seal paravalvular leaks in accordance with a preferred embodiment of the present invention. Valve 121 is held in holder stent 124 with sealing element 120 attached circumferentially around stent 124's outer surface. When valve 121 is implanted, sealing element 120 is expanded to seal any peripheral paravalvular leaks. Several means can be used to implement expansion of sealing element 120. In the implementation shown in Figure 12, sealing element 120 is inflated by operator application of syringe 123, and it constitutes a balloon-like portion, made of a pliant physiologically acceptable polymeric material such as polyurethane. The inflation media can be saline solution, the patient's blood, or another physiologically acceptable fluid.

[0093] Alternatively, the sealing portion can be made of a material that, on contact with a fluid, soaks up the fluid and swells up. Once inserted into the body, the sealing portion comes into contact with the blood, causing it to swell and seal the cavity.

[0094] Figures 13a to 13d depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing component 126 is comprised of a plurality of flaps 127 and expands to a larger diameter than the principal diameter of the stent 125, creating an extra sealing line to prevent paravalvular leaks. Figure 13b depicts a top view of valve 124. Sealing component 126 comprises a plurality of flaps 127 that, independent of one another, are connected to the valve stent 125. Each flap 127 is made of spring wire 131, which, after the valve is deployed, causes flap 127 to extend out. Flaps 127 are covered with impermeable sealing material 128. Flaps 127 are arranged such that they are substantially perpendicular to the longitudinal axis of stent 124 and overlap one another, ensuring a full seal.

[0095] Figure 13c shows stent-mounted valve 124 in its crimped configuration. Introducing sheath tube 130 holds stent 125 and sealing component 126 crimped on balloon 129. After deployment, flaps 127 of sealing component 126 open to their final diameter.

[0096] Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by mechanical attachment means 134, which can be a rivet, a screw, etc. Spring wire ring 131 can be folded into introducing sheath tube 130 shown in Figure 13c and, when released from tube 130, springs back to its shape as shown in Figure 13d.

[0097] Figure 14 illustrates a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. This design includes balloon-inflatable stent 140 (containing a prosthetic valve) and balloon-inflated sealing ring 145, which is similar to sealing component 126 of Figure 13, only here balloon-inflatable wire 145 is used instead of spring wire ring 131. Stent 140 is inflated using a double balloon. First balloon section 142 inflates stent 140 to the desired diameter, and then second balloon section 143 inflates sealing flaps 145 perpendicular to stent 140, creating a larger diameter and thus sealing any cavities around the stent.

[0098] Figures 15a and 15b depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. In this embodiment the sealing ring comprises flexible sealing elements 150. Each sealing element 150 is independently spring-actuated. When the valve is crimped, sealing elements 150 fold, enabling valve to be reduced to a small diameter for insertion. When valve is expanded to its final diameter, sealing elements 150 open to a larger diameter 154 to seal cavities around the valve, preventing paravalvular leaks. Since each sealing element 150 is independent, sealing elements adjacent to native valve tissue 152 remain closed. These closed elements provide a further benefit of adding compressive forces that improve the anchoring of the valve.

[0099] Figures 16a to 16c depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Here the sealing ring 165 comprises at least one of a plurality of flexible, self-expanding sealing elements 165 connected to the outer surface of stent 160. Similar to the embodi-

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ment shown in Figure 15, when stent 160 is pressed against the native tissue, sealing element 165 will stay compressed against the wall. But where there is a gap between stent 160 and the surrounding tissue, sealing element 165 will expand and block any possible leak. With reference to Figure 16b, sealing element 165 is made of self-expanding mesh 166 covered with PET (polyethylene terephthalate) mesh 167 or other impermeable material.

[0100] Figures 17a to 17e depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention, wherein the sealing component is built into a ring 172 of the stent struts. In the figure the ring of struts 172 is located at the stent's inlet; however, the ring of struts can equally be implemented at another point along the stent. The modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

[0101] Figures 17c and 17d show front and side views of the geometrical restriction in modified strut 173 that causes the displacement of point 175, creating enlarged diameter 169. Figure 17c shows modified strut 173 before stent expansion and in line with the rest of the stent wall. Figure 17d shows modified strut 173 after stent expansion, which has caused modified strut 173 to rise up and out, creating the sealing ring. Figure 17e details the operation of the geometric restriction: when stent 170 is crimped, the strut legs are relatively close to each other 176, making strut height relatively large 177. After expansion, the strut legs are spaced further apart 176a, leading to displacement of point 175, and lessening of strut height 177a. The result of the movement of point 175 is shown in Figures 17c, 17d, and 17e. When the stent is crimped, as shown in Figure 17c and the left side of Figure 17e, point 175 is low. When the stent is expanded, as shown in the right side of Figure 17e, point 175 moves up, pulling the stent to the shape shown in 17d .

[0102] Figures 18a to 18e depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. In Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic aortic valve 175. At least one of a plurality of sutures 181 are connected to valve 180 at inlet end 187. The sutures spread back along the balloon's shaft 183 and continue back along the deployment path and out of the patient's body as shown in Figure 18b.

[0103] Inflating balloon 183, as shown in Figure 18c, anchors valve 185 in annulus 179 with sutures 181 arranged around it. In cases where paravalvular cavities 178 are present, it is possible to repair them assisted by sutures 181. Figure 18d shows a patch 189 made of pericardium (or other suitable patch material) inserted on sutures 181 and pushed to the leaking cavity by means of a pushing catheter 190. After the patch is in place, a knot or clip 191 is used to secure it, thereby repairing the leak (18e).

[0104] Figures 19a to 19d depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. First elastic sealing stent 195 is inserted in the desired location. Then, valve 196 is inserted into sealing stent 195. Figure 19a shows inserting catheter 191 with sealing stent 195 and valve 196 mounted on it. Sealing stent 195 and valve 196 can be either balloon inflated as shown in this figure, or self-expanding which would then require an introducing sheath.

[0105] Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the stented valve 196, which is mounted inside sealing stent 195, can be absolutely round. Sealing stent 195 is able to avoid leaks caused by cavities or irregularities caused by pieces of calcification as described earlier in this patent. The sealing component of sealing stent 195 can be self-expandable hydrophilic sponge 197 (Figure 19c) or other suitable material. Sealing stent 195 can include hooks 198 that open when the stent is inserted, improving the anchoring of the stent in the annulus as well as improving sealing around the stent by blocking blood (Figure 19d).

[0106] Figure 20a depicts a stented valve 201 having a valvular structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks in accordance with yet another preferred embodiment. In this embodiment, a flexible sealing element 203 provides a sealing ring. The sealing element 203 may be formed of any material suitable for implantation in the human body, such as, for example, a sponge material. When the stented valve 201 is crimped to a smaller diameter, sealing element 203 is also crimped, thereby enabling valve to be easily advanced to a treatment site. For purposes of illustration, figure 20f illustrates sealing element 203 before crimping, while Figure 20g illustrates sealing element in a crimped condition. When the valve is expanded to its final diameter, sealing element 203 expands to its original size diameter by internal spring forces and/or by absorbing blood. Expansion of the sealing element seals cavities around the valve and thereby prevents paravalvular leaks. In addition to the mechanical effect of blocking cavities, blood protein preferably adheres to the sealing element, thereby causing coagulation for further leak prevention. Figures 20c and 20d provide cross-sectional views of preferred sealing elements. A tubular form 203a shown in figure 20c is configured to be crimped to a smaller size than a rod form 203b shown in figure 20d. Figure 20e illustrates the sealing element with additional fibers 206, which increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing. Figure 20e also illustrates a suture 207 as one preferred means for attachment to the valve body. Figure 20b is a per-

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spective view illustrating another preferred embodiment of a valve 210 having a sealing mechanism. In this variation, two sealing elements 204, 205 are provided along an exterior region.

[0107] Figure 21 depicts yet another stented valve 220 adapted to seal paravalvular leaks. In this embodiment, a sealing element 223, which is preferably made of the same materials described above with respect to figures 20a through 20g, is attached to the stent in a non-linear sealing line. In preferred configurations, the line can be adjacent to the connection of a valvular structure 222 to the stent or according to the lines of the stent structure. In one feature, an improved crimped profile may be achieved using the illustrated attachment line.

[0108] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks. The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254. The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration.

[0109] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps. Any suitable tissue growth factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

[0110] In yet another embodiment, a biocompatible hydrogel may be applied to the outside surface of a prosthetic valve. After deployment, the hydrogel absorbs fluids from the blood and expands to the fill the gaps between the valve and surrounding tissue (e.g., host annulus). In preferred methods, the hydrogel may be applied to the surface of the stented valve before deployment or may be applied after deployment.

[0111] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

[0112] The present invention may be defined in accordance with the following clauses:

1. A catheter-delivered device for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

2. The device of Clause 1 further comprising a spacing element to maintain the wires adjacent to the wall of the body vessel.

3. A catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the stent delivered via guide wire to the cavity, held in place in the cavity by friction, and comprising a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

4. The device of Clause 3, wherein the sealing stent is balloon-expandable type and the membrane comprises a tab spring-hinged to the inside of the stent lumen and sized to occlude the lumen when closed, the tab being held open by the stent balloon during insertion and springing closed when the balloon is removed after the stent is expanded.

5. The device of Clause 3, wherein the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

6. The device of Clause 5, wherein the stent is comprised of shape memory material.

7. The device of Clause 6, wherein the material is nitinol.

8. The device of Clause 5 further covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

9. The device of Clause 3, wherein the distal end of

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the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

10. The device of Clause 9, wherein the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter delivery into the vessel wall whereupon the hook extends out, anchoring the guide wire into the vessel wall.

11. The device-of Clause 10, wherein the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guide wire into the vessel wall.

12. A device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first wire and inserted such that the slidable coupling is moved to a point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the point, a second component of the two-component adhesive inserted through the second catheter to the point, and the two components thereby mixing to form a plug that seals the cavity.

13. The device of Clause 12 adapted to apply an adhesive with more than two components.

14. The device of Clause 12, wherein, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, the catheter terminating in a mixer that forces the components to mix when the exit the catheter in the cavity, thereby creating the plug that seals the cavity.

15. The device of clause 12, wherein, instead of two component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive to create the plug in the cavity.

16. A catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the assembly delivered via guidewire to the cavity and comprising two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane, one stent of the assembly inserted underneath the cavity and the other stent inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

17. A prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

18. The device of Clause 17, wherein the ring comprises a balloon.

19. The device of Clause 17, wherein the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane and wherein the tabs are folded against the body of the valve during catheter delivery and where, upon egress from the catheter, the tabs spring out to form the sealing ring.

20. The device of Clause 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprising a balloon under the tabs and wherein the tabs are folded down on the deflated balloon during catheter delivery and wherein, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

21. The device of Clause 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve and wherein the tabs are folded against the body of the valve during catheter delivery and wherein, upon egress from the catheter, the tabs spring out to form the sealing ring.

22. The device of Clause 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

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23. The device of Clause 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

24. The device of Clause 17, wherein the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

25. A prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body and wherein patches can be pushed down the sutures and attached to the point where the suture is attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

26. A catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed, the elastic stent sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

27. A prosthetic valve for implantation in a body channel, comprising: a substantially cylindrical stent structure configured for radial expansion; a valvular structure providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets; a layer of compressible material disposed along an outer surface of the stent structure, the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel.

28. The prosthetic valve of clause 27, wherein the compressible material is formed of polyethylene terephthalate.

29. The prosthetic valve of clause 28, further comprising a tissue growth factor disposed along the compressible material and wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

Claims

1. A prosthetic valve for implantation in a body channel, comprising:
   a substantially cylindrical stent structure configured for radial expansion;
   a valvular structure having an inlet and an outlet, the valvular structure being formed of a pliant material located within the stent structure and forming three valve leaflets;
   a layer of compressible material disposed along an outer surface of the stent structure, the compressible material being adapted after deployment to fill gaps between the prosthetic valve and the body channel.

2. The prosthetic valve of Claim 1, wherein the compressible material extends entirely around the stent structure.

3. The prosthetic valve of Claim 2, wherein the compressible material forms a sleeve.

4. The prosthetic valve of Claim 3, wherein the sleeve surrounds an inflow end of the stent structure.

5. The prosthetic valve of any preceding claim, wherein the compressible material is formed of polyethylene terephthalate.

6. The prosthetic valve of Claim 5, wherein the compressible material has a thickness ranging from 1 to 5mm.

7. The prosthetic valve as claimed in any preceding claim, wherein the compressible material comprises a cloth or fabric.

8. The prosthetic valve as claimed in any preceding claim, further comprising a tissue growth factor disposed along the compressible material.

9. The prosthetic valve as claimed in Claim 8, wherein the growth factor is applied along the outer surface of the compressible material or the material is soaked or dipped in the growth factor before use.

10. The prosthetic valve as claimed in any preceding claim, wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

11. The prosthetic valve of Claim 10, wherein the fibers are straight, curved or hook-shaped.

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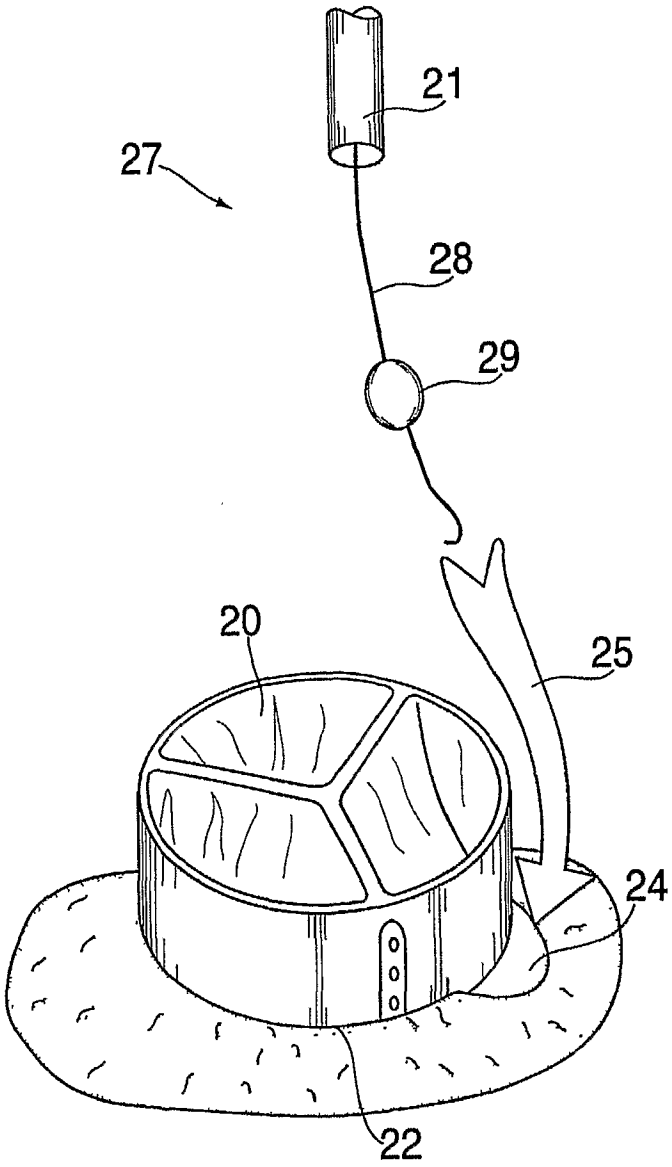


FIG. 1

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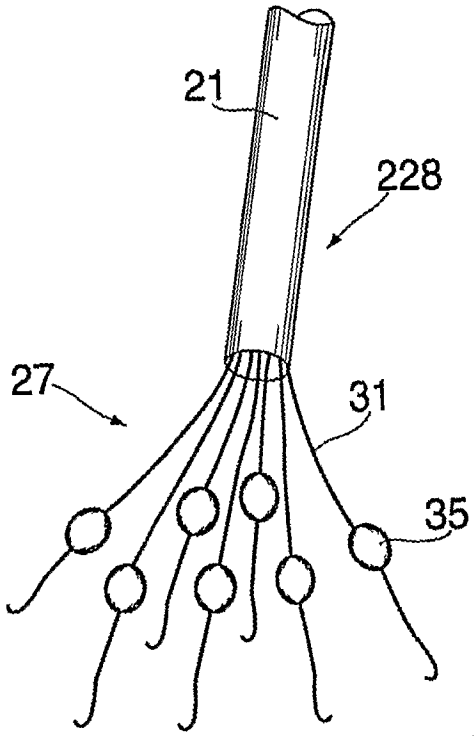


FIG. 2a

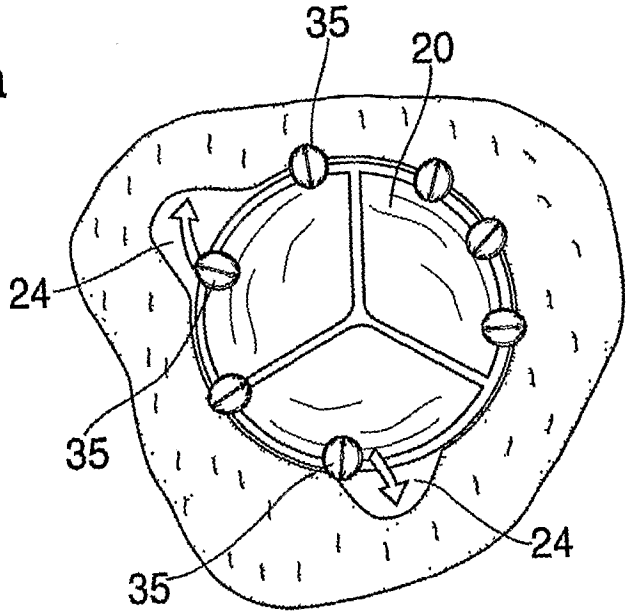


FIG. 2b

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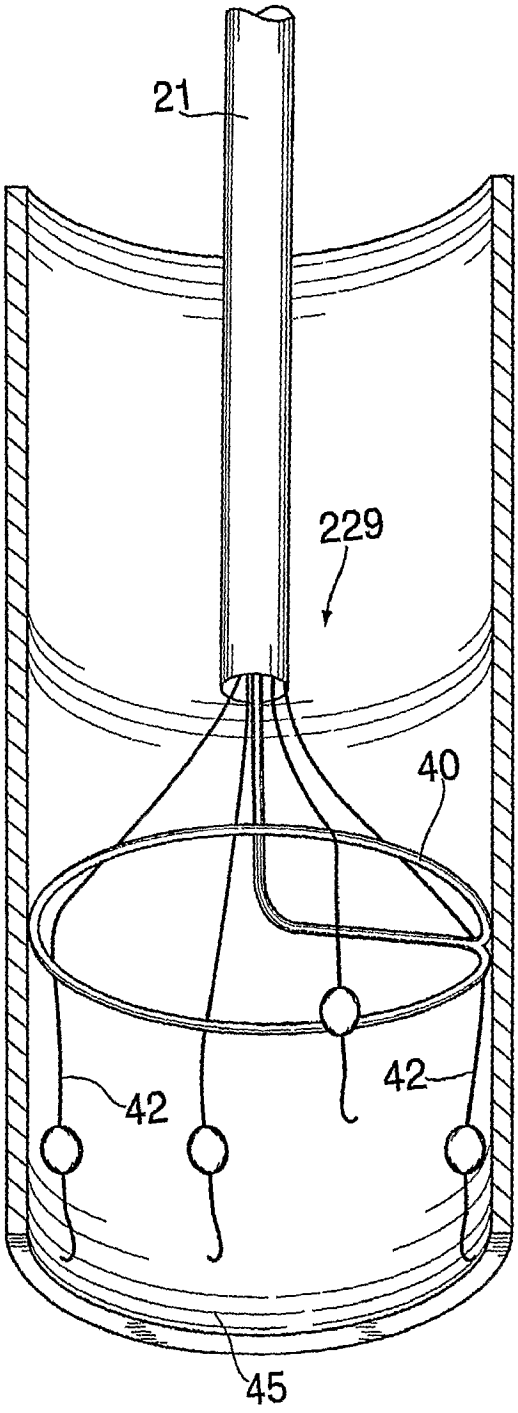


FIG. 3

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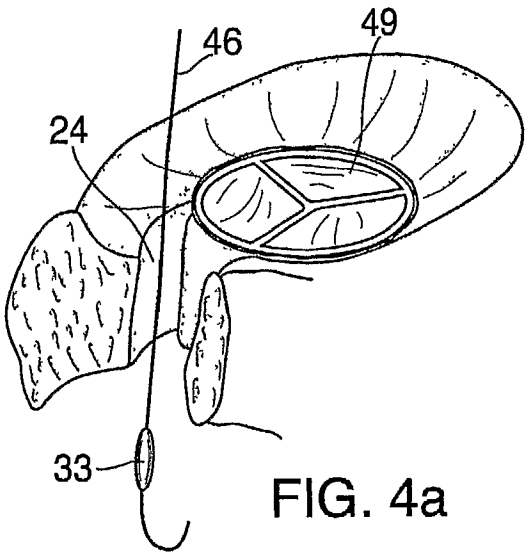


FIG. 4a

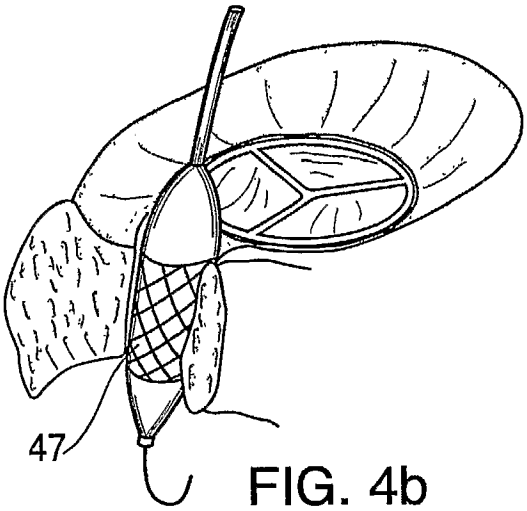


FIG. 4b

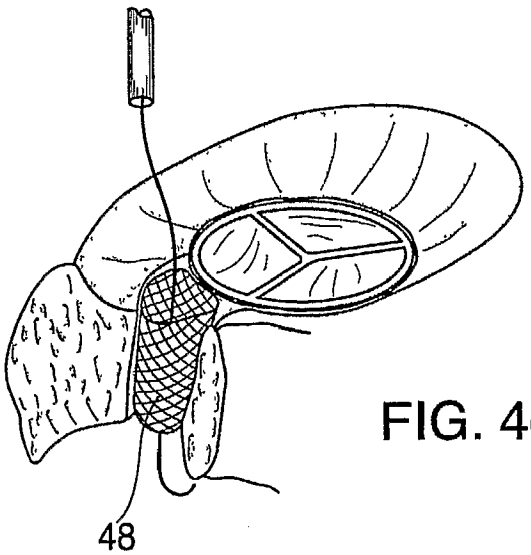


FIG. 4c

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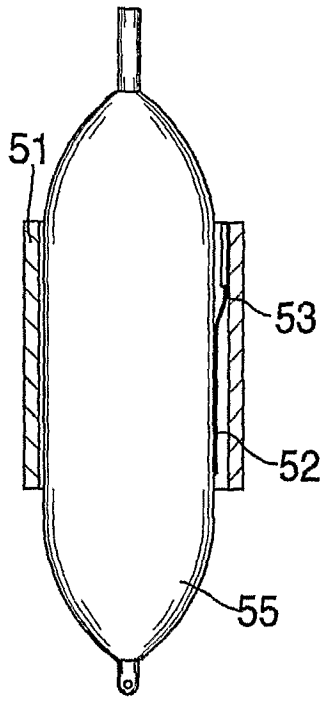


FIG. 5a

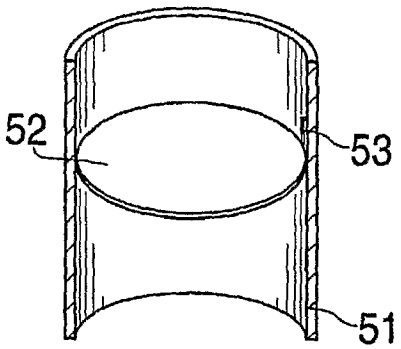


FIG. 5b

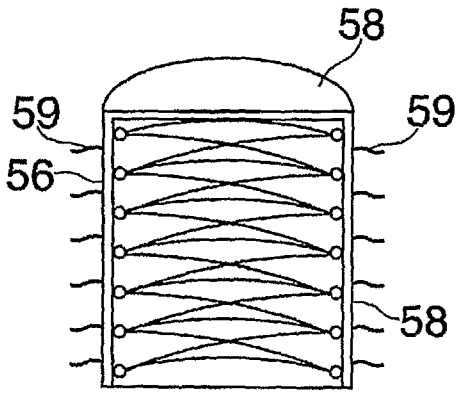


FIG. 5c

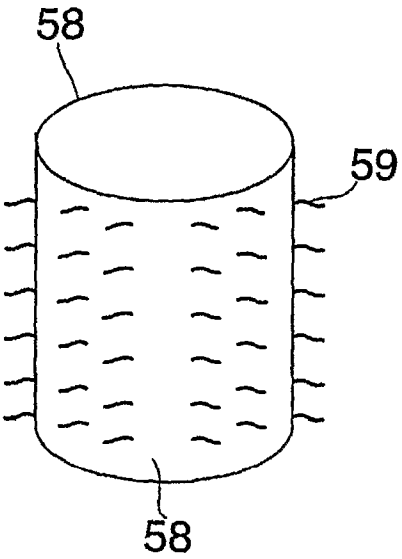


FIG. 5d

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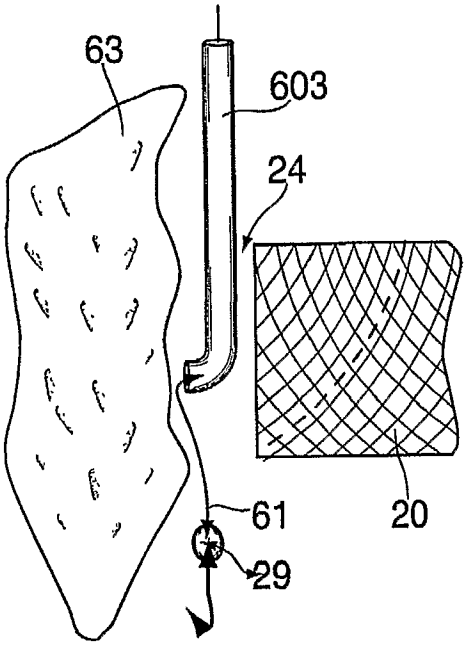


FIG. 6a

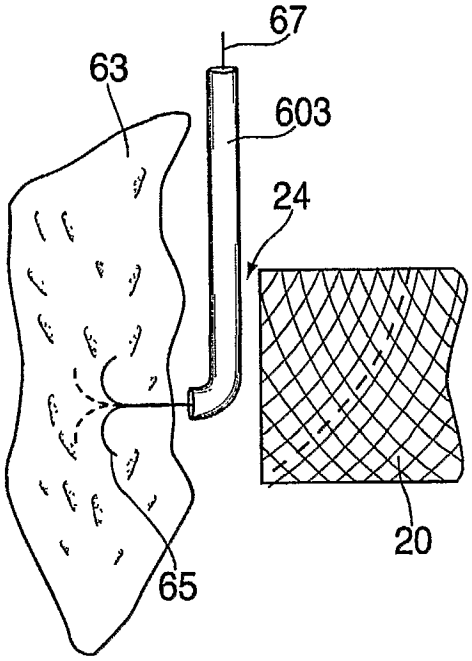


FIG. 6b

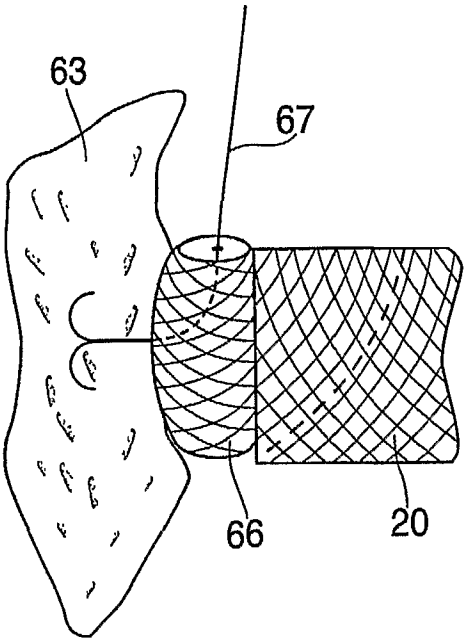


FIG. 6c

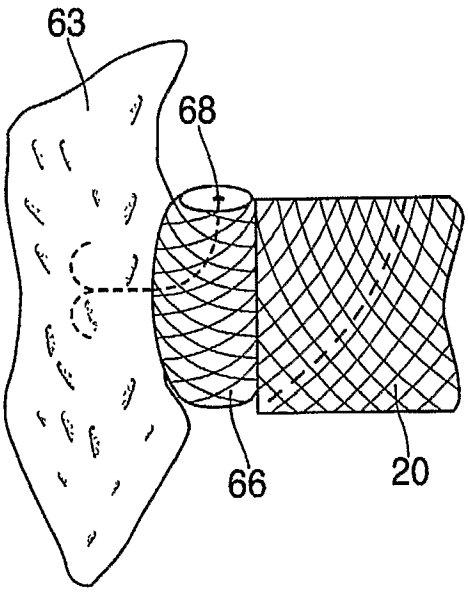


FIG. 6d

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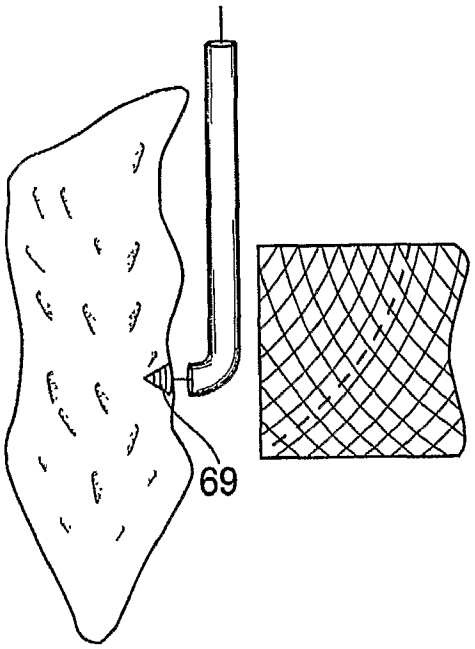


FIG. 7

Aortic Innovations, LLC, Exhibit 2040
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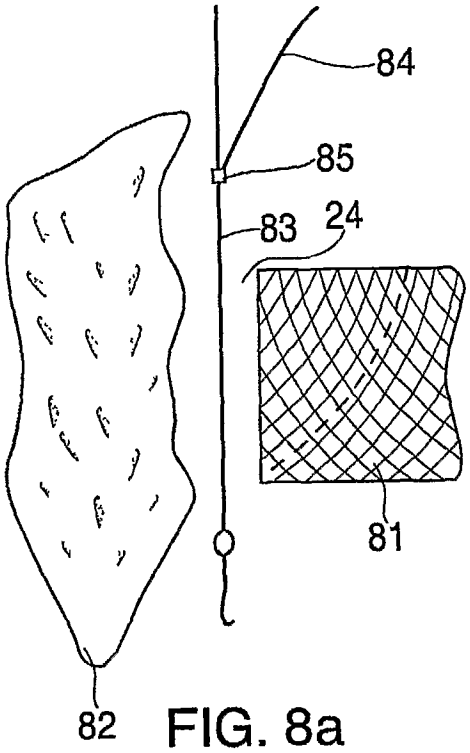


FIG. 8a

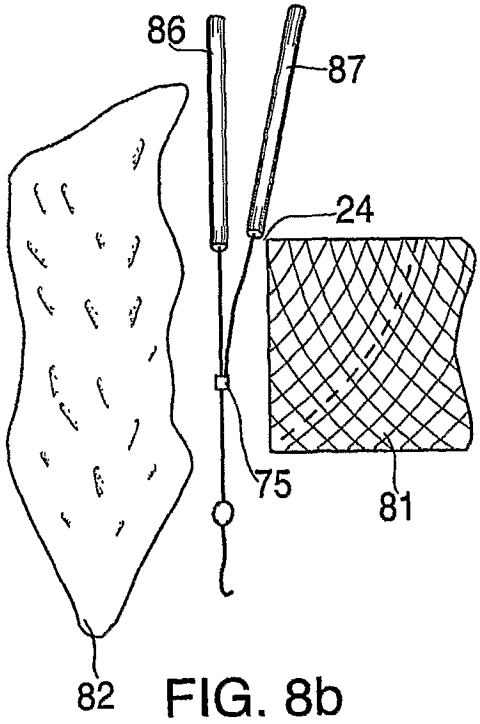


FIG. 8b

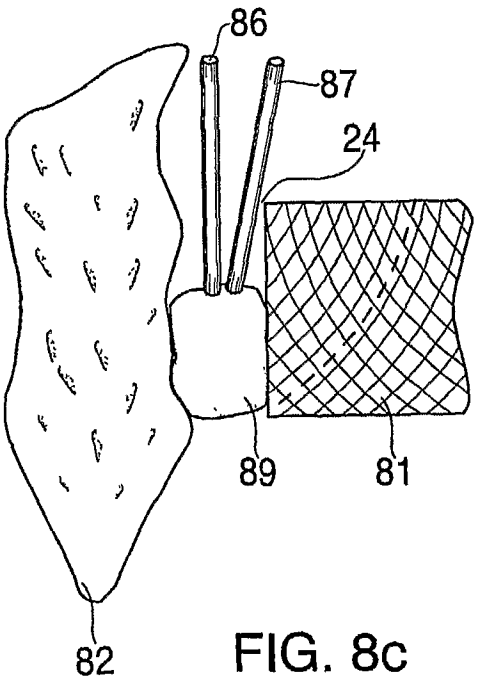


FIG. 8c

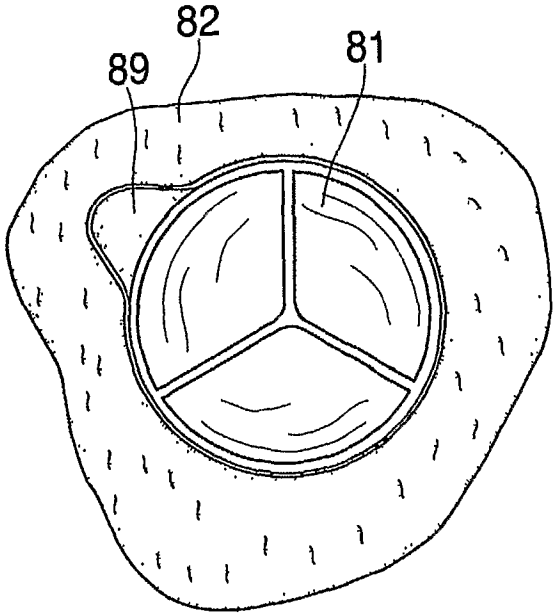


FIG. 8d

Aortic Innovations, LLC, Exhibit 2040
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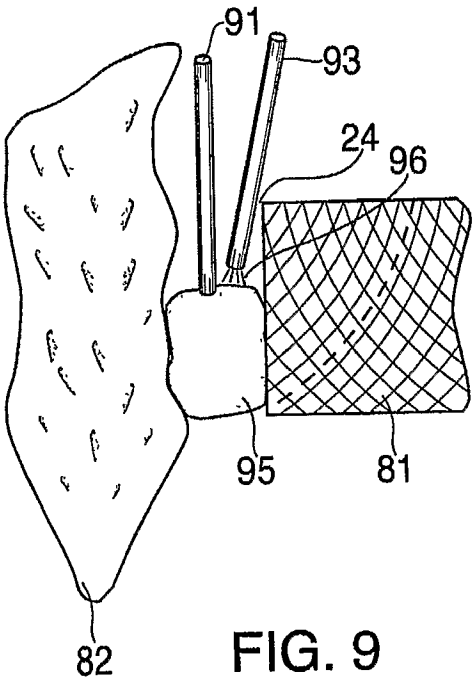


FIG. 9

Aortic Innovations, LLC, Exhibit 2040
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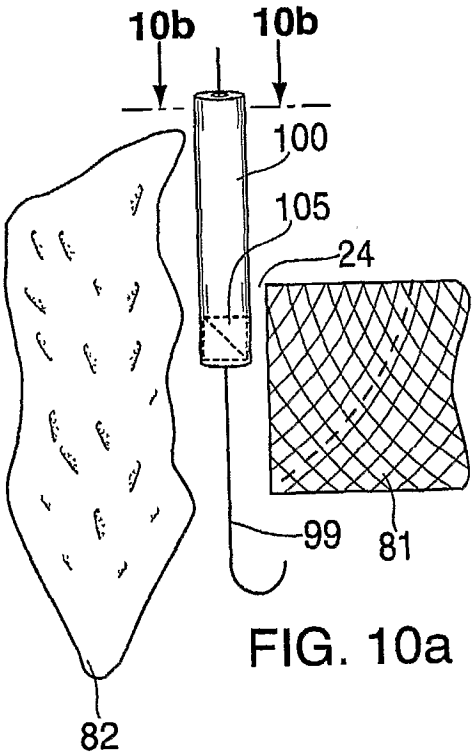


FIG. 10a

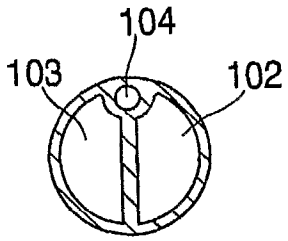


FIG. 10b

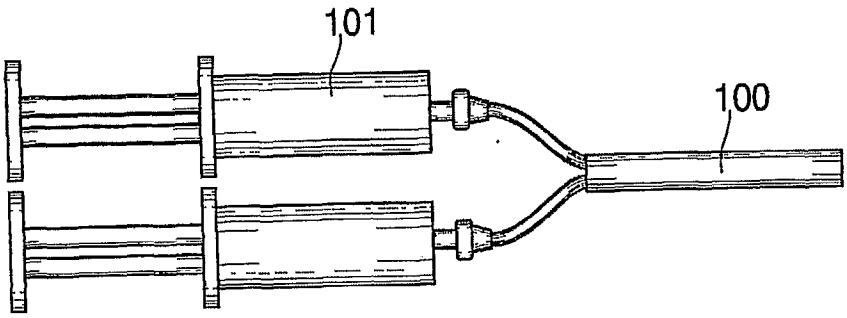


FIG. 10c

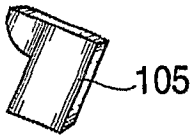


FIG. 10d

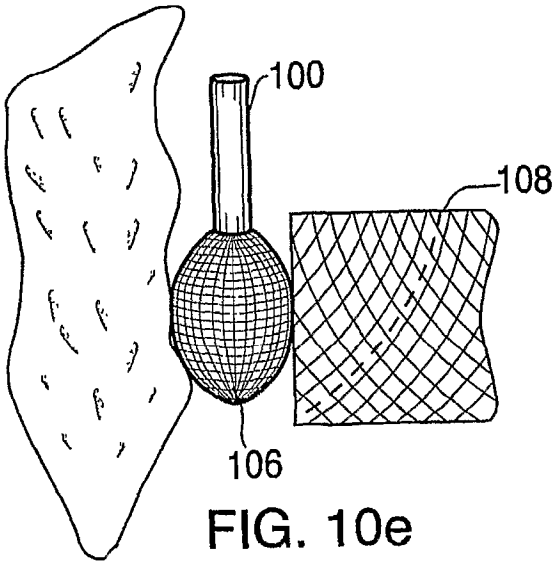


FIG. 10e

Aortic Innovations, LLC, Exhibit 2040
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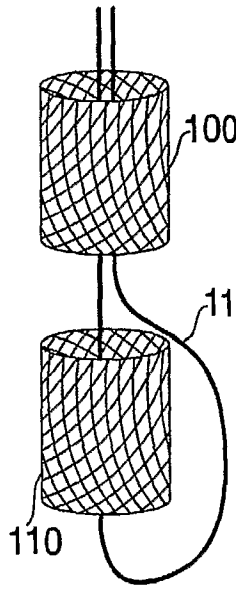


FIG. 11a

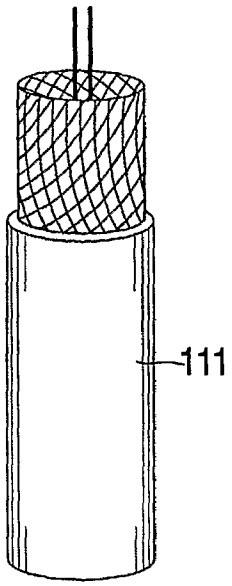


FIG. 11b

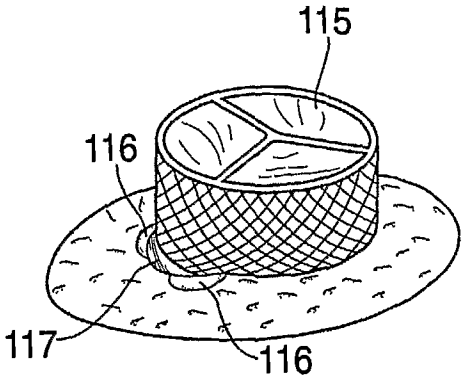


FIG. 11c

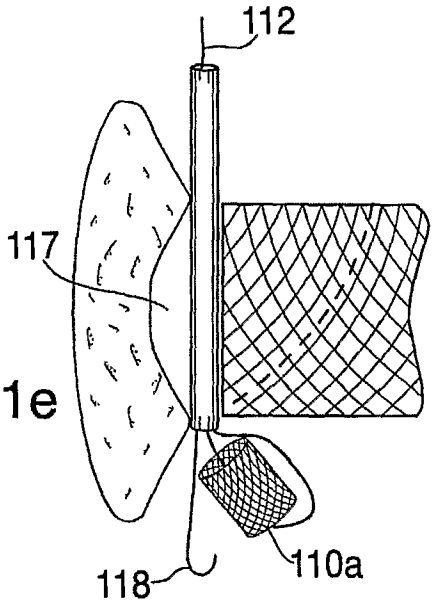


FIG. 11e

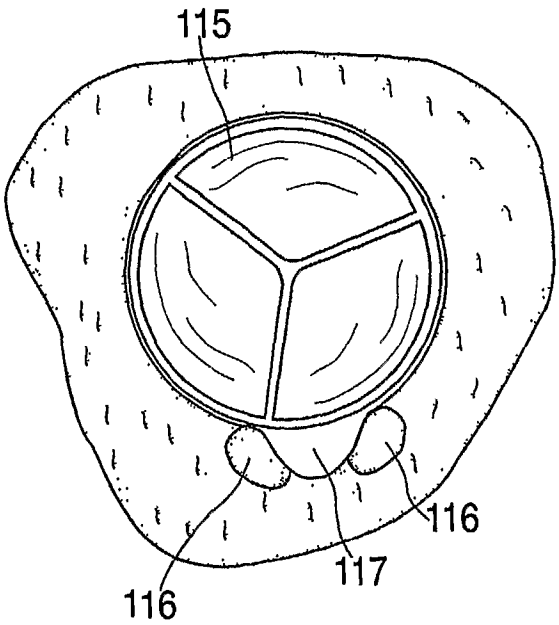


FIG. 11d

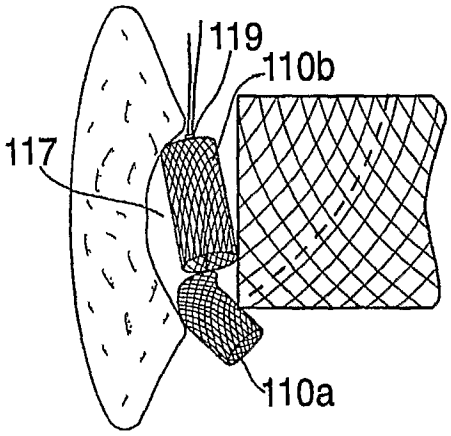


FIG. 11f

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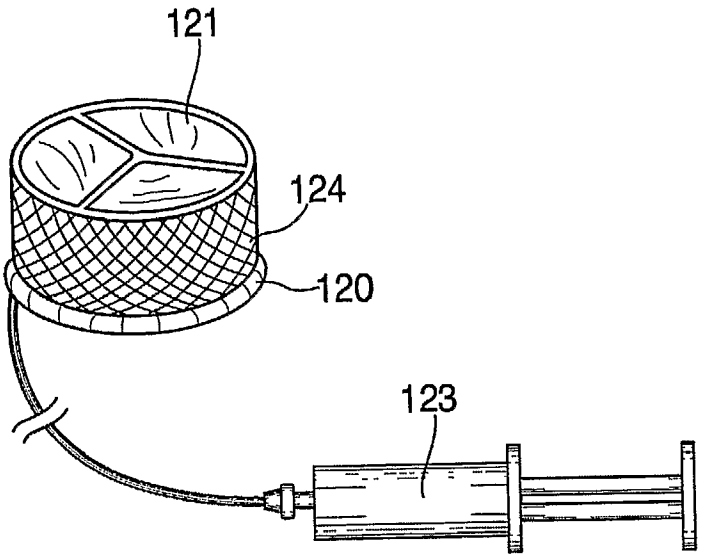


FIG. 12

Aortic Innovations, LLC, Exhibit 2040
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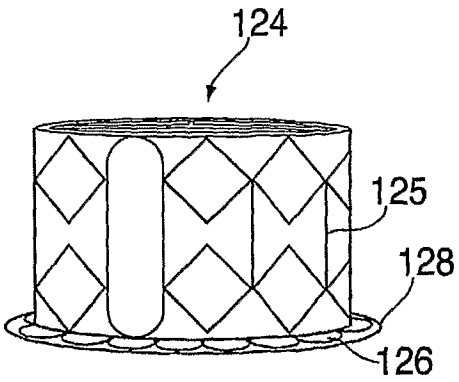


FIG. 13a

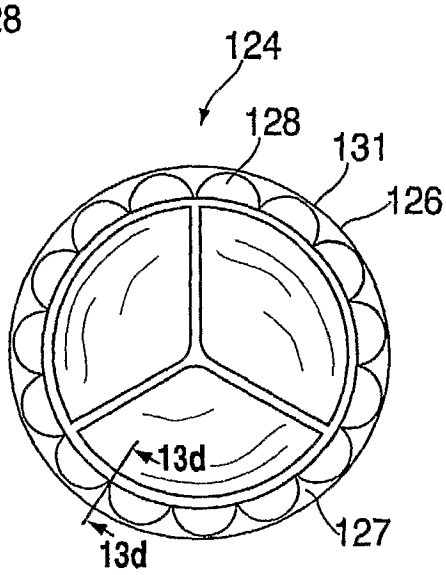


FIG. 13b

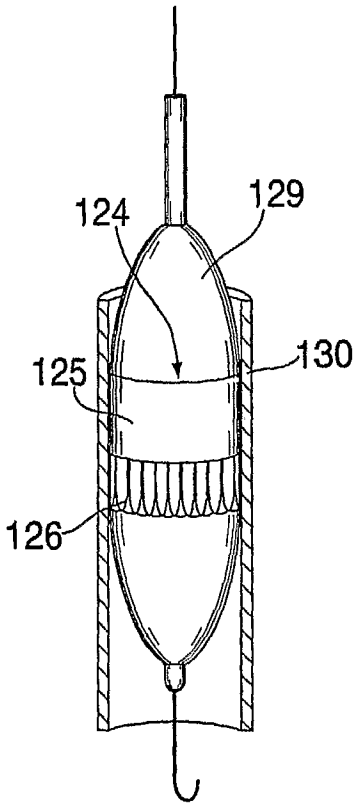


FIG. 13c

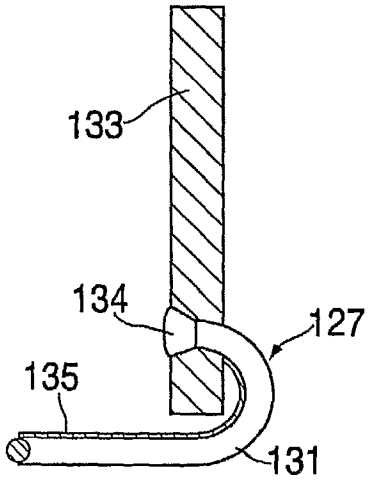


FIG. 13d

Aortic Innovations, LLC, Exhibit 2040
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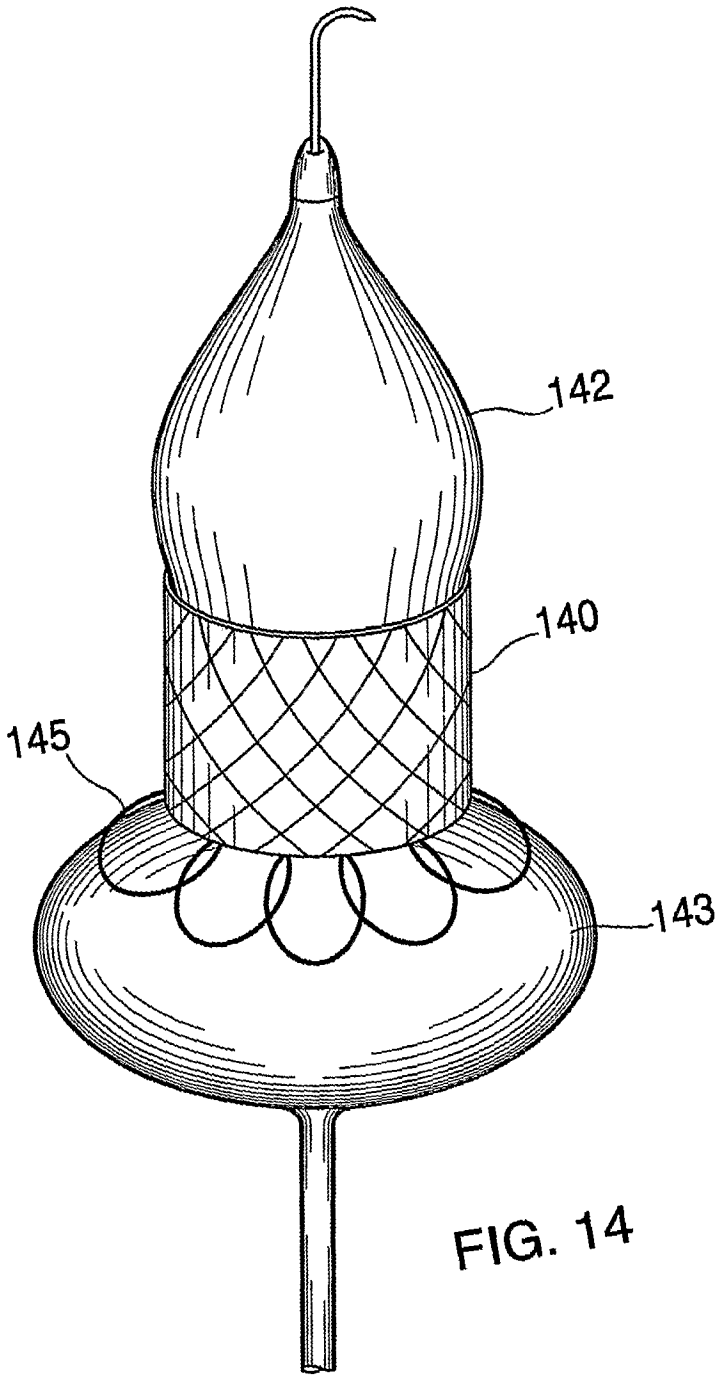


FIG. 14

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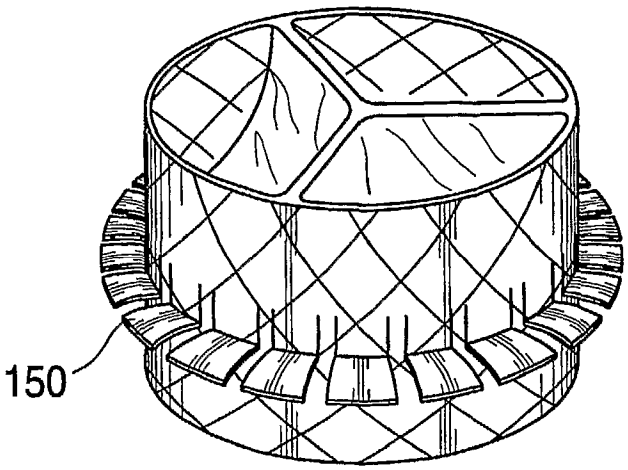


FIG. 15a

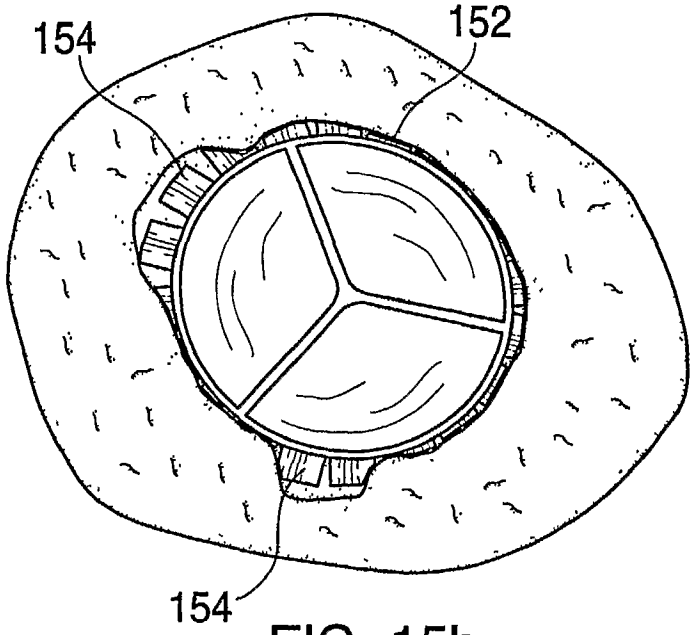


FIG. 15b

Aortic Innovations, LLC, Exhibit 2040
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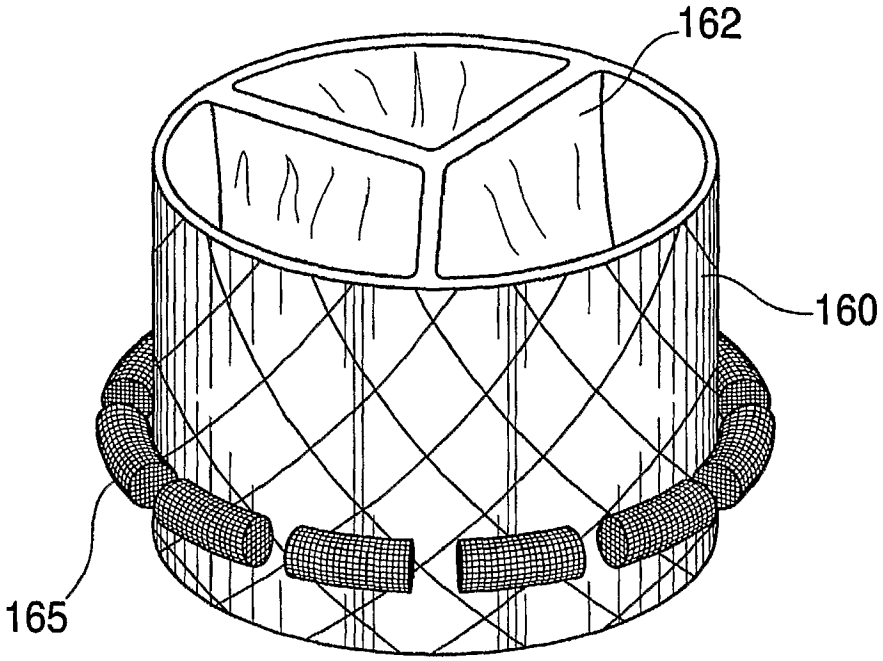


FIG. 16a

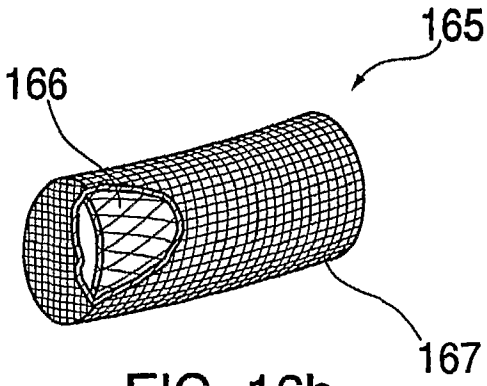


FIG. 16b

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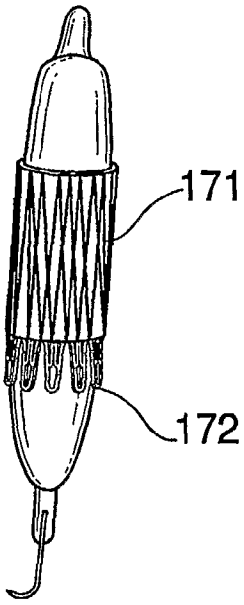


FIG. 17a

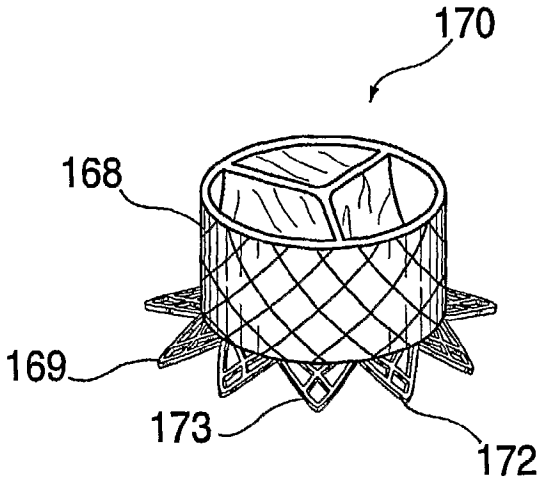


FIG. 17b

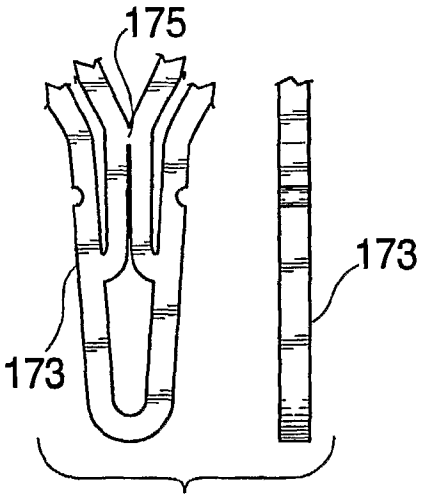


FIG. 17c

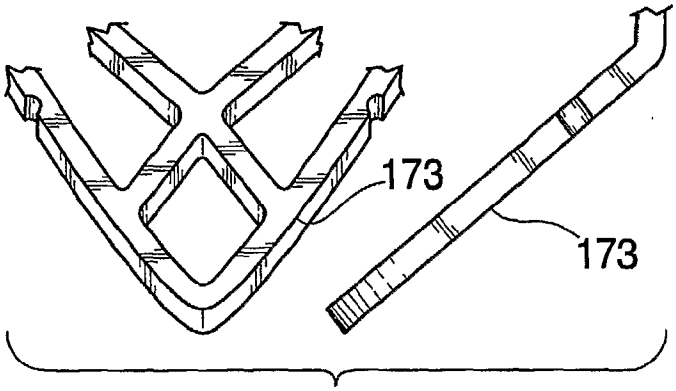


FIG. 17d

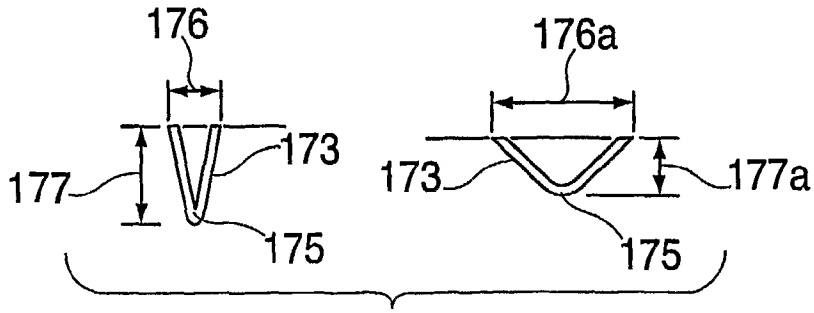


FIG. 17e

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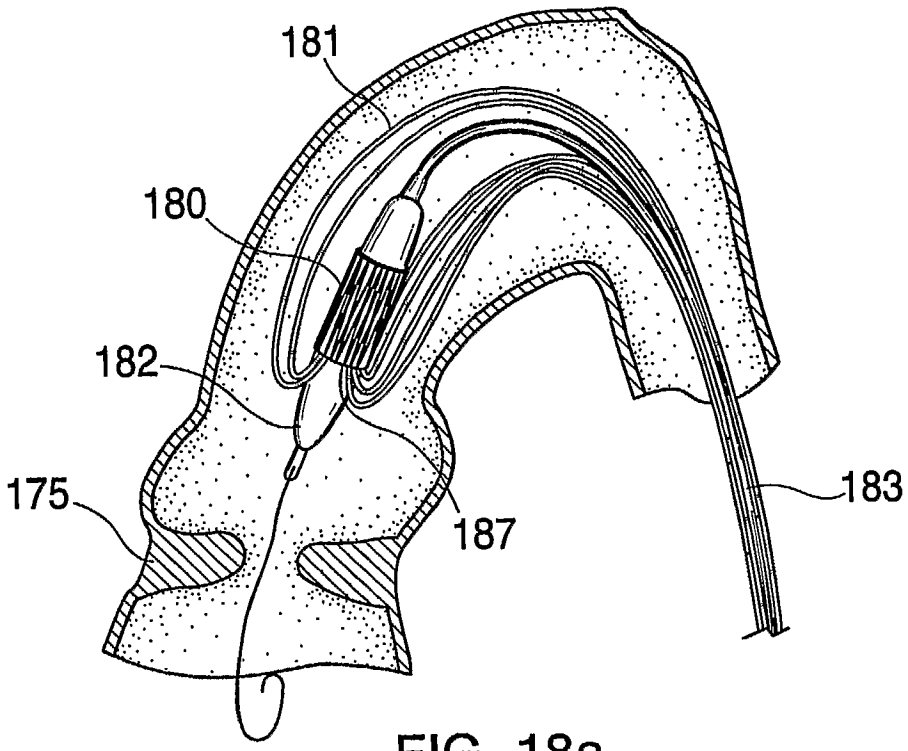


FIG. 18a

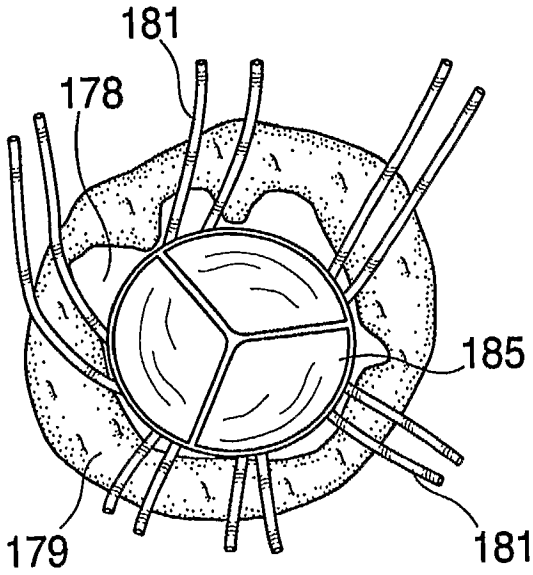


FIG. 18c

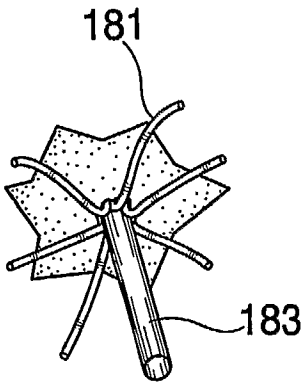


FIG. 18b

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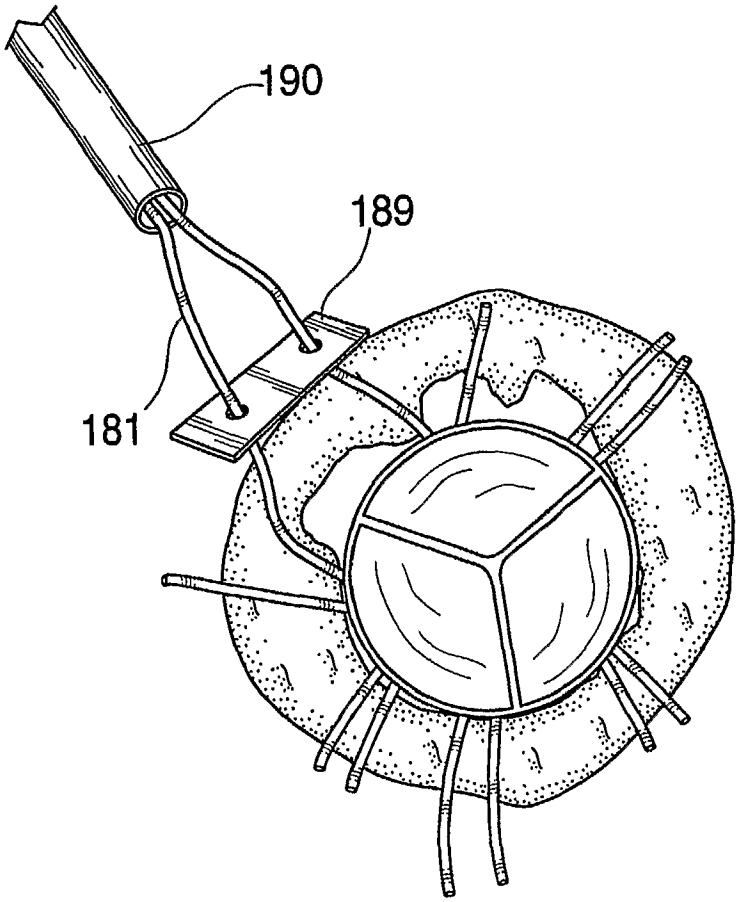


FIG. 18d

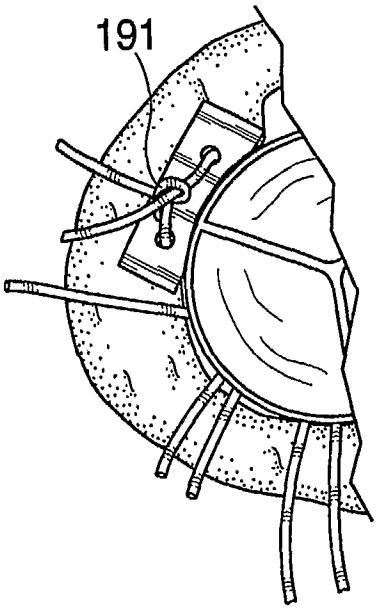


FIG. 18e

Aortic Innovations, LLC, Exhibit 2040
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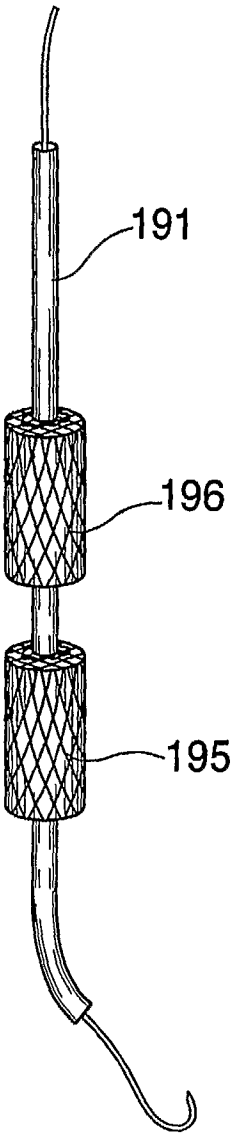


FIG. 19a

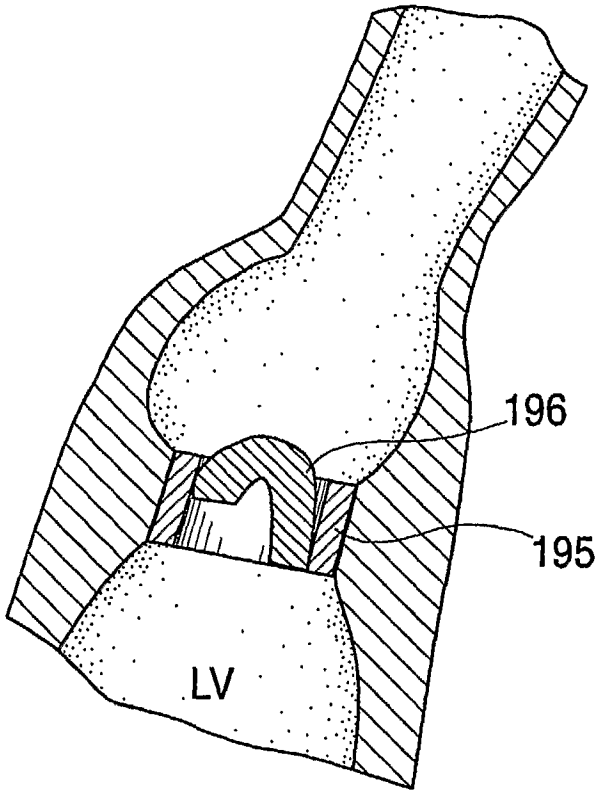


FIG. 19b

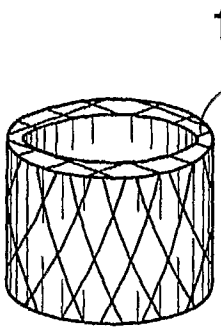


FIG. 19c

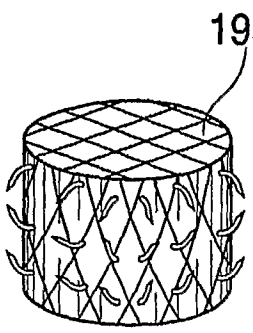


FIG. 19d

Aortic Innovations, LLC, Exhibit 2040
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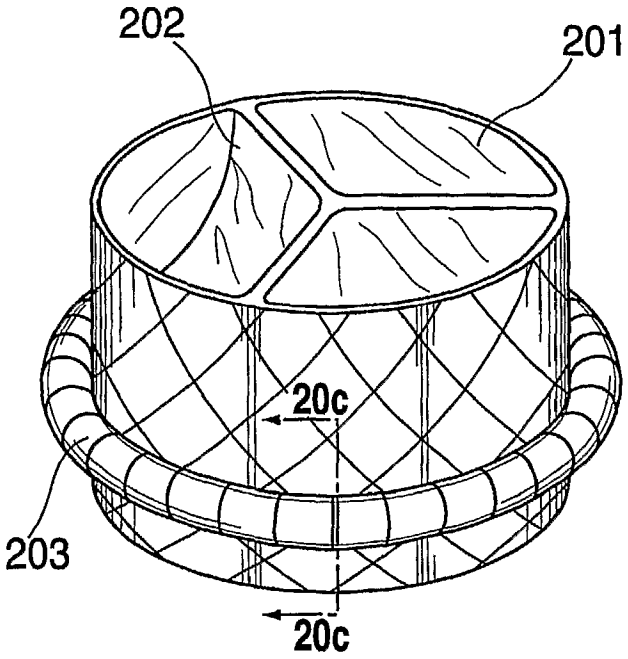


FIG. 20a

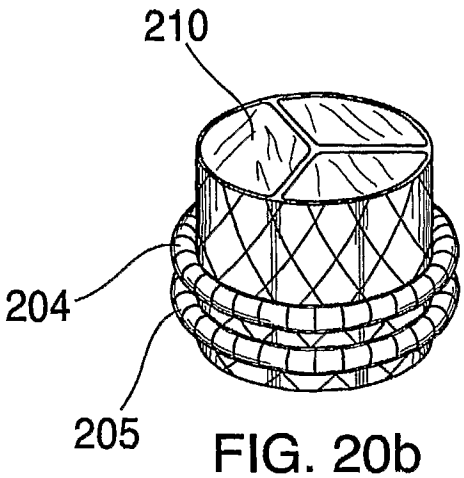


FIG. 20b

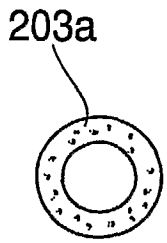


FIG. 20c

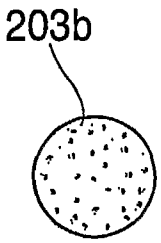


FIG. 20d

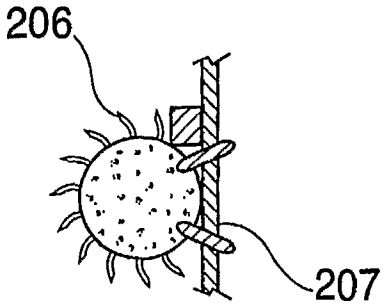


FIG. 20e

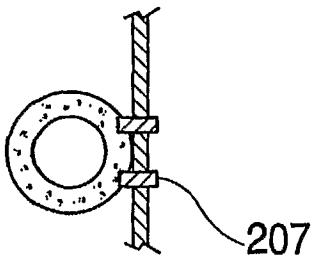


FIG. 20f



FIG. 20g

Aortic Innovations, LLC, Exhibit 2040
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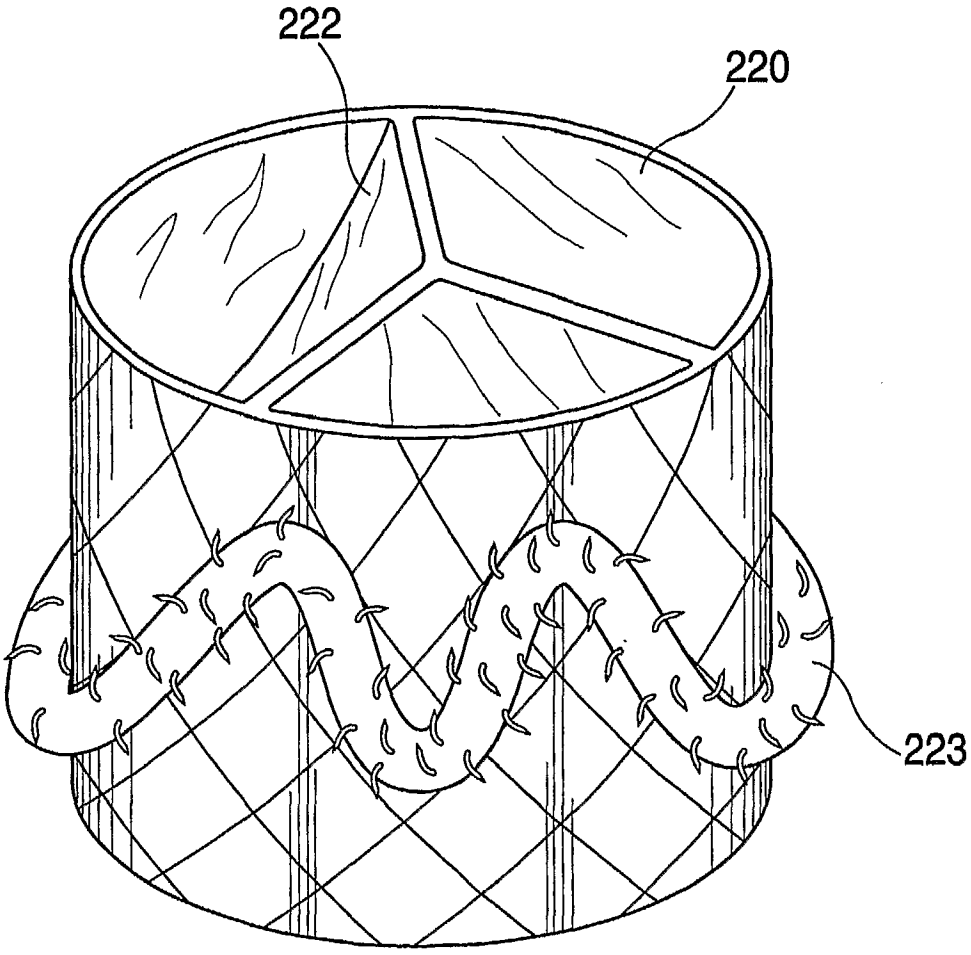


FIG. 21

Aortic Innovations, LLC, Exhibit 2040
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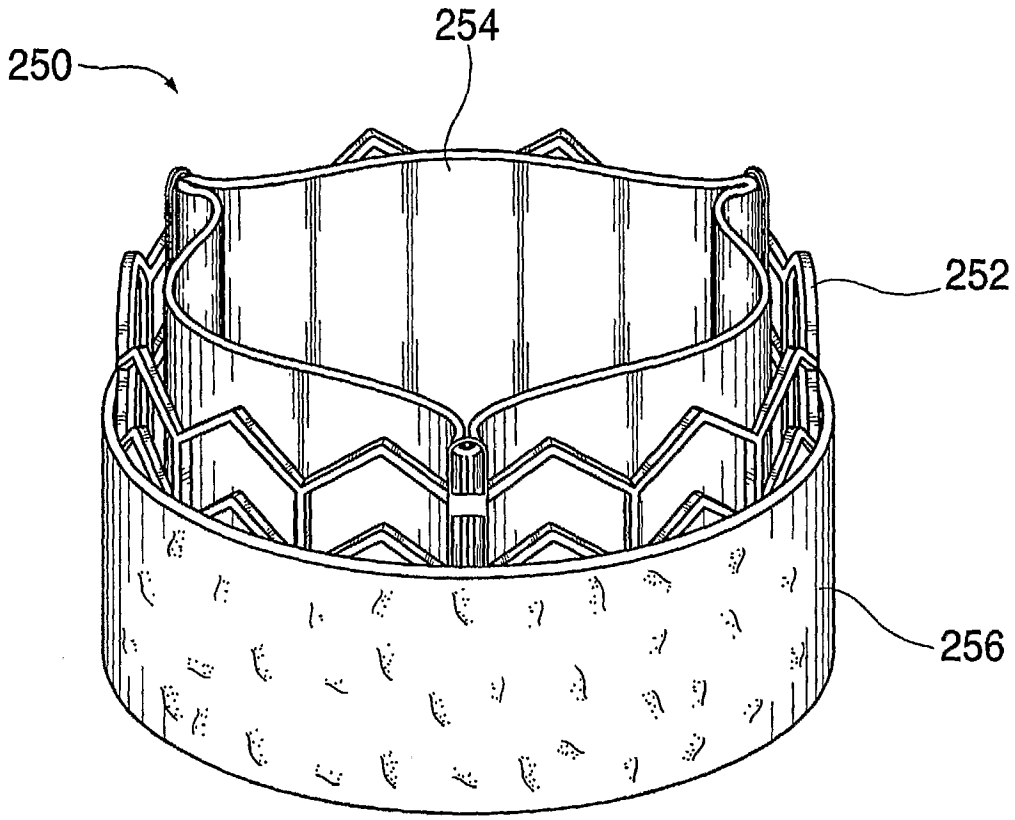


FIG. 22

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EUROPEAN SEARCH REPORT

Application Number
EP 15 18 0327

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 5 258 023 A (REGER VINCENT A [US]) 2 November 1993 (1993-11-02) * the whole document *	1-11	INV. A61F2/24
X	FR 2 337 543 A1 (AMERICAN HOSPITAL SUPPLY CORP [US]) 5 August 1977 (1977-08-05) * the whole document *	1-7	
X	WO 00/64380 A1 (ST JUDE MEDICAL CARDIOVASCULAR [US]) 2 November 2000 (2000-11-02) * page 3, line 1 - line 21; figures 1,2 * * page 6, line 34 - page 7, line 10 *	1-4,7	
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			TECHNICAL FIELDS SEARCHED (IPC) A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	16 December 2015	Steiner, Bronwen

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 15 18 0327

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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US005258023A

United States Patent [19]

Reger

[11] Patent Number: 5,258,023

[45] Date of Patent: Nov. 2, 1993

[54] PROSTHETIC HEART VALVE

[75] Inventor: **Vincent A. Reger**, Portland, Oreg.

[73] Assignee: **Reger Medical Development, Inc.**, Portland, Oreg.

[21] Appl. No.: **834,416**

[22] Filed: **Feb. 12, 1992**

[51] **Int. Cl.**[5] **A61F 2/24**

[52] **U.S. Cl.** **623/2**

[58] **Field of Search** 623/2, 11, 66, 900

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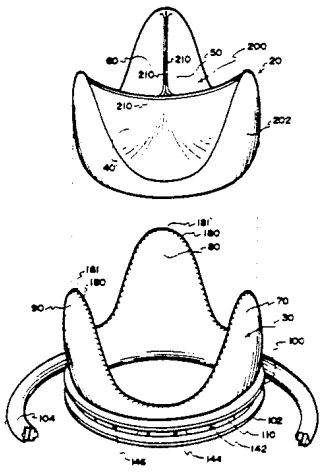
Primary Examiner—Paul Prebilic

Attorney, Agent, or Firm—Lynn G. Foster

[57] **ABSTRACT**

A novel long lasting prosthetic heart valve compatible with implantation in a human natural heart valve annulus. The prosthetic heart valve comprises a trileaflet heart valve apparatus which in form, dimension, and function resembles a human trileaflet heart valve, but which is formed of synthetic resinous material. A seamless supporting frame capable of annular deformation and limited perimetric expansion during each heartbeat is totally enveloped in an essentially biologically inert cylindrical cover to form a cusp supporting stent for the valve leaflet apparatus. The free top and bottom edges of the cylindrical cover are disposed on the exterior of the stent and everted outward to provide at least one sewing ring. Valve embodiments comprise aortic and mitral implantable valves. For the aortic implant, the outwardly everting free sewing ring forming edges are separated by circumferentially disposed compressible and expandable material which provides a pliable, compliant interface between the valve and the natural valve annulus at the implanting site. Valve sewing ring covers can be selectively impregnated with antibiotic medicants to substantially eliminate early post implant infection. Use of non-thrombogenic biochemically inert materials in a valve apparatus which mimics operation of a natural heart valve essentially eliminates the need for long term administration of anticoagulants.

32 Claims, 5 Drawing Sheets



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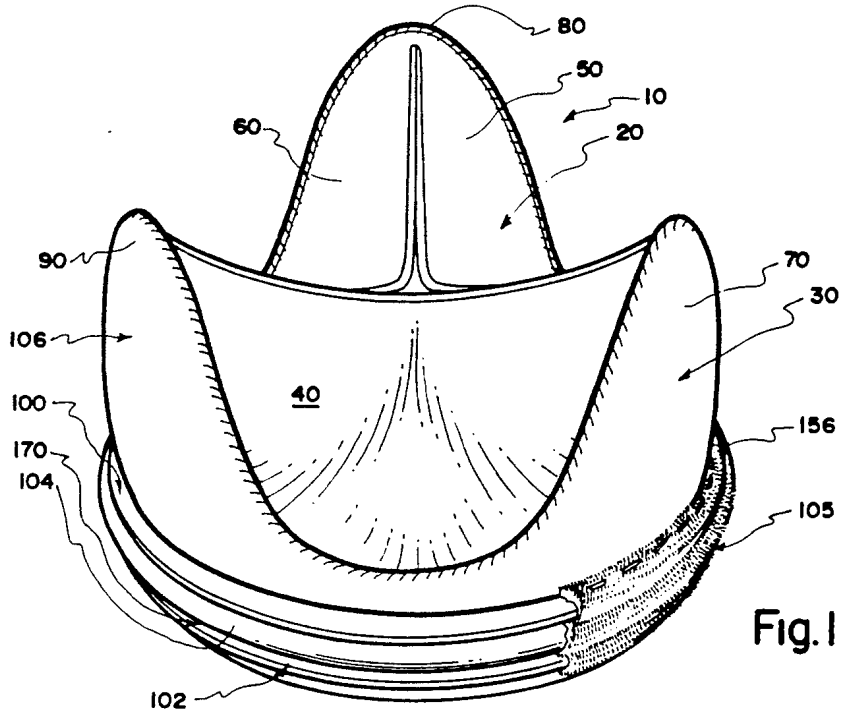


Fig. 1

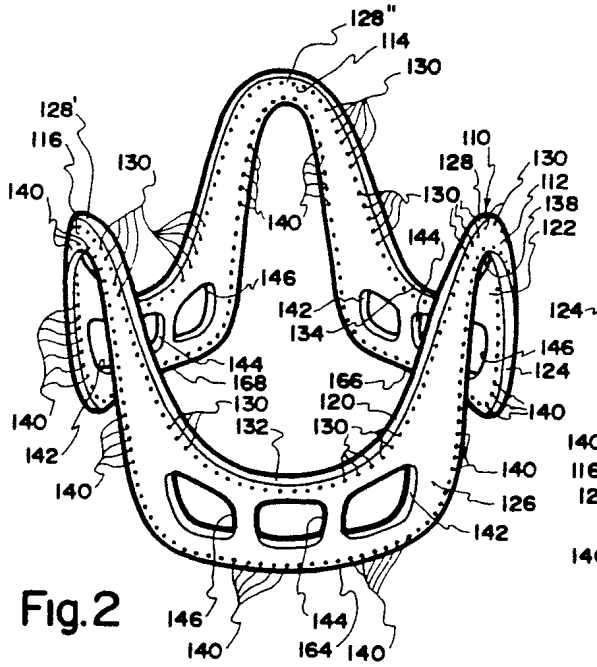


Fig. 2

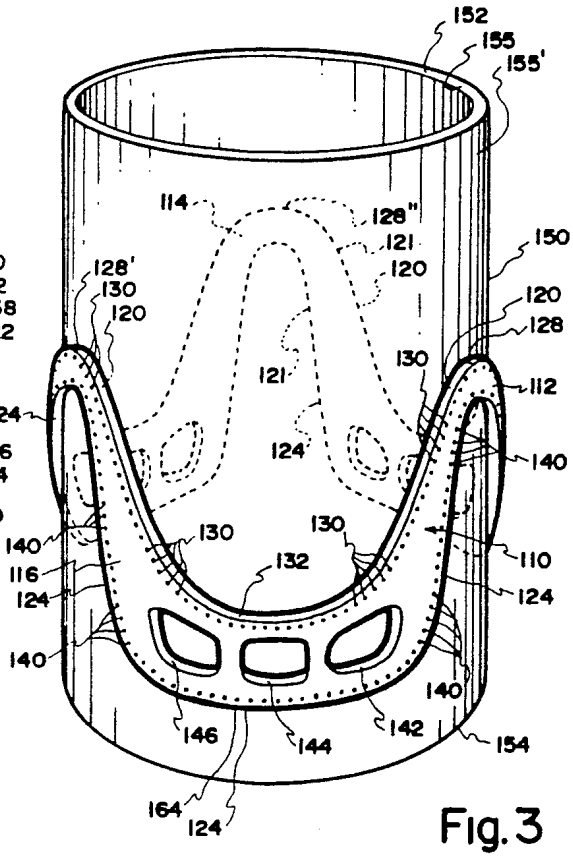
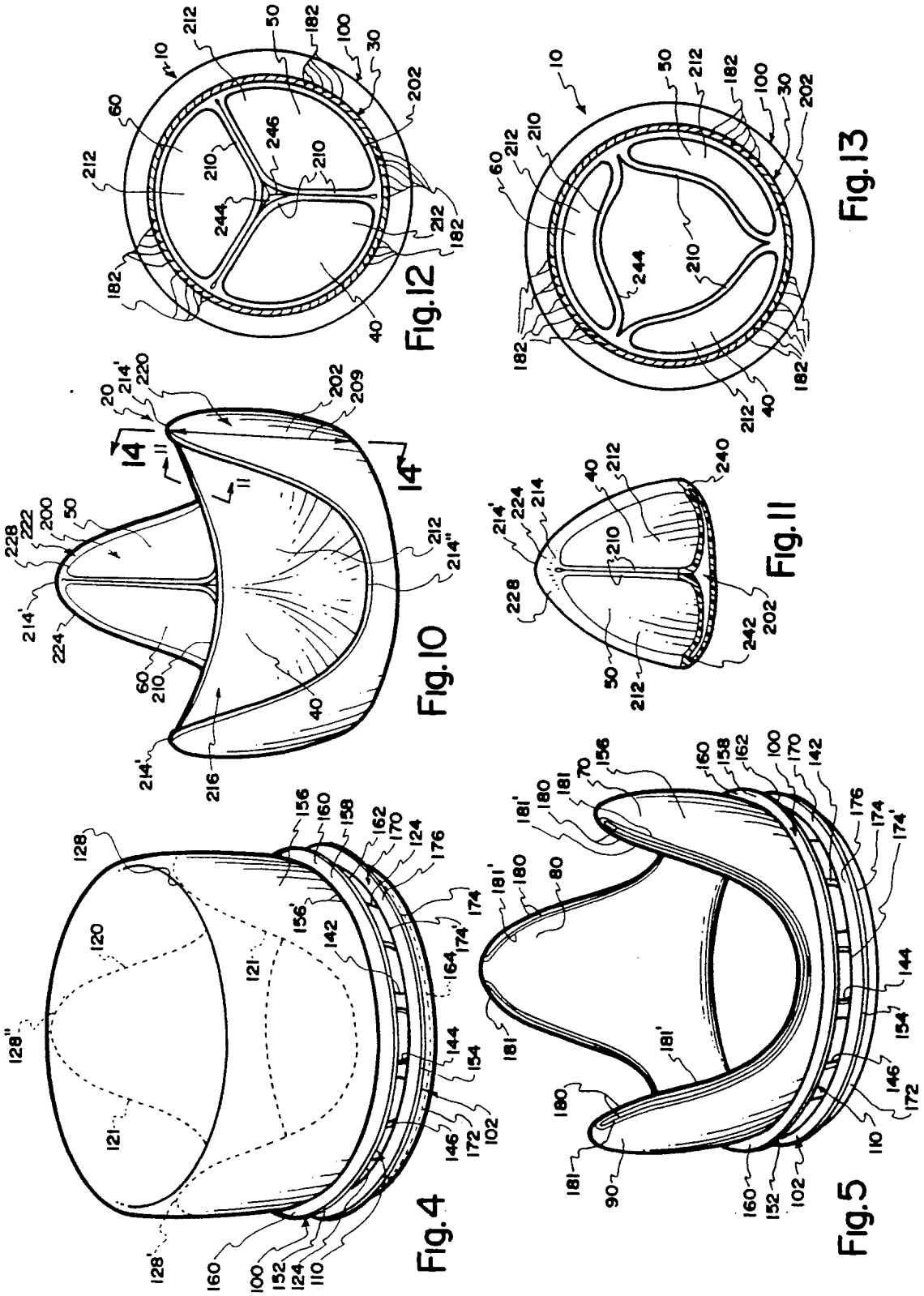


Fig. 3



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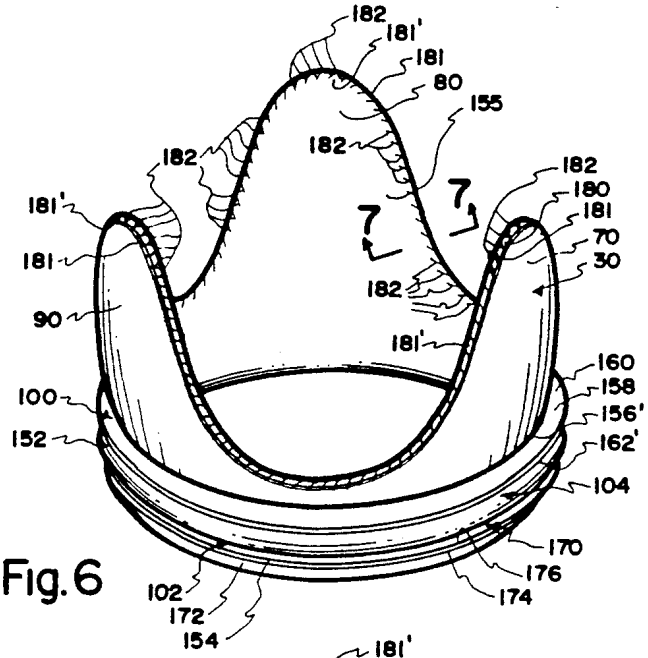


Fig. 6

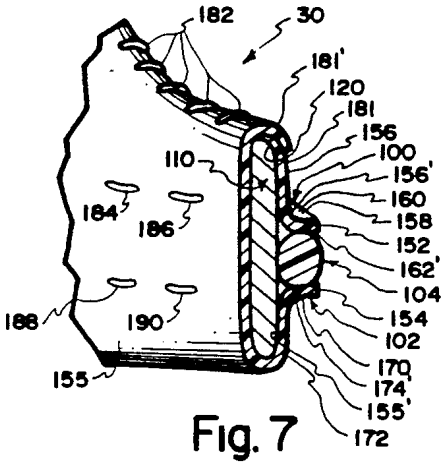


Fig. 7

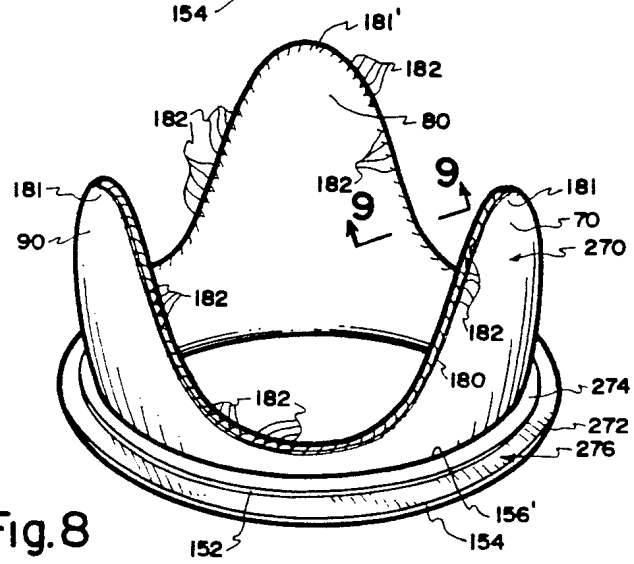


Fig. 8

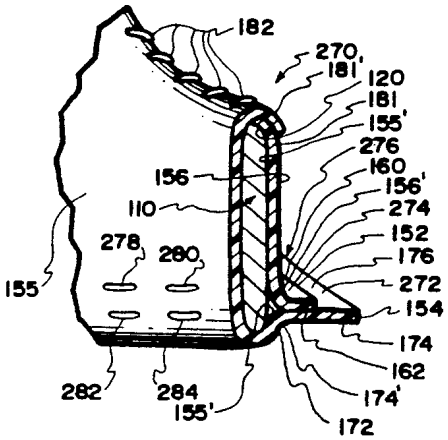


Fig. 9

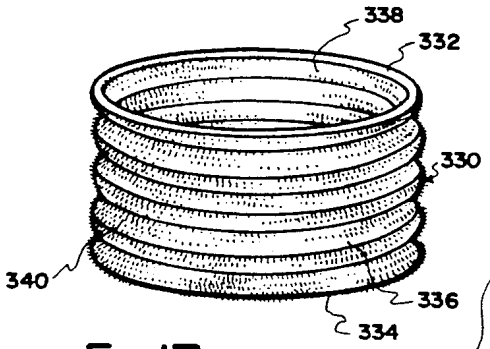


Fig. 17

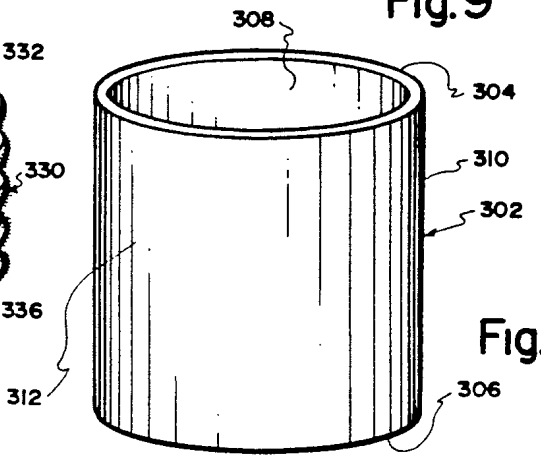
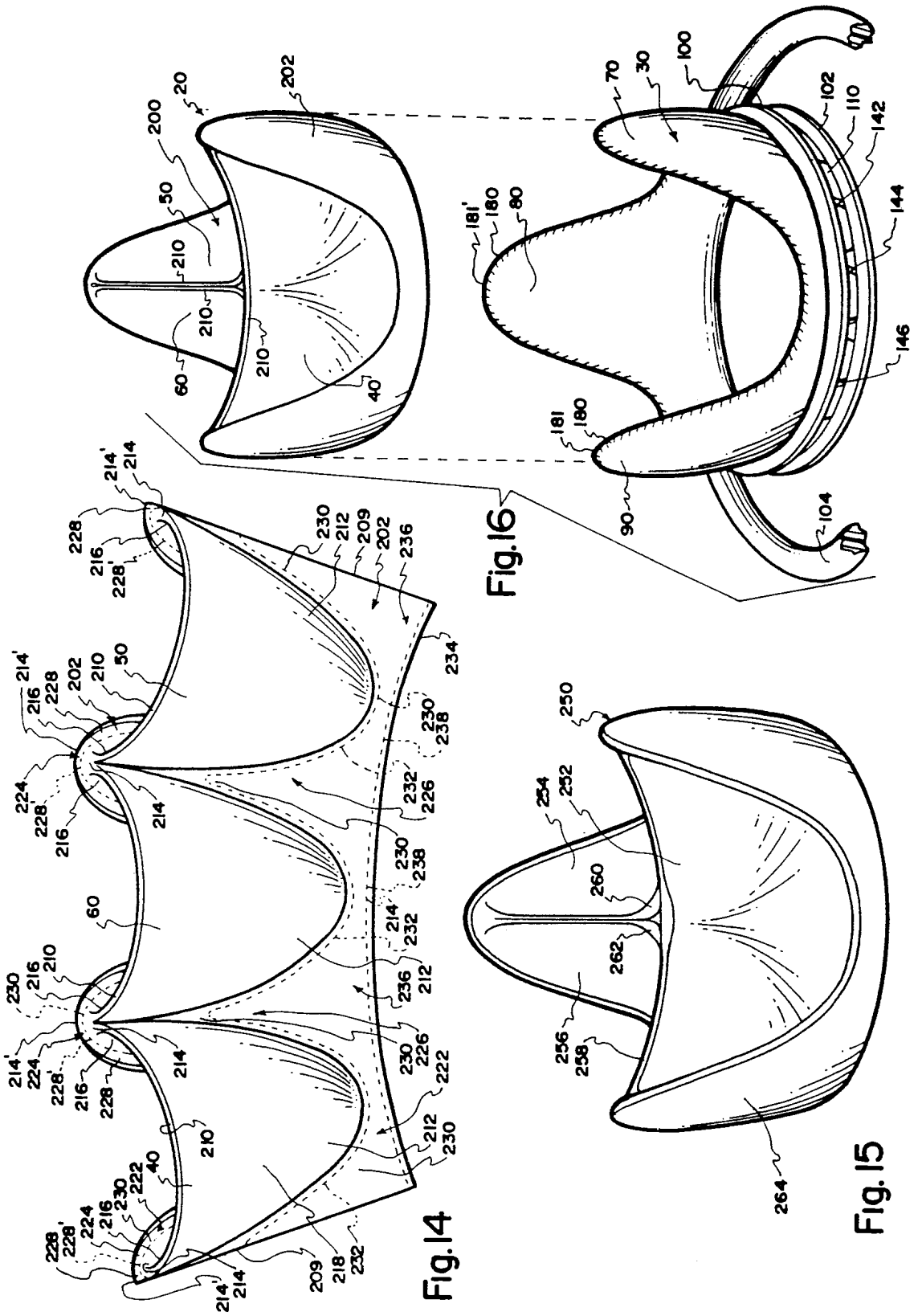


Fig. 20


Fig. 14
Fig. 15
Fig. 16

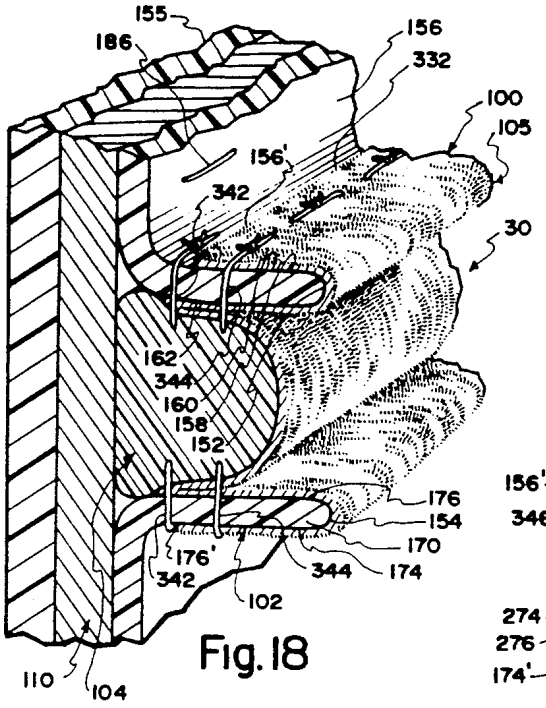


Fig. 18

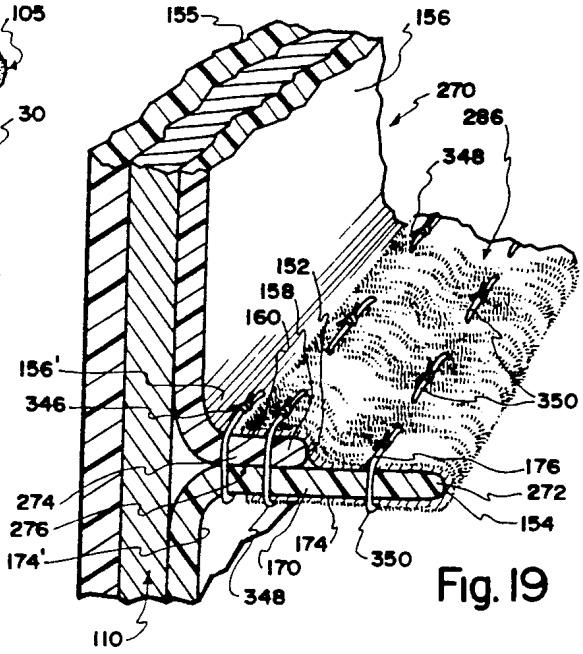


Fig. 19

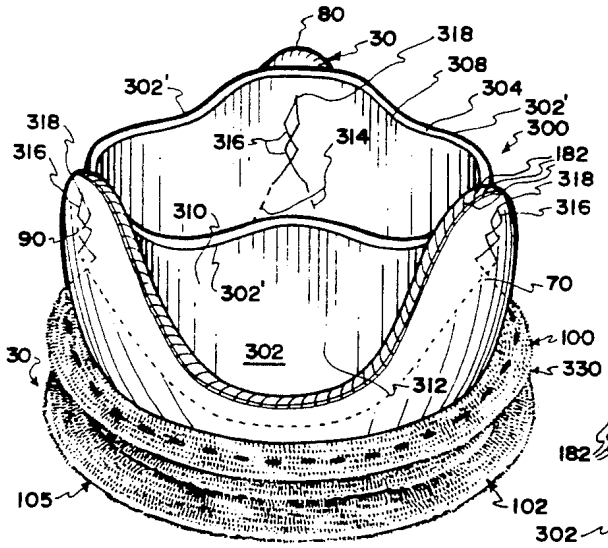


Fig. 21

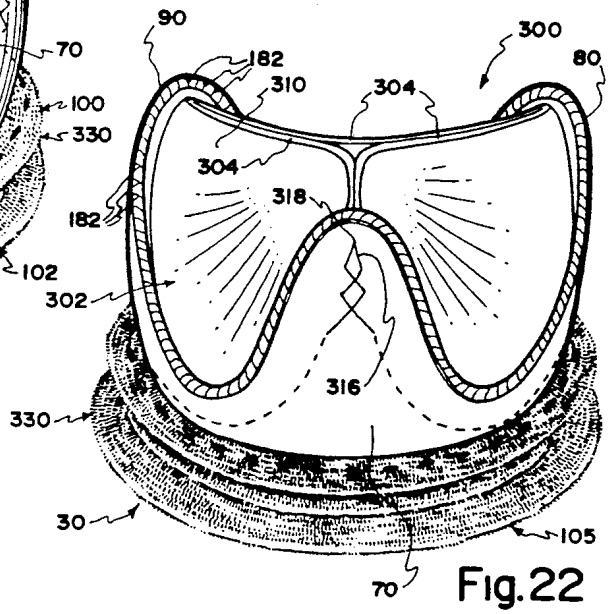


Fig. 22

PROSTHETIC HEART VALVE

FIELD OF INVENTION

This invention relates to implantable heart valves and in particular to long-lasting implantable prosthetic heart valves comprising valve leaflets made from synthetic materials.

BACKGROUND AND DESCRIPTION OF RELATED ART

Two types of replacement heart valve prostheses are generally known in the art. A first replacement type comprises totally mechanical heart valves which effect unidirectional blood flow through the use of a device using a mechanical closure. The more common mechanical heart valves comprise pressure responsive, pressure directed movement of a ball in a cage or tilting or caged discs.

Examples of pressure responsive, pressure directed ball movement devices are found in U.S. Pat. Nos. 3,263,239, 3,365,728, 3,466,671, 3,509,582, 3,534,410, and 3,723,996. Earliest valve designs were strictly concerned with providing a one-way valve which could be used as a replacement for natural mitral and aortic valves. The earliest known artificial caged ball prothesis was first successfully used for treatment of cardiac valve disease in 1953. With improvements in valves and medical procedures, caged valve prosthesis rapidly became commonplace in the early 1960's.

A source of historical and background information in Mechanical Valve Prostheses is found in The Fourth Edition of Thoracic and Cardiovascular Surgery, published in 1983 by Appleton-Century-Crofts, a publishing division of Prentice-Hall, inc. The earliest caged ball valves comprised stainless steel outflow orifice and rib cages and silicone rubber poppets. Such valves experienced a high incidence of thromboembolism associated with the outflow orifices and rib cages. The silicone rubber poppets after a period of use often became grossly deformed with resulting incompetence.

To slow the degeneration of the silicone rubber poppets, cloth and plastic coverings were provided for the metal parts. Such coverings resulted in effects of wear and tissue growth in the coverings. The tissue growth, especially in the coverings over struts of the cages led to a thickening of the struts which slowed or stopped ball movement Fibrous growth across the orifice of the valve led to severe valvular stenosis.

The use of hollow metal spheres and metal tracks in later models of the caged ball rib valves have overcome some of the original problems, and improvements continue to be made to make caged rib ball valve safer and more efficacious.

However, problems inherent with the geometry of the caged ball valve also leads to physiological problems with the use of the valve as a heart valve replacement prosthesis. The caged rib ball valve comprises three orifices through which blood must flow. The primary orifice is the orifice through which blood passes from the effluent chamber being valved. From the primary orifice the blood passes through a secondary orifice defined by the cage and ball, the size of which is determined by the height of the cage and diameter of the ball. The third orifice is the hollow cylindrical path between the ball and cage and the surrounding influent chamber into which the blood flows from the effluent chamber.

The three orifice pattern in a caged ball valve requires sometimes difficult tradeoffs to be made in design. For example, when the ball is large, the third orifice is relatively smaller leading to third orifice stenosis. When the ball is small, the primary orifice is small and relatively stenotic. Further, if travel of the ball in the cage is restricted, as may be required by physiological free space in either the ascending aorta or left ventricle of a patient, the second orifice size must be reduced with resulting relative stenosis thereat. For these reasons, even in a caged ball valve without physiological or structural complications, use is restricted by the inherent three orifice geometry.

Disc valves have been made in the form of caged disc valves and tilting disc valves. Disc valves are generally preferred over caged ball valves because of the inherent low profile configuration of the disk valve. One of the major problems with disc valves and in particular with caged disc valves, is thrombogenicity. Other problems comprise obstructive characteristics inherent to the basic geometry of caged disc valves and degeneration of the disc occluder and strut fracture. Also hemolysis with disc prostheses is especially common.

An example of a tilting disc valve is found in U.S. Pat. No. 4,892,540. Tilting disc valve prostheses have proved to be more satisfactory than the caged disc valves The tilting disc valve prostheses generally have less hemolysis, lower cross valve gradients, and little wear of carbon pyrolyte discs. However, the tilting disc prostheses have a tendency to clot, and a strict anticoagulant regimen is required. Also movement of the disc in close relation with the sewing ring generally increases chances of interference by contact with adjacent mural endocardium or aortic intima and requires extra care be taken to prevent interference with movement of the disc.

A second replacement type of heart valve prothesis is the "tissue-type" valve which structurally resembles and functions similarly to at least one of the human heart valves. Such valves are most often harvested from pigs or cows and are mounted on a prosthetic stent with an affiliated sewing ring for attachment to the annulus of the valve being replaced. Problems related to the requirement for anticoagulants are usually short term with "tissue-type" valves and failure of such valves is seldom abrupt.

However, such valves are generally slowly rejected from the patient as a foreign body. The rejection is manifested as motion limiting calcification of the leaflets of the "tissue-type" valve and slowly ensuing functional failure. Such failure commonly necessitates replacement within fifteen years of original implantation. Examples of devices which apply to human and other animal "tissue-type" valvular prostheses are found in U.S. Pat. Nos. 3,656,185 and 4,106,129. Two examples of currently manufactured and marketed "tissue-type" valves are the MITROFLOW TM Heart Valve by Mitroflow International, Inc., 11220 Voyager Way, Unit 1, Richmond, B.C., Canada V6X 351 and Bovine Pericardial Valve by Sorin Biomedical, S.P.A., 13040 Saluggia (VC), Italy.

BRIEF SUMMARY AND OBJECTS OF THE INVENTION

In brief summary, this novel invention alleviates all of the known problems related to the substantial and long

term requirement for administrating anticoagulants, "tissue-type" rejection, stenotic operation especially with a low profile valve prostheses, thrombogenesis, and post placement infection. The invention is a long-lasting implantable prosthetic heart valve which contains no tissue component.

The valve leaflet apparatus is produced as a unicast or extruded prosthetic valve leaflet apparatus and is devoid of tilting or traveling metal or plastic components. The invention comprises a stent which provides an implanting support for the valve leaflet apparatus. The stent has a novel sewing ring which provides a hard surface component to which anchoring sutures are tied and an optionally used soft component against which the anchoring valve receiving orifice of the heart is free to compliantly expand and contract as the heart beats.

The stent comprises a frame which is fully covered by a biochemically inert or physiologically compatible shroud. The frame is generally a light weight, hollow cylinder, machined or trimmed to provide a suturing support ring, extended cusp stanchions, and interference free blood flow to the coronary arteries. The frame is joint free and is slightly deformable to conform to contractile changes of the heart.

The shroud comprises two or three parts, depending upon use of the valve. A first part of the shroud comprises a hollow cylindrical seamless material which has substantially the same diameter as the frame. The seamless material is inserted into the cylinder of the frame and folded outward and downward at the top and outward and upward at the bottom such that the top and bottom parts meet at a site at the more medial part of the suturing support ring. If the shroud is made of two parts, each top and bottom part is folded outward at the site to form a contiguous two-layered brim. The brim provides the hard surface component forming a sewing ring for suturing the stent for the anchoring sutures. If the shroud comprises three parts, the top and bottom parts are folded outward to form two separated sewing rings.

Above the sewing ring or rings, the shroud is trimmed and sewn or otherwise fused together such as by heat bonding to conform to the shape of the frame and provide an encompassing cover therefor. When the sewing rings are separated, a soft, compliant material is interposed to provide a cushion between the stent and the natural orifice in which the valve resides between the two sewing rings.

Another part of each shroud is a brim cover. In the case of the two part shroud, the brim cover comprises a cylinder of material surrounding, folded over, and securely sutured to the two-layered brim to provide a tissue adhering cover above and below the brim. For the three part shroud, the brim area also comprises a cylinder of material. However, in this latter case, more central portions of the brim cover are folded and inserted between the interfaces between each brim and the soft compliant material, thereby providing a continuous tissue adhering cover which covers each brim, the soft compliant material and interface there between. Each brim cover is selectively complexed and impregnated with antibiotics to reduce the likelihood of infections, anticoagulant and endothelial cells or endothelial growth factors to selectively control incorporation of surrounding tissue of the natural orifice interface.

The valve leaflet apparatus comprises a multiple leaf valve which resembles in form and function a natural heart valve. The valve is a resilient synthetic resinous material part having an outside diameter which is substantially the same size as the stent. The valve leaflet apparatus may be formed by molding or extruding. The valve comprises a plurality of cusps which form medially disposed leaves which coapt upon closure to reduce leaflet wear and tear. When the synthetic resinous material from which the valve is molded is porous and chemically compatible, it is selectively complexed and impregnated with antibiotic medications to decrease the risk of post placement valve infection and anticoagulants to totally eliminate the need for initial exogenous anticoagulation o the part of the patient. The valves are sutured or otherwise permanently attached to the stent.

Accordingly, it is a primary object to provide a prosthetic heart valve having a mean-time-to-failure which is substantially longer than the expected life span of the patient.

It is another primary object to provide such a durable prosthetic heart valve which is simple in construction and low in manufacturing cost.

It is a significant object to provide a prosthetic heart valve configured entirely of biochemically-inert and biocompatible materials.

It is another significant object to provide a heart valve which is devoid of adhesives or bonding resins which might be released into the bloodstream of a receiving patient over a period of time.

It is another significant object to provide a prosthetic heart valve comprising an artificial leaflet valve mechanism which is similar to a natural valve in shape and function and which is assembled into a stent which provides mounting support for the valve in a native orifice from which a natural valve has been excised.

It is another significant object to provide the prosthetic heart valve with a sewing ring comprising a superior and an inferior hard surface against which knots in anchoring sutures are securely affixed.

It is a key object to provide at least one embodiment of a prosthetic heart valve configured to replace a natural mitral valve.

It is another key object to provide at least one embodiment of a prosthetic heart valve conformably configured to replace a natural aortic valve.

It is another key object to provide the prosthetic hear valve with a soft portion interposed between superior and inferior hard valve anchoring surfaces which perimetrically expands between the two hard surfaces and a juxtaposed natural and somewhat irregular native valve annulus to form a conformable seal.

It is still another key object to provide the soft portion comprising material which comprises a cover, the surface of which is permissive only to limited tissue ingrowth such that the soft portion is separable from the native valve annulus should removal of the valve become necessary.

It is fundamental object to provide a stent which comprises a frame, a frame shroud or cover comprising a two part sewing ring which encompasses at least a large measure of the frame, and optional additional cover parts which cover otherwise uncovered parts of the frame in the area where the sewing ring is attached to the native valve orifice.

It is significant object to provide a stent which permits the prosthetic valve to deform slightly with heart motion thereby permitting leaflets of the valve mechanism to coapt with a sliding motion to reduce wear at the free margins of the leaflets.

It is another significant object to provide a stent frame which is capable of annular deformity and slight perimetric expansion such that the stent frame diametrally varies expansively and contractually with the natural valve orifice within which the stent frame is disposed.

It is another significant object to provide a stent which permits the prosthetic valve to expand and contract with the natural valve orifice in which the prosthetic valve resides to reduce tugging forces upon the sutures and thereby reduce the likelihood of eventual valve dehiscence.

It is a basic object to provide a stent frame comprised of metal or synthetic resinous material which describes a continuous, seamless circular plane.

It is an essential object to provide a stent frame which comprises a plurality of circumferentially-spaced, axially projecting cusp supports.

It is consequential object to provide a stent frame comprising a plurality of windows which reduce the weight of the stent frame.

It is another object to provide a stent frame comprising a series of holes therein which allow margins of a valve leaflet apparatus to be securely affixed to the stent frame.

It is vital object to provide a double walled shroud of biocompatible material which covers at least a large measure of the stent frame.

It is another vital object to provide the double walled envelope which comprises pockets which receive and cover the cusp supports of the stent frame.

It is another significant object to provide a stent frame enveloping cover which comprises superior and inferior members of a sewing ring by which the prosthetic heart valve is sewingly affixed about the native orifice.

It is another fundamental object to provide the double walled stent frame enveloping cover comprising a continuous connection to each sewing ring.

It is another important object to provide at least one sewing ring comprising a firm, knot supporting inferior and superior surface for sewingly affixing the prosthetic heart valve to the native valve orifice.

It is another key object to provide a cover for the sewing rings and a soft, deformable, space filling material intermediate portion interposed between two sewing rings, the space filling material perimetrically expanding to fill and seal against a native valve annulus when the sewing ring are drawn tightly into place around the annulus.

It is another key object to provide a soft, deformable intermediate portion which comprises material which results in variable incorporation of surrounding tissue, thereby providing optimal balance between ease of removal and prevention of infection.

It is a notable object to provide a cover for the stent frame at least a part of which is impregnated with at least one active biochemical from a group comprising antibiotics, anticoagulant medications, endothelial cells or endothelial cell growth factors.

It is a main object to provide a heart valve leaflet apparatus which resembles in form and function a human trileaflet heart valve.

It is another main object to provide a valve mechanism which comprises no centrally disposed members during the time the valve is open.

It is another main object to provide a valve leaflet apparatus comprising members which move toward the inner surface of the stent when the valve is coursed with maximum flow thereby providing a valve having a flow cross section substantially as large as the stent.

It is another notable object to provide a valve mechanism which comprises a trileaflet configuration of substantially the same dimensions as a natural aortic valve thereby providing a prosthetic valve of relatively low silhouette compared to a caged ball valve.

It is another fundamental object to provide a valve mechanism which comprises a functionally continuous surface over all aspects of the valve.

It is a principal object to provide a valve mechanism which is non-thrombogenic.

It is another notable object to provide at least one valve leaflet apparatus which is impregnated with anticoagulant medication to eliminate the need for initial exogenous anticoagulation on the part of the patient.

These and other objects and features of the present invention will be apparent from the detailed description taken with reference to accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective of an implantable prosthetic aortic heart valve comprising a heart valve leaflet apparatus suitably joined to a supporting stent and brim-formed double sewing rings seen partially covered by a brim cover, a portion of the brim covering portion of the apparatus being removed to reveal other details of the sewing rings.

FIG. **2** is a perspective of the frame of the stent.

FIG. **3** is a perspective of the frame and a length of foldable cylindrical covering material disposed therein as a first step in a stent assembly process.

FIG. **4** is a perspective of steps following the step of FIG. **3** in the stent assembly process wherein the covering material is folded outward and over the frame at both the top and bottom and then folded outward to form double brim sewing rings of the implantable prosthetic aortic heart valve.

FIG. **5** is a perspective of a partially completed aortic heart valve stent with the covering trimmed along dashed lines seen in FIG. **4** to encompass rising cusp supports of the frame.

FIG. **6** is a perspective of a covered aortic heart valve stent wherein the trimmed cover is sewn together.

FIG. **7** is a section along lines **7—7** of FIG. **6**.

FIG. **8** is a perspective of a covered stent for a mitral heart valve prosthesis.

FIG. **9** is a section along lines **9—9** of FIG. **8**.

FIG. **10** is a perspective of a heart valve leaflet apparatus.

FIG. **11** is a section along lines **11—11** of FIG. **10**.

FIG. **12** is a top elevation of a closed trileaflet valve.

FIG. **13** is a top elevation of an open trileaflet valve.

FIG. **14** is a perspective of the heart valve leaflet apparatus incised along line **14—14** in FIG. **10** and opened for clarity of presentation.

FIG. **15** is a perspective of a prosthetic heart valve leaflet apparatus wherein the leaflets are leaflet models cast from a mold of a natural heart valve.

FIG. **16** is an exploded perspective of the heart valve prosthesis seen in FIG. **1**.

FIG. **17** is a perspective of a cylinder of material used to cover a brim portion of the stent.

FIG. **18** is an exterior perspective of a medial section of the aortic valve prosthesis stent of FIG. **7** showing the cylinder of material seen in FIG. **17** disposed about

and securely affixed to the brim portion of the aortic valve stent.

FIG. **19** is an exterior perspective of a medial section of the mitral heart valve prosthesis stent of FIG. **9** showing the cylinder of material seen in FIG. **17** disposed about and securely affixed to the brim of the mitral valve stent.

FIG. **20** is a perspective of a cylinder of material from which a trileaflet valve is made.

FIG. **21** is a perspective of the cylinder of material of FIG. **20** sewn into a stent to form an aortic valve prosthesis, said valve being seen in a nearly fully open configuration.

FIG. **22** is a perspective of the aortic valve seen in FIG. **21** rotated about a vertical axis and closed.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Reference is now made to the embodiments illustrated in FIGS. **1–22** wherein like numerals are used to designate like parts throughout.

A first illustrated embodiment of the invention, seen in FIG. **1**, is a prosthetic aortic heart valve **10**. Aortic heart valve **10** comprises a heart valve leaflet apparatus **20** and a heart valve leaflet apparatus supporting stent **30**. Heart valve leaflet apparatus **20** is disposed medially to stent **30** and therein comprises three cusps **40**, **50**, and **60** which are similar in form and function to cusps of a natural heart valve. Stent **30** comprises three upright, cusp supports **70**, **80**, and **90**, each of which provides a vertical stay for the cusps **40**, **50**, and **60**.

Further, in this embodiment, aortic valve **10** comprises two radially projecting sewing rings **100** and **102**. Interposed between sewing rings **100** and **102** is a soft, deformable intermediate natural valve orifice interfacing portion **104**, the purpose and character of which is provided in detail hereafter.

Seen in part, covering sewing rings **100** and **102** and interfacing portion **104**, is a brim cover **105**. Brim cover **105** is described in detail hereafter.

While sewing rings may be differently constructed within the scope of the invention, in this first illustrated embodiment, sewing rings **100** and **102** are contiguous segments of a stent cover **106** which, in large measure, covers and protects a supporting frame **110**, seen in FIG. **2**, from biologic activity. The reasons for so making and the method for fabricating sewing rings **100** and **102** is covered fully below.

Frame **110** is generally of a continuous hollow cylindrical form and is substantially rectangular in cross section. Although frame **110** is completely covered and sealed from biological fluid in each implanted aortic valve **10**, the material selected for frame **110** is non-corrosive, fatigue resistant, and substantially biologically inert. As such, frame **110** may be made from stainless steel or a carbon based material such as pyrolytic carbon on a graphite substrate. However, frame **110** may be made from materials having comparable weight, biocompatibility, flexibility, and strength characteristics similar to the materials of preference within the scope of this invention.

To provide support for stent **30** and the three superior circumferential edges of cusps **40**, **50**, and **60** of valve leaflet apparatus **20**, frame **110** comprises three inverted "U" shaped stanchions **112**, **114**, and **116**. In this first illustrated embodiment, each of the stanchions **112**, **114**, and **116** are identical. For this reason, only stanchion **112** will be described in detail with the understanding the description of stanchion **112** applies equally to stanchions **114** and **116**.

Inverted "U" shaped stanchion **112** comprises a superior edge **120**, an inner surface **122**, an inferior edge **124**, and an outer surface **126**, as best seen in FIG. **2**. At the highest point, inverted "U" shaped stanchion **112** comprises an apex **128** superiorly disposed on edge **120**. Similarly, stanchion **114** comprises an apex **128"** and stanchion **116** comprises a stanchion **128'**. Disposed below apex **128** and inferior to superior edge **120**, frame **110** comprises a plurality of holes, generally numbered **130**, disposed between surfaces **122** and **124**. Holes **130** are provided for the purpose of sewing corresponding margins of the heart valve leaflet apparatus **20** to stent **30**. For this reason, superior edge **120** is arcuately formed to follow a path which provides a margin superior to holes. Thus, edge **120** arcuately follows a distally descending path from apex **128** to a most inferiorly disposed medial point **132** where stanchion **112** extends to circumferentially smoothly connect to stanchion **116**. Edge **120** similarly descends distally from apex **128** on the other side of stanchion **112** to an inferiorly disposed medial point **134** extending circumferentially to connect smoothly to stanchion **114**.

Inferior edge **124** comprises an apex **138** disposed immediately below apex **128** and offset from apex **128** to provide inferiorly disposed support for attaching marginally disposed portions o heart valve leaflet apparatus **20** associated with cusps **40** and **50**, as is described in detail hereafter. As seen in FIG. **2**, proximally disposed in a margin of frame **110** above inferior edge **124**, are a plurality of holes, generally numbered **140**, disposed between surfaces **122** and **126**. Holes **140** comprise a second set of holes inferior to holes **130** through which heart valve leaflet apparatus **20** is also sewingly or otherwise attached to stent **30**. While attachment of the heart valve leaflet apparatus **20** to stent **30** is described to be accomplished by sewing, one who is skilled in the art would understand that other methods of attachment, such as by a plastic connector or by fusing parts together through the holes, generally numbered **130** and **140**, are within the scope of the invention.

As seen in FIG. **2**, superior edge **120** and inferior edge **124** combine to describe the inverted "U" shape of stanchion **112**. Flexibility of the material used to make frame **110** in combination with the inferior opening of the inverted "U" of stanchion **112** provides a frame capable of annular deformity and slight perimetric expansion. Such deformity and expansion permits the frame to compliantly respond to expansion and contraction of the native valve orifice of the beating heart in which aortic valve **10** is implanted to reduce beat by beat stress on aortic valve **10** anchoring sutures and thereby reduce the likelihood of eventual valve dehiscence. Also, to reduce the likelihood of valve dehiscence, the mass of frame **110** is reduced by excising material which is essentially unnecessary for strength, but which adds to the weight of frame **110** and therefore of stent **30**. Therefor, windows **142**, **144**, and **146** are formed as best seen in FIG. **2**.

Reference is now made to FIGS. **3–5** wherein the steps used to cover at least a large measure of frame **110** are seen. As seen in FIG. **3**, the covering is a cylindrical seamless section **150** of material which is essentially biologically inert. A material such as GORTEX TM , a polytetrafluoroethylene (PTFE) composite, is preferable, however materials such as continuous knit comprising a commercially available, medical grade DA-

CRON TM velour for example, knitted velour polyethylene glycol terephthalate or other materials having biochemically inert and compatible characteristics similar to those of PTFE derivatives may be used. All GORTEX TM materials referenced hereafter are products of and available from W.L. Gore and Associates, Inc., Medical Products Division, P.0. Box 900, Flagstaff, Ariz. 86002. Section **150** is of substantially the same exterior diametrical size as the interior diameter of frame **110** and comprises a length which exceeds twice the height of stanchions **112**, **114**, and **116** for reasons which are described in detail hereafter. Section **150** comprises a top edge **152**, a bottom edge **154**, an inside surface **155**, and an outside surface **155'**.

As a first step in covering frame **110**, section **150** is inserted into frame **110** as seen in FIG. **3** to cover inner surface **122**. That portion of frame **110** which is hidden from view by the insertion of section **150** is shown by dashed lines **121**.

As seen in FIG. **4**, the top edge **152** of section **150** is folded radially outward and downward until the originally outside disposed surface **155'** of section **150** rests upon apex **128** of stanchion **112** and resides similarly upon apex **128'** of stanchion **116** and upon apex **128''** of stanchion **114** whereby the originally inside disposed surface **155** forms an outside sidewall **156**. So downwardly extended, section **150** comprises sufficient length such that edge **152** is everted radially outward to form a brim **158**.

Thus brim **158** is a continuous, seamless extension of sidewall **156**, along a connecting line **156'**. The originally inside disposed surface **155** of section **150** therefore becomes a superior surface **160** and the originally outside disposed surface **155'** of section **150** becomes an inferior surface **162** of brim **158**. Brim **158** extends radially outward a sufficient distance from the vertical portion of sidewall **156** to provide a superiorly disposed sewing ring **100**. Sewing ring **100** comprises a width which is adequate for aortic valve **10** implanting purposes as is well known in the art.

Similarly bottom edge **154** is turned outward and upward until originally outside disposed surface **155'** is in firm contact with an inferior segment **164** of inferior edge **124** of frame **110** between stanchions **112** and **116** (see also FIGS. **2** and **3**). Inferior segment **164** is seen as a hidden dashed line in FIG. **4**. Thereat, originally outside disposed surface **155'** is likewise in firm contact with each inferior segment **166** and **168** (see FIG. **2**) which resides between stanchions **112** and **114** and stanchions **114** and **116**, respectively. So disposed, inferior edge **154** is everted outward to form a second brim **170**. Thereby originally inside disposed surface **155** forms an exterior inferior sidewall **172** which forms a contiguous, seamless connecting line with an inferior side **174** of brim **170**. Similarly, originally outside disposed surface **155'** forms a contiguous, seamless connection **174'** with a superior side **176** of brim **170**. In aortic heart valve **10**, the width of brim **170** is similar to the width of brim **158** thereby providing a second sewing ring **102** of substantially the same dimensions as sewing ring **100** but separated therefrom as seen in FIG. **4**.

Following the pattern of the superior edge **120** seen as dashed lines **121** in FIG. **4**, material is trimmed away along trim line **180** along a pattern superior to edge **120** to reveal parted edges **181** and **181'** as seen in FIG. **5**. Sufficient material is retained superior to edge **120** to close and completely cover superior edge **120** of frame **110** by tightly sewing parted edges **181** and **181'** together along trim line **180**, as seen in FIG. **6**.

Sewing to join parted edges **181** and **181'** together is currently preferred; however, the parted edges **181** and **181'** may be tightly bonded together by other methods such as heat fusing. The method of bonding depends upon the frame covering material selected. In any event, the edges are tightly bound together and completely cover frame **110** along edge **120**, as seen in FIG. **6**. So covered, stent **30** comprises the three cusp supports **70**, **80** and **90** respectively supported by covered stanchions **112**, **114**, and **116**.

Reference is now made to FIGS. **6**, **7** and **16–19**, wherein additional details of construction of stent **30** are seen. Stent **30** is particularly configured for use as an aortic valve. As a natural aortic valve orifice, in which aortic valve **10** is implanted, comprises tissue which changes the lateral dimensions of the natural valve orifice during each cycle of a beating heart, it is important to compensate for those changes to reduce effects which might increase the likelihood of valve dehiscence due to structural failure of the sewing ring, sutures, or natural tissue surrounding the valve.

For these reasons, stent **30** comprises the flexible frame **110**, as earlier described, which responsively reacts to expansion and contraction of the natural valve orifice. Also, an intermediate, orifice size compensating and interfacing portion **104** is disposed between sewing ring **100** and **102** and to provide a soft elastically compressible space filling component which perimetrically expands and compresses to effect a good annular seal between frame **110** and the natural orifice by valve **30**. As seen in FIG. **6**, the orifice interfacing portion **104** is externally and peripherally disposed about frame **11** between superiorly disposed sewing ring **100** and inferiorly disposed sewing ring **102**.

Natural valve interfacing portion **104** is preferably formed to be a contiguous ring of material which is compressible, but which comprises memory which responsively expands to fill space previously vacated and unfilled by the remainder of stent **30** when compressive pressures are relieved. Such material may be non-expanded GORTEX TM . However, interfacing portion **104** may be a linear segment of deformable material sewn or otherwise secured end-to-end to form a continuous ring.

When the interfacing and sewing ring materials are biochemically inert such that tissue does not adhesively attach thereto, brim cover **105** is used to provide the interface between the natural excised valve orifice and implanted prosthetic heart valve. Referring again to FIG. **1**, a portion of brim cover **105** is seen on the right viewing side of aortic heart valve **10**. As seen therein, brim cover **105** covers each sewing ring **100** and **102** and the orifice interfacing portion **104** disposed therebetween.

Brim cover **105** is preferably made from a material which is permissive to tissue in-growth so that a degree of adhesion improves adhesion of the grafted valve within the native excised valve orifice. Such material is preferably velour a commercially available, medical grade DACRON TM , but other relatively biologically compatible, biologically inert and physiologically stable materials may be used within the scope of the invention. A detailed description of the process for making and attaching brim **105** is provided hereafter. One important factor in the selection of materials for brim cover **105** is the choice of materials which may be complexed with

appropriate biochemicals from a group comprising antibiotics, anticoagulant medications, endothelial cells or endothelial cell growth factors.

Incorporation of complexed antibiotics about the site of the excision significantly reduces the risk of post placement infection thereat, potentially reducing the amount of otherwise administered antibiotics and relieving the valve **10** recipient o a post placement antibiotics regimen. Incorporating complexed anticoagulants when possible, in prosthetic leaflet apparatus **20**, reduces or eliminates the need for an initial exogenous anticoagulation regimen on the part of the valve recipient. Such a regimen is currently common place for prosthetic heart valve recipients.

A cross section of stent **30** made along line 7—7 in FIG. **6** is seen in FIG. 7. The cross section of stent **30** comprises frame **110** totally enclosed by material of section **150** and interfacing portion **104**. As seen therein, material remaining after being parted along trim line **180** is folded to form a seam along superior edge **120** of frame **110** and tightly bound thereat with a plurality of sutures **182** to close parted edge **181'** over parted edge **181**.

Additional sutures, represented by sutures **184** and **186** in FIG. 7, tightly bind sewing ring **100** through windows and inferiorly disposed openings in frame **110** to outside sidewall **156** along seamless connection line **156'**. Similarly, sewing ring **102** is tightly bound through the windows and inferiorly disposed openings in frame **110** to exterior inferior sidewall **172** along seamless connection line **174'** by sutures, represented by sutures **188** and **190** in FIG. 7. All such sutures used in valve **10** and similarly constructed valves preferably constitute GORTEX TM 3-0 suture material. However, other strong, long-lasting suture material which is essentially biochemically inert and of other preferable sizes can be used within the scope of the invention.

The ring comprising interfacing portion **104** is snugly inserted between sewing rings **100** and **102** and firmly affixed thereat by additional sutures or by a ring-tight fit against frame **110** between sewing rings **100** and **102**. Thus covered, frame **110** is enclosed and substantially free from interfacing liquids and tissue which surround an operative valve **10**.

In this first illustrated embodiment, heart valve leaflet apparatus **20** comprises a prosthetic trileaflet valve apparatus **200** which is operatively similar to a natural aortic heart valve. See FIG. **10**. Heart valve leaflet apparatus **20** comprises a support collar **202** and thereto integrally connected leaflet cusps **40**, **50**, and **60** of prosthetic trileaflet valve apparatus **200**. In FIG. **14**, heart valve leaflet apparatus **20** is excised along line **209**, seen in FIG. **10**, and opened to provide a view of the inside of cusps **40**, **50**, and **60** and collar **202**. FIG. **11** comprises a section along lines **11—11** of FIG. **10** and shows the unitary construction of heart valve leaflet apparatus **20** and attachment between collar **202** and cusps **40** and **50** of prosthetic apparatus **200**.

In a natural aortic heart valve, the cusps are individually identifiable as an anterior cusp, a left posterior cusp, and a right posterior cusp. Identifying features of the anterior cusp and left posterior cusp are depressions for connecting coronary arteries. In prosthetic apparatus **200**, each leaflet cusp **40**, **50**, and **60** is substantially like the others. For this reason, only one cusp **40** will be described in detail with the understanding that a like description applies for cusps **50** and **60** as well.

Cusp **40** comprises a thickened superior edge which forms a commissure or lip **210** and a thin substantially uniform leaf membrane **212**. In this embodiment, Cusp **40** is preferably molded as a unitary part of heart valve leaflet apparatus **20** and thereby comprises a thickened connecting intersection **214** disposed along the interface between collar **202** and commissure **210** and leaf membrane **212**, as best seen in FIG. **11**. The thickening of commissure **210** and connecting intersection **214** is necessary to provide reliable structure where flexing and wear is the greatest in heart valve leaflet apparatus **20**. As seen in FIG. **10**, cusp **40** comprises an exterior facing side **216**. An interior facing side **218** of cusp **40** is best seen in FIG. **14**.

Collar **202** is a stent interconnecting structure which supports cusps **40**, **50**, and **60**, substitutes for natural supporting structure in the native orifice and, thereby, provides an interface to stent **30**. As such collar **202** rises to an apex **214'** above connecting intersection **214** where collar **202** interconnects to each commissure **210**. To provide effluent access for blood flow to the coronary arteries during diastole, collar **202** is dramatically decreased in vertical height between each apex **214'** to a medially disposed low point **214''**.

The connecting features of collar **202** are seen from an exterior perspective in FIG. **10** and from an interior perspective in FIG. **14**. Collar **202** comprises an exterior side **220** and an interior side **222**. The interface with each cusp **40**, **50** and **60** is entirely disposed on interior side **222** of collar **202**. Generally, inner side **222** is divided into a section **224** superior to the interface with each cusp **40**, **50**, and **60** and a section **226** inferior to the interface with each cusp **40**, **50**, and **60**.

For the purpose of affixing each cusp **40**, **50**, and **60** solidly to stent **30** and, in particular, to frame **110**, collar **202** comprises a superior binding margin **228** and an inferior binding margin **230**. Superior binding margin **228** is disposed within superior section **224** and comprises an area adequate to suture collar **202** to stent **30** thereat. A dashed line **228'** traces a portion of the suture trail within superior binding margin **228** in FIG. **14**.

Similarly, inferior binding margin **230** is disposed within inferior section **226** and comprises an area adequate to suture collar **202** to stent **30** thereat also. Another dashed line **232** traces the suture trail inferiorly disposed to cusps **40**, **50**, and **60** in FIG. **14**. As seen therein, collar **202** comprises a bottom edge **234** and a binding margin **236** immediately superior to bottom edge **234**. A third suturing trail, seen as dashed line **238**, is disposed within binding margin **236** for the purpose of providing a region for binding the bottom of collar **202** to stent **30** to eliminate any cavities of low or no liquid flow between collar **202** and stent **30**.

While it is within the scope of the invention to provide prosthetic trileaflet valve apparatus having cusps which are manufactured separately and later affixed to a collar, it is preferred in this embodiment that heart valve leaflet apparatus **20** be cast as a unit or unicast. Methods for casting such a valve are well known in the art. One material which may be used is silicone. An advantage derived from the use of silicone is the opportunity for complexing with other materials, such as antibiotics to decrease the risk of post placement valve infection and anticoagulant medication to eliminate the need for initial exogenous anticoagulation on the part of the patient.

Referring to the section along lines **11—11** of FIG. **10** as seen in FIG. **11**, continuity between cusp **40** and

collar **202** is seen at juncture **240** and similar continuity between cusp **50** and collar **202** is seen at juncture **242**. Each cusp **40** and **50** is seen to comprise a separate commissure **210** and a pliant leaf membrane **212** there below. The separation of each juncture **240** and **242** is seen to occur medial to superior binding margin **228** such that binding sutures do not impair movement of any leaf membrane **212**.

Leaflet apparatus **20**, comprising prosthetic trileaflet valve apparatus **200** and collar **202**, is inserted to snugly fit into stent **30**. So disposed, collar **202** is firmly affixed to stent **30** by suturing along dashed lines **228'**, **232**, and **238**. Suturing along dashed lines **228'** and **232** comprises passing suturing materials through holes **130** and **140** circumferentially disposed in frame **110**, as earlier described. Suturing along dashed line **238** may alternatively attach collar **202** to sites inferior to edge **164** of frame **110** in inside surface **155** or directly through frame **110** through a series of holes therein which are not shown.

Thereby, heart valve leaflet apparatus **20** is firmly affixed to stent **30** to complete prosthetic aortic valve **10** providing an aortic replacement valve which comprises a soft portion **104** with a tissue compatible brim cover **105** for interfacing with an irregular native annulus from which the natural valve has been excised and hard surfaced sewing rings **100** and **102**, also covered by brim cover **105**, externally disposed upon the stent **30**. As the sutures which anchor valve **10** in the native orifice pass through sewing rings **100** and **102** and are firmly, tightly affixed thereto, the deformable intermediate interfacing portion **104** and brim cover **105** perimetrically compress and expand to fill and seal against the irregular native valve annulus.

Reference is now made to FIGS. **12** and **13** wherein valve **10** is seen closed and opened, respectively. As seen in FIG. **12**, each commissure **210** is aligned with the other two juxtaposed commissures **210** to substantially close valve **10**. However, as each commissure **210** is not perfectly flexible and pliant, a triangular orifice **244** is formed which, if not otherwise closed, provides a regurgitant pathway through orifice **244** and a resulting valvular insufficiency. However, the flexibility of frame **110** and therefore stent **30** and the pliability of each leaf membrane **212** permits membranes **212** to coapt and close valve **10** at contacting surfaces inferior to commissures **210**. exemplarily seen as contact lines **246** within triangular orifice **244**.

When valve **10** is open, triangular orifice **244** is enlarged, providing a medially free passageway through which blood courses. Each commissure **210** and associated leaf membrane **212** is forced radially outward to provide an orifice operatively similar to a natural aortic valve orifice opening.

A second illustrated embodiment of an aortic valve leaflet apparatus **250** is seen in FIG. **15**. Aortic valve leaflet apparatus **250** is similar to heart valve leaflet apparatus **20** seen in FIG. **10**, comprising three leaflets membranes **252**, **254**, and **256**, each membrane **252**, **254**, and **256** comprising a superiorly disposed commissure **258**, **260**, and **262**, respectively. However, in this case, the leaflet membranes **252**, **254**, and **256** are not alike. Similarly, each commissure **258**, **260**, and **262** is different from the other two commissures.

Such is the case because aortic valve leaflet apparatus **250** is produced from a mold of a natural valve. As such, the more medial portions of the each commissure **258**, **260**, and **262** comprises a thicker, non-uniform appearance associated with naturally grown valves. Material from which aortic valve leaflet apparatus **250** is made is the same as that specified for heart valve leaflet apparatus **20**. The characteristics of a surrounding, mounting collar **264** are the same as that described for collar **202**, including all cusp-collar interfaces and suturing lines.

Another illustrated embodiment for a stent **270** is seen in FIG. **8** and **9**. Except for the steps of outward eversion of each brim, stent **270** is made as stent **30** is made. As is the case for stent **30**, a section **150** of cylindrical material is used to cover frame **110**. However, in this case, section **150** is disposed to entirely cover frame **110** and produce a stent preferably for a prosthetic valve used as a valve replacement in a native orifice having the geometry of an orifice similar to that from which a natural mitral valve has been excised To provide a stent **270** with sewing rings which correspond to the funnel-like contour of an excised mitral valve orifice, the structure and steps in manufacture of the sewing ring forming brims are markedly different than similar steps in forming brims for stent **30**.

Reference is again made to FIGS. **3-5** wherein the steps used to cover at least a large measure of frame **110** are seen. As seen in FIG. **3**, the covering is cylindrical seamless section **150** of the same essentially biologically inert material used to make stent **30**. The frame **110** covering process to the step of everting each edge **152** and **154** outwardly to form a brim is the same as the covering steps for stent **30**.

Therefore, as the first step in covering frame **110** to make stent **270**, section **150** is inserted into frame **110** as seen in FIG. **3** to cover inner surface **122**. As seen in FIG. **4**, the top edge **152** of section **150** is folded radially outward and downward until the outside surface **155'** of section **150** rests upon apex **128** of stanchion **112** and resides similarly upon apex **128'** of stanchion **116** and upon apex **128"** of stanchion **114** whereby inside surface **155** forms an outside sidewall **156**.

Similarly bottom edge **154** is turned outward and upward until outside surface **155'** is in firm contact with an inferior segment **164** of inferior edge **124** of frame **110** between stanchions **112** and **116** and is likewise in firm contact with each inferior segment **166** and **168** which resides between stanchions **112** and **114** and stanchions **114** and **116**, respectively. So disposed, inferior edge **154** is everted outward to form an inferiorly disposed wide brim **272**. See FIG. **8**. Thereby inner surface **155** forms an exterior inferior sidewall **172**, see FIG. **9**, which forms a contiguous, seamless connecting line **174'** with an inferior side **174** of brim **272**. Similarly, originally outside surface **155'** forms a contiguous, seamless connection with a superior side **176** of brim **272**.

The downwardly extended portion of section **150** comprises sufficient length such that edge **152** is everted radially outward to form a narrow brim **274** in direct contact with brim **272**. The originally inside disposed surface **155** of section **150** therefore becomes a superior surface **160** and the originally outside surface **155'** of section **150** becomes an inferior surface **162** of narrow brim **274**. Thus brim **274** is a continuous, seamless extension of sidewall **156**, along connecting line **156'**.

Note that, in the case of stent **270**, the eversion of edge **152** occurs at a site inferior to the eversion of brim **158** of stent **30**. Brim **274** extends radially outward a sufficient distance from the vertical portion of sidewall **156** to provide a connecting surface with brim **272** to form a single sewing ring **276**. As seen in FIG. **8**, sewing ring **276** comprises a width which is adequate for ex-

cised mitral valve orifice implanting purposes as is well known in the art.

The steps of trimming material along trim line **180** and joining parted edges **181** and **181'** together are the same as for stent **30**.

FIG. **9** shows a cross section of stent **270** made along line **9—9** in FIG. **8**. The cross section of stent **270** comprises frame **110** totally enclosed by material of section **150**. As seen therein, material remaining after being parted along trim line **180** is folded to form a seam along superior edge **120** and tightly bound thereat with a plurality of sutures **182** to close parted edge **181'** over parted edge **181**.

Additional sutures, represented by sutures **278** and **280** in FIG. **9**, tightly bind brim **274** through windows and inferiorly disposed openings of frame **110** to inner surface **155** along seamless connection line **156'**. Similarly, sewing ring **276** is tightly bound through the windows and inferiorly disposed openings in frame **110** to inner surface **155** along seamless connection line **174'** by sutures, represented by sutures **282** and **284** in FIG. **9**. All such sutures used in stent **270** are preferably GORTEX TM 3-0 suture material. However, other strong, long-lasting suture material which is essentially biochemically inert can be used within the scope of the invention. A brim cover **286**, as seen in FIG. **19**, for covering stent **270** sewing ring **276** is described in detail hereafter.

Thus covered, frame **110** is substantially free from interfacing liquids and tissue which surround an operative prosthetic mitral valve replacement.

A third illustrated embodiment of a heart valve **300** is seen in FIGS. **21** and **22**. Valve cusps are formed from a single piece of material, such as a hollow cylinder of material **302** seen in FIG. **20**. Cylinder **302** may be formed by a cylindrical extrusion or by suturing vertical edges together. Material cylinder **302** comprises a substantially planar superior edge **304** and an oppositely disposed inferior edge **306**. Further material cylinder **302** comprises an inner surface **308** and an outer surface **310** disposed between edges **304** and **306** forming cylindrical wall **312**. Cylindrical wall **312** is of uniform thickness and is preferably thin and pliable, yet strong and enduring under pressure and flexure.

One material from which heart valve leaflet apparatus **20** may be made is a synthetic, stretchable polytetrafluoroethylene (PTFE) material known as GORTEX SURGICAL MEMBRANE TM. GORTEX SURGICAL MEMBRANE TM is essentially biochemically inert, hydrophobic and non-thrombogenic. It has been used in pleural, peritoneal and pericardial reconstruction where absolute prevention of tissue adhesion to it is desired.

The outside diameter of cylinder **302** is essentially the same as the internal diameter of stent **30**. To form valve **300**, cylinder **302** is displaced into stent **30**, as seen in FIG. **21**. Cusp **302'** forming, attaching sutures **314** are sewn through cylinder **302** and stent **30** to securely tie cylinder **302** to each cusp **302'** support **70**, **80**, and **90** as seen in FIG. **21**. The more superior sutures **316** are cross stitched at apical connections **318** of each cusp **302'** support **70**, **80**, and **90** attachment site and then securely stitched in place along each cusp **302'** periphery in a descending and ascending pattern similar to that seen in FIG. **14**. The manner of suturing seen in FIG. **21** is used in valves where cusps are formed from tissue such as flattened pericardium derived from living organs and is well known in the art. Also, cylinder **302** may be doubly attached at a second suture line (not shown) similar to suturing line **238** seen in FIG. **14** to provide a guard against eventual dehiscence due to systolic blood flow. The free leaflet surfaces forming each cusp **302'** between cusp supports **70**, **80**, and **90** are preferably made concave so that the leaflet surfaces of each cusp **302'** tend to reside in the closed position. The leaflet surfaces of each cusp **302'** can be made concave by heat treatment or other material forming methods generally known in the art.

As earlier specified, sutures are preferably GORTEX TM 3-0 suture material; however, other suture material comprising acceptable biochemical inertness and lasting characteristics may be used. As cylinder **302** is attached to stent **30** and as see in FIG. **21**, valve **300** is completely centrally, patently open as in systole. In FIG. **22**, valve **300** is rotated and closed such that corresponding sections of superior edge **304** closes upon itself to provide a closed orientation. To reduce pressure loss across valve **300**, thin walled GORTEX SURGICAL MEMBRANE TM having a wall thickness of 0.10 mm may be used. While valve **300** is seen to be an aortic valve configuration in FIGS. **21** and **22**, the material of cylinder **302** is similarly configured and equally as effectively incorporated into a mitral valve stent **270**.

As earlier indicated, each stent **30** and **270** comprises a brim cover **105** and **286**, respectively. There are two important reasons for providing a brim cover. First, controlled and limited tissue in-growth at the site of each stent **30** and **270** emplacement allows a balance to be struck between valve adherence to and valve removability from the annulus into which it is implanted. Second, it is desirable to implant the material of cylinder **330** with antibiotics to decrease the risk of post placement valve infection.

As described earlier, all other parts of each stent **30** and **270** comprise exterior surfaces which are biochemically inert, each brim cover **105** and **286** provides the only surface area whereat adhesion is permitted to occur due to such tissue ingrowth. Such tissue ingrowth improves adhesion of the grafted valve within the native excised valve orifice. Providing the limited surface area of the brim cover for tissue in-growth also selectively permits a relatively easy excision should valve replacement be necessary.

Each brim cover **105** and **286** is formed from a hollow cylinder **330** of pliant, biocompatible material cut to a length which covers brims of sewing rings **100** and **102** and **276**, respectively. A section of such cylinder material is seen in FIG. **17**. Cylinder **330** is preferably made of velour a commercially available, medical grade DACRON TM, similar to straight knitted a commercially available, medical grade DACRON TM velour available Bard Implants Division, C. R. Inc., Concord Road, P.O. Box M, Billerica, Mass. 01821. Velour a commercially available, medical grade DACRON TM is compatible with earlier mentioned antibiotic implantation and tissue in-growth.

As seen in FIG. **17**, cylinder **330** comprises a free top edge **332**, a free bottom edge **334**, an exterior surface **336**, and an interior surface **338**. Disposed between exterior surface **336** and interior surface **338** and between top edge **332** and bottom edge **334** is a plaint, foldable material wall **340**. As seen by the section shown in FIG. **18**, pliant, foldable wall **340** comprises an inside diameter which distends to the same outside diameter as sewing rings **100** and **102** or alternatively with sewing ring **276** without losing structural integrity.

Preparatory to adding brim cover **105** to stent **30**, brims **158** and **170** are securely attached to deformable intermediate interfacing portion **104**. As seen in FIG. **18**, sutures, generally numbered **342**, securely anchor portion **104** between brims **158** and **170**. Cylinder **330** is then disposed about sewing rings **100** and **102** such that top edge **332** is foldably disposed in proximity to seamless connection line **156'**, earlier described. Similarly, free bottom edge **334** is disposed in the proximity of seamless connection line **174'**.

Between top edge **332** and bottom edge **334**, wall **340** is folded upon itself, in two places, and interposed between interfacing portion **104** and each of the sewing rings **100** and **102** such that interior surface **338** contacts, in seriatum, brim **158** superior surface **160**, edge **152**, inferior surface **162**, the associated exterior surface of interfacing portion **104**, and brim **170** superior surface **176**, edge **154**, and inferior surface **174**. So disposed, sutures, generally numbered **344**, tightly secure wall **336** to sewing ring **100** and interfacing portion **104** at the top and to sewing ring **102** and interfacing portion **104** at the bottom as seen in FIG. **18**.

In similar fashion, sewing ring **276** is covered by another cylinder **330** as seen in FIG. **19**. Preparatory to adding brim cover **286** to stent **270**, brims **272** and **274** are securely attached to each other. As seen in FIG. **19**, sutures, generally numbered **346**, affix brim **272** to brim **274**. Cylinder **330** is then disposed about sewing ring **276** such that top edge **332** is foldably disposed in proximity to seamless connection line **156'**. Similarly, free bottom edge **334** is disposed in the proximity of seamless connection line **174'**.

Sutures, generally numbered **348**, are affixed to tightly secure wall **336** more medially to brims **158** and **170**. Other sutures, generally numbered **350**, are disposed radially outwardly from edge **152** to affix wall **336** to brim **170** alone. So disposed wall **336** provides a smooth transition between the otherwise discontinuous connection between edge **152** and superior surface **176** as seen in FIG. **19**.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by Letters Patent is:

1. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between and seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

2. The long lasting prosthetic heart valve according to claim **1** further comprising means for adjoining unitable parts of the long lasting prosthetic heart valve by stitching or other connecting means void of resins which release into the blood stream of a patient over a period of time.

3. The long lasting prosthetic heart valve according to claim **1** wherein the leaflet valve means comprise a trileaflet valve.

4. The long lasting prosthetic heart valve according to claim **1** wherein the cusp means comprise exposed side means having free margins which coapt, in combination with associated commissures, to close the valve thereby reducing wear on the cusps at contacting areas of the free margins.

5. The long lasting prosthetic heart valve according to claim **1** wherein the essentially biochemically inert material means of the leaflet valve means is combined with at least one biologically active impregnating substance from a group of biologically active substances consisting of antibiotics, anticoagulant medicants, endothelial cells and endothelial cell growth factors.

6. The long lasting prosthetic heart valve according to claim 1 wherein the leaflet valve means comprise valve means molded in the form of a human aortic valve.

7. The long lasting prosthetic heart valve according to claim 1 wherein the leaflet valve means comprise a unicast valve means.

8. The long lasting prosthetic heart valve according to claim 1 wherein the essentially biochemically inert material means comprise silicone.

9. The long lasting prosthetic heart valve according to claim 1 wherein the leaflet means comprise surface means which are functionally continuous and non-thrombogenic.

10. The long lasting prosthetic heart valve according to claim 1 wherein the cusp means and stent attachment means, in combination, comprise means for joining together in a smooth, seamless interface.

11. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame means comprise windows primarily disposed in the base means, said windows providing a reduction of weight of the frame and a plurality of orifices through which each sewing ring is affixed to the interior an exterior interfacing wall means.

12. The long lasting prosthetic heart valve according to claim 1 wherein said cylindrical frame means comprise interior and exterior surface means which in combination comprise a plurality of holes disposed therebetween for firmly anchoring the leaflet valve means to the stent.

13. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises stainless steel.

14. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises flexible resilient synthetic resinous material.

15. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises graphite.

16. The long lasting prosthetic heart valve according to claim 1 wherein the cylindrical frame comprises pyrolytic carbon.

17. The long lasting prosthetic heart valve according to claim 1 wherein the enveloping cover means comprise tailored pocket means which conformably cover the substantially symmetrical extending members.

18. The long lasting prosthetic heart valve according to claim 17 wherein the tailored pocket means comprise mean for tightly sealing edges thereof.

19. The long lasting prosthetic heart valve according to claim 18 wherein said sealing means comprise means for suturing.

20. The long lasting prosthetic heart valve according to claim 18 wherein said sealing means comprise means for heat sealing the edges thereof.

21. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice said essentially biochemically inert material means comprising a porous material comprising at least one medically advantageous biochemical selected from a group of biochemicals consisting of antibiotics, anticoagulant medications, and endothelial cell growth factors

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between the seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending member which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

22. The long lasting prosthetic heart valve according to claim 1 wherein said essentially biochemically inert material means of said covering means comprise PTFE.

23. The long lasting prosthetic heart valve according to claim 1 wherein said essentially biochemically inert material means comprise polyethylene glycol terephtalate.

24. The long lasting prosthetic heart valve according to claim 1 wherein said essentially biochemically inert material means comprise firm surface support means whereby sutures are firmly and securely affixed to the at least one sewing ring.

25. The long lasting prosthetic heart valve according to claim 1 wherein the sewing ring means comprise two separated sewing rings.

26. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised form a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice, the leaflet valve means comprising surface means which are functionally continuous and non-thrombogenic;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between and seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the based of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall mans interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve, the covering means comprising a perimetrically variable compliant ring of soft material means disposed between the two separated sewing rings adapted to be an annulus left by excision of a natural valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

27. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction form bases of said cusps, and stent attachment means comprising cusp supporting means which extend int eh first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for enveloping covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between the seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve, the covering means comprising perimetrically variable compliant ring of soft material means comprising non-expanded polytetrafluoroethylene disposed between the two separated sewing rings adapted to be placed in an annulus left by excision of a natural valve;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring

thereby comprising only contiguous and continuous connection with the exterior wall means.

28. The long lasting prosthetic heart valve according to claim **1** wherein said covering means comprise means for covering the at least one sewing ring and for interfacing with tissue within the annulus from which a natural valve has been excised.

29. A long lasting, biocompatible prosthetic heart valve which is used as a replacement valve for a natural valve excised from a native orifice and is patently permissive to liquid flow in a first direction and non-regurgently occlusive to liquid flow in the opposite direction, said prosthetic heart valve comprising:

leaflet valve means comprising essentially non-thrombogenic biochemically inert material means, cusp means which comprise a plurality of cusps which are similar in shape, size, and function to cusps of a natural heart valve having compliant commissures at free edges superiorly disposed in the first direction from bases of said cusps, and stent attachment means comprising cusp supporting means which extend in the first direction to provide an attachment surface about each commissure and retreat inferiorly therefrom about adjoining cusp lines to provide an attachment surface about each cusp base and to thereby provide a non-occlusive passageway for liquid flow from within each cusp to natural vessel pathways in the region of attachment of the valve within the native orifice;

stent means comprising flexible, cylindrical frame means which provide structural support for the leaflet valve means and means for envelopingly covering the frame means, the covering means comprising essentially biochemically inert material means, central orifice means for snugly, insertably receiving and affixing the leaflet valve means within the stent means, and means for securing the long lasting prosthetic heart valve in the native orifice;

the flexible, cylindrical frame means being of substantially rectangular cross section and comprising base means alternately disposed between the seamlessly attached to means for providing support for the stent attachment means at the superiorly disposed position of the commissures, the base means substantially comprising arcs of a cylindrical band transversely disposed across a plane defined by the bases of the cusps and the support providing means comprising a pair of substantially symmetrical extending members which are seamlessly joined in the region of the attachment surface of each commissure and separated in the region adjoining the bases of the cusps thereby providing circumferential, deformable support in the plane of the bases of the cusps;

the covering means comprising at least one section of hollow cylindrical seamless material means which comprises a first hollow continuous end, a second hollow continuous end, interior wall means interposed between the leaflet valve means and means which define the exterior wall of the long lasting prosthetic heart valve, said covering means comprising means for covering the at least one sewing ring and for interfacing with tissue within the annulus from which a natural valve has been excised, the at least one sewing ring covering and interfacing means comprising at least one impregnated biochemical selected form a group consisting of antibiotics and anticoagulant medicants;

said first and second hollow continuous ends being radially outwardly everted in the plane of the bases of the cusps to form the securing means which comprise at least one sewing ring, each sewing ring thereby comprising only contiguous and continuous connection with the exterior wall means.

30. The long lasting prosthetic heart valve according to claim **28** wherein at least one sewing ring covering and interfacing means comprise means for variably incorporating surrounding tissue, said ring of soft material means comprising means having variable porosity and providing a predetermined balance between ease of removal of the ring of soft material means and prevention of infection.

31. The long lasting prosthetic heart valve according to claim **30** wherein variable incorporating means ring of soft material means comprise at least one impregnated biochemical selected form a group comprising antibiotics, anticoagulant medicants, and endothelial cell growth factors.

32. The long lasting prosthetic heart valve according to claim **1** wherein the sewing ring means comprise a single sewing ring wherein each of the outwardly everted ends are joined to form the single sewing ring.

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DEMANDE DE BREVET D'INVENTION

(21) **N° 76 36928**

(54) **Valve cardiaque bioprothétique supportée par un cadre souple.**

(51) Classification internationale (Int. Cl.²). **A 61 F 1/22.**

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(71) Déposant : Société dite : AMERICAN HOSPITAL SUPPLY CORPORATION, résidant aux Etats-Unis d'Amérique.

(72) Invention de :

(73) Titulaire : *Idem* (71)

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Vente des fascicules à l'IMPRIMERIE NATIONALE, 27, rue de la Convention — 75732 PARIS *CEDEX 15*

Aortic Innovations, LLC, Exhibit 2040
Page 2040 - 1186
IPR2023-01232, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Les valvules bioprothétiques supportées, c'est-à-dire les greffes valvulaires supportées qui peuvent être soit des hétérogreffes (xénogreffes) soit des homogreffes (allogreffes) sont considérées comme possédant des avantages cliniques importants par rapport aux valvules prothétiques mécaniques non tissulaires. Les rapports établis concernant l'application de valvules hétérogreffes indiquent que les risques de thromboembolie sont plus faibles, que le traitement prolongé par anti-coagulants est réduit au minimum et que le risque d'une défaillance éventuelle de la valvule est progressif, ce qui permet une réopération élective dans des conditions optimales. Voir à cet égard les ouvrages de Carpentier et al "J. Thorac. Cardiovasc. Surg." 68:771 (1974), de "Zuhdi et al", Ann. Thorac Surg." 17:479 (1974) et de Horowitz et al, "J. Thorac. Cardiovasc. Surg." 67:885 (1974).

De façon générale, ces greffes ont été placées sur des montures de support qui forment des anneaux circulaires rigides (voir les brevets des Etats Unis d'Amérique N° 3.570.014, N° 3.755.823 et l'ouvrage de Weldon et al, "J. Surg. Research 6:548 (1966)), même si certains cadres comportent des branches capables de s'infléchir vers l'intérieur dans une mesure limitée, en réduisant par là même les contraintes imposées à ces greffes pendant le fonctionnement de la valvule et en diminuant l'érosion éventuelle des tissus environnants du patient (voir Sugie et al, J. Thorac. Cardiovasc. Surg" 57:455 (1969), Hardy, Human Organ Support and Replacement, 338 et suivantes (Thomas 1971) et le brevet des Etats Unis d'Amérique N° 3.755.823). Malgré des résultats encourageants en ce qui concerne l'utilisation de greffes valvulaires supportées et les avantages très marqués des valvules cardiaques bioprothétiques par rapport aux valvules prothétiques entièrement artificielles, il est encore nécessaire d'améliorer en particulier la durabilité et la fiabilité pendant une longue durée des greffes valvulaires supportées.

La présente invention concerne un cadre perfectionné pour valvules cardiaques bioprothétiques (hétérogreffes ou homogreffes) qui est flexible et en particulier capable de céder dans une

mesure limitée, en réponse aux forces qui tendent à modifier la configuration et la circonférence de l'anneau. Cette flexibilité et cette déformabilité permettent aux valves de se fermer avec un mouvement glissant le long de leurs bords libres qui est semblable à celui qui est observé physiologiquement et elles sont considérées comme importantes pour l'amélioration de la fiabilité des valvules pendant une longue durée.

La conformabilité de la partie délimitant l'orifice de la valvule prothétique est assurée en premier lieu par l'utilisation d'une monture de support flexible constituée essentiellement d'un seul brin de fil métallique flexible préformé. Le cadre en fil métallique est conformé de manière à définir trois supports de commissure faisant saillie axialement et circonférentiellement espacés. Chaque support de commissure présente une configuration généralement en U inversé dont les branches se raccordent à leurs extrémités inférieures espacées avec les parties de liaison curvilignes du cadre en fil métallique qui s'étendent circonférentiellement entre les branches des supports de commissure adjacents. Chaque partie de liaison curviligne peut subir une flexion lui imprimant une courbure plus ou moins prononcée, en permettant ainsi une déformation limitée des éléments du cadre délimitant l'orifice. En outre, chacune des parties de liaison curvilignes peut être déplacée d'une distance faible, mais définie, indépendamment des autres parties. Etant donné que la monture en fil métallique de chaque support de commissure est profilée en U inversé, et que les extrémités inférieures de ses branches sont normalement espacées d'une certaine distance, les parties curvilignes avec lesquelles les extrémités inférieures des branches se raccordent peuvent être sollicitées circonférentiellement de façon à se rapprocher et à s'éloigner en réponse aux forces exercées pendant le fonctionnement du coeur. Il en résulte un cadre flexible qui peut changer de dimensions et de forme dans une mesure limitée pendant le fonctionnement du coeur.

Des éléments rapportés s'étendent entre les supports de commissure circonférentiellement espacés, chacun de ces éléments présentant une bordure supérieure curviligne qui s'élève à ses

extrémités pour épouser le contour des supports de commissure. Les éléments rapportés en question peuvent être réalisés d'une seule pièce et constituer des parties d'une bande de matière plastique perforée flexible circonscrivant le cadre en fil métallique. Un revêtement d'étoffe poreuse entoure le cadre et les éléments rapportés pour constituer un moyen permettant de suturer la valvule et favorisant la croissance des tissus. Une garniture annulaire d'amortissement est également enfermée dans le revêtement externe pour faciliter la coaption, la configuration de cette garniture dépendant de l'application de la valvule en position mitrale, aortique ou tricuspide.

L'invention sera décrite plus en détail en regard des dessins annexés à titre d'exemple nullement limitatif et sur lesquels :-

La fig. 1 est une vue en perspective d'une valvule cardiaque bioprothétique conforme à la présente invention.

La fig. 2 est une vue en perspective montrant la monture en fil métallique de support de la valvule.

La fig. 3 est une vue par-dessus du cadre en fil métallique.

La fig. 4 est nne vue en élévation latérale du cadre.

Les fig. 5-7 sont des vues en perspective à échelle réduite mettant en évidence les phases de la fabrication du cadre.

La fig. 8 est une vue en plan à échelle réduite montrant les éléments rapportés mutuellement reliés de la valvule.

La fig. 9 est une coupe verticale à grande échelle d'une valvule aortique bioprothétique complète conforme à l'invention.

La fig. 10 est une coupe à plus grande échelle d'une valvule mitrale conforme à l'invention.

Si l'on examine la fig. 1, on voit que le numéro de référence 10 désigne généralement une valvule bioprothétique destinée à être implantée en position aortique. Le fait que cette valvule soit destinée à remplacer une valvule aortique naturelle ou une valvule mitrale ou tricuspide, dépend principalement des dimensions de la valvule et de la construction de son manchon ou anneau de suturation. En ce qui concerne l'invention, les trois types de valvules présentent les mêmes caractéristiques essen-

tielles et, par conséquent, une valvule aortique a été choisie simplement à titre illustratif.

La valvule 10 comprend un cadre 11 et une greffe valvulaire 12. Par exemple, la greffe est une hétérogreffe conservée d'origine porcine. Toutefois, le cadre peut être utilisé pour supporter des greffes provenant d'autres espèces et peut constituer éventuellement le support d'une homogreffe.

La greffe 12 comporte trois valves 13-15 qui se touchent le long de commissures 15. Le traitement et la conservation de la greffe sont bien connus, comme indiqué dans l'ouvrage de Carpentier et al, "J. Thorac. Cardiovasc. Surg." 68:771 (1974) et les références citées dans le présent mémoire et n'ont pas besoin d'être décrits en détail.

Le cadre 11 consiste essentiellement en une monture 16 en fil métallique flexible qui est recouverte et garnie d'un tissu ou étoffe poreux biologiquement compatible formant des goussets de telle sorte que la valvule complète puisse être suturée à l'intérieur d'un coeur humain et permette la croissance des tissus dans le revêtement d'étoffe. La monture 16 est de configuration généralement annulaire et est constituée essentiellement d'une seule pièce de fil métallique flexible façonnée de manière à définir trois supports de commissure 17 à 19 circonférentiellement espacés. Comme représenté sur la fig. 2, chaque support de commissure est généralement profilé en U inversé et comporte des branches 20 en fil métallique se raccordant en arrondi à leurs extrémités inférieures espacées avec des parties de liaison curvilignes 21. Ces dernières s'étendent circonférentiellement et se raccordent aux branches adjacentes des supports de commissure voisins.

Les extrémités 22 du fil métallique qui constitue la monture sont réunies le long d'une des parties de liaison curvilignes 21 au moyen d'un manchon serti 23. L'emplacement et le mode de liaison sont tous deux importants si l'on veut obtenir une grande durabilité du cadre. On a constaté que la zone médiane d'une partie de liaison curviligne 21 forme une zone de contrainte relativement faible et l'utilisation d'un manchon ou tube d'accouplement serti sur chacune des parties terminales évite les difficultés

dues à la dégradation de la matière et à une défaillance rapide résultant de la fatigue, qu'entraîne un soudage.

Le fil métallique est de section circulaire et, sauf en ce qui concerne le manchon 23, a un diamètre sensiblement uniforme dans toute sa longueur. Chaque support de commissure en U inversé comporte une extrémité supérieure arrondie ou de courbure régulière. De même, les extrémités inférieures des branches 20 des supports de commissure s'incurvent vers l'extérieur pour se raccorder régulièrement en arrondi avec les parties de liaison 21.

La monture en fil métallique peut être en toute matière flexible non corrosive, résistant bien à la fatigue et biologiquement compatible. Une patière particulièrement efficace est l'acier qui est mis sur le marché sous la marque "Elgiloy" par la firme Elgiloy Company, Elgin (Illinois), bien que d'autre aciers ou alliages inoxydables possédant des propriétés semblables puissent être utilisés.

On remarquera que les parties de liaison curvilignes 21 définissent dans l'ensemble le pourtour de l'anneau de la valvule. Etant donné que les parties ou segments de liaison sont interrompus par des supports de commissure 17 à 19 et que les extrémités inférieures de chaque paire de branches 20 sont espacées, la flexion vers l'intérieur des branches (comme le montre la fig. 4) réduit l'écartement des segments de liaison adjacents 21 et diminue donc le périmètre effectif de l'anneau. Ainsi, la monture 16 peut subir une contraction et une expansion limitée lorsque les branches flexibles des supports de commissure subissent une flexion vers l'intérieur et vers l'extérieur.

De plus, les parties ou segments de liaison 21 sont eux-mêmes capables de subir une flexion limitée. Ainsi, en particulier, la courbure de chaque segment curviligne 21 peut augmenter ou diminuer légèrement. Cette flexion permet des changements légers, mais notables, des positions des supports de commissure les uns par rapport aux autres et par rapport à l'axe de la valvule, comme indiqué en traits interrompus sur la fig. 3. De façon générale, la configuration de l'anneau peut être modifiée en réponse aux forces exercées lors de chaque battement du coeur

dans lequel est implantée la valvule bioprothétique. Il en résulte un cadre de valvule capable de subir une déformation limitée, c'est-à-dire qui peut se déployer et se contracter dans une mesure faible mais définie, pendant le fonctionnement du coeur. Cette souplesse est considérée comme importante non seulement pour l'obtention d'une plus grande durabilité ou d'une fiabilité prolongée de l'hétérogreffe ou de l'homogreffe, mais également pour permettre aux valves de se fermer en glissant le long de leurs bords libres, qui est plus semblable au phénomène observé physiologiquement.

La monture en fil métallique est recouverte d'un revêtement poreux rembourré et formant des goussets pour faciliter la fixation, l'invasion des tissus et l'enrobage. Les fig. 5-7 représentent plusieurs phases de la fabrication du cadre final. Un manchon 27 constitué par une étoffe poreuse biologiquement compatible est ajusté autour de la monture en fil métallique et est fixé à celle-ci par des piqûres, comme indiqué sur la fig.5. Des éléments rapportés qui, sous la forme représentée, sont constitués par des parties 25 d'une bande 26 de matière plastique, sont ensuite placés à l'extérieur du manchon 27 entre chacun des supports de commissure 17 à 19. Le manchon est rogné et fixé par piquage en 27 aux bordures des éléments rapportés. Un revêtement d'une étoffe poreuse 28 biologiquement compatible est ensuite ajusté autour du cadre pour envelopper complètement la monture en fil métallique et les éléments rapportés, comme le montre la fig. 7. Alors que l'étoffe peut être repliée sur elle-même autour du cadre pour former une bordure de suture rembourrée, il est préférable que ce rembourrage soit effectué en enfermant un anneau de caoutchouc mousse 29 (Fig.9) à l'intérieur du revêtement d'étoffe 28. La réalisation et la fonction de ces bordures rembourrées de suturation sont bien connues d'ailleurs dans la construction des valvules prothétiques et sont décrites, par exemple, dans les brevets des Etats Unis d'Amérique N° 3.099.016, N° 3.365.728 et N° 3.371.352.

Les couches d'étoffe 24 et 28 peuvent être constituées par un tissu ou tricot poreux de "Teflon", bien que d'autres matières

telles que le "Dacron", puissent être utilisées. Les éléments rapportés 25 peuvent être constitués par une ou plusieurs feuilles de téréphtalate de polyglycol ("Mylar"), bien que d'autres matières inertes biologiquement compatibles, telles que le polypropylène, puissent être utilisées.

Les éléments rapportés 25 forment des goussets pour augmenter les dimensions axiales du cadre dans les zones comprises entre les supports de commissure 17 à 19 et pour assurer la fixation de l'étoffe 24 et de l'hétérogreffe ou homogreffe 12. Chaque élément rapporté 25 de la bande représentée sur la fig. 8 est percé d'ouvertures 30 par lesquelles les fils de piqûre 27 passent pendant la fabrication du cadre. La bordure supérieure 31 de chaque élément rapporté est de forme incurvée pour établir une transition régulière à partir de l'extérieur de la partie supérieure de chaque support de commissure.

Les trois éléments rapportés 25 pourraient être des composants distincts fixés individuellement à la monture en fil métallique recouverte d'étoffe mais, pour faciliter la fabrication, il est préférable de constituer ces éléments sous la forme d'une bande continue 26, les éléments successifs étant reliés par des parties de liaison 32 (Fig.8). Il doit être entendu que ni les parties de liaison 32, ni les autres parties des éléments rapportés ne modifient de façon notable les caractéristiques de flexion de la monture en fil métallique précédemment décrites.

La fig. 9 représente les détails de la valvule complète dont la greffe est fixée au cadre par des points de suture 33. La configuration et l'emplacement de la garniture 29 en mousse conviennent particulièrement à l'utilisation de la valvule pour remplacer une valvule aortique. La valvule représentée dans la fig.10 est destinée à remplacer la valvule mitrale et par conséquent présente des proportions assez différentes. La garniture annulaire 29' en mousse est placée et conformée pour s'engager dans l'orifice mitral, comme ceci est bien connu d'ailleurs dans la technique chirurgicale. Sauf pour les différences évidentes qui ressortent des fig. 9 et 10 et les différences dues aux caractéristiques anatomiques des parties du coeur humain auxquelles les

valvules respectives doivent être fixées, les valvules représentées sur ces figures sont essentiellement les mêmes et utilisent toutes des montures en fil métallique comme celle représentée généralement sur les fig. 2-4.

Les détails de réalisation peuvent être modifiés, sans s'écarter de l'invention, dans le domaine des équivalences techniques.

REVENDICATIONS

1.- Valvule cardiaque bioprothétique supportée, caractérisée en ce qu'elle comprend un cadre auquel est fixée une greffe valvulaire, ce cadre présentant une monture annulaire constituée essentiellement d'un seul tronçon de fil métallique flexible préformé, ladite monture étant conformée de manière à constituer trois supports de commissure circonférentiellement espacés faisant saillie axialement, chaque support de commissure étant profilé en U inversé et comportant des branches raccordées en arrondi à leurs extrémités inférieures avec des parties de liaison curvilignes s'étendant circonférentiellement entre les branches des supports de commissure adjacents et reliant ces branches.

2.- Valvule suivant la revendication 1, caractérisée en ce que le cadre comprend des éléments rapportés s'étendant entre les supports de commissure et présentant des bordures supérieures curvilignes au-dessus des parties de liaison de la monture.

3.- Valvule suivant la revendication 2, caractérisée en ce que les éléments rapportés sont percés de plusieurs ouvertures.

4.- Valvule suivant la revendication 2, caractérisée en ce que les éléments rapportés sont constitués par des parties solidaires d'une bande de matière plastique perforée flexible circonscrivant la monture.

5.- Valvule suivant la revendication 4, caractérisée en ce que la bande présente des parties ayant des bordures supérieures incurvées entre les supports de commissure.

6.- Valvule suivant la revendication 2, caractérisée en ce que la greffe est reliée par des lignes de piqûres à la monture et aux éléments rapportés.

7.- Valvule suivant la revendication 1, caractérisée en ce que ledit cadre comprend un revêtement d'étoffe poreuse biologiquement compatible pour assurer la suturation de la valvule et pour permettre la croissance des tissus lorsqu'elle est implantée.

8.- Valvule suivant la revendication 1, caractérisée en ce que les extrémités du fil métallique de la monture sont reliées en un point situé le long d'une des parties de liaison curvilignes.

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9.- Valvule suivant la revendication 8, caractérisée en ce que lesdites extrémités sont réunies par un manchon tubulaire s'emboîtant sur elles et auxquelles il est fixé.

10.- Valvule suivant la revendication 9, caractérisée en ce que le manchon est serti autour des deux extrémités.

11.- Valvule suivant la revendication 1, caractérisée en ce que chacun des supports de commissure de la monture est arrondi à son extrémité supérieure.

12.- Cadre flexible pour supporter une greffe valvulaire, caractérisé en ce qu'il comporte une monture annulaire constitué par un fil métallique flexible et comprenant trois supports de commissure faisant saillie axialement et circonférentiellement espacés, chaque support de commissure étant profilé en U inversé ayant des branches en fil métallique normalement espacées à ses extrémités inférieures, qui se raccordent en arrondi avec des segments de liaison curvilignes de la monture s'étendant circonférentiellement entre les branches adjacentes des supports de commissure voisins et les reliant, ces supports de commissure et ces segments de liaison étant constitués d'un seul tenant en fil métallique élastique.

13.- Cadre suivant la revendication 12, caractérisé en ce que les éléments rapportés s'étendent entre les supports de commissure, ces éléments rapportés étant flexibles et comportant des bordures supérieures curvilignes au-dessus des segments de liaison de la monture.

14.- Cadre suivant la revendication 13, caractérisé en ce que les éléments rapportés sont constitués d'une matière foliiforme perforée flexible.

15.- Cadre suivant la revendication 13, caractérisé en ce que les éléments rapportés sont des parties intégrantes d'une bande de matière plastique perforée flexible circonscrivant la monture.

16.- Cadre suivant la revendication 15, caractérisé en ce que la bande présente des bordures supérieures incurvées entre les supports de commissure.

17.- Cadre suivant la revendication 12, caractérisé en ce qu'un revêtement d'étoffe poreuse biologiquement compatible entoure la monture pour permettre de fixer le cadre par suturation et pour favoriser la croissance des tissus.

18.- Cadre suivant la revendication 12, caractérisé en ce que les extrémités du fil métallique de la monture sont réunies en un point intermédiaire situé le long d'un des segments de liaison curvilignes.

19.- Cadre suivant la revendication 18, caractérisé en ce que lesdites extrémités sont reliées par un manchon tubulaire emboîté sur lesdites extrémités auxquelles il est fixé.

20.- Cadre suivant la revendication 19, caractérisé en ce que ce manchon est serti sur lesdites extrémités.

21.- Cadre suivant la revendication 12, caractérisé en ce que chacun des supports de commissure de la monture est arrondi à son extrémité supérieure.

FIG. 2

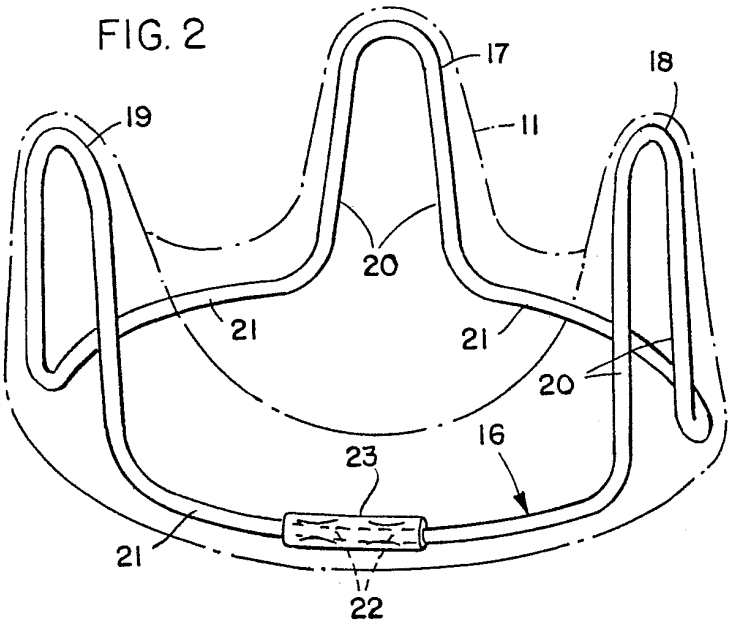


FIG. 3

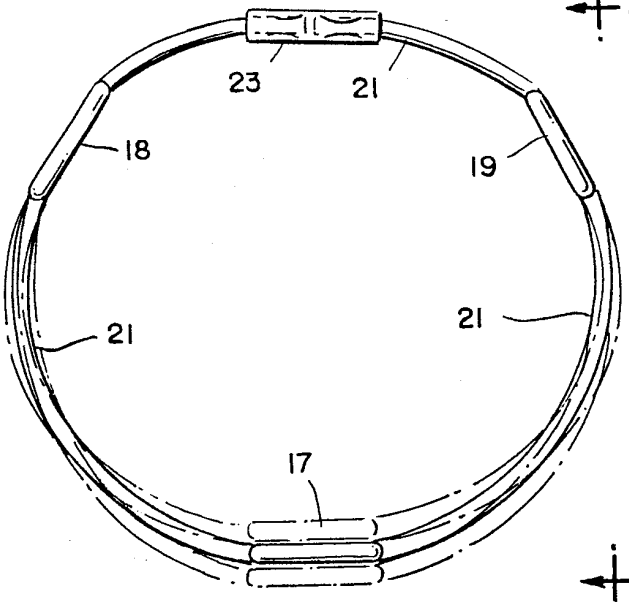
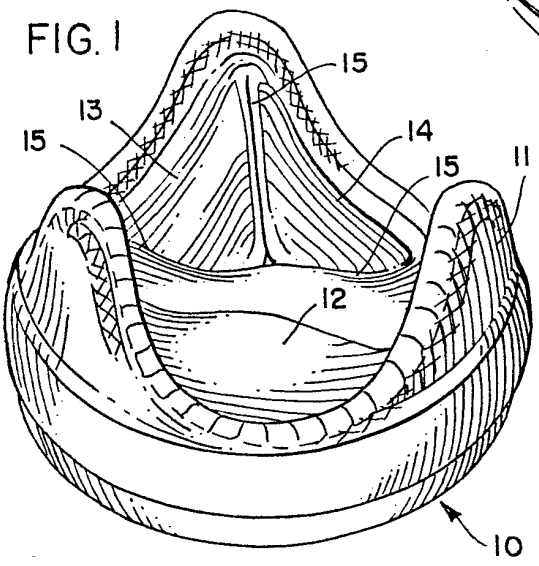


FIG. 1



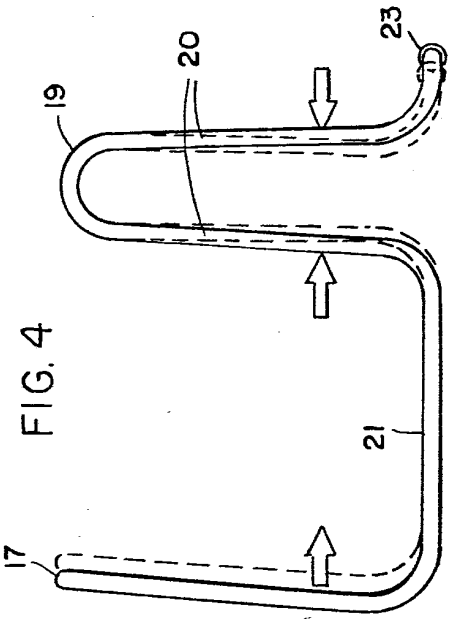


FIG. 4

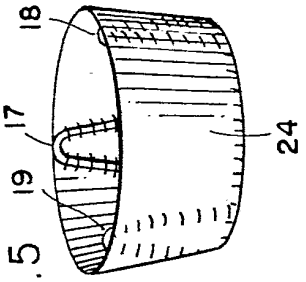


FIG. 5

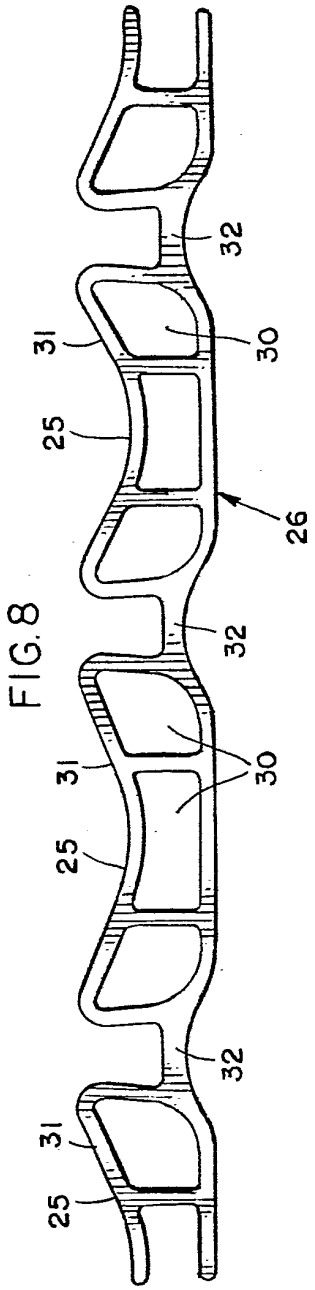


FIG. 8

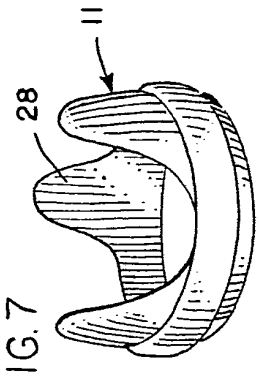


FIG. 7

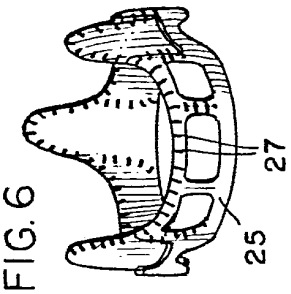


FIG. 6

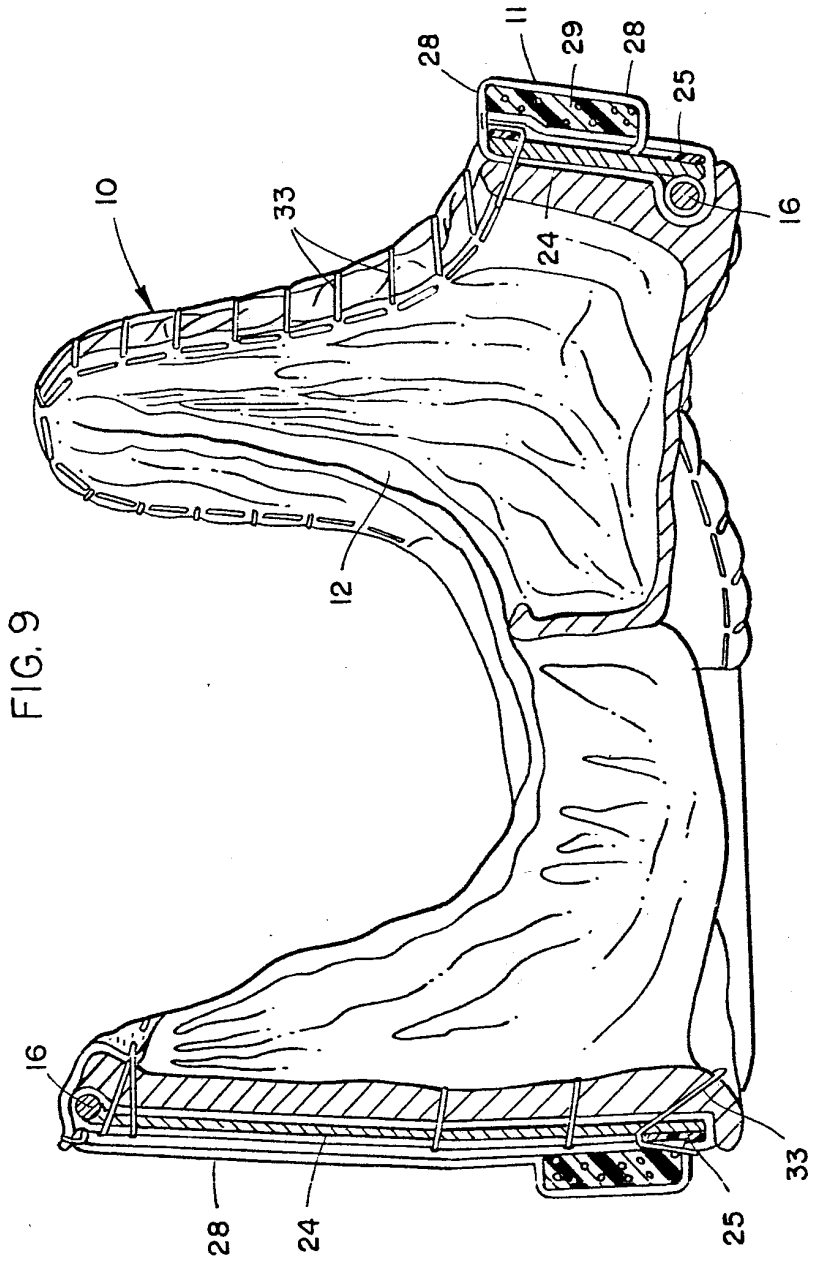


FIG. 9