Doc Code: TRACK1.REQ
Document Description: **TrackOne Request**

PTO/AIA/424 (03-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	David PANIAGUA	Nonprovisional Application Number (if known):	
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature / Mark L. Yaskanin /	Date 15 April 2014
Name (Print/Typed) Mark L. Yaskanin	Practitioner Registration Number 45246

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	David		PANIAGUA	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Houston	State/Province	TX	Country of Residence i	US

Mailing Address of Inventor:

Address 1	3813 Drummond Street		
Address 2			
City	Houston	State/Province	TX
Postal Code	77025	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	R.	David	FISH	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Houston	State/Province	TX	Country of Residence i	US

Mailing Address of Inventor:

Address 1	6349 Vanderbilt Street		
Address 2			
City	Houston	State/Province	TX
Postal Code	77005	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

City		State/Province		Country of Residence [i]	

Mailing Address of Inventor:

Address 1			
Address 2			
City		State/Province	
Postal Code		Country [i]	

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City		State/Province		Country of Residence [i]	

Mailing Address of Inventor:

Address 1			
Address 2			
City		State/Province	
Postal Code		Country [i]	

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City		State/Province		Country of Residence [i]	

Mailing Address of Inventor:

Address 1			
Address 2			
City		State/Province	
Postal Code		Country [i]	

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Customer Number	29880		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM		
Attorney Docket Number	109978.10104	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	12	Suggested Figure for Publication (if any)	8

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	29880		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	13675665	2012-11-13

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13675665	Continuation of	10887688	2004-07-10	8308797	2012-11-13

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
10887688	Continuation in part of	10037266	2002-01-04

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i]the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	Colibri Heart Valve LLC		
Mailing Address Information:			
Address 1	2150 W. 6th Ave, Unit M		
Address 2			
City	Broomfield	**State/Province**	CO
Country [i]	US	Postal Code	80020
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	109978.10104
	Application Number	
Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/ Mark L. Yaskanin /			Date (YYYY-MM-DD)	2014-04-15
First Name	Mark	Last Name	Yaskanin	Registration Number	45246

Additional Signature may be generated within this form by selecting the Add button. Add

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Filer:	Mark Lauren Yaskanin/Carol Donahue
Attorney Docket Number:	109978.10104
Filed as Small Entity	

Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	70	70
Utility Search Fee	2111	1	300	300
Utility Examination Fee	2311	1	360	360
Request for Prioritized Examination	2817	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		2730

Electronic Acknowledgement Receipt	
EFS ID:	18768381
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	15-APR-2014
Filing Date:	
Time Stamp:	18:23:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2730
RAM confirmation Number	4952
Deposit Account	501943
Authorized User	YASKANIN, MARK L.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees) Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees) Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Colibri_10101_Application.PDF	185656 e2953f78621cfe12118c40aec760737cad53d5c7	yes	33

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	25
	Claims	26	32
	Abstract	33	33

Warnings:					
Information:					
2	Drawings-only black and white line drawings	Colibri_10101_original_drawings.PDF	121176 7cb75a9d3294f0d041d3ad10012088fe23589be6	no	12
Warnings:					
Information:					
3		Colibri_10104_Preliminary_Amendment.PDF	524571 9c6494590e03b0ffdeb921d355b5dd13ea5fa5a9	yes	66

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Specification	2	5
	Claims	6	7
	Drawings-only black and white line drawings	8	8
	Applicant Arguments/Remarks Made in an Amendment	9	10
	Specification	11	36
	Specification	37	62

	Drawings-only black and white line drawings		63	66	
Warnings:					
Information:					
4	TrackOne Request	Colibri_10104_Certification_Request_Prioritized_Examination.PDF	136209 f6de237e5cdefecb1218a472b85052b89a4ceec9	no	2
Warnings:					
Information:					
5	Application Data Sheet	Colibri_10104_Application_Data_Sheet_.PDF	1617103 b8b57696e551879ac8dd1f91bb55abcac769ccc4	no	8
Warnings:					
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6	Fee Worksheet (SB06)	fee-info.pdf	36923 2f530c1cbd77d0a6d140f2dcca3e644f793dbd31	no	2
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Electronic Acknowledgement Receipt

EFS ID:	18768381
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	15-APR-2014
Filing Date:	
Time Stamp:	18:23:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2730
RAM confirmation Number	4952
Deposit Account	501943
Authorized User	YASKANIN, MARK L.

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Colibri_10101_Application.PDF	185656 e2953f78621cfe12118c40aec760737cad53d5c7	yes	33

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	25
Claims	26	32
Abstract	33	33

Warnings:

Information:

2	Drawings-only black and white line drawings	Colibri_10101_original_drawings.PDF	121176 7cb75a9d3294f0d041d3ad10012088fe23589be6	no	12

Warnings:

Information:

3		Colibri_10104_Preliminary_Amendment.PDF	524571 9c6494590e03b0ffdeb921d355b5dd13ea5fa5a9	yes	66

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	5
Claims	6	7
Drawings-only black and white line drawings	8	8
Applicant Arguments/Remarks Made in an Amendment	9	10
Specification	11	36
Specification	37	62

	Drawings-only black and white line drawings		63	66	
Warnings:					
Information:					
4	TrackOne Request	Colibri_10104_Certification_Request_Prioritized_Examination.PDF	136209 f6de237e5cdefecb1218a472b85052b89a4ceec9	no	2
Warnings:					
Information:					
5	Application Data Sheet	Colibri_10104_Application_Data_Sheet_.PDF	1617103 b8b57696e551879ac8dd1f91bb55abcac769ccc4	no	8
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6	Fee Worksheet (SB06)	fee-info.pdf	36923 2f530c1cbd77d0a6d140f2dcca3e644f793dbd31	no	2
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PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

CONTINUITY INFORMATION

[0001] The present application is a continuation application of U.S. Patent Application No. 10/887,688 filed on July 10, 2004, now U.S. Patent No. 8,308,797, which is a continuation-in-part application of U.S. Patent Application No. 10/037,266, filed on January 4, 2002 (now abandoned). Both applications of which are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] Field of the Invention

The present invention is in the field of heart valve replacement. More specifically, the present invention is directed to a method of making a percutaneously implantable replacement heart valve.

[0003] 2. Description of Related Art

There have been numerous efforts in the field of heart valve replacement to improve both the durability and effectiveness of replacement heart valves as well as the ease of implantation. A brief description of heart valves and heart function follows to provide relevant background for the present invention.

[0004] There are four valves in the heart that serve to direct the flow of blood through the two sides of the heart in a forward direction. On the left (systemic) side of the heart are: 1) the mitral valve, located between the left atrium and the left ventricle, and 2) the aortic valve, located between the left ventricle and the aorta. These two valves direct oxygenated blood coming from the lungs through the left side of the heart into the aorta for distribution to the body.

On the right (pulmonary) side of the heart are: 1) the tricuspid valve, located between the right atrium and the right ventricle, and 2) the pulmonary valve, located between the right ventricle and the pulmonary artery. These two valves direct de-oxygenated blood coming from the body through the right side of the heart into the pulmonary artery for distribution to the lungs, where it again becomes re-oxygenated to begin the circuit anew.

[0005] Heart valves are passive structures that simply open and close in response to differential pressures on either side of the particular valve. They consist of moveable "leaflets" that are designed simply to open and close in response to differential pressures on either side of the valve's leaflets. The mitral valve has two leaflets and the tricuspid valve has three. The aortic and pulmonary valves are referred to as "semilunar valves" because of the unique appearance of their leaflets, which are more aptly termed "cusps" and are shaped somewhat like a half-moon. The aortic and pulmonary valves each have three cusps.

[0006] In general, the components of heart valves include the valve annulus, which will remain as a roughly circular open ring after the leaflets of a diseased or damaged valve have been removed; leaflets or cusps; papillary muscles which are attached at their bases to the interior surface of the left or right ventricular wall; and multiple chordae tendineae, which couple the valve leaflets or cusps to the papillary muscles. There is no one-to-one chordal connection between the leaflets and the papillary muscles; instead, numerous chordae are present, and chordae from each papillary muscle attach to both of the valve leaflets.

[0007] When the left ventricular wall relaxes so that the ventricular chamber enlarges and draws in blood, the leaflets of the mitral valve separate and the valve opens. Oxygenated blood flows in a downward direction through the valve, to fill the expanding ventricular cavity. Once the left ventricular cavity has filled, the left ventricle contracts, causing a rapid rise in the left

ventricular cavitary pressure. This causes the mitral valve to close while the aortic valve opens, allowing the oxygenated blood to be ejected from the left ventricle into the aorta. The chordae tendineae of the mitral valve prevent the mitral leaflets from prolapsing back into the left atrium when the left ventricular chamber contracts.

[0008] The three leaflets, chordae tendineae, and papillary muscles of the tricuspid valve function in a similar manner, in response to the filling of the right ventricle and its subsequent contraction. The cusps of the aortic valve also respond passively to pressure differentials between the left ventricle and the aorta. When the left ventricle contracts, the aortic valve cusps open to allow the flow of oxygenated blood from the left ventricle into the aorta. When the left ventricle relaxes, the aortic valve cusps reapproximate to prevent the blood which has entered the aorta from leaking (regurgitating) back into the left ventricle. The pulmonary valve cusps respond passively in the same manner in response to relaxation and contraction of the right ventricle in moving de-oxygenated blood into the pulmonary artery and thence to the lungs for re-oxygenation. Neither of these semilunar valves has associated chordae tendineae or papillary muscles.

[0009] Problems that can develop with heart valves consist of stenosis, in which a valve does not open properly, and/or insufficiency, also called regurgitation, in which a valve does not close properly. In addition to stenosis and insufficiency of heart valves, heart valves may need to be surgically repaired or replaced due to certain types of bacterial or fungal infections in which the valve may continue to function normally, but nevertheless harbors an overgrowth of bacteria (vegetation) on the leaflets of the valve that may embolize and lodge downstream in a vital artery. If such vegetations are on the valves of the left side (i.e., the systemic circulation side) of the heart, embolization may occur, resulting in sudden loss of the blood supply to the affected

body organ and immediate malfunction of that organ. The organ most commonly affected by such embolization is the brain, in which case the patient suffers a stroke. Thus, surgical replacement of either the mitral or aortic valve (left-sided heart valves) may be necessary for this problem even though neither stenosis nor insufficiency of either valve is present. Likewise, bacterial or fungal vegetations on the tricuspid valve may embolize to the lungs resulting in a lung abscess and therefore, may require replacement of the tricuspid valve even though no tricuspid valve stenosis or insufficiency is present.

[0010] These problems are treated by surgical repair of valves, although often the valves are too diseased to repair and must be replaced. If a heart valve must be replaced, there are currently several options available, and the choice of a particular type of artificial valve depends on factors such as the location of the valve, the age and other specifics of the patient, and the surgeon's experiences and preferences. Currently in the United States over 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 and without having to repeat the procedure within a matter of years due to the lack of durability of the replacement heart valve. 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.

[0011] 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.

[0012] Replacement heart valves can be categorized as either artificial mechanical valves, transplanted valves and tissue valves. Replacement heart valves are designed to optimize hemodynamic performance, thrombogenicity and durability. Another factor taken into consideration is the relative ease of surgical implantation.

[0013] Mechanical valves are typically constructed from nonbiological materials such as plastics, metals and other artificial materials which, while durable, are expensive and prone to blood clotting which increases the risk of an embolism. Anticoagulants taken to help against blood clotting can further complicate the patient's health due to increased risks for hemorrhages.

[0014] Transplanted valves are natural valves taken from cadavers. These valves are typically removed and frozen in liquid nitrogen, and are stored for later use. They are typically fixed in glutaraldehyde to eliminate antigenicity and are sutured in place, typically with a stent.

[0015] Artificial tissue valves are valves constructed from animal tissue, such as bovine or porcine tissue. Efforts have also been made at using tissue from the patient for which the valve will be constructed.

[0016] Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position, or by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent. The porcine or bovine tissue is chemically

treated to alleviate any antigenicity. The pericardium is a membrane that surrounds the heart and isolates it from the rest of the chest wall structures. The pericardium is a thin and very slippery, which makes it difficult for suturing in a millimetricly precise way. The method of making the replacement heart valve of the present invention solves this problem through a process that includes drying and compressing the pericardium using photo-mechanical compression in such a way that makes it possible to handle and fold the material more easily.

[0017] For example, one prior replacement heart valve requires each sculpted leaflet to be trimmed in a way that forms an extended flap, which becomes a relatively narrow strand of tissue near its tip. The tip of each pericardial tissue strand is sutured directly to a papillary muscle, causing the strand to mimic a chordae tendineae. Each strand extends from the center of a leaflet in the valve, and each strand is sutured directly to either an anterior and posterior papillary muscle. This requires each leaflet to be positioned directly over a papillary muscle. This effectively rotates the leaflets of the valve about 90 degrees as compared to the leaflets of a native valve. The line of commissure between the leaflets, when they are pressed together during systole, will bisect (at a perpendicular angle) an imaginary line that crosses the peaks of the two papillary muscles, instead of lying roughly along that line as occurs in a native valve.

[0018] A different approach to creating artificial tissue valves is described in U.S. Pat. No. 5,163,955 to Calvin, *et al*. and U.S. Pat. Nos. 5,571,174 and 5,653,749 to Love. Using a cutting die, the pericardial tissue is cut into a carefully defined geometric shape, treated with glutaraldehyde, then clamped in a sandwich-fashion between two stent components. This creates a tri-leaflet valve that resembles an aortic or pulmonary valve, having semilunar-type cusps rather than atrioventricular-type leaflets.

[0019] U.S. Pat. No. 3,671,979 to Moulopoulos describes an endovascularly inserted conical shaped umbrella-like valve positioned and held in place by an elongated mounting catheter at a supra-annular site to the aortic valve in a nearby arterial vessel. The conical end points toward the malfunctioning aortic valve and the umbrella's distal ends open up against the aorta wall with reverse blood flow, thereby preventing regurgitation.

[0020] U.S. Pat. No. 4,056,854 to Boretos describes an endovascularly inserted, catheter mounted, supra-annular valve in which the circular frame abuts the wall of the artery and attached flaps of flexible membrane extend distally in the vasculature. The flaps lie against the artery wall during forward flow, and close inward towards the central catheter to prevent regurgitation during reverse blood flow. The Boretos valve was designed to be positioned against the artery wall during forward flow, as compared to the mid-center position of the Moulopoulos valve, to reduce the stagnation of blood flow and consequent thrombus and embolic formation expected from a valve at mid-center position.

[0021] The main advantage of tissue valves is that they do not cause blood clots to form as readily as do the mechanical valves, and therefore, they do not absolutely require systemic anticoagulation. The major disadvantage of tissue valves is that they lack the long-term durability of mechanical valves. Tissue valves have a significant failure rate, usually within ten years following implantation. One cause of these failures is believed to be the chemical treatment of the animal tissue that prevents it from being antigenic to the patient. In addition, the presence of extensive suturing prevents the artificial tissue valve from being anatomically accurate in comparison to a normal heart valve, even in the aortic valve position.

[0022] A shortcoming of prior artificial tissue valves has been the inability to effectively simulate the exact anatomy of a native heart valve. Although transplanted human or porcine

aortic valves have the gross appearance of native aortic valves, the fixation process (freezing with liquid nitrogen, and chemical treatment, respectively) alters the histologic characteristics of the valve tissue. Porcine and bovine pericardial valves not only require chemical preparation (usually involving fixation with glutaraldehyde), but the leaflets must be sutured to cloth-covered stents in order to hold the leaflets in position for proper opening and closing of the valve. Additionally, the leaflets of most such tissue valves are constructed by cutting or suturing the tissue material, resulting in leaflets that do not duplicate the form and function of a real valve and are more susceptible to failure.

SUMMARY OF THE INVENTION

[0023] The present invention is a replacement heart valve device and method of making same. The replacement heart valve device, in a preferred embodiment, comprises a stent made of stainless steel or self-expanding nitinol and a completely newly designed artificial biological tissue valve disposed within the inner space of the stent. The cusp or leaflet portion of the valve means is formed by folding of the pericardium material preferably used to create the valve without cutting of slits to form leaflets or suturing or otherwise affixing of separate leaflet portions. Other forms of tissue and suitable synthetic materials can also be used for the valve, formed in a sheet of starting material. The folded design provides a number of advantages over prior designs, including improved resistance to tearing at suture lines. The cusps/leaflets open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the tubular portion of the valve means contains the same number of cusps as the native valve being replaced, in substantially the same size and configuration. The outer surface of the valve means is attached to the stent member.

[0024] The replacement heart valve device is preferably implanted using a delivery system having a central part which consists of a flexible hollow tube catheter that allows a metallic guide wire to be advanced inside it. The stented valve is collapsed over the central tube and it is covered by a movable sheath. The sheath keeps the stented valve in the collapsed position. Once the cover sheath is moved backwards, the stented valve can be deployed. The endovascular stented-valve, in a preferred embodiment, is a glutaraldehyde fixed mammal pericardium or synthetic biocompatible material which has two or three cusps that open distally to permit unidirectional blood flow. The stent can either be self-expanding or the stent can be expandable through use of a balloon catheter.

[0025] The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the pericardium starting material is isolated and all the fat tissue and extra fibers are removed. The biological membrane material is cleaned by mechanical separation of unwanted layers using hydromechanical force means. Once the pericardium is completely clean, the material is dried in order to make it easier to handle and fold. Preferably, this drying is done by exposing the biocompatible membrane material to photo-mechanical compression to remove all lipids from the pericardium or other biocompatible membrane material and to cause protein denaturalization, transforming the material into a stronger and more homogeneous surface. The valve is formed by taking a flat sheet of the material and folding in such a way that forms a three-leaflet or other number of leaflet valve. Then it is placed in a sequence of solutions, one of isopropyl alcohol of about 70-100%, one of ethanol of about 70-100%, one of glycerol and one of glutaraldehyde, preferably at a concentration of about 0.07-25% for approximately 36 hours. The material is dried in order to make it easier to handle and fold. Preferably this drying is done by exposing the biocompatible

membrane material to light and then mechanically compressing the material to cause protein denaturation. This results in material that is stronger and more homogeneous. The valve is formed by taking a flat sheet of bovine or procine pericardium and folding it in such a way that forms a three-leaflet valve. The valve can also be made in the same manner from fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts or synthetic non-biological, non-thrombogenic material. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. The cleaning, pressing and drying technique used to create the valve material makes the folding more practicable. The valve is rehydrated after being formed. The method of the present invention also greatly reduces the risk of tearing of the cusps or leaflets, since they are formed by folding a single uncut portion of material forming the valve rather than being attached by suturing.

[0026] Once the endovascular implantation of the prosthetic valve device is completed in the host, the function of the prosthetic valve device can be monitored by the same methods as used to monitor valve replacements done by open heart surgery. Routine physical examination, periodic echocardiography or angiography can be performed. In contrast to open heart surgery, however, the host requires a short recovery period and can return home within one day of the endovascular procedure. The replacement heart valve device of the present invention can be used in any patient where bioprosthetic valves are indicated, namely elderly patients with cardiac valve diseases, and patients unable to tolerate open heart procedures or life-long anticoagulation medication and treatment. The present invention can be practiced in applications with respect to each of the heart's valves.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 depicts a side perspective view of the replacement heart valve device of the present invention in one embodiment with the valve in the closed position.

[0028] FIG. 2 depicts the folds which form the leaflets or cusps of the replacement heart valve of the present invention in one embodiment.

[0029] FIGS. 3A and 3B depict a preferred procedure for folding the pericardium tissue starting material to create the replacement heart valve of the present invention.

[0030] FIG. 4 depicts a side perspective view of the replacement heart valve device of the present invention in one embodiment represented as if implanted within an artery.

[0031] FIG. 5 depicts a side view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent, with the stent in the expanded position.

[0032] FIG. 6 depicts a side perspective view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent in the collapsed position.

[0033] FIG. 7 depicts the suture points of one embodiment of the replacement heart valve device of the present invention.

[0034] FIG. 8 depicts the implantation/delivery system used with the present invention in a preferred embodiment.

[0035] FIGS. 9A, 9B and 9C depict a representation of a sheet of biocompatible valve material showing preferred folds.

DESCRIPTION OF A PREFERRED EMBODIMENT

[0036] The present invention comprises a percutaneously implantable replacement heart valve and a method for making same. The artificial heart valve device of the present invention is capable of exhibiting a variable diameter between a compressed or collapsed position and an expanded position. A preferred embodiment of the replacement heart valve device according to the present invention is set forth in FIG. 5. The replacement heart valve device comprises a stent member 100 and a flexible valve means 200. The stent member 100 is preferably self-expanding, although balloon-expandable stents can be used as well, and has a first polygonal shape in its compressed or collapsed configuration and a second, larger polygonal shape in its expanded configuration. Referring to FIG. 1, the valve means 200 comprises a generally tubular portion 210 and, preferably, a peripheral upstanding cusp or leaflet portion 220. The valve means 200 is disposed within the cylindrical stent member 100 with the tubular portion 210 transverse of and at some acute angle relative to the stent walls. The diameter of the tubular portion 210 is substantially the same as the inside diameter of the stent member in its initial expanded configuration. The peripheral upstanding cusp or leaflet portion 220 is disposed on valve means 200 substantially parallel to the walls of the stent member similar to a cuff on a shirt. The cusp or leaflet portion 220 of the valve means 200 is generally tubular in shape and comprises three leaflets 221, 222 and 223 as shown, although it is understood that there could be from two to four leaflets. The tubular portion of the valve means 200 is attached to the stent member 100 by a plurality of sutures 300, as depicted in FIG. 7.

[0037] The leaflet portion 220 of the valve means 200 extends across or transverse of the cylindrical stent 100. The leaflets 221, 222 and 223 are the actual valve and allow for one-way flow of blood. The leaflet portion 220 as connected to the rest of the valve resembles the cuff of

a shirt. FIG. 9 depicts the folds preferred for valve cusp and leaflet formation involving three leaflets. The configuration of the stent member 100 and the flexible, resilient material of construction allows the valve to collapse into a relatively small cylinder as seen in FIG. 6. The replacement heart valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member 100 will cause the artificial heart valve to take its expanded configuration, as seen in FIG. 5.

Stent Member

[0038] The stent member 100 preferably comprises a self-expanding nickel-titanium alloy stent, also called "nitinol," in a sine wave-like configuration as shown in FIG. 5. An enlarged view of a preferred embodiment of the stent member for use in the replacement heart valve of the invention is depicted in FIG. 5. The stent member 100 includes a length of wire 110 formed in a closed zigzag configuration. The wire can be a single piece, stamped or extruded, or it could be formed by welding the free ends together. The straight sections of the stent member 100 are joined by bends. The stent is readily compressible to a small cylindrical shape as depicted in FIGS. 6 and 8, and resiliently self-expandable to the shape shown in FIG. 5.

[0039] The stent member 100 of the artificial heart valve device of the present invention may be made from various metal alloys, titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials. The configuration may be the zigzag 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 zigzag or sine wave configured stent member is used, the diameter of the wire from which the stent is made is preferably from about 0.010 to 0.035 inches and still, 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.

[0040] The stent used in a preferred embodiment of the present invention is fabricated from a "shaped memory" alloy, nitinol, which is composed of nickel and titanium. Nitinol wire is first fashioned into the desired shape for the device and then the device is heat annealed. A meshwork of nitinol wire of approximately 0.008 inch gauge is formed into a tubular structure with a minimum central diameter of 20 min to make the stent. Away from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration. The maximum diameter of the flared ends of the stent is approximately 50 mm. The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its implantation.

[0041] When the components of the replacement heart valve device are exposed to cold temperatures, they become very flexible and supple, allowing them to be compressed down and pass easily through the delivery sheath. A cold temperature is maintained within the sheath during delivery to the deployment site by constantly infusing the sheath with an iced saline solution. Once the valve components are exposed to body temperature at the end of the sheath, they instantaneously reassume their predetermined shapes, thus allowing them to function as designed.

[0042] Preferably the stent member 100 carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve device 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 zigzag configuration so that the stent member will readily collapse and expand as pressure is applied and released, respectively.

Valve Means

[0043] The valve means 200 is flexible, compressible, host-compatible, and non-thrombogenic. The valve means 200 can be made from various materials, for example, fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts. Synthetic biocompatible materials such as polytetrafluoroethylene, polyester, polyurethane, nitinol or other alloy/metal foil sheet material and the like may be used. The preferred material for the valve means 200 is mammal pericardium tissue, particularly juvenile-age animal pericardium tissue. The valve means 200 is disposed within the cylindrical stent member 100 with the tubular portion 210 transverse of and at some acute angle relative to the stent walls. The diameter of the tubular portion 210 is substantially the same as the inside diameter of the stent member 100 in its initial expanded configuration. The peripheral upstanding cusp or leaflet portion 220 is disposed substantially parallel to the walls of the stent member 100 similar to a cuff on a shirt.

[0044] The cusp or leaflet portion 220 of the valve means 200 is formed by folding of the pericardium material used to create the valve. FIGS. 3A and 3B depict the way the sheet of heart valve starting material is folded. The starting material is preferably a flat dry sheet, which can be rectangular or other shaped. The cusps/leaflets 221, 222 and 223 open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the cusp or leaflet portion 220 of the valve means 200 contains the same number of cusps as the

native valve being replaced, in substantially the same size and configuration. FIGS. 9A-9C depict a preferred configuration for folds to create the leaflets/cusps. The leaflet forming portion is a single, continuous, uncut layer affixed to the interior of the cuff layer to form the leaflets/cusps, unlike prior efforts that have involved suturing of three separate leaflet/cusp portions onto the main valve body portion. The leaflets are formed from the free edge of the material after forming the cuff portion. Referring now to FIGS. 9-A, 9B, and 9C, with flat sheet on a table, a person facing the sheet would create a cuff at the upper border of sheet by folding the horizontal top edge away/downwardly (fold no. 1). The leaflet portion is formed by folding the sheet's lower half towards the folder/upwardly, as shown in FIG. 9A (fold no. 2). The sheet, now with the upper cuff and bottom inward fold, is folded inwardly at two preferably equidistant vertical points as shown in FIG. 9B to create the leaflet/cusp portion (folds nos. 3 and 4). The leaflets/cusps are formed by folding fold nos. 6, 7 and 8 after the two opposite vertical edges of sheet are joined to create a cylindrical valve shape, depicted in FIGS. 1 and 3B. The inner leaflet layer is preferably attached to the outer cuff layer by curved or straight continuous suturing. Although a preferred embodiment of the invention comprises a single piece of valve material folded to create the valve body and a leaflet-forming portion that has no cuts or sutures, the inventors have discovered that as long as the leaflet portion of the valve itself is formed from a single piece of biocompatible valve material, the other portions of the valve can be formed by suturing of one or more separate pieces of material without losing the novel and improved qualities of the present invention. This allows for the valve to be made even stronger, more durable and easier to make. This alternate embodiment comprises a leaflet forming layer made of a single piece of valve material attached to a separate piece forming the valve body having a folded cuff portion. The single piece leaflet forming layer is preferably cylindrical in shape and

can be formed with or without folding. In this embodiment the single piece leaflet layer can itself be attached to the stent with or without a cylindrical cuff portion. Attachment is preferably by suturing, particularly continuous single or double sutures.

Method of Making Replacement Heart Valve Device

[0045] The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the biocompatible tissue material is isolated and all the fat tissue and extra fibers are removed. Cleaning is preferably accomplished by using a hydromechanical force-based cleaning device to separate tissue layers and hydration with distilled water to remove unwanted layers. Once the pericardium is completely clean, it is subjected to photo-mechanical compression, then the valve is formed and placed in sequential solutions of isopropyl alcohol of about 70-100%, ethanol of about 70-100% glycerol and glutaraldehyde preferably at a concentration of about 0.07-25% for about 36 hours, respectively. The material is preferably photomechanically compressed to remove lipids and produce protein coagulation to make the surface smoother and more compact and biocompatible, decreasing the molecular distance of collagen fibers. The exposure to light and mechanical compression cause protein denaturation making the material stronger and more homogeneous and biocompatible. Gas sterilization can also be used to sterilize the tissue membrane material. The valve is formed by taking a flat sheet of the material and folding it in such a way that forms a three-leaflet or desired number of leaflet valve as shown in FIGS. 3A and 3B and/or FIGS. 9A, 9B and 9C. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. It also greatly reduces the risk of tearing of the cusps or leaflets, since they are integral to the valve rather than being attached by suturing.

[0046] In a preferred embodiment, the single continuous piece of membrane is folded inward to form an inner leaflet layer within the outer cuff. The single leaflet layer is then attached to the cuff layer to form valve cusps in one of three preferred ways: (i) by curved or straight continuous single or double sutures that affix and form the bases or recesses of the valve cusps; (ii) by lengthwise suture lines attaching the leaflet layer to the cuff layer with the bases or recesses of the valve cusps being thus formed of the folded edge of the membrane; (iii) by further folding of the membrane into lengthwise pleats secured by lengthwise suture attaching the leaflet layer to the cuff layer with the bases or recesses of the valve cusps being thus formed of the folded edge of the membrane, done for the purpose of giving greater strength and durability to the attachment points of the leaflet layer.

[0047] In order to make the pericardium material less slippery and easier to fold, the pericardium is dried, preferably with artificial light using a multi-watt lamp with the pericardium or other biocompatible membrane material placed in a flat aluminum surface to dry it homogeneously. A photomechanical drying machine can also be used. The final result is a homogeneous tissue that looks like plastic paper and makes it easy to manipulate to fold and suture the valve. Once the valve is formed, it is re-hydrated by placing it in a solution of water and 70% alcohol. In approximately 3 days the valve is fully rehydrated. The suturing of membrane layers to form the valve is done with single, double, or more continuous suture material. This form of suturing has great advantages for durability and avoidance of damage to the membrane and can be performed by sewing machines. The attachment points of the leaflet layer to the cuff layer may be reinforced by folding an additional layer of membrane over the attachment point before suturing, this layer being formed of a projected tab of the continuous piece of leaflet membrane. The free edge of the leaflet layer may be straight or curved, and this

free edge forming the free edges of the individual leaflets may be contoured in parabolic or curved shape.

Attachment of the Valve Means to the Stent Member

[0048] The valve means 200 is then attached to the inner channel of the stent member 100 by suturing the outer surface of the valve means' pericardium material to the stent member. FIG. 7 depicts preferred suture points of one embodiment of the present invention: 3-point fixation or 6-point fixation at each border of the stent. Other fixation schemes can be utilized, such as, by way of non-limiting example, fixation on both borders 18 points at each end following a single plane and 36 fixation points following to adjacent vertical planes. The use of only one plane of fixation points helps prevent systolic collapse of the proximal edge of the valve means. A fold on the border of the pericardium material prevents tearing. The attachment position of the valve is preferably closer to the proximal and wider part of the stent.

[0049] The sequence of steps can vary. The pericardium material can be fixed in glutaraldehyde before attachment to the stent or the valve can be formed and then fixed with glutaraldehyde after mounting it in the stent. One observation noted is that the material becomes whiter and apparently increases its elasticity. 1 mm vascular clips keep the cusps coapted while fixing them in glutaraldehyde. The use of metallic clips to keep both cusps adjacent to each other after 24 hours of fixation in glutaraldehyde helps to educate the material and make the primary position of the valve cusps adjacent to each other. After the clips are removed, there are no lesions to the valve.

[0050] Different suture materials can be used, including, in a preferred embodiment, Prolene 1-0 to 8-0 and Mersilene 1-0 to 8-0 which is a braided suture.

Implantation of Replacement Heart Valve Device

[0051] The replacement heart valve device of the present invention is preferably used in surgical procedures involving 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. To remove the native heart valve that is being replaced, 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 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 can be monitored by observation of radiopaque markers. Collector member is preferably inflated and occludes the aorta at a point between the origin of the coronary artery and the right subclavian artery. Next, a balloon and cutting tool are advanced through the catheter so that the cutting tool and uninflated balloon 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 also 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 is in place, the balloon is inflated and flexible shaft is rotated. Once the cutting tool has reached the appropriate rotation speed, the cutting tool is pulled proximally to remove the defective heart valve. The balloon and the cutting tool are spaced apart so that the inflated balloon 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. Once it is determined that the defective heart valve has been removed, the cutting tool is slowed or stopped altogether and the balloon is deflated. The cutting tool and the deflated balloon are pulled proximally through catheter. Then, a catheter containing an artificial heart valve is inserted and the artificial heart valve is placed as described above.

[0052] The delivery and implantation system of the replacement artificial heart valve of the present invention percutaneously and transluminally includes a flexible catheter 400 which may be inserted into a vessel of the patient and moved within that vessel as depicted in FIG. 8. The distal end 410 of the catheter 400, which is hollow and carries the replacement heart valve device of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the replacement heart valve. The catheter has a pusher member 420 disposed within the catheter lumen 430 and extending from the proximal end 440 of the catheter to the hollow section at the distal end 410 of the catheter. Once the distal end 410 of the catheter is positioned as desired, the pusher mechanism 420 is activated and the distal portion of the replacement heart valve device is pushed out of the catheter and the stent member 100 partially expands. In this position the stent member 100 is restrained so that it doesn't pop out and is held for controlled release, with the potential that the replacement heart valve device can be recovered if there is a problem with the positioning. The catheter 400 is then retracted slightly and the

replacement heart valve device is completely pushed out of the catheter 400 and released from the catheter to allow the stent member 100 to fully expand. If the stent member 100 preferably 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 replacement heart valve device will set the other circle of barbs in adjacent tissue and securely fix the replacement heart valve device in place when the device is released from the catheter.

[0053] Alternatively, or in combination with the above, the replacement heart valve device could be positioned over a metallic guidewire that is advanced through the catheter. The replacement heart valve device of the present invention is preferably implanted percutaneously through an aortic passageway to, or near to, the location from which the natural heart valve has been removed. Referring to FIG. 8, the implantation system comprises a flexible hollow tube catheter 410 with a metallic guide wire 450 disposed within it. The stented valve device is collapsed over the tube and is covered by a moveable sheath 460. The moveable sheath 460 maintains the stented valve device in the collapsed position. The implantation method comprises the following steps: inserting the replacement heart valve device in the lumen of a central blood vessel via entry through the brachial or femoral artery using a needle or exposing the artery surgically; placing a guide wire 450 through the entry vessel and advancing it to the desired position; advancing dilators over the wire to increase the lumen of the entry site, thereby preparing the artery to receive the heart-valve; and advancing the heart-valve device to the desired place. The stented-valve device is released by pulling the cover sheath 460 of the delivery system allowing the self-expanding stent to achieve its full expansion. A balloon expandable stent can alternately be used to deliver the valve to its desired position. At this point,

a pigtail catheter is advanced over the wire and an aortogram is performed to assess the competency of the valve.

[0054] Before creation of the valve means and implantation, 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 size for the replacement heart valve.

[0055] In one procedure for implantation of the replacement heart valve device of the present invention, the femoral artery of the patient is canulated using a Cook needle and a standard J wire is advanced into the artery either percutaneously or after surgical exposure of the artery. An 8 F introducer is advanced into the femoral artery over the wire. The J wire is then withdrawn and anticoagulation is started using heparin 60 U/Kg intravenously. Once vascular access is obtained an aortogram is performed for anatomical evaluation. A special wire (Lunderquist or Amplatz superstiff) is advanced into the aortic arch and dilators progressively larger are advanced over the wire, starting with 12 F all the way to 18 F. After this the valve introducer device containing the prosthetic valve device is then inserted and used to transport the replacement valve over a guidewire to the desired position. The stented-valve is released by pulling the cover sheath of the delivery system allowing the self-expanding stent to achieve its full expansion. At this point, a pigtail catheter is advanced over the wire and repeat aortogram is performed to assess the competency of the valve.

[0056] When the device is used to treat severe leakage of the aortic valve, the native valve is left in place and the prosthetic stented valve is deployed below the subclavian artery. When the device is used to treat aortic stenosis, first the stenotic valve needs to be opened using

either aortic valvuloplasty or cutting and if this procedure induces aortic insufficiency the stented valve is placed to prevent the regurgitation.

[0057] Intravascular ultrasound or an angioscope passed intravascularly via either the venous system through the intra-atrial septum across the mitral valve and into the left ventricle or retrograde via the femoral artery would provide the added benefit of allowing constant high definition imaging of the entire procedure and high flow irrigation.

[0058] Once the endovascular implantation of the prosthetic valve device is completed in the host, the function of the prosthetic valve device can be monitored by the same methods as used to monitor valve replacements done by open heart surgery. Routine physical examination, periodic echocardiography or angiography can be performed. In contrast to open heart surgery, however, the host requires a short recovery period and can return home within one day of the endovascular procedure. The prosthetic valve device can be used in any patient where bioprosthetic valves are indicated, namely elderly patients with cardiac valve diseases, and patients unable to tolerate open heart procedures or life-long anticoagulation. In addition, with the development of longer-life, flexible, non-thrombogenic synthetic valve alternatives to bioprosthesis, the prosthetic valve device will be indicated in all patients where the relative advantages of the life-span, the non-thrombogenic quality, and the ease of insertion of prosthetic valve devices outweigh the disadvantages of mechanical valves. Anticoagulation may be beneficial in certain clinical situations for either short or long term use.

[0059] This method of percutaneous endovascular heart-valve replacement, in contrast to open heart surgical procedures, requires only local anesthesia, partial or no cardiac bypass, one to two days hospitalization, and should result in a reduced mortality rate as compared to open heart procedures.

[0060] While the present invention has been shown and described herein in what is considered to be a preferred embodiment thereof, illustrating the results and advantages over the prior art obtained through the present invention, the invention is not limited to the specific embodiments described above. Thus, the forms of the invention shown and described herein are to be taken as illustrative and other embodiments may be selected without departing from the spirit and scope of the present invention.

CLAIMS

What is claimed is:

1. A percutaneously implantable replacement heart valve device comprising an expandable stent member and a flexible, compressible artificial valve made of biocompatible tissue material and disposed within the inner cavity of said stent member affixed at one or more points on said artificial valve's outer surface to said stent member, said artificial valve having cusps or leaflets formed by folding of a sheet of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into said material to form said cusps or leaflets.

2. The percutaneously implantable replacement heart valve device of claim 1, wherein said expandable stent member is made of a metal or alloy of metals selected from the group consisting of nickel-titanium alloy, titanium and stainless steel.

3. The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said artificial valve comprises mammal pericardium tissue.

4. The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said artificial valve comprises porcine pericardium tissue.

5. The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said artificial valve is obtained from a juvenile animal pericardium.

6. The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said artificial valve comprises autologous tissue obtained from the patient into whom said replacement heart valve device will be implanted.

7. The percutaneously implantable heart valve device of claim 1 , wherein said biocompatible tissue material of said artificial valve comprises a synthetic biocompatible material.

8. The percutaneously implantable heart valve device of claim 7, wherein said synthetic biocompatible material is selected from the group consisting of polytetrafluoroethylene, polyester, metal, metal alloy including combinations thereof.

9. The percutaneously implantable heart valve device of claim 1, wherein said stent member is self-expanding when implanted.

10. The percutaneously implantable heart valve device of claim 1, wherein said stent member is balloon catheter expandable when implanted.

11. A method of making a percutaneously implantable replacement heart valve device comprising the following steps:

obtaining a sheet of biocompatible tissue material;

drying said biocompatible tissue material;

folding said dried biocompatible tissue material to create inner cusps or leaflets and an outer tubular cuff structure without affixing of separate cusps or leaflets or cutting slits into said material to form said cusps or leaflets;

affixing said folded biocompatible tissue material at one or more points on its outer surface to the inner cavity of a stent; and

soaking said biocompatible tissue material in one or more alcohol solutions and a solution of glutaraldehyde.

12. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said soaking step comprises soaking said biocompatible tissue material in a solution of isopropyl alcohol, a solution of ethanol, a solution of glycerol and a solution of gluteraldehyde.

13. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said biocompatible tissue material comprises bovine pericardium tissue.

14. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said biocompatible tissue material comprises porcine pericardium tissue.

15. The method of making a percutaneously implantable replacement heart valve device of claim 11 , wherein said biocompatible tissue material is obtained from a juvenile animal pericardium.

16. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said biocompatible tissue material comprises autologous tissue obtained from the patient into whom said replacement heart valve device will be implanted.

17. The percutaneously implantable heart valve device of claim 11, wherein said biocompatible tissue material of said artificial valve comprises a synthetic biocompatible material.

18. The percutaneously implantable heart valve device of claim 17, wherein said synthetic biocompatible material is selected from the group consisting of polytetrafluoroethylene, polyester, metal, metal alloy including combinations thereof.

19. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said stent is made of a metal or alloy of metals selected from the group consisting of nickel-titanium alloy, titanium and stainless steel.

20. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said stent is self-expanding when implanted.

21. The method of making a percutaneously implantable replacement heart valve device of claim 11, wherein said stent is balloon catheter expandable when implanted.

22. The method of making a percutaneously implantable replacement heart valve device of claim 11, further comprising the step of cleaning said biocompatible tissue material using hydromechanical force means.

23. The method of making a percutaneously implantable replacement heart valve of claim 11, further comprising the step of compressing said biocompatible tissue material.

24. The method of making a percutaneously implantable replacement heart valve of claim 11, further comprising the step of gas sterilization of said biocompatible tissue material.

25. The method of making a percutaneously implantable replacement heart valve of claim 11, wherein said drying step comprises photomechanical compression of said biocompatible tissue material.

26. The method of making a percutaneously implantable replacement heart valve of claim 11, wherein said folding step comprises folding of a first piece of said biocompatible tissue material to create an outer tubular cuff structure, folding of a second separate piece of biocompatible tissue material to create inner cusps or leaflets without affixing of separate cusps or cutting slits into said second separate piece of biocompatible tissue material, and afixing said second separate piece to said first piece.

27. A percutaneously implantable replacement heart valve device comprising an expandable stent member and a flexible, compressible artificial valve made of biocompatible tissue material and disposed within the inner cavity of said stent member affixed at one or more points on said artificial valve's outer surface to said stent member, said artificial valve comprising a leaflet or cusp portion formed by folding of a first sheet portion of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into said sheet to form said cusps or leaflets, and an outer tubular cuff structure formed by folding a second sheet portion of biocompatible tissue material, said first and second sheet portions being affixed together.

28. The device of claim 27, wherein said first sheet portion and said second sheet portions are affixed together by suturing.

29. The device of claim 28, wherein said suturing is in the form of double continuous sutures.

30. A percutaneously implantable replacement heart valve device comprising an outer cylindrical cuff portion and an inner uncut/unslit leaflet layer attached within said outer cuff portion.

31. The device of claim 30, wherein said leaflet layer is attached within said outer cuff portion by suturing.

32. The device of claim 31, wherein said suturing is in the form of double continuous sutures.

33. A percutaneously implantable replacement heart valve device comprising an expandable stent member and a flexible, compressible artificial valve made of biocompatible tissue material and disposed within the inner cavity of said stent member affixed at one or more points on said artificial valve's outer surface to said stent member, said artificial valve comprising a leaflet or cusp portion formed by folding of a first sheet portion of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into said sheet to form said cusps or leaflets.

ABSTRACT

A method of making a replacement heart valve device whereby a fragment of biocompatible tissue material is treated and soaked in one or more alcohol solutions and a solution of glutaraldehyde. The dried biocompatible tissue material is folded and rehydrated in such a way that forms a two- or three-leaflet/cusp valve without affixing of separate cusps or leaflets or cutting slits into the biocompatible tissue material to form the cusps or leaflets. After the biocompatible tissue material is folded, it is affixed at one or more points on the outer surface to the inner cavity or a stent.

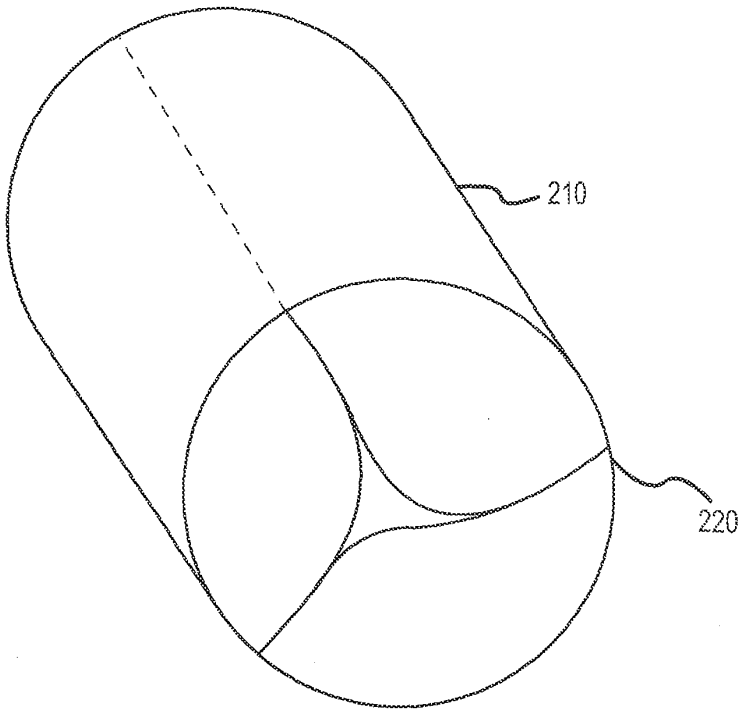

FIG.1

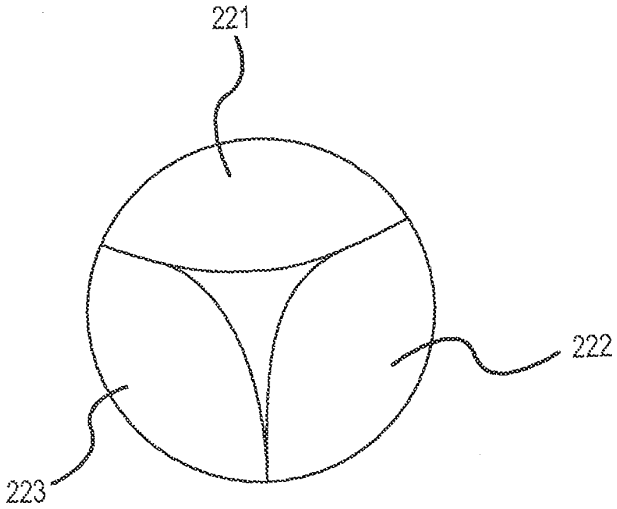

FIG.2

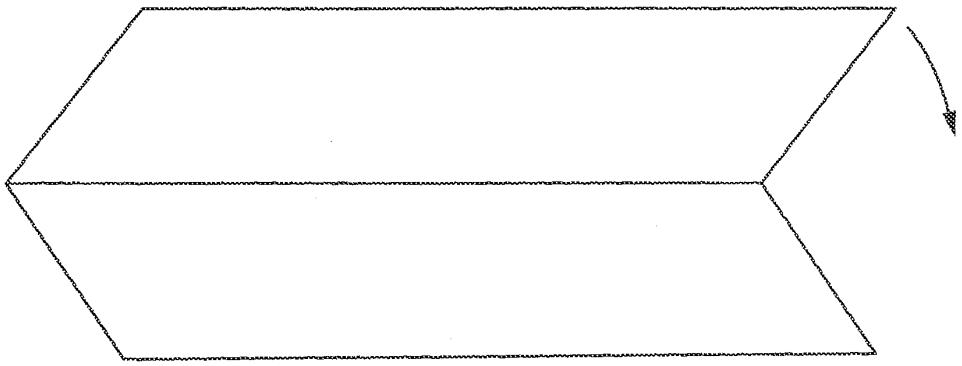

FIG.3A

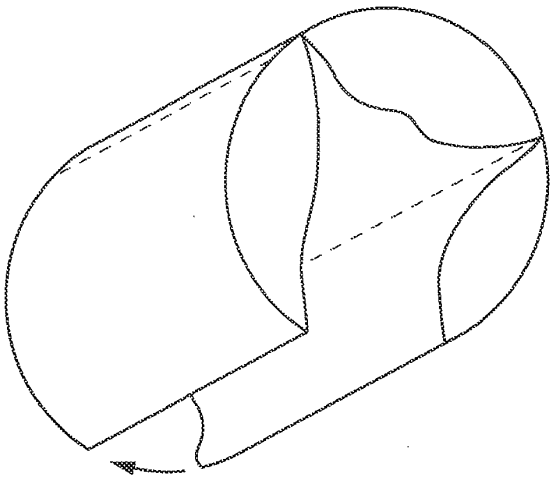

FIG.3B

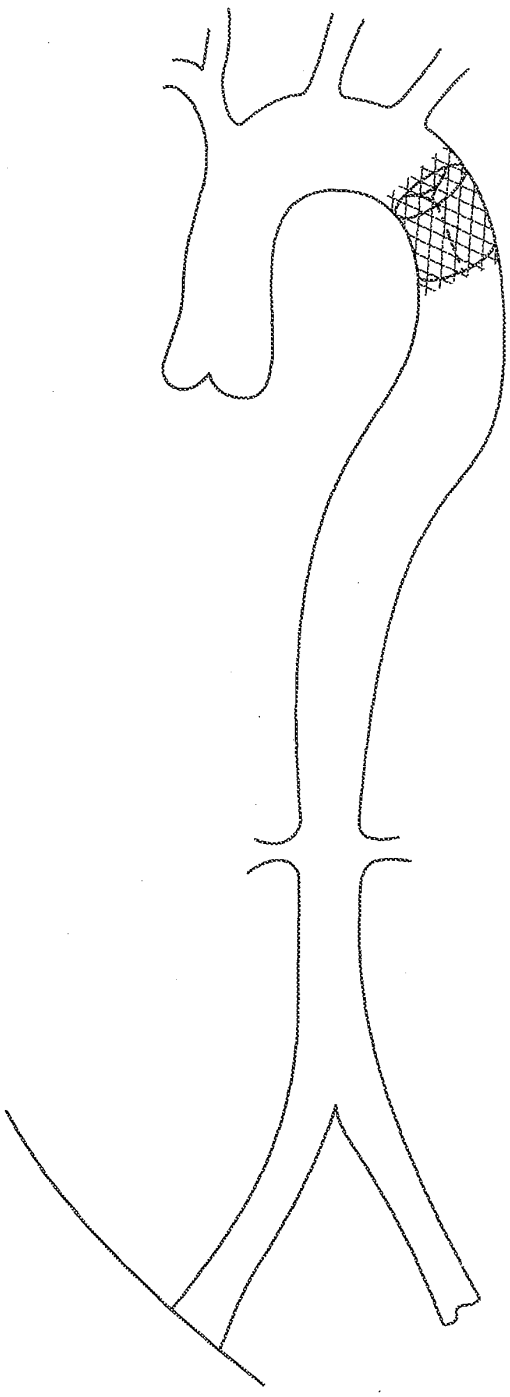

FIG.4

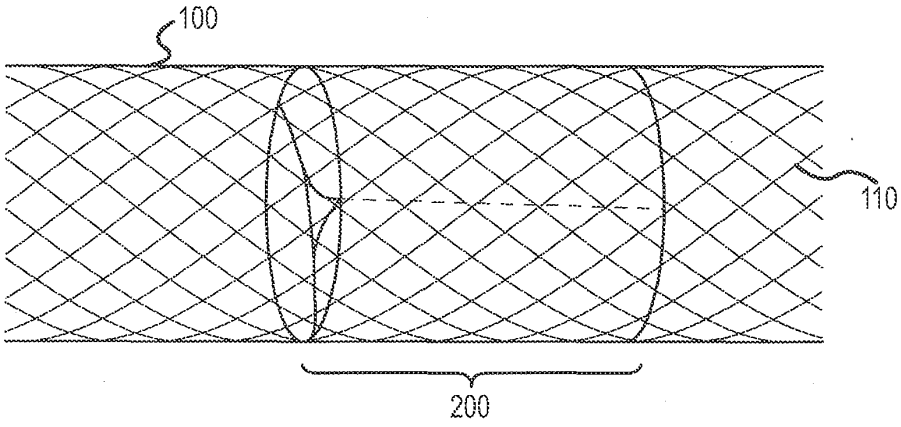

FIG.5

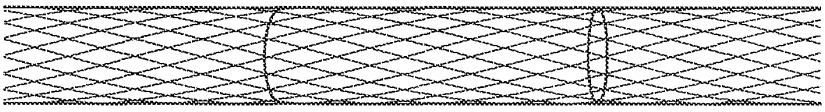

FIG.6

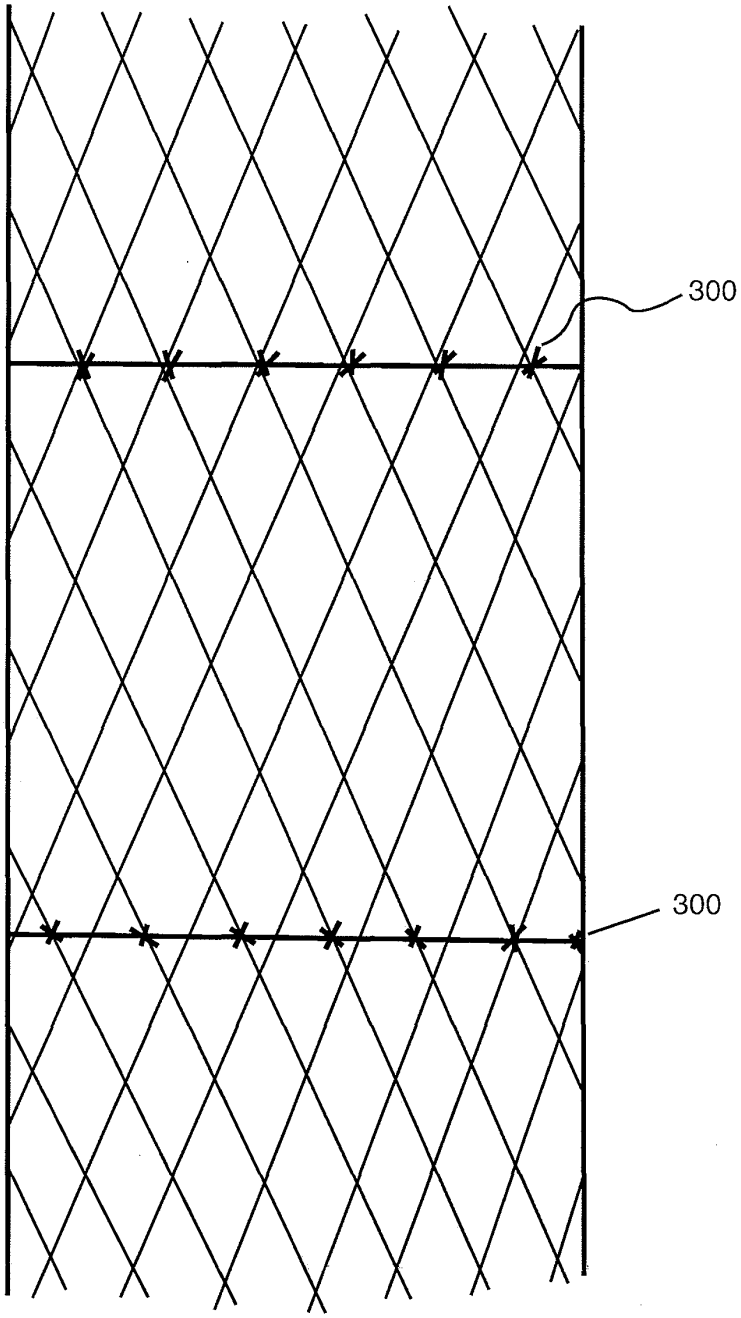

FIG. 7

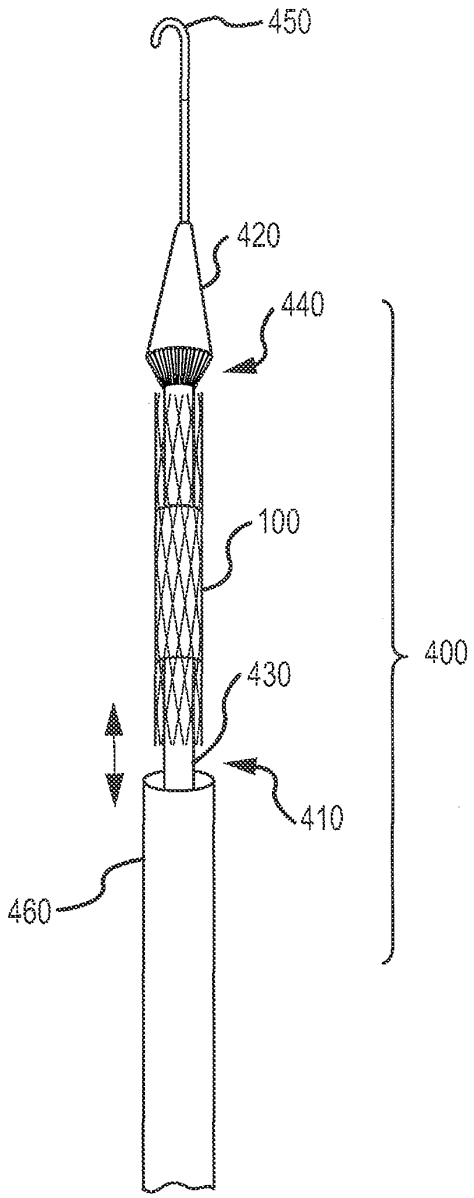

FIG.8

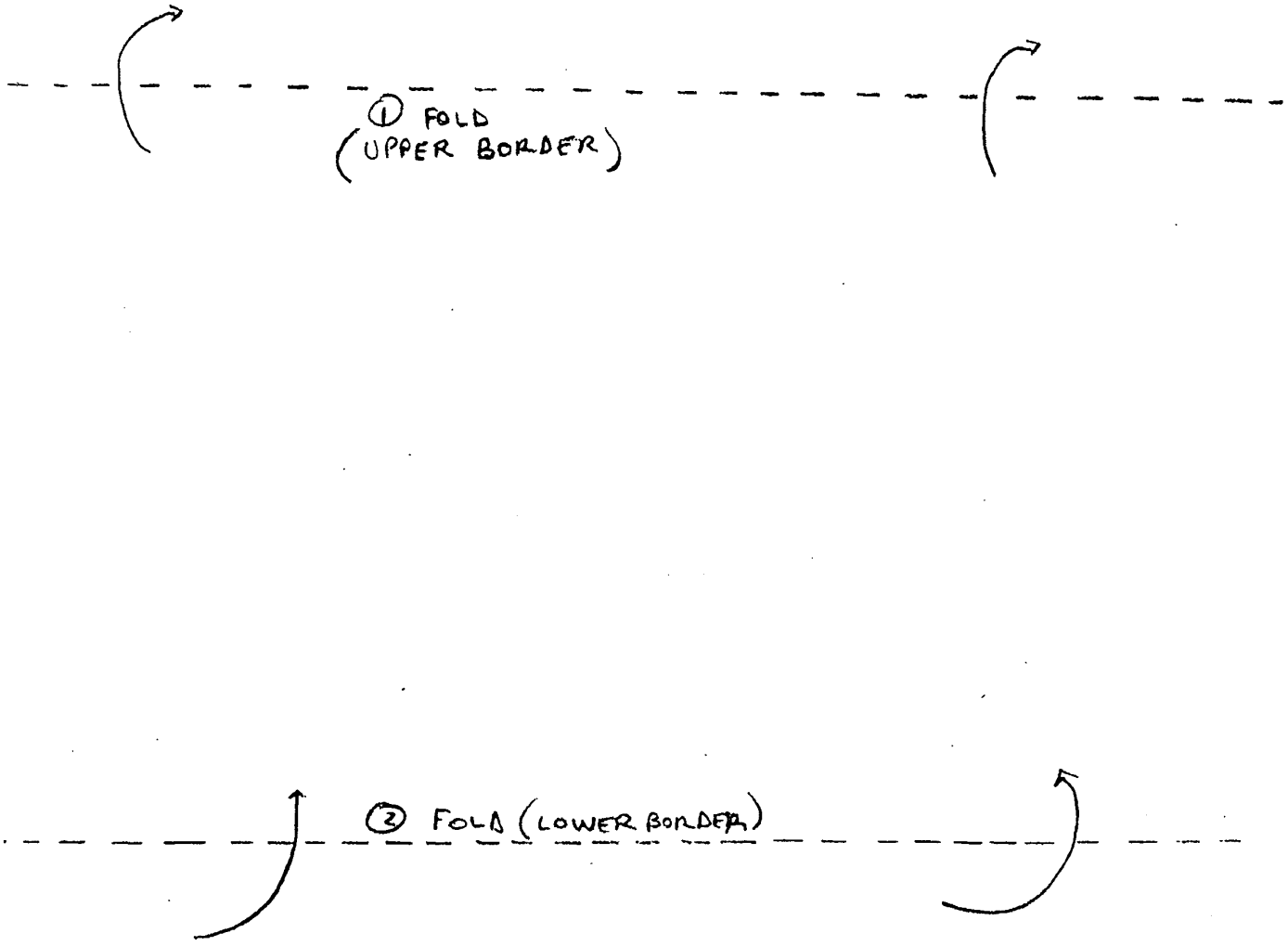

Fig. 9A

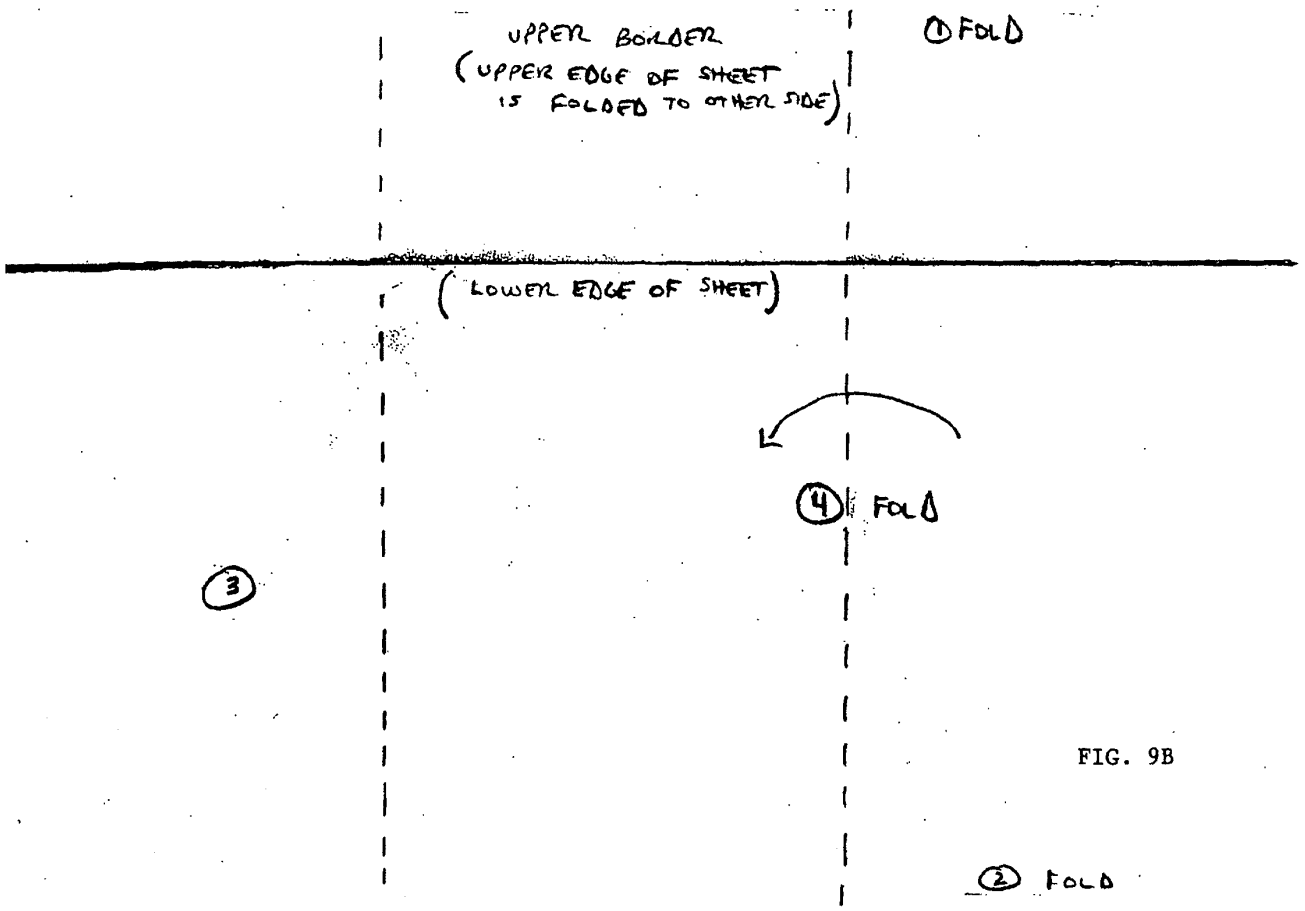
UPPER BORDER
(UPPER EDGE OF SHEET IS FOLDED TO OTHER SIDE)
(1) FOLD
(LOWER EDGE OF SHEET)
(4) FOLD
(3)
(2) FOLD

FIG. 9B

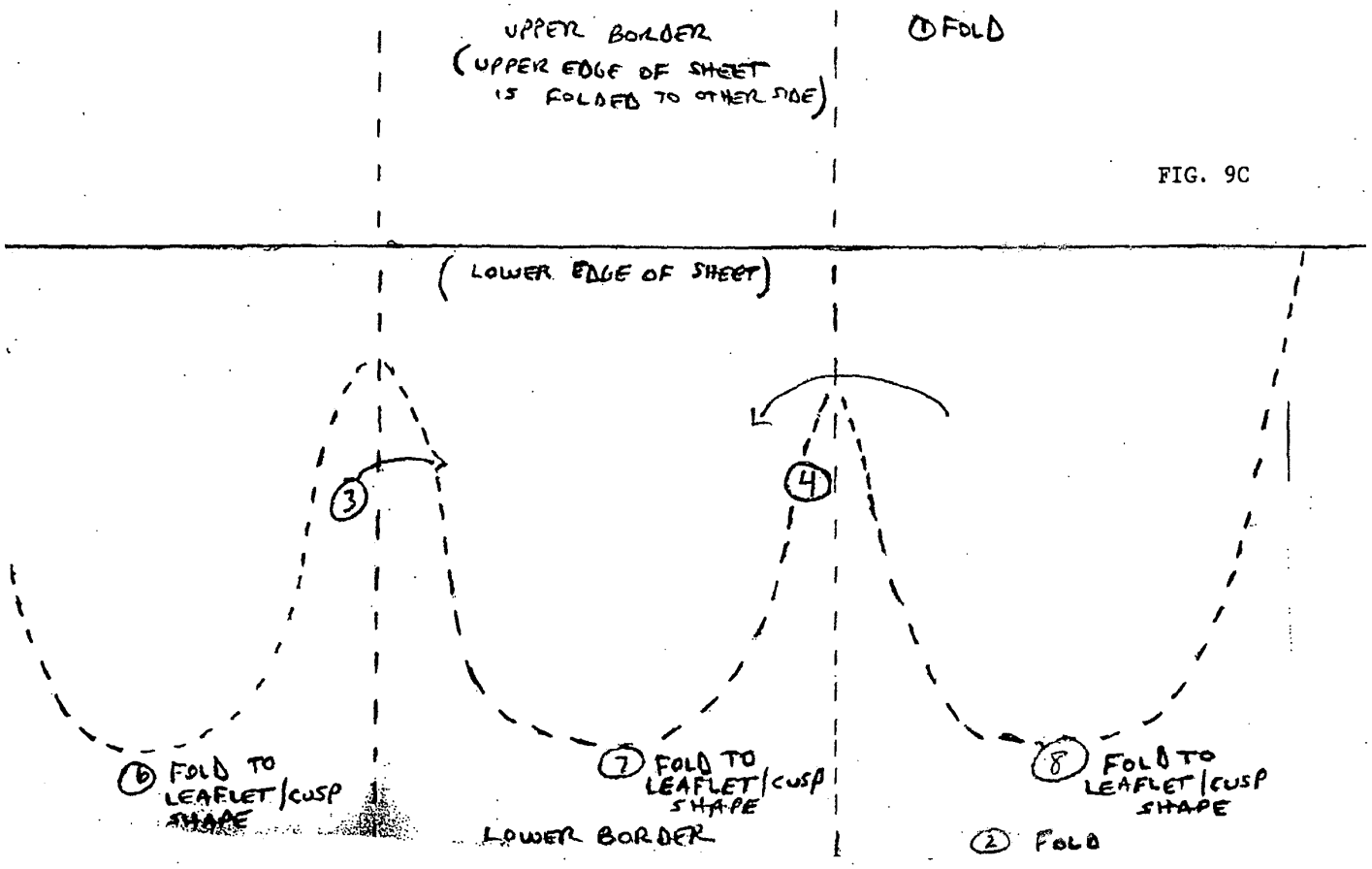
UPPER BORDER
(UPPER EDGE OF SHEET IS FOLDED TO OTHER SIDE)
① FOLD
(LOWER EDGE OF SHEET)
③
④
⑥ FOLD TO LEAFLET/CUSP SHAPE
⑦ FOLD TO LEAFLET/CUSP SHAPE
⑧ FOLD TO LEAFLET/CUSP SHAPE
LOWER BORDER
② FOLD

FIG. 9C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)	Confirmation No.: Not Yet Assigned
	)	
PANIAGUA et al.	)	Group Art Unit: Not Yet Assigned
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Application No.: Not Yet Assigned	)	Examiner: Not Yet Assigned
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Atty. File No.: 109978.10104	)	***(Filed Electronically)***
	)	
For: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	)	**Certificate of EFS-Web Transmission** I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent And Trademark Office on April 15, 2014 Typed or printed name of person signing this certificate: Carol Donahue Signature: / Carol Donahue /

Commissioner for Patents
P.O. Box 1450
Alexandria Virginia 22313-1450

Dear Sir:

Prior to the initial review of the above-identified patent application by the Examiner, please enter the following Preliminary Amendment.

Please amend the above-entitled patent application as follows:

Amendments To The Specification begin on page 2 of this paper.

Amendments To The Claims begin on page 6 of this paper.

Amendments To The Drawings begin on page 8 of this paper.

Remarks begin on page 9 of this paper.

Attachments begin after page 10 of this paper.

Applicants believe no additional fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

AMENDMENTS TO THE SPECIFICATION

Please amend the following paragraphs as noted. A marked up and a clean Specification are in the Attachments to the Preliminary Amendment.

Please amend the Title as follows:

~~PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME~~

PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

[0001] The present application is a continuation application of U.S. Patent Application No. 13/675,665 filed on November 13, 2012, which is a continuation application of U.S. Patent Application No. 10/887,688 filed on July 10, 2004, now U.S. Patent No. 8,308,797, which is a continuation-in-part application of U.S. Patent Application No. 10/037,266, filed on January 4, 2002 (now abandoned). [[Both]] All of the foregoing applications ~~of which~~ are incorporated herein by reference in their entireties.

[0025] The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the pericardium starting material is isolated and all the fat tissue and extra fibers are removed. The biological membrane material is cleaned by mechanical separation of unwanted layers using hydromechanical force means. Once the pericardium is completely clean, the material is dried in order to make it easier to handle and fold. Preferably, this drying is done by exposing the biocompatible membrane material to photomechanical compression to remove all lipids from the pericardium or other biocompatible membrane

material and to cause protein denaturalization, transforming the material into a stronger and more homogeneous surface. The valve is formed by taking a flat sheet of the material and folding in such a way that forms a three-leaflet or other number of leaflet valve. Then it is placed in a sequence of solutions, one of isopropyl alcohol of about 70-100%, one of ethanol of about 70-100%, one of glycerol and one of ~~gluteraldehyde~~ glutaraldehyde, preferably at a concentration of about 0.07-25% for approximately 36 hours. The material is dried in order to make it easier to handle and fold. Preferably this drying is done by exposing the biocompatible membrane material to light and then mechanically compressing the material to cause protein denaturation. This results in material that is stronger and more homogeneous. The valve is formed by taking a flat sheet of bovine or ~~procine~~ porcine pericardium and folding it in such a way that forms a three-leaflet valve. The valve can also be made in the same manner from fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts or synthetic non-biological, non- thrombogenic material. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. The cleaning, pressing and drying technique used to create the valve material makes the folding more practicable. The valve is rehydrated after being formed. The method of the present invention also greatly reduces the risk of tearing of the cusps or leaflets, since they are formed by folding a single uncut portion of material forming the valve rather than being attached by suturing.

[0040] The stent used in a preferred embodiment of the present invention is fabricated from a "shaped memory" alloy, nitinol, which is composed of nickel and titanium. Nitinol wire is first fashioned into the desired shape for the device and then the device is heat annealed. A

meshwork of nitinol wire of approximately 0.008 inch gauge is formed into a tubular structure with a minimum central diameter of 20 [[min]] mm to make the stent. Away from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration. The maximum diameter of the flared ends of the stent is approximately 50 mm. The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its implantation.

[0045] The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the biocompatible tissue material is isolated and all the fat tissue and extra fibers are removed. Cleaning is preferably accomplished by using a hydromechanical force-based cleaning device to separate tissue layers and hydration with distilled water to remove unwanted layers. Once the pericardium is completely clean, it is subjected to photo-mechanical compression, then the valve is formed and placed in sequential solutions of isopropyl alcohol of about 70-100%, ethanol of about 70-100%, glycerol and glutaraldehyde preferably at a concentration of about 0.07-25% for about 36 hours, respectively. The material is preferably photomechanically compressed to remove lipids and produce protein coagulation to make the surface smoother and more compact and biocompatible, decreasing the molecular distance of collagen fibers. The exposure to light and mechanical compression cause protein denaturation making the material stronger and more homogeneous and biocompatible. Gas sterilization can also be used to sterilize the tissue membrane material. The valve is formed by taking a flat sheet of the material and folding it in such a way that forms a three-leaflet or desired number of leaflet valve as shown in FIGS. 3A and 3B and/or FIGS. 9A, 9B and 9C. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing

otherwise required, and resembles the natural form and function of the valve leaflets. It also greatly reduces the risk of tearing of the cusps or leaflets, since they are integral to the valve rather than being attached by suturing.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1.-33. (Cancelled)

34. (New) A percutaneous bioprosthetic heart valve and a delivery and implantation system configured for percutaneous use where a bioprosthetic heart valve is indicated, comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for percutaneous delivery, wherein the stent member includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration; and

a valve means residing entirely within the inner channel of the stent member, the valve means including an outer cuff layer and two to four individual leaflets;

a catheter including a pusher member and a moveable sheath, both the pusher member and the moveable sheath each including a lumen, wherein the pusher member is disposed within the lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the moveable sheath.

35. (New) The percutaneous bioprosthetic heart valve and the delivery and implantation system of Claim 34, wherein the stent member is self-expanding.

36. (New) The percutaneous bioprosthetic heart valve and the delivery and implantation system of Claim 35, wherein the stent member comprises nitinol.

37. (New) The percutaneous bioprosthetic heart valve and the delivery and implantation system of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (New) The percutaneous bioprosthetic heart valve and the delivery and implantation system of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include replacement Figures 9A-9C. Please replace Figures 9A-9C currently on file with the attached replacement drawings. Applicants believe no new matter has been added with submittal of replacement drawings 9A-9C.

REMARKS

Applicants request that this Preliminary Amendment be entered and the claims presented herein be examined in this application.

Several typographical errors have been corrected in the amendments to the specification noted herein. Applicants believe no new matter has been added with submittal of replacement drawings 9A-9C.

Claims 1-33 have been cancelled and new Claims 34-38 have been added. Applicants believe that support for all claims presented herein is provided in the first application in the priority chain, namely, U.S. Pat. App. No. 10/037,266 filed on January 4, 2002. Applicants are providing the following information to assist the examiner with assessing support for the claims as presented herein. It is noted that other locations in the application may also provide support.

Citations below note the location for claim limitation support within U.S. Pat. App. No. 10/037,266 filed on January 4, 2002 (with paragraph numbering provided below matching that within U.S. Pat. App. Pub. No. 2003/0130729 that corresponds to U.S. Pat. App. No. 10/037,266 filed on January 4, 2002).

Support for new independent Claim 34 can be found in at least Paragraphs 0037, 0042, 0057, 0058, and 0063 and in the figures including Figure 8 of U.S. Pat. App. No. 10/037,266 filed on January 4, 2002.

With regard to the dependent claims, the following summarizes locations with support for the limitations:

Claim 35: Paragraph 40 within U.S. Pat. App. Pub. No. 2003/0130729 that corresponds to U.S. Pat. App. No. 10/037,266 filed on January 4, 2002.

Claim 36: Paragraph 40 within U.S. Pat. App. Pub. No. 2003/0130729 that corresponds to U.S. Pat. App. No. 10/037,266 filed on January 4, 2002.

Claim 37: Paragraph 57 within U.S. Pat. App. Pub. No. 2003/0130729 that corresponds to U.S. Pat. App. No. 10/037,266 filed on January 4, 2002.

Claim 38: Paragraph 57 within U.S. Pat. App. Pub. No. 2003/0130729 that corresponds to U.S. Pat. App. No. 10/037,266 filed on January 4, 2002.

In the event that the Examiner has any questions regarding this Preliminary Amendment, the Examiner is invited to contact the below-named attorney at (303) 446-3852.

Respectfully submitted,

FOX ROTHSCHILD LLP

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Dated: April 15, 2014

MARKED UP SPECIFICATION

~~PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME~~

PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

CONTINUITY INFORMATION

[0001] The present application is a continuation application of U.S. Patent Application No. 13/675,665 filed on November 13, 2012, which is a continuation application of U.S. Patent Application No. 10/887,688 filed on July 10, 2004, now U.S. Patent No. 8,308,797, which is a continuation-in-part application of U.S. Patent Application No. 10/037,266, filed on January 4, 2002 (now abandoned). [[Both]] All of the foregoing applications ~~of which~~ are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] Field of the Invention

The present invention is in the field of heart valve replacement. More specifically, the present invention is directed to a method of making a percutaneously implantable replacement heart valve.

[0003] 2. Description of Related Art

There have been numerous efforts in the field of heart valve replacement to improve both the durability and effectiveness of replacement heart valves as well as the ease of implantation. A brief description of heart valves and heart function follows to provide relevant background for the present invention.

[0004] There are four valves in the heart that serve to direct the flow of blood through the two sides of the heart in a forward direction. On the left (systemic) side of the heart are: 1) the mitral valve, located between the left atrium and the left ventricle, and 2) the aortic valve, located between the left ventricle and the aorta. These two valves direct oxygenated blood coming from the lungs through the left side of the heart into the aorta for distribution to the body. On the right (pulmonary) side of the heart are: 1) the tricuspid valve, located between the right atrium and the right ventricle, and 2) the pulmonary valve, located between the right ventricle and the pulmonary artery. These two valves direct de-oxygenated blood coming from the body through the right side of the heart into the pulmonary artery for distribution to the lungs, where it again becomes re-oxygenated to begin the circuit anew.

[0005] Heart valves are passive structures that simply open and close in response to differential pressures on either side of the particular valve. They consist of moveable "leaflets" that are designed simply to open and close in response to differential pressures on either side of the valve's leaflets. The mitral valve has two leaflets and the tricuspid valve has three. The aortic and pulmonary valves are referred to as "semilunar valves" because of the unique appearance of their leaflets, which are more aptly termed "cusps" and are shaped somewhat like a half-moon. The aortic and pulmonary valves each have three cusps.

[0006] In general, the components of heart valves include the valve annulus, which will remain as a roughly circular open ring after the leaflets of a diseased or damaged valve have been removed; leaflets or cusps; papillary muscles which are attached at their bases to the interior surface of the left or right ventricular wall; and multiple chordae tendineae, which couple the valve leaflets or cusps to the papillary muscles. There is no one-to-one chordal connection

between the leaflets and the papillary muscles; instead, numerous chordae are present, and chordae from each papillary muscle attach to both of the valve leaflets.

[0007] When the left ventricular wall relaxes so that the ventricular chamber enlarges and draws in blood, the leaflets of the mitral valve separate and the valve opens. Oxygenated blood flows in a downward direction through the valve, to fill the expanding ventricular cavity. Once the left ventricular cavity has filled, the left ventricle contracts, causing a rapid rise in the left ventricular cavitary pressure. This causes the mitral valve to close while the aortic valve opens, allowing the oxygenated blood to be ejected from the left ventricle into the aorta. The chordae tendineae of the mitral valve prevent the mitral leaflets from prolapsing back into the left atrium when the left ventricular chamber contracts.

[0008] The three leaflets, chordae tendineae, and papillary muscles of the tricuspid valve function in a similar manner, in response to the filling of the right ventricle and its subsequent contraction. The cusps of the aortic valve also respond passively to pressure differentials between the left ventricle and the aorta. When the left ventricle contracts, the aortic valve cusps open to allow the flow of oxygenated blood from the left ventricle into the aorta. When the left ventricle relaxes, the aortic valve cusps reapproximate to prevent the blood which has entered the aorta from leaking (regurgitating) back into the left ventricle. The pulmonary valve cusps respond passively in the same manner in response to relaxation and contraction of the right ventricle in moving de-oxygenated blood into the pulmonary artery and thence to the lungs for re-oxygenation. Neither of these semilunar valves has associated chordae tendineae or papillary muscles.

[0009] Problems that can develop with heart valves consist of stenosis, in which a valve does not open properly, and/or insufficiency, also called regurgitation, in which a valve does not

close properly. In addition to stenosis and insufficiency of heart valves, heart valves may need to be surgically repaired or replaced due to certain types of bacterial or fungal infections in which the valve may continue to function normally, but nevertheless harbors an overgrowth of bacteria (vegetation) on the leaflets of the valve that may embolize and lodge downstream in a vital artery. If such vegetations are on the valves of the left side (i.e., the systemic circulation side) of the heart, embolization may occur, resulting in sudden loss of the blood supply to the affected body organ and immediate malfunction of that organ. The organ most commonly affected by such embolization is the brain, in which case the patient suffers a stroke. Thus, surgical replacement of either the mitral or aortic valve (left-sided heart valves) may be necessary for this problem even though neither stenosis nor insufficiency of either valve is present. Likewise, bacterial or fungal vegetations on the tricuspid valve may embolize to the lungs resulting in a lung abscess and therefore, may require replacement of the tricuspid valve even though no tricuspid valve stenosis or insufficiency is present.

[0010] These problems are treated by surgical repair of valves, although often the valves are too diseased to repair and must be replaced. If a heart valve must be replaced, there are currently several options available, and the choice of a particular type of artificial valve depends on factors such as the location of the valve, the age and other specifics of the patient, and the surgeon's experiences and preferences. Currently in the United States over 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 and without having to repeat the procedure within a matter of years due to the lack of durability of the replacement heart valve. 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.

[0011] 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.

[0012] Replacement heart valves can be categorized as either artificial mechanical valves, transplanted valves and tissue valves. Replacement heart valves are designed to optimize hemodynamic performance, thrombogenicity and durability. Another factor taken into consideration is the relative ease of surgical implantation.

[0013] Mechanical valves are typically constructed from nonbiological materials such as plastics, metals and other artificial materials which, while durable, are expensive and prone to blood clotting which increases the risk of an embolism. Anticoagulants taken to help against blood clotting can further complicate the patient's health due to increased risks for hemorrhages.

[0014] Transplanted valves are natural valves taken from cadavers. These valves are typically removed and frozen in liquid nitrogen, and are stored for later use. They are typically fixed in glutaraldehyde to eliminate antigenicity and are sutured in place, typically with a stent.

[0015] Artificial tissue valves are valves constructed from animal tissue, such as bovine or porcine tissue. Efforts have also been made at using tissue from the patient for which the valve will be constructed.

[0016] Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position, or by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent. The porcine or bovine tissue is chemically treated to alleviate any antigenicity. The pericardium is a membrane that surrounds the heart and isolates it from the rest of the chest wall structures. The pericardium is a thin and very slippery, which makes it difficult for suturing in a millimetricly precise way. The method of making the replacement heart valve of the present invention solves this problem through a process that includes drying and compressing the pericardium using photo-mechanical compression in such a way that makes it possible to handle and fold the material more easily.

[0017] For example, one prior replacement heart valve requires each sculpted leaflet to be trimmed in a way that forms an extended flap, which becomes a relatively narrow strand of tissue near its tip. The tip of each pericardial tissue strand is sutured directly to a papillary muscle, causing the strand to mimic a chordae tendineae. Each strand extends from the center of a leaflet in the valve, and each strand is sutured directly to either an anterior and posterior papillary muscle. This requires each leaflet to be positioned directly over a papillary muscle. This effectively rotates the leaflets of the valve about 90 degrees as compared to the leaflets of a native valve. The line of commissure between the leaflets, when they are pressed together during systole, will bisect (at a perpendicular angle) an imaginary line that crosses the peaks of the two papillary muscles, instead of lying roughly along that line as occurs in a native valve.

[0018] A different approach to creating artificial tissue valves is described in U.S. Pat. No. 5,163,955 to Calvin, *et al*. and U.S. Pat. Nos. 5,571,174 and 5,653,749 to Love. Using a cutting die, the pericardial tissue is cut into a carefully defined geometric shape, treated with glutaraldehyde, then clamped in a sandwich-fashion between two stent components. This creates a tri-leaflet valve that resembles an aortic or pulmonary valve, having semilunar-type cusps rather than atrioventricular-type leaflets.

[0019] U.S. Pat. No. 3,671,979 to Moulopoulos describes an endovascularly inserted conical shaped umbrella-like valve positioned and held in place by an elongated mounting catheter at a supra-annular site to the aortic valve in a nearby arterial vessel. The conical end points toward the malfunctioning aortic valve and the umbrella's distal ends open up against the aorta wall with reverse blood flow, thereby preventing regurgitation.

[0020] U.S. Pat. No. 4,056,854 to Boretos describes an endovascularly inserted, catheter mounted, supra-annular valve in which the circular frame abuts the wall of the artery and attached flaps of flexible membrane extend distally in the vasculature. The flaps lie against the artery wall during forward flow, and close inward towards the central catheter to prevent regurgitation during reverse blood flow. The Boretos valve was designed to be positioned against the artery wall during forward flow, as compared to the mid-center position of the Moulopoulos valve, to reduce the stagnation of blood flow and consequent thrombus and embolic formation expected from a valve at mid-center position.

[0021] The main advantage of tissue valves is that they do not cause blood clots to form as readily as do the mechanical valves, and therefore, they do not absolutely require systemic anticoagulation. The major disadvantage of tissue valves is that they lack the long-term durability of mechanical valves. Tissue valves have a significant failure rate, usually within ten

years following implantation. One cause of these failures is believed to be the chemical treatment of the animal tissue that prevents it from being antigenic to the patient. In addition, the presence of extensive suturing prevents the artificial tissue valve from being anatomically accurate in comparison to a normal heart valve, even in the aortic valve position.

[0022] A shortcoming of prior artificial tissue valves has been the inability to effectively simulate the exact anatomy of a native heart valve. Although transplanted human or porcine aortic valves have the gross appearance of native aortic valves, the fixation process (freezing with liquid nitrogen, and chemical treatment, respectively) alters the histologic characteristics of the valve tissue. Porcine and bovine pericardial valves not only require chemical preparation (usually involving fixation with glutaraldehyde), but the leaflets must be sutured to cloth-covered stents in order to hold the leaflets in position for proper opening and closing of the valve. Additionally, the leaflets of most such tissue valves are constructed by cutting or suturing the tissue material, resulting in leaflets that do not duplicate the form and function of a real valve and are more susceptible to failure.

SUMMARY OF THE INVENTION

[0023] The present invention is a replacement heart valve device and method of making same. The replacement heart valve device, in a preferred embodiment, comprises a stent made of stainless steel or self-expanding nitinol and a completely newly designed artificial biological tissue valve disposed within the inner space of the stent. The cusp or leaflet portion of the valve means is formed by folding of the pericardium material preferably used to create the valve without cutting of slits to form leaflets or suturing or otherwise affixing of separate leaflet portions. Other forms of tissue and suitable synthetic materials can also be used for the valve, formed in a sheet of starting material. The folded design provides a number of advantages over

prior designs, including improved resistance to tearing at suture lines. The cusps/leaflets open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the tubular portion of the valve means contains the same number of cusps as the native valve being replaced, in substantially the same size and configuration. The outer surface of the valve means is attached to the stent member.

[0024] The replacement heart valve device is preferably implanted using a delivery system having a central part which consists of a flexible hollow tube catheter that allows a metallic guide wire to be advanced inside it. The stented valve is collapsed over the central tube and it is covered by a movable sheath. The sheath keeps the stented valve in the collapsed position. Once the cover sheath is moved backwards, the stented valve can be deployed. The endovascular stented-valve, in a preferred embodiment, is a glutaraldehyde fixed mammal pericardium or synthetic biocompatible material which has two or three cusps that open distally to permit unidirectional blood flow. The stent can either be self-expanding or the stent can be expandable through use of a balloon catheter.

[0025] The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the pericardium starting material is isolated and all the fat tissue and extra fibers are removed. The biological membrane material is cleaned by mechanical separation of unwanted layers using hydromechanical force means. Once the pericardium is completely clean, the material is dried in order to make it easier to handle and fold. Preferably, this drying is done by exposing the biocompatible membrane material to photomechanical compression to remove all lipids from the pericardium or other biocompatible membrane material and to cause protein denaturalization, transforming the material into a stronger and more homogeneous surface. The valve is formed by taking a flat sheet of the

material and folding in such a way that forms a three-leaflet or other number of leaflet valve. Then it is placed in a sequence of solutions, one of isopropyl alcohol of about 70-100%, one of ethanol of about 70-100%, one of glycerol and one of ~~gluteraldehyde~~ glutaraldehyde, preferably at a concentration of about 0.07-25% for approximately 36 hours. The material is dried in order to make it easier to handle and fold. Preferably this drying is done by exposing the biocompatible membrane material to light and then mechanically compressing the material to cause protein denaturation. This results in material that is stronger and more homogeneous. The valve is formed by taking a flat sheet of bovine or ~~procine~~ porcine pericardium and folding it in such a way that forms a three-leaflet valve. The valve can also be made in the same manner from fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts or synthetic non-biological, non- thrombogenic material. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. The cleaning, pressing and drying technique used to create the valve material makes the folding more practicable. The valve is rehydrated after being formed. The method of the present invention also greatly reduces the risk of tearing of the cusps or leaflets, since they are formed by folding a single uncut portion of material forming the valve rather than being attached by suturing.

[0026] Once the endovascular implantation of the prosthetic valve device is completed in the host, the function of the prosthetic valve device can be monitored by the same methods as used to monitor valve replacements done by open heart surgery. Routine physical examination, periodic echocardiography or angiography can be performed. In contrast to open heart surgery, however, the host requires a short recovery period and can return home within one day of the endovascular procedure. The replacement heart valve device of the present invention can be

used in any patient where bioprosthetic valves are indicated, namely elderly patients with cardiac valve diseases, and patients unable to tolerate open heart procedures or life-long anticoagulation medication and treatment. The present invention can be practiced in applications with respect to each of the heart's valves.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 depicts a side perspective view of the replacement heart valve device of the present invention in one embodiment with the valve in the closed position.

[0028] FIG. 2 depicts the folds which form the leaflets or cusps of the replacement heart valve of the present invention in one embodiment.

[0029] FIGS. 3A and 3B depict a preferred procedure for folding the pericardium tissue starting material to create the replacement heart valve of the present invention.

[0030] FIG. 4 depicts a side perspective view of the replacement heart valve device of the present invention in one embodiment represented as if implanted within an artery.

[0031] FIG. 5 depicts a side view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent, with the stent in the expanded position.

[0032] FIG. 6 depicts a side perspective view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent in the collapsed position.

[0033] FIG. 7 depicts the suture points of one embodiment of the replacement heart valve device of the present invention.

[0034] FIG. 8 depicts the implantation/delivery system used with the present invention in a preferred embodiment.

[0035] FIGS. 9A, 9B and 9C depict a representation of a sheet of biocompatible valve material showing preferred folds.

DESCRIPTION OF A PREFERRED EMBODIMENT

[0036] The present invention comprises a percutaneously implantable replacement heart valve and a method for making same. The artificial heart valve device of the present invention is capable of exhibiting a variable diameter between a compressed or collapsed position and an expanded position. A preferred embodiment of the replacement heart valve device according to the present invention is set forth in FIG. 5. The replacement heart valve device comprises a stent member 100 and a flexible valve means 200. The stent member 100 is preferably self-expanding, although balloon-expandable stents can be used as well, and has a first polygonal shape in its compressed or collapsed configuration and a second, larger polygonal shape in its expanded configuration. Referring to FIG. 1, the valve means 200 comprises a generally tubular portion 210 and, preferably, a peripheral upstanding cusp or leaflet portion 220. The valve means 200 is disposed within the cylindrical stent member 100 with the tubular portion 210 transverse of and at some acute angle relative to the stent walls. The diameter of the tubular portion 210 is substantially the same as the inside diameter of the stent member in its initial expanded configuration. The peripheral upstanding cusp or leaflet portion 220 is disposed on valve means 200 substantially parallel to the walls of the stent member similar to a cuff on a shirt. The cusp or leaflet portion 220 of the valve means 200 is generally tubular in shape and comprises three leaflets 221, 222 and 223 as shown, although it is understood that there could be

from two to four leaflets. The tubular portion of the valve means 200 is attached to the stent member 100 by a plurality of sutures 300, as depicted in FIG. 7.

[0037] The leaflet portion 220 of the valve means 200 extends across or transverse of the cylindrical stent 100. The leaflets 221, 222 and 223 are the actual valve and allow for one-way flow of blood. The leaflet portion 220 as connected to the rest of the valve resembles the cuff of a shirt. FIG. 9 depicts the folds preferred for valve cusp and leaflet formation involving three leaflets. The configuration of the stent member 100 and the flexible, resilient material of construction allows the valve to collapse into a relatively small cylinder as seen in FIG. 6. The replacement heart valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member 100 will cause the artificial heart valve to take its expanded configuration, as seen in FIG. 5.

Stent Member

[0038] The stent member 100 preferably comprises a self-expanding nickel-titanium alloy stent, also called "nitinol," in a sine wave-like configuration as shown in FIG. 5. An enlarged view of a preferred embodiment of the stent member for use in the replacement heart valve of the invention is depicted in FIG. 5. The stent member 100 includes a length of wire 110 formed in a closed zigzag configuration. The wire can be a single piece, stamped or extruded, or it could be formed by welding the free ends together. The straight sections of the stent member 100 are joined by bends. The stent is readily compressible to a small cylindrical shape as depicted in FIGS. 6 and 8, and resiliently self-expandable to the shape shown in FIG. 5.

[0039] The stent member 100 of the artificial heart valve device of the present invention may be made from various metal alloys, titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible

materials. The configuration may be the zigzag 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 zigzag or sine wave configured stent member is used, the diameter of the wire from which the stent is made is preferably from about 0.010 to 0.035 inches and still, 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.

[0040] The stent used in a preferred embodiment of the present invention is fabricated from a "shaped memory" alloy, nitinol, which is composed of nickel and titanium. Nitinol wire is first fashioned into the desired shape for the device and then the device is heat annealed. A meshwork of nitinol wire of approximately 0.008 inch gauge is formed into a tubular structure with a minimum central diameter of 20 [[min]] mm to make the stent. Away from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration. The maximum diameter of the flared ends of the stent is approximately 50 mm. The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its implantation.

[0041] When the components of the replacement heart valve device are exposed to cold temperatures, they become very flexible and supple, allowing them to be compressed down and pass easily through the delivery sheath. A cold temperature is maintained within the sheath during delivery to the deployment site by constantly infusing the sheath with an iced saline solution. Once the valve components are exposed to body temperature at the end of the sheath, they instantaneously reassume their predetermined shapes, thus allowing them to function as designed.

[0042] Preferably the stent member 100 carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve device 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 zigzag configuration so that the stent member will readily collapse and expand as pressure is applied and released, respectively.

Valve Means

[0043] The valve means 200 is flexible, compressible, host-compatible, and non-thrombogenic. The valve means 200 can be made from various materials, for example, fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts. Synthetic biocompatible materials such as polytetrafluoroethylene, polyester, polyurethane, nitinol or other alloy/metal foil sheet material and the like may be used. The preferred material for the valve means 200 is mammal pericardium tissue, particularly juvenile-age animal pericardium tissue. The valve means 200 is disposed within the cylindrical stent member 100 with the tubular portion 210 transverse of and at some acute angle relative to the stent walls. The diameter of the tubular portion 210 is substantially the same as the inside diameter of the stent member 100 in its initial expanded configuration. The peripheral upstanding cusp or leaflet portion 220 is disposed substantially parallel to the walls of the stent member 100 similar to a cuff on a shirt.

[0044] The cusp or leaflet portion 220 of the valve means 200 is formed by folding of the pericardium material used to create the valve. FIGS. 3A and 3B depict the way the sheet of heart valve starting material is folded. The starting material is preferably a flat dry sheet, which can be rectangular or other shaped. The cusps/leaflets 221, 222 and 223 open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the cusp or leaflet portion 220 of the valve means 200 contains the same number of cusps as the native valve being replaced, in substantially the same size and configuration. FIGS. 9A-9C depict a preferred configuration for folds to create the leaflets/cusps. The leaflet forming portion is a single, continuous, uncut layer affixed to the interior of the cuff layer to form the leaflets/cusps, unlike prior efforts that have involved suturing of three separate leaflet/cusp portions onto the main valve body portion. The leaflets are formed from the free edge of the material after forming the cuff portion. Referring now to FIGS. 9-A, 9B, and 9C, with flat sheet on a table, a person facing the sheet would create a cuff at the upper border of sheet by folding the horizontal top edge away/downwardly (fold no. 1). The leaflet portion is formed by folding the sheet's lower half towards the folder/upwardly, as shown in FIG. 9A (fold no. 2). The sheet, now with the upper cuff and bottom inward fold, is folded inwardly at two preferably equidistant vertical points as shown in FIG. 9B to create the leaflet/cusp portion (folds nos. 3 and 4). The leaflets/cusps are formed by folding fold nos. 6, 7 and 8 after the two opposite vertical edges of sheet are joined to create a cylindrical valve shape, depicted in FIGS. 1 and 3B. The inner leaflet layer is preferably attached to the outer cuff layer by curved or straight continuous suturing. Although a preferred embodiment of the invention comprises a single piece of valve material folded to create the valve body and a leaflet-forming portion that has no cuts or sutures, the inventors have discovered that as long as the leaflet portion of the valve itself is formed from a

single piece of biocompatible valve material, the other portions of the valve can be formed by suturing of one or more separate pieces of material without losing the novel and improved qualities of the present invention. This allows for the valve to be made even stronger, more durable and easier to make. This alternate embodiment comprises a leaflet forming layer made of a single piece of valve material attached to a separate piece forming the valve body having a folded cuff portion. The single piece leaflet forming layer is preferably cylindrical in shape and can be formed with or without folding. In this embodiment the single piece leaflet layer can itself be attached to the stent with or without a cylindrical cuff portion. Attachment is preferably by suturing, particularly continuous single or double sutures.

Method of Making Replacement Heart Valve Device

[0045] T The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the biocompatible tissue material is isolated and all the fat tissue and extra fibers are removed. Cleaning is preferably accomplished by using a hydromechanical force-based cleaning device to separate tissue layers and hydration with distilled water to remove unwanted layers. Once the pericardium is completely clean, it is subjected to photo-mechanical compression, then the valve is formed and placed in sequential solutions of isopropyl alcohol of about 70-100%, ethanol of about 70-100%, glycerol and glutaraldehyde preferably at a concentration of about 0.07-25% for about 36 hours, respectively. The material is preferably photomechanically compressed to remove lipids and produce protein coagulation to make the surface smoother and more compact and biocompatible, decreasing the molecular distance of collagen fibers. The exposure to light and mechanical compression cause protein denaturation making the material stronger and more homogeneous and biocompatible. Gas sterilization can also be used to sterilize the tissue membrane material. The valve is formed

by taking a flat sheet of the material and folding it in such a way that forms a three-leaflet or desired number of leaflet valve as shown in FIGS. 3A and 3B and/or FIGS. 9A, 9B and 9C. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. It also greatly reduces the risk of tearing of the cusps or leaflets, since they are integral to the valve rather than being attached by suturing.

[0046] In a preferred embodiment, the single continuous piece of membrane is folded inward to form an inner leaflet layer within the outer cuff. The single leaflet layer is then attached to the cuff layer to form valve cusps in one of three preferred ways: (i) by curved or straight continuous single or double sutures that affix and form the bases or recesses of the valve cusps; (ii) by lengthwise suture lines attaching the leaflet layer to the cuff layer with the bases or recesses of the valve cusps being thus formed of the folded edge of the membrane; (iii) by further folding of the membrane into lengthwise pleats secured by lengthwise suture attaching the leaflet layer to the cuff layer with the bases or recesses of the valve cusps being thus formed of the folded edge of the membrane, done for the purpose of giving greater strength and durability to the attachment points of the leaflet layer.

[0047] In order to make the pericardium material less slippery and easier to fold, the pericardium is dried, preferably with artificial light using a multi-watt lamp with the pericardium or other biocompatible membrane material placed in a flat aluminum surface to dry it homogeneously. A photomechanical drying machine can also be used. The final result is a homogeneous tissue that looks like plastic paper and makes it easy to manipulate to fold and suture the valve. Once the valve is formed, it is re-hydrated by placing it in a solution of water and 70% alcohol. In approximately 3 days the valve is fully rehydrated. The suturing of

membrane layers to form the valve is done with single, double, or more continuous suture material. This form of suturing has great advantages for durability and avoidance of damage to the membrane and can be performed by sewing machines. The attachment points of the leaflet layer to the cuff layer may be reinforced by folding an additional layer of membrane over the attachment point before suturing, this layer being formed of a projected tab of the continuous piece of leaflet membrane. The free edge of the leaflet layer may be straight or curved, and this free edge forming the free edges of the individual leaflets may be contoured in parabolic or curved shape.

Attachment of the Valve Means to the Stent Member

[0048] The valve means 200 is then attached to the inner channel of the stent member 100 by suturing the outer surface of the valve means' pericardium material to the stent member. FIG. 7 depicts preferred suture points of one embodiment of the present invention: 3-point fixation or 6-point fixation at each border of the stent. Other fixation schemes can be utilized, such as, by way of non-limiting example, fixation on both borders 18 points at each end following a single plane and 36 fixation points following to adjacent vertical planes. The use of only one plane of fixation points helps prevent systolic collapse of the proximal edge of the valve means. A fold on the border of the pericardium material prevents tearing. The attachment position of the valve is preferably closer to the proximal and wider part of the stent.

[0049] The sequence of steps can vary. The pericardium material can be fixed in glutaraldehyde before attachment to the stent or the valve can be formed and then fixed with glutaraldehyde after mounting it in the stent. One observation noted is that the material becomes whiter and apparently increases its elasticity. 1 mm vascular clips keep the cusps coapted while fixing them in glutaraldehyde. The use of metallic clips to keep both cusps adjacent to each

other after 24 hours of fixation in glutaraldehyde helps to educate the material and make the primary position of the valve cusps adjacent to each other. After the clips are removed, there are no lesions to the valve.

[0050] Different suture materials can be used, including, in a preferred embodiment, Prolene 1-0 to 8-0 and Mersilene 1-0 to 8-0 which is a braided suture.

Implantation of Replacement Heart Valve Device

[0051] The replacement heart valve device of the present invention is preferably used in surgical procedures involving 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. To remove the native heart valve that is being replaced, 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 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 can be monitored by observation of radiopaque markers. Collector member is preferably inflated and occludes the aorta at a point between the origin of the coronary artery and the right subclavian artery. Next, a balloon and cutting tool are advanced through the catheter so that the cutting tool and uninflated balloon 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 also 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 is in place, the balloon is inflated and flexible shaft is rotated. Once the cutting tool has reached the appropriate rotation speed, the cutting tool is pulled proximally to remove the defective heart valve. The balloon and the cutting tool are spaced apart so that the inflated balloon 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. Once it is determined that the defective heart valve has been removed, the cutting tool is slowed or stopped altogether and the balloon is deflated. The cutting tool and the deflated balloon are pulled proximally through catheter. Then, a catheter containing an artificial heart valve is inserted and the artificial heart valve is placed as described above.

[0052] The delivery and implantation system of the replacement artificial heart valve of the present invention percutaneously and transluminally includes a flexible catheter 400 which may be inserted into a vessel of the patient and moved within that vessel as depicted in FIG. 8. The distal end 410 of the catheter 400, which is hollow and carries the replacement heart valve device of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the replacement heart valve. The catheter has a pusher member 420 disposed within the catheter lumen 430 and extending from the proximal end 440 of the catheter to the hollow section at the distal end 410 of the catheter. Once the distal end 410 of the catheter is

positioned as desired, the pusher mechanism 420 is activated and the distal portion of the replacement heart valve device is pushed out of the catheter and the stent member 100 partially expands. In this position the stent member 100 is restrained so that it doesn't pop out and is held for controlled release, with the potential that the replacement heart valve device can be recovered if there is a problem with the positioning. The catheter 400 is then retracted slightly and the replacement heart valve device is completely pushed out of the catheter 400 and released from the catheter to allow the stent member 100 to fully expand. If the stent member 100 preferably 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 replacement heart valve device will set the other circle of barbs in adjacent tissue and securely fix the replacement heart valve device in place when the device is released from the catheter.

[0053] Alternatively, or in combination with the above, the replacement heart valve device could be positioned over a metallic guidewire that is advanced through the catheter. The replacement heart valve device of the present invention is preferably implanted percutaneously through an aortic passageway to, or near to, the location from which the natural heart valve has been removed. Referring to FIG. 8, the implantation system comprises a flexible hollow tube catheter 410 with a metallic guide wire 450 disposed within it. The stented valve device is collapsed over the tube and is covered by a moveable sheath 460. The moveable sheath 460 maintains the stented valve device in the collapsed position. The implantation method comprises the following steps: inserting the replacement heart valve device in the lumen of a central blood vessel via entry through the brachial or femoral artery using a needle or exposing the artery surgically; placing a guide wire 450 through the entry vessel and advancing it to the desired position; advancing dilators over the wire to increase the lumen of the entry site, thereby

preparing the artery to receive the heart-valve; and advancing the heart-valve device to the desired place. The stented-valve device is released by pulling the cover sheath 460 of the delivery system allowing the self-expanding stent to achieve its full expansion. A balloon expandable stent can alternately be used to deliver the valve to its desired position. At this point, a pigtail catheter is advanced over the wire and an aortogram is performed to assess the competency of the valve.

[0054] Before creation of the valve means and implantation, 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 size for the replacement heart valve.

[0055] In one procedure for implantation of the replacement heart valve device of the present invention, the femoral artery of the patient is canulated using a Cook needle and a standard J wire is advanced into the artery either percutaneously or after surgical exposure of the artery. An 8 F introducer is advanced into the femoral artery over the wire. The J wire is then withdrawn and anticoagulation is started using heparin 60 U/Kg intravenously. Once vascular access is obtained an aortogram is performed for anatomical evaluation. A special wire (Lunderquist or Amplatz superstiff) is advanced into the aortic arch and dilators progressively larger are advanced over the wire, starting with 12 F all the way to 18 F. After this the valve introducer device containing the prosthetic valve device is then inserted and used to transport the replacement valve over a guidewire to the desired position. The stented-valve is released by pulling the cover sheath of the delivery system allowing the self-expanding stent to achieve its full expansion. At this point, a pigtail catheter is advanced over the wire and repeat aortogram is performed to assess the competency of the valve.

[0056] When the device is used to treat severe leakage of the aortic valve, the native valve is left in place and the prosthetic stented valve is deployed below the subclavian artery. When the device is used to treat aortic stenosis, first the stenotic valve needs to be opened using either aortic valvuloplasty or cutting and if this procedure induces aortic insufficiency the stented valve is placed to prevent the regurgitation.

[0057] Intravascular ultrasound or an angioscope passed intravascularly via either the venous system through the intra-atrial septum across the mitral valve and into the left ventricle or retrograde via the femoral artery would provide the added benefit of allowing constant high definition imaging of the entire procedure and high flow irrigation.

[0058] Once the endovascular implantation of the prosthetic valve device is completed in the host, the function of the prosthetic valve device can be monitored by the same methods as used to monitor valve replacements done by open heart surgery. Routine physical examination, periodic echocardiography or angiography can be performed. In contrast to open heart surgery, however, the host requires a short recovery period and can return home within one day of the endovascular procedure. The prosthetic valve device can be used in any patient where bioprosthetic valves are indicated, namely elderly patients with cardiac valve diseases, and patients unable to tolerate open heart procedures or life-long anticoagulation. In addition, with the development of longer-life, flexible, non-thrombogenic synthetic valve alternatives to bioprosthesis, the prosthetic valve device will be indicated in all patients where the relative advantages of the life-span, the non-thrombogenic quality, and the ease of insertion of prosthetic valve devices outweigh the disadvantages of mechanical valves. Anticoagulation may be beneficial in certain clinical situations for either short or long term use.

[0059] This method of percutaneous endovascular heart-valve replacement, in contrast to open heart surgical procedures, requires only local anesthesia, partial or no cardiac bypass, one to two days hospitalization, and should result in a reduced mortality rate as compared to open heart procedures.

[0060] While the present invention has been shown and described herein in what is considered to be a preferred embodiment thereof, illustrating the results and advantages over the prior art obtained through the present invention, the invention is not limited to the specific embodiments described above. Thus, the forms of the invention shown and described herein are to be taken as illustrative and other embodiments may be selected without departing from the spirit and scope of the present invention.

CLEAN SPECIFICATION

PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

CONTINUITY INFORMATION

[0001] The present application is a continuation application of U.S. Patent Application No. 13/675,665 filed on November 13, 2012, which is a continuation application of U.S. Patent Application No. 10/887,688 filed on July 10, 2004, now U.S. Patent No. 8,308,797, which is a continuation-in-part application of U.S. Patent Application No. 10/037,266, filed on January 4, 2002 (now abandoned). All of the foregoing applications are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] Field of the Invention

The present invention is in the field of heart valve replacement. More specifically, the present invention is directed to a method of making a percutaneously implantable replacement heart valve.

[0003] 2. Description of Related Art

There have been numerous efforts in the field of heart valve replacement to improve both the durability and effectiveness of replacement heart valves as well as the ease of implantation. A brief description of heart valves and heart function follows to provide relevant background for the present invention.

[0004] There are four valves in the heart that serve to direct the flow of blood through the two sides of the heart in a forward direction. On the left (systemic) side of the heart are: 1) the mitral valve, located between the left atrium and the left ventricle, and 2) the aortic valve,

located between the left ventricle and the aorta. These two valves direct oxygenated blood coming from the lungs through the left side of the heart into the aorta for distribution to the body. On the right (pulmonary) side of the heart are: 1) the tricuspid valve, located between the right atrium and the right ventricle, and 2) the pulmonary valve, located between the right ventricle and the pulmonary artery. These two valves direct de-oxygenated blood coming from the body through the right side of the heart into the pulmonary artery for distribution to the lungs, where it again becomes re-oxygenated to begin the circuit anew.

[0005] Heart valves are passive structures that simply open and close in response to differential pressures on either side of the particular valve. They consist of moveable "leaflets" that are designed simply to open and close in response to differential pressures on either side of the valve's leaflets. The mitral valve has two leaflets and the tricuspid valve has three. The aortic and pulmonary valves are referred to as "semilunar valves" because of the unique appearance of their leaflets, which are more aptly termed "cusps" and are shaped somewhat like a half-moon. The aortic and pulmonary valves each have three cusps.

[0006] In general, the components of heart valves include the valve annulus, which will remain as a roughly circular open ring after the leaflets of a diseased or damaged valve have been removed; leaflets or cusps; papillary muscles which are attached at their bases to the interior surface of the left or right ventricular wall; and multiple chordae tendineae, which couple the valve leaflets or cusps to the papillary muscles. There is no one-to-one chordal connection between the leaflets and the papillary muscles; instead, numerous chordae are present, and chordae from each papillary muscle attach to both of the valve leaflets.

[0007] When the left ventricular wall relaxes so that the ventricular chamber enlarges and draws in blood, the leaflets of the mitral valve separate and the valve opens. Oxygenated blood

flows in a downward direction through the valve, to fill the expanding ventricular cavity. Once the left ventricular cavity has filled, the left ventricle contracts, causing a rapid rise in the left ventricular cavitary pressure. This causes the mitral valve to close while the aortic valve opens, allowing the oxygenated blood to be ejected from the left ventricle into the aorta. The chordae tendineae of the mitral valve prevent the mitral leaflets from prolapsing back into the left atrium when the left ventricular chamber contracts.

[0008] The three leaflets, chordae tendineae, and papillary muscles of the tricuspid valve function in a similar manner, in response to the filling of the right ventricle and its subsequent contraction. The cusps of the aortic valve also respond passively to pressure differentials between the left ventricle and the aorta. When the left ventricle contracts, the aortic valve cusps open to allow the flow of oxygenated blood from the left ventricle into the aorta. When the left ventricle relaxes, the aortic valve cusps reapproximate to prevent the blood which has entered the aorta from leaking (regurgitating) back into the left ventricle. The pulmonary valve cusps respond passively in the same manner in response to relaxation and contraction of the right ventricle in moving de-oxygenated blood into the pulmonary artery and thence to the lungs for re-oxygenation. Neither of these semilunar valves has associated chordae tendineae or papillary muscles.

[0009] Problems that can develop with heart valves consist of stenosis, in which a valve does not open properly, and/or insufficiency, also called regurgitation, in which a valve does not close properly. In addition to stenosis and insufficiency of heart valves, heart valves may need to be surgically repaired or replaced due to certain types of bacterial or fungal infections in which the valve may continue to function normally, but nevertheless harbors an overgrowth of bacteria (vegetation) on the leaflets of the valve that may embolize and lodge downstream in a vital

artery. If such vegetations are on the valves of the left side (i.e., the systemic circulation side) of the heart, embolization may occur, resulting in sudden loss of the blood supply to the affected body organ and immediate malfunction of that organ. The organ most commonly affected by such embolization is the brain, in which case the patient suffers a stroke. Thus, surgical replacement of either the mitral or aortic valve (left-sided heart valves) may be necessary for this problem even though neither stenosis nor insufficiency of either valve is present. Likewise, bacterial or fungal vegetations on the tricuspid valve may embolize to the lungs resulting in a lung abscess and therefore, may require replacement of the tricuspid valve even though no tricuspid valve stenosis or insufficiency is present.

[0010] These problems are treated by surgical repair of valves, although often the valves are too diseased to repair and must be replaced. If a heart valve must be replaced, there are currently several options available, and the choice of a particular type of artificial valve depends on factors such as the location of the valve, the age and other specifics of the patient, and the surgeon's experiences and preferences. Currently in the United States over 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 and without having to repeat the procedure within a matter of years due to the lack of durability of the replacement heart valve. 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.

[0011] 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.

[0012] Replacement heart valves can be categorized as either artificial mechanical valves, transplanted valves and tissue valves. Replacement heart valves are designed to optimize hemodynamic performance, thrombogenicity and durability. Another factor taken into consideration is the relative ease of surgical implantation.

[0013] Mechanical valves are typically constructed from nonbiological materials such as plastics, metals and other artificial materials which, while durable, are expensive and prone to blood clotting which increases the risk of an embolism. Anticoagulants taken to help against blood clotting can further complicate the patient's health due to increased risks for hemorrhages.

[0014] Transplanted valves are natural valves taken from cadavers. These valves are typically removed and frozen in liquid nitrogen, and are stored for later use. They are typically fixed in glutaraldehyde to eliminate antigenicity and are sutured in place, typically with a stent.

[0015] Artificial tissue valves are valves constructed from animal tissue, such as bovine or porcine tissue. Efforts have also been made at using tissue from the patient for which the valve will be constructed.

[0016] Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position, or by constructing valve leaflets from the pericardial

sac of cows or pigs and sewing them to a stent. The porcine or bovine tissue is chemically treated to alleviate any antigenicity. The pericardium is a membrane that surrounds the heart and isolates it from the rest of the chest wall structures. The pericardium is a thin and very slippery, which makes it difficult for suturing in a millimetricly precise way. The method of making the replacement heart valve of the present invention solves this problem through a process that includes drying and compressing the pericardium using photo-mechanical compression in such a way that makes it possible to handle and fold the material more easily.

[0017] For example, one prior replacement heart valve requires each sculpted leaflet to be trimmed in a way that forms an extended flap, which becomes a relatively narrow strand of tissue near its tip. The tip of each pericardial tissue strand is sutured directly to a papillary muscle, causing the strand to mimic a chordae tendineae. Each strand extends from the center of a leaflet in the valve, and each strand is sutured directly to either an anterior and posterior papillary muscle. This requires each leaflet to be positioned directly over a papillary muscle. This effectively rotates the leaflets of the valve about 90 degrees as compared to the leaflets of a native valve. The line of commissure between the leaflets, when they are pressed together during systole, will bisect (at a perpendicular angle) an imaginary line that crosses the peaks of the two papillary muscles, instead of lying roughly along that line as occurs in a native valve.

[0018] A different approach to creating artificial tissue valves is described in U.S. Pat. No. 5,163,955 to Calvin, *et al*. and U.S. Pat. Nos. 5,571,174 and 5,653,749 to Love. Using a cutting die, the pericardial tissue is cut into a carefully defined geometric shape, treated with glutaraldehyde, then clamped in a sandwich-fashion between two stent components. This creates a tri-leaflet valve that resembles an aortic or pulmonary valve, having semilunar-type cusps rather than atrioventricular-type leaflets.

[0019] U.S. Pat. No. 3,671,979 to Moulopoulos describes an endovascularly inserted conical shaped umbrella-like valve positioned and held in place by an elongated mounting catheter at a supra-annular site to the aortic valve in a nearby arterial vessel. The conical end points toward the malfunctioning aortic valve and the umbrella's distal ends open up against the aorta wall with reverse blood flow, thereby preventing regurgitation.

[0020] U.S. Pat. No. 4,056,854 to Boretos describes an endovascularly inserted, catheter mounted, supra-annular valve in which the circular frame abuts the wall of the artery and attached flaps of flexible membrane extend distally in the vasculature. The flaps lie against the artery wall during forward flow, and close inward towards the central catheter to prevent regurgitation during reverse blood flow. The Boretos valve was designed to be positioned against the artery wall during forward flow, as compared to the mid-center position of the Moulopoulos valve, to reduce the stagnation of blood flow and consequent thrombus and embolic formation expected from a valve at mid-center position.

[0021] The main advantage of tissue valves is that they do not cause blood clots to form as readily as do the mechanical valves, and therefore, they do not absolutely require systemic anticoagulation. The major disadvantage of tissue valves is that they lack the long-term durability of mechanical valves. Tissue valves have a significant failure rate, usually within ten years following implantation. One cause of these failures is believed to be the chemical treatment of the animal tissue that prevents it from being antigenic to the patient. In addition, the presence of extensive suturing prevents the artificial tissue valve from being anatomically accurate in comparison to a normal heart valve, even in the aortic valve position.

[0022] A shortcoming of prior artificial tissue valves has been the inability to effectively simulate the exact anatomy of a native heart valve. Although transplanted human or porcine

aortic valves have the gross appearance of native aortic valves, the fixation process (freezing with liquid nitrogen, and chemical treatment, respectively) alters the histologic characteristics of the valve tissue. Porcine and bovine pericardial valves not only require chemical preparation (usually involving fixation with glutaraldehyde), but the leaflets must be sutured to cloth-covered stents in order to hold the leaflets in position for proper opening and closing of the valve. Additionally, the leaflets of most such tissue valves are constructed by cutting or suturing the tissue material, resulting in leaflets that do not duplicate the form and function of a real valve and are more susceptible to failure.

SUMMARY OF THE INVENTION

[0023] The present invention is a replacement heart valve device and method of making same. The replacement heart valve device, in a preferred embodiment, comprises a stent made of stainless steel or self-expanding nitinol and a completely newly designed artificial biological tissue valve disposed within the inner space of the stent. The cusp or leaflet portion of the valve means is formed by folding of the pericardium material preferably used to create the valve without cutting of slits to form leaflets or suturing or otherwise affixing of separate leaflet portions. Other forms of tissue and suitable synthetic materials can also be used for the valve, formed in a sheet of starting material. The folded design provides a number of advantages over prior designs, including improved resistance to tearing at suture lines. The cusps/leaflets open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the tubular portion of the valve means contains the same number of cusps as the native valve being replaced, in substantially the same size and configuration. The outer surface of the valve means is attached to the stent member.

[0024] The replacement heart valve device is preferably implanted using a delivery system having a central part which consists of a flexible hollow tube catheter that allows a metallic guide wire to be advanced inside it. The stented valve is collapsed over the central tube and it is covered by a movable sheath. The sheath keeps the stented valve in the collapsed position. Once the cover sheath is moved backwards, the stented valve can be deployed. The endovascular stented-valve, in a preferred embodiment, is a glutaraldehyde fixed mammal pericardium or synthetic biocompatible material which has two or three cusps that open distally to permit unidirectional blood flow. The stent can either be self-expanding or the stent can be expandable through use of a balloon catheter.

[0025] The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the pericardium starting material is isolated and all the fat tissue and extra fibers are removed. The biological membrane material is cleaned by mechanical separation of unwanted layers using hydromechanical force means. Once the pericardium is completely clean, the material is dried in order to make it easier to handle and fold. Preferably, this drying is done by exposing the biocompatible membrane material to photomechanical compression to remove all lipids from the pericardium or other biocompatible membrane material and to cause protein denaturalization, transforming the material into a stronger and more homogeneous surface. The valve is formed by taking a flat sheet of the material and folding in such a way that forms a three-leaflet or other number of leaflet valve. Then it is placed in a sequence of solutions, one of isopropyl alcohol of about 70-100%, one of ethanol of about 70-100%, one of glycerol and one of glutaraldehyde, preferably at a concentration of about 0.07-25% for approximately 36 hours. The material is dried in order to make it easier to handle and fold. Preferably this drying is done by exposing the biocompatible

membrane material to light and then mechanically compressing the material to cause protein denaturation. This results in material that is stronger and more homogeneous. The valve is formed by taking a flat sheet of bovine or porcine pericardium and folding it in such a way that forms a three-leaflet valve. The valve can also be made in the same manner from fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts or synthetic non-biological, non-thrombogenic material. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. The cleaning, pressing and drying technique used to create the valve material makes the folding more practicable. The valve is rehydrated after being formed. The method of the present invention also greatly reduces the risk of tearing of the cusps or leaflets, since they are formed by folding a single uncut portion of material forming the valve rather than being attached by suturing.

[0026] Once the endovascular implantation of the prosthetic valve device is completed in the host, the function of the prosthetic valve device can be monitored by the same methods as used to monitor valve replacements done by open heart surgery. Routine physical examination, periodic echocardiography or angiography can be performed. In contrast to open heart surgery, however, the host requires a short recovery period and can return home within one day of the endovascular procedure. The replacement heart valve device of the present invention can be used in any patient where bioprosthetic valves are indicated, namely elderly patients with cardiac valve diseases, and patients unable to tolerate open heart procedures or life-long anticoagulation medication and treatment. The present invention can be practiced in applications with respect to each of the heart's valves.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 depicts a side perspective view of the replacement heart valve device of the present invention in one embodiment with the valve in the closed position.

[0028] FIG. 2 depicts the folds which form the leaflets or cusps of the replacement heart valve of the present invention in one embodiment.

[0029] FIGS. 3A and 3B depict a preferred procedure for folding the pericardium tissue starting material to create the replacement heart valve of the present invention.

[0030] FIG. 4 depicts a side perspective view of the replacement heart valve device of the present invention in one embodiment represented as if implanted within an artery.

[0031] FIG. 5 depicts a side view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent, with the stent in the expanded position.

[0032] FIG. 6 depicts a side perspective view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent in the collapsed position.

[0033] FIG. 7 depicts the suture points of one embodiment of the replacement heart valve device of the present invention.

[0034] FIG. 8 depicts the implantation/delivery system used with the present invention in a preferred embodiment.

[0035] FIGS. 9A, 9B and 9C depict a representation of a sheet of biocompatible valve material showing preferred folds.

DESCRIPTION OF A PREFERRED EMBODIMENT

[0036] The present invention comprises a percutaneously implantable replacement heart valve and a method for making same. The artificial heart valve device of the present invention is capable of exhibiting a variable diameter between a compressed or collapsed position and an expanded position. A preferred embodiment of the replacement heart valve device according to the present invention is set forth in FIG. 5. The replacement heart valve device comprises a stent member 100 and a flexible valve means 200. The stent member 100 is preferably self-expanding, although balloon-expandable stents can be used as well, and has a first polygonal shape in its compressed or collapsed configuration and a second, larger polygonal shape in its expanded configuration. Referring to FIG. 1, the valve means 200 comprises a generally tubular portion 210 and, preferably, a peripheral upstanding cusp or leaflet portion 220. The valve means 200 is disposed within the cylindrical stent member 100 with the tubular portion 210 transverse of and at some acute angle relative to the stent walls. The diameter of the tubular portion 210 is substantially the same as the inside diameter of the stent member in its initial expanded configuration. The peripheral upstanding cusp or leaflet portion 220 is disposed on valve means 200 substantially parallel to the walls of the stent member similar to a cuff on a shirt. The cusp or leaflet portion 220 of the valve means 200 is generally tubular in shape and comprises three leaflets 221, 222 and 223 as shown, although it is understood that there could be from two to four leaflets. The tubular portion of the valve means 200 is attached to the stent member 100 by a plurality of sutures 300, as depicted in FIG. 7.

[0037] The leaflet portion 220 of the valve means 200 extends across or transverse of the cylindrical stent 100. The leaflets 221, 222 and 223 are the actual valve and allow for one-way flow of blood. The leaflet portion 220 as connected to the rest of the valve resembles the cuff of

a shirt. FIG. 9 depicts the folds preferred for valve cusp and leaflet formation involving three leaflets. The configuration of the stent member 100 and the flexible, resilient material of construction allows the valve to collapse into a relatively small cylinder as seen in FIG. 6. The replacement heart valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member 100 will cause the artificial heart valve to take its expanded configuration, as seen in FIG. 5.

Stent Member

[0038] The stent member 100 preferably comprises a self-expanding nickel-titanium alloy stent, also called "nitinol," in a sine wave-like configuration as shown in FIG. 5. An enlarged view of a preferred embodiment of the stent member for use in the replacement heart valve of the invention is depicted in FIG. 5. The stent member 100 includes a length of wire 110 formed in a closed zigzag configuration. The wire can be a single piece, stamped or extruded, or it could be formed by welding the free ends together. The straight sections of the stent member 100 are joined by bends. The stent is readily compressible to a small cylindrical shape as depicted in FIGS. 6 and 8, and resiliently self-expandable to the shape shown in FIG. 5.

[0039] The stent member 100 of the artificial heart valve device of the present invention may be made from various metal alloys, titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials. The configuration may be the zigzag 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 zigzag or sine wave configured stent member is used, the diameter of the wire from which the stent is made is preferably from about 0.010 to 0.035 inches and still, 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.

[0040] The stent used in a preferred embodiment of the present invention is fabricated from a "shaped memory" alloy, nitinol, which is composed of nickel and titanium. Nitinol wire is first fashioned into the desired shape for the device and then the device is heat annealed. A meshwork of nitinol wire of approximately 0.008 inch gauge is formed into a tubular structure with a minimum central diameter of 20 mm to make the stent. Away from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration. The maximum diameter of the flared ends of the stent is approximately 50 mm. The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its implantation.

[0041] When the components of the replacement heart valve device are exposed to cold temperatures, they become very flexible and supple, allowing them to be compressed down and pass easily through the delivery sheath. A cold temperature is maintained within the sheath during delivery to the deployment site by constantly infusing the sheath with an iced saline solution. Once the valve components are exposed to body temperature at the end of the sheath, they instantaneously reassume their predetermined shapes, thus allowing them to function as designed.

[0042] Preferably the stent member 100 carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve device 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 zigzag configuration so that the stent member will readily collapse and expand as pressure is applied and released, respectively.

Valve Means

[0043] The valve means 200 is flexible, compressible, host-compatible, and non-thrombogenic. The valve means 200 can be made from various materials, for example, fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts. Synthetic biocompatible materials such as polytetrafluoroethylene, polyester, polyurethane, nitinol or other alloy/metal foil sheet material and the like may be used. The preferred material for the valve means 200 is mammal pericardium tissue, particularly juvenile-age animal pericardium tissue. The valve means 200 is disposed within the cylindrical stent member 100 with the tubular portion 210 transverse of and at some acute angle relative to the stent walls. The diameter of the tubular portion 210 is substantially the same as the inside diameter of the stent member 100 in its initial expanded configuration. The peripheral upstanding cusp or leaflet portion 220 is disposed substantially parallel to the walls of the stent member 100 similar to a cuff on a shirt.

[0044] The cusp or leaflet portion 220 of the valve means 200 is formed by folding of the pericardium material used to create the valve. FIGS. 3A and 3B depict the way the sheet of heart valve starting material is folded. The starting material is preferably a flat dry sheet, which can be rectangular or other shaped. The cusps/leaflets 221, 222 and 223 open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the cusp or leaflet portion 220 of the valve means 200 contains the same number of cusps as the

native valve being replaced, in substantially the same size and configuration. FIGS. 9A-9C depict a preferred configuration for folds to create the leaflets/cusps. The leaflet forming portion is a single, continuous, uncut layer affixed to the interior of the cuff layer to form the leaflets/cusps, unlike prior efforts that have involved suturing of three separate leaflet/cusp portions onto the main valve body portion. The leaflets are formed from the free edge of the material after forming the cuff portion. Referring now to FIGS. 9-A, 9B, and 9C, with flat sheet on a table, a person facing the sheet would create a cuff at the upper border of sheet by folding the horizontal top edge away/downwardly (fold no. 1). The leaflet portion is formed by folding the sheet's lower half towards the folder/upwardly, as shown in FIG. 9A (fold no. 2). The sheet, now with the upper cuff and bottom inward fold, is folded inwardly at two preferably equidistant vertical points as shown in FIG. 9B to create the leaflet/cusp portion (folds nos. 3 and 4). The leaflets/cusps are formed by folding fold nos. 6, 7 and 8 after the two opposite vertical edges of sheet are joined to create a cylindrical valve shape, depicted in FIGS. 1 and 3B. The inner leaflet layer is preferably attached to the outer cuff layer by curved or straight continuous suturing. Although a preferred embodiment of the invention comprises a single piece of valve material folded to create the valve body and a leaflet-forming portion that has no cuts or sutures, the inventors have discovered that as long as the leaflet portion of the valve itself is formed from a single piece of biocompatible valve material, the other portions of the valve can be formed by suturing of one or more separate pieces of material without losing the novel and improved qualities of the present invention. This allows for the valve to be made even stronger, more durable and easier to make. This alternate embodiment comprises a leaflet forming layer made of a single piece of valve material attached to a separate piece forming the valve body having a folded cuff portion. The single piece leaflet forming layer is preferably cylindrical in shape and

can be formed with or without folding. In this embodiment the single piece leaflet layer can itself be attached to the stent with or without a cylindrical cuff portion. Attachment is preferably by suturing, particularly continuous single or double sutures.

Method of Making Replacement Heart Valve Device

[0045] T The present invention also comprises a method of making a replacement heart valve device. In order to make the valve, the biocompatible tissue material is isolated and all the fat tissue and extra fibers are removed. Cleaning is preferably accomplished by using a hydromechanical force-based cleaning device to separate tissue layers and hydration with distilled water to remove unwanted layers. Once the pericardium is completely clean, it is subjected to photo-mechanical compression, then the valve is formed and placed in sequential solutions of isopropyl alcohol of about 70-100%, ethanol of about 70-100%, glycerol and glutaraldehyde preferably at a concentration of about 0.07-25% for about 36 hours, respectively. The material is preferably photomechanically compressed to remove lipids and produce protein coagulation to make the surface smoother and more compact and biocompatible, decreasing the molecular distance of collagen fibers. The exposure to light and mechanical compression cause protein denaturation making the material stronger and more homogeneous and biocompatible. Gas sterilization can also be used to sterilize the tissue membrane material. The valve is formed by taking a flat sheet of the material and folding it in such a way that forms a three-leaflet or desired number of leaflet valve as shown in FIGS. 3A and 3B and/or FIGS. 9A, 9B and 9C. The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. It also greatly reduces the risk of tearing of the cusps or leaflets, since they are integral to the valve rather than being attached by suturing.

[0046] In a preferred embodiment, the single continuous piece of membrane is folded inward to form an inner leaflet layer within the outer cuff. The single leaflet layer is then attached to the cuff layer to form valve cusps in one of three preferred ways: (i) by curved or straight continuous single or double sutures that affix and form the bases or recesses of the valve cusps; (ii) by lengthwise suture lines attaching the leaflet layer to the cuff layer with the bases or recesses of the valve cusps being thus formed of the folded edge of the membrane; (iii) by further folding of the membrane into lengthwise pleats secured by lengthwise suture attaching the leaflet layer to the cuff layer with the bases or recesses of the valve cusps being thus formed of the folded edge of the membrane, done for the purpose of giving greater strength and durability to the attachment points of the leaflet layer.

[0047] In order to make the pericardium material less slippery and easier to fold, the pericardium is dried, preferably with artificial light using a multi-watt lamp with the pericardium or other biocompatible membrane material placed in a flat aluminum surface to dry it homogeneously. A photomechanical drying machine can also be used. The final result is a homogeneous tissue that looks like plastic paper and makes it easy to manipulate to fold and suture the valve. Once the valve is formed, it is re-hydrated by placing it in a solution of water and 70% alcohol. In approximately 3 days the valve is fully rehydrated. The suturing of membrane layers to form the valve is done with single, double, or more continuous suture material. This form of suturing has great advantages for durability and avoidance of damage to the membrane and can be performed by sewing machines. The attachment points of the leaflet layer to the cuff layer may be reinforced by folding an additional layer of membrane over the attachment point before suturing, this layer being formed of a projected tab of the continuous piece of leaflet membrane. The free edge of the leaflet layer may be straight or curved, and this

free edge forming the free edges of the individual leaflets may be contoured in parabolic or curved shape.

Attachment of the Valve Means to the Stent Member

[0048] The valve means 200 is then attached to the inner channel of the stent member 100 by suturing the outer surface of the valve means' pericardium material to the stent member. FIG. 7 depicts preferred suture points of one embodiment of the present invention: 3-point fixation or 6-point fixation at each border of the stent. Other fixation schemes can be utilized, such as, by way of non-limiting example, fixation on both borders 18 points at each end following a single plane and 36 fixation points following to adjacent vertical planes. The use of only one plane of fixation points helps prevent systolic collapse of the proximal edge of the valve means. A fold on the border of the pericardium material prevents tearing. The attachment position of the valve is preferably closer to the proximal and wider part of the stent.

[0049] The sequence of steps can vary. The pericardium material can be fixed in glutaraldehyde before attachment to the stent or the valve can be formed and then fixed with glutaraldehyde after mounting it in the stent. One observation noted is that the material becomes whiter and apparently increases its elasticity. 1 mm vascular clips keep the cusps coapted while fixing them in glutaraldehyde. The use of metallic clips to keep both cusps adjacent to each other after 24 hours of fixation in glutaraldehyde helps to educate the material and make the primary position of the valve cusps adjacent to each other. After the clips are removed, there are no lesions to the valve.

[0050] Different suture materials can be used, including, in a preferred embodiment, Prolene 1-0 to 8-0 and Mersilene 1-0 to 8-0 which is a braided suture.

Implantation of Replacement Heart Valve Device

[0051] The replacement heart valve device of the present invention is preferably used in surgical procedures involving 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. To remove the native heart valve that is being replaced, 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 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 can be monitored by observation of radiopaque markers. Collector member is preferably inflated and occludes the aorta at a point between the origin of the coronary artery and the right subclavian artery. Next, a balloon and cutting tool are advanced through the catheter so that the cutting tool and uninflated balloon 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 also 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 is in place, the balloon is inflated and flexible shaft is rotated. Once the cutting tool has reached the appropriate rotation speed, the cutting tool is pulled proximally to remove the defective heart valve. The balloon and the cutting tool are spaced apart so that the inflated balloon 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. Once it is determined that the defective heart valve has been removed, the cutting tool is slowed or stopped altogether and the balloon is deflated. The cutting tool and the deflated balloon are pulled proximally through catheter. Then, a catheter containing an artificial heart valve is inserted and the artificial heart valve is placed as described above.

[0052] The delivery and implantation system of the replacement artificial heart valve of the present invention percutaneously and transluminally includes a flexible catheter 400 which may be inserted into a vessel of the patient and moved within that vessel as depicted in FIG. 8. The distal end 410 of the catheter 400, which is hollow and carries the replacement heart valve device of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the replacement heart valve. The catheter has a pusher member 420 disposed within the catheter lumen 430 and extending from the proximal end 440 of the catheter to the hollow section at the distal end 410 of the catheter. Once the distal end 410 of the catheter is positioned as desired, the pusher mechanism 420 is activated and the distal portion of the replacement heart valve device is pushed out of the catheter and the stent member 100 partially expands. In this position the stent member 100 is restrained so that it doesn't pop out and is held for controlled release, with the potential that the replacement heart valve device can be recovered if there is a problem with the positioning. The catheter 400 is then retracted slightly and the

replacement heart valve device is completely pushed out of the catheter 400 and released from the catheter to allow the stent member 100 to fully expand. If the stent member 100 preferably 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 replacement heart valve device will set the other circle of barbs in adjacent tissue and securely fix the replacement heart valve device in place when the device is released from the catheter.

[0053] Alternatively, or in combination with the above, the replacement heart valve device could be positioned over a metallic guidewire that is advanced through the catheter. The replacement heart valve device of the present invention is preferably implanted percutaneously through an aortic passageway to, or near to, the location from which the natural heart valve has been removed. Referring to FIG. 8, the implantation system comprises a flexible hollow tube catheter 410 with a metallic guide wire 450 disposed within it. The stented valve device is collapsed over the tube and is covered by a moveable sheath 460. The moveable sheath 460 maintains the stented valve device in the collapsed position. The implantation method comprises the following steps: inserting the replacement heart valve device in the lumen of a central blood vessel via entry through the brachial or femoral artery using a needle or exposing the artery surgically; placing a guide wire 450 through the entry vessel and advancing it to the desired position; advancing dilators over the wire to increase the lumen of the entry site, thereby preparing the artery to receive the heart-valve; and advancing the heart-valve device to the desired place. The stented-valve device is released by pulling the cover sheath 460 of the delivery system allowing the self-expanding stent to achieve its full expansion. A balloon expandable stent can alternately be used to deliver the valve to its desired position. At this point,

a pigtail catheter is advanced over the wire and an aortogram is performed to assess the competency of the valve.

[0054] Before creation of the valve means and implantation, 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 size for the replacement heart valve.

[0055] In one procedure for implantation of the replacement heart valve device of the present invention, the femoral artery of the patient is canulated using a Cook needle and a standard J wire is advanced into the artery either percutaneously or after surgical exposure of the artery. An 8 F introducer is advanced into the femoral artery over the wire. The J wire is then withdrawn and anticoagulation is started using heparin 60 U/Kg intravenously. Once vascular access is obtained an aortogram is performed for anatomical evaluation. A special wire (Lunderquist or Amplatz superstiff) is advanced into the aortic arch and dilators progressively larger are advanced over the wire, starting with 12 F all the way to 18 F. After this the valve introducer device containing the prosthetic valve device is then inserted and used to transport the replacement valve over a guidewire to the desired position. The stented-valve is released by pulling the cover sheath of the delivery system allowing the self-expanding stent to achieve its full expansion. At this point, a pigtail catheter is advanced over the wire and repeat aortogram is performed to assess the competency of the valve.

[0056] When the device is used to treat severe leakage of the aortic valve, the native valve is left in place and the prosthetic stented valve is deployed below the subclavian artery. When the device is used to treat aortic stenosis, first the stenotic valve needs to be opened using

either aortic valvuloplasty or cutting and if this procedure induces aortic insufficiency the stented valve is placed to prevent the regurgitation.

[0057] Intravascular ultrasound or an angioscope passed intravascularly via either the venous system through the intra-atrial septum across the mitral valve and into the left ventricle or retrograde via the femoral artery would provide the added benefit of allowing constant high definition imaging of the entire procedure and high flow irrigation.

[0058] Once the endovascular implantation of the prosthetic valve device is completed in the host, the function of the prosthetic valve device can be monitored by the same methods as used to monitor valve replacements done by open heart surgery. Routine physical examination, periodic echocardiography or angiography can be performed. In contrast to open heart surgery, however, the host requires a short recovery period and can return home within one day of the endovascular procedure. The prosthetic valve device can be used in any patient where bioprosthetic valves are indicated, namely elderly patients with cardiac valve diseases, and patients unable to tolerate open heart procedures or life-long anticoagulation. In addition, with the development of longer-life, flexible, non-thrombogenic synthetic valve alternatives to bioprosthesis, the prosthetic valve device will be indicated in all patients where the relative advantages of the life-span, the non-thrombogenic quality, and the ease of insertion of prosthetic valve devices outweigh the disadvantages of mechanical valves. Anticoagulation may be beneficial in certain clinical situations for either short or long term use.

[0059] This method of percutaneous endovascular heart-valve replacement, in contrast to open heart surgical procedures, requires only local anesthesia, partial or no cardiac bypass, one to two days hospitalization, and should result in a reduced mortality rate as compared to open heart procedures.

[0060] While the present invention has been shown and described herein in what is considered to be a preferred embodiment thereof, illustrating the results and advantages over the prior art obtained through the present invention, the invention is not limited to the specific embodiments described above. Thus, the forms of the invention shown and described herein are to be taken as illustrative and other embodiments may be selected without departing from the spirit and scope of the present invention.

REPLACEMENT DRAWINGS

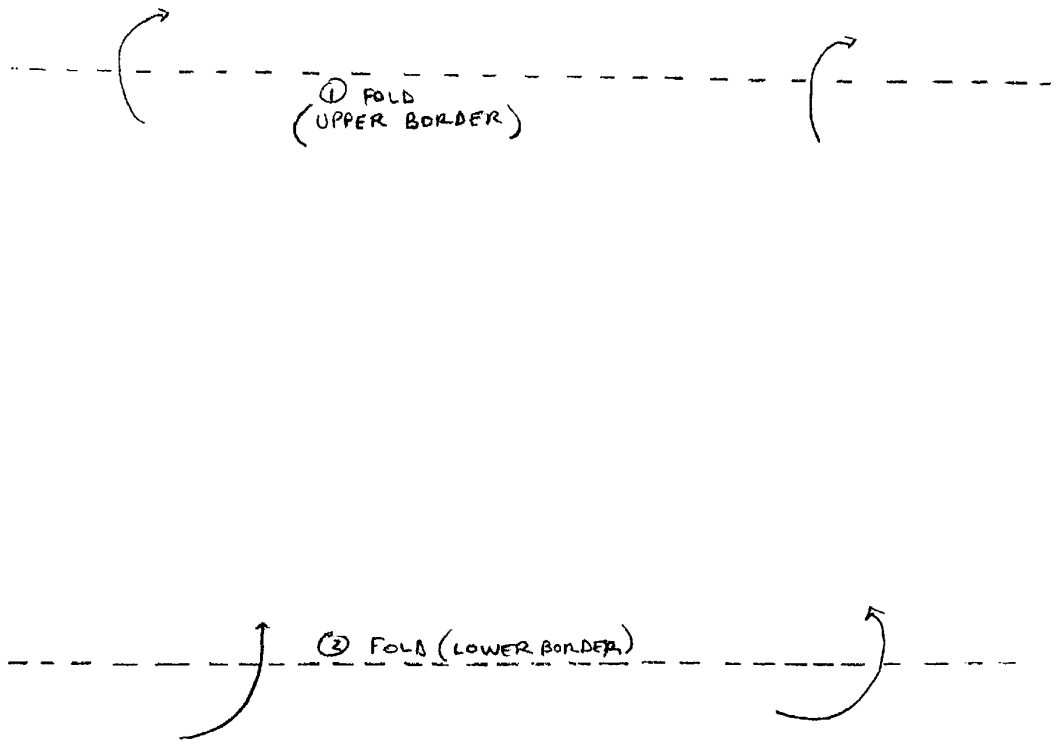

FIG. 9A

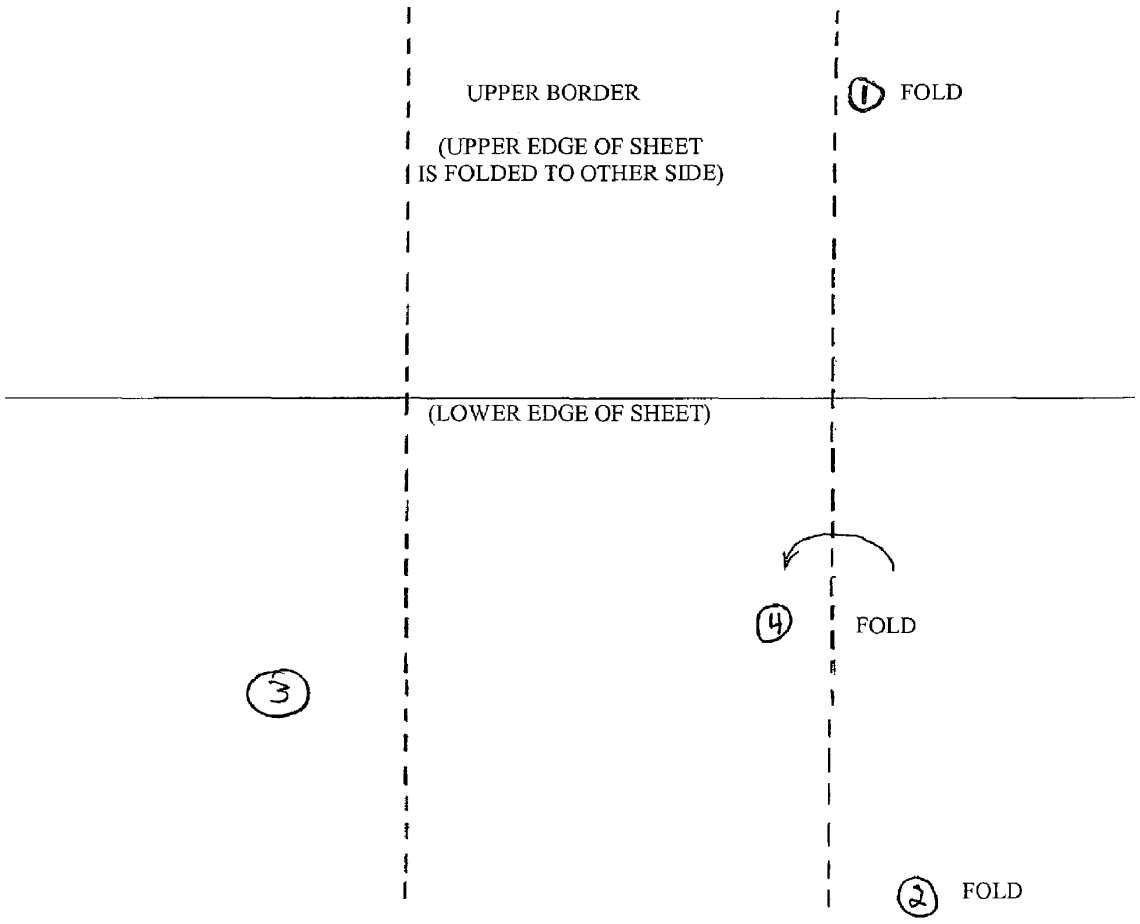
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FIG. 9B

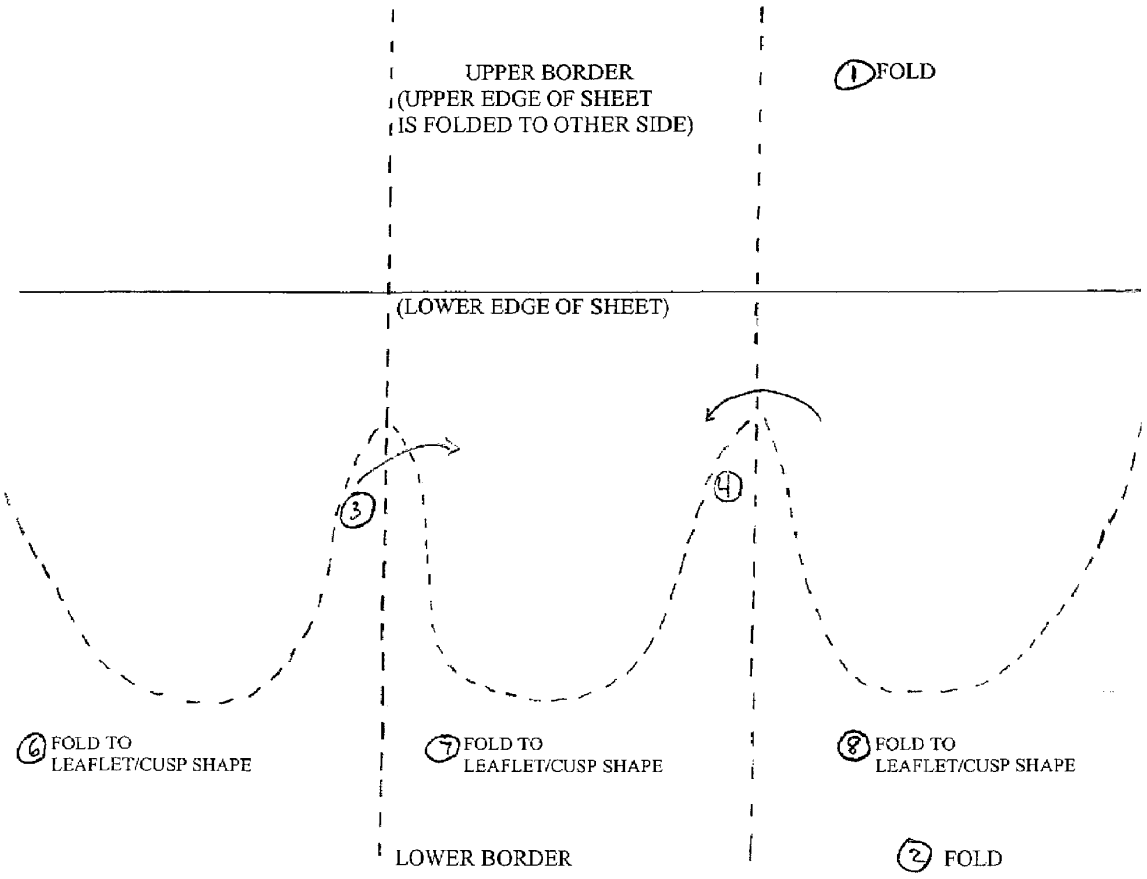
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FIG. 9C

Document code: WFEE

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MNGUYEN	SALE	#00000011	Mailroom Dt:	04/15/2014	501943	14253650	
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Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/253,650	Filing Date 04/15/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 04/15/2014

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 5	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/LAVINIA JOHNSON/

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/253,650	Filing Date 04/15/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 04/15/2014

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 5	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/LAVINIA JOHNSON/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	14/253,650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Title	Percutaneous Bioprosthetic Heart Valve and a Delivery and Implantation System
Art Unit	not assigned
Examiner Name	not assigned
Attorney Docket Number	109978.10104

SIGNATURE of Applicant or Patent Practitioner

Signature	/ Mark L. Yaskanin /	Date (Optional)	18 April 2014
Name	Mark L. Yaskanin	Registration Number	45246
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/80 (07-12)
Approved for use through 11/30/2014. OMB 0651-0035
U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

■ Practitioners associated with Customer Number: 29880

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

■ The address associated with Customer Number: 29880

OR

☐	Firm or Individual Name		
	Address		
	City	State	Zip
	Country		
	Telephone	Email	

Assignee Name and Address: Colibri Heart Valve LLC
2150 W. 6th Ave., Suite M
Broomfield, Colorado 80020

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record
The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	Joseph B. Horn	Date	1-17-2013
Name	Joseph B. Horn	Telephone	303 460 8667
Title	President and CEO for Colibri Heart Valve LLC		

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office;U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of1995, no persons arerequired to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Colibri Heart Valve LLC

Application No./Patent No.: 14/253,650 Filed/Issue Date: 2014-04-15

Titled: Percutaneous Bioprosthetic Heart Valve and a Delivery and Implantation System

Colibri Heart Valve LLC, a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Inventor Paniagua To: Edoluminal Technology Research, LLC

   The document was recorded in the United States Patent and Trademark Office at
   Reel 032697, Frame 0683, or for which a copy thereof is attached.

2. From: Endoluminal Technology Research, LLC To: Endoluminal Technology LLC

   The document was recorded in the United States Patent and Trademark Office at
   Reel 032697, Frame 0830, or for which a copy thereof is attached.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

3. From: Inventor Fish To: Endoluminal Technology LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 032697, Frame 0960, or for which a copy thereof is attached.

4. From: Endoluminal Technology LLC To: Vela Biosystems LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 032698, Frame 0121, or for which a copy thereof is attached.

5. From: Vela Biosystems LLC To: R. David Fish and David Paniagua

The document was recorded in the United States Patent and Trademark Office at
Reel 032698, Frame 0313, or for which a copy thereof is attached.

6. From: R. David Fish and David Paniagua To: Colibri Heart Valve LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 032698, Frame 0481, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/ Mark L. Yaskanin /	18 April 2014
Signature	Date
Mark L. Yaskanin	45246
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that yoube given certain informationin connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, pleasebe advised that: (1) the general authority forthe collection of thisinformation is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and(3) the principal purpose forwhich the information isused by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent applicationor patent. If you do not furnish the requested information,the U.S. Patent and Trademark Office may not be able to process and/or examineyour submission,which may result in termination of proceedings or abandonment of the applicationor expiration of the patent.

The informationprovided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the informationin order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an InternationalApplication filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, arecord may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from thissystem of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	18806913
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	18-APR-2014
Filing Date:	
Time Stamp:	17:28:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	Colibri_10104_POA_transmittal.PDF	73878 dbd15e15823ff848bcb1f50d185068bb15221642	no	1

Warnings:	
Information:	

2	Power of Attorney	Colibri_10104_POA.PDF	71712 ed8922bd73ce946fc238091e3bf3aa784eff4f52	no	1
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73.	Colibri_10104_statement_re_ownership_under_3-73.PDF	135764 668f64966f1a51f047391923343a08b7edbbafb2	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	281354		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/253,650

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	5 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/253,650	04/15/2014	3738	800	109978.10104	5	1

CONFIRMATION NO. 5427

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

FILING RECEIPT

OC000000068203270

Date Mailed: 05/05/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

David PANIAGUA, Houston, TX;
R. David FISH, Houston, TX;

Applicant(s)

Colibri Heart Valve LLC, Broomfield, CO

Assignment For Published Patent Application

Colibri Heart Valve LLC, Broomfield, CO

Power of Attorney: The patent practitioners associated with Customer Number 29880

Domestic Priority data as claimed by applicant

This application is a CON of 13/675,665 11/13/2012
which is a CON of 10/887,688 07/10/2004 PAT 8308797
which is a CIP of 10/037,266 01/04/2002 ABN

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 05/01/2014
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/253,650**

Projected Publication Date: 08/14/2014

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

Preliminary Class

623

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/253,650	04/15/2014	David PANIAGUA	109978.10104

CONFIRMATION NO. 5427

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

NOTICE

OC000000068203271

Date Mailed: 05/05/2014

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  David PANIAGUA
  R. David FISH

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FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE NJ 08648

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/253,650

1. THE REQUEST FILED April 15, 2014 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

/Brian W. Brown/
[*Signature*]

Petitions Examiner, Office of Petitions
(Title)

Electronic Acknowledgement Receipt

EFS ID:	19119381
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	23-MAY-2014
Filing Date:	15-APR-2014
Time Stamp:	16:48:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	10102_US-14136516_Notice_of_Allowance_2014-03-31.PDF	460326 3128b041e5be6e6e22eff142abb5b16cc40c6839	no	9

Warnings:

Information:

2	Non Patent Literature	10100_US_10-887688_Office_Action_2007-11-28.pdf	298533 4e1a45e526a9809e3b1daa5b288452b8fef6e39a	no	7
Warnings:					
Information:					
3	Non Patent Literature	10100_US_10-887688_Final_Office_Action_2008-07-15.pdf	300122 42d0ed78e24f18c3aceff2930efc6c1a247da450	no	8
Warnings:					
Information:					
4	Non Patent Literature	10100_US_10-887688_Office_Action_2009-03-16.pdf	466502 46114e18c58b1e61a58e34408e03bd083204767b	no	12
Warnings:					
Information:					
5	Non Patent Literature	10100_US_10-887688_Examiner_Interview_Summary_2009-06-12.pdf	176346 7b6caf69e2177226a6a149d3a9451e4825355a3a	no	4
Warnings:					
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6	Non Patent Literature	10100_US_10-887688_Final_Office_Action_2010-03-02.pdf	633907 daae3008a0a10457e705d8fc6b2dd604c0bd5a69	no	15
Warnings:					
Information:					
7	Non Patent Literature	10100_US_10-887688_Declaration_of_Inventors_2009-09-14.pdf	5008347 c391469d79fd4897bdd9a67dfad10d4ee0482c1e	no	128
Warnings:					
Information:					
8	Non Patent Literature	10100_US_10-887688_Declaration_of_Inventors_2008-02-28.pdf	3870953 657ad588a4b50407c16834948af838827e65db3b	no	85
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10	Non Patent Literature	10100_US_10-887688_Examiner_Interview_Summary_2010-07-26.pdf	187781 3287a1e03afacd01db7c7c1bfd60e9db8223977f	no	4
Warnings:					
Information:					

11	Non Patent Literature	10100_US_10-887688_Office_Action_2012-02-16.pdf	385115 edd156e8dd690f32a2d5eaf862602e7b5972d9c2	no	10
Warnings:					
Information:					
12	Non Patent Literature	10110_US_12-228192_Office_Action_2010-09-29.pdf	303920 70c49a9433dd0acbff8507779bf833421e8acdb1	no	9
Warnings:					
Information:					
13	Non Patent Literature	10110_US_12-228192_Examiner_Interview_Summary_2011-04-05.pdf	161803 8cd2ca6493510b177d8cfa48b7db348f7fb1ef65	no	3
Warnings:					
Information:					
14	Non Patent Literature	10110_US_12-228192_Final_Office_Action_2011-07-14.pdf	12085622 48467f8222486a3724a21d8328047ae8fd63e4b7	no	14
Warnings:					
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15	Non Patent Literature	US_10-037266_Office_Action_2003-05-08.pdf	259047 914d4eb72f062d336803af5d89d99ff82c7a41b0	no	7
Warnings:					
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16	Non Patent Literature	US_10-037266_Final_Office_Action_2004-03-09.pdf	249887 3b61cf802da3c247d0aabdb2afe1ae201b5b1ac5	no	7
Warnings:					
Information:					
		Total Files Size (in bytes):	26747294		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	RE42395		2011-05-24	Wright et al.	
	3	3014024		1961-12-19	Lieberman et al.	
	4	3029819		1962-04-17	Edward	
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	2	Cross-reference is made to U.S. Application No. 14/268,184 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10114)	☐
	3	Cross-reference is made to U.S. Application No. 14/268,190 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10115)	☐
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Name/Print	Mark Yaskanin	Registration Number	45246

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

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Name/Print	Mark L. Yaskanin	Registration Number	45246

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	30	Office Action issued in U.S. Application No. 14/136,516, dated March 10, 2014 (109978.10102)	☐
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	32	Office Action issued in U.S. Application 10/887,688, dated November 28, 2007 (54813-10100)	☐
	33	Final Office Action issued in U.S. Application 10/887,688, dated July 15, 2008 (54813-10100)	☐

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	37	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed September 14, 2009 (54813-10100)	☐
	38	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed February 28, 2008 (54813-10100)	☐
	39	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed December 15, 2008 (54813-10100)	☐
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	42	Office Action issued September 29, 2010, issued in U.S. Application 12/228,192 (54813-10110)	☐
	43	Examiner Interview Summary, dated 04/05/2011 in U.S. Application No. 12/228,192 (54813-10110)	☐
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Electronic Acknowledgement Receipt	
EFS ID:	19117938
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	23-MAY-2014
Filing Date:	15-APR-2014
Time Stamp:	16:50:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_IDS_1.pdf	607953 7711e5d5efb8453e643b756fd2b2f6983ff04ea8	no	31

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A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
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		Total Files Size (in bytes):	89441241		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	19118844
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	23-MAY-2014
Filing Date:	15-APR-2014
Time Stamp:	16:52:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Fishbein_Cardiac_pathology.PDF	778550 2aaf2fb31ef72da6417306a2f4f1eaa2494e48cb	no	6

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45	Non Patent Literature	Sellaro_Effects_of_Collagen_Fiber_Medium_term_Fatigue.PDF	1073715 cd287a8777b23026c4a7be5a5777467a974dc692	no	12
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46	Non Patent Literature	Sellaro_Effects_of_Collagen_Fiber.PDF	4016322 1b0154df51d6b35c01174b4e32a1c80a2ce71ce6	no	93
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47	Non Patent Literature	Shandas_Method_for_Determining.PDF	618161 a9868be0708de5efc8515492c3281a8649ba164d	no	8
Warnings:					
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48	Non Patent Literature	Shen_Effect_of_Ethanol_and_Ether.PDF	121067 d574ba13fcd303eea8cbba5d95977defdacb2c3c	no	4
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49	Non Patent Literature	Shen_Protein_adsorption.PDF	242606 2b5fa6df708fe69b690844cc07eb391e74b66a91	no	4
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50	Non Patent Literature	Simionescu_Mapping_Glutaraldehyde-treated_ARTICLE.PDF	12862309 46f0ddd8d9e9a9dcf7c4c0d5534d96a246963cb4	no	8
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51	Non Patent Literature	Sun_Response_of_heterograft.PDF	378209 0ee8524826d07372cd39b222a4becefefdc5b28a	no	12
Warnings:					
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52	Non Patent Literature	Topol_Textbook_of_Interventional_Cardiology.PDF	4225303 511d60021cec8bae1413a3eaca66792d91c043bc	no	40
Warnings:					
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53	Non Patent Literature	Vyavahare_Mechanics_of_Bioprosthetic.PDF	603983 d9140785f6c37c4ebc0c6c67ddddc5b833f9dce5	no	7
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55	Non Patent Literature	Werner_testing_the_hydrodynamic_properties.PDF	95402 aa85009f41fa024ab5edffa0cfe1bbb34674d77c	no	1
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Warnings:					
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60	Non Patent Literature	10102_US-14136516_Office_Action_2014-03-10.PDF	793847 3b87faee238a76cecaa885d3b3b5119f9bc9bf54	no	13
Warnings:					
Information:					
		Total Files Size (in bytes):	145507905		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 06/09/2014

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

NOTIFICATION DATE	DELIVERY MODE
06/09/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 14/253,650	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/15/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *34-38* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *34-38* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *4/15/2014* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *5/23/2014, 5/23/2014, 5/23/2014*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-38 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 34 line 4 and 14 recite "a prosthetic heart valve" and "the prosthetic heart valve" respectively. This is unclear as the preamble requires "A percutaneous bioprosthetic heart valve", thus it is unclear if the "prosthetic heart valve" is intended to refer to the percutaneous bioprosthetic heart valve, or intended to be a different, additional heart valve thereto. Claims 35-38 depend upon claim 34 and inherit all issues with the claim. It is suggested to change "a prosthetic heart valve" to --the bioprosthetic heart valve--.

Claim 34, last line recites "a collapsed configuration". It is unclear if this is intending to refer to the collapsed configuration of line 15, or to be a different, additional collapsed configuration. It is suggested to change "a collapsed configuration" in line 16 to --the collapsed configuration--.

Claim 34, line 7, "its" is indefinite as this is unclear what "its" is referring to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34 and 38 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916 B1). Garrison discloses a percutaneous bioprosthetic heart valve and delivery and implantation system (see figures 31-38) configured for percutaneous use (see fig.31, 38; other delivery methods may also be used, col.11, lines 10-12; for example fig.3-6) comprising: a stent member (111+26d+8d; see fig.38) having an inner channel (central lumen), the stent member (8d+26d+111) being collapsible (seen in fig.31, 36, 37) and expandable (seen in fig.32, 33, 38) and configured for percutaneous delivery (see fig.31; col.11, lines 10-12; figs.3-6), the stent member (111+26d+8d) including a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.38), a valve means (6d) residing entirely within the inner channel (see fig.38) of the stent member (111+26d+8d), the valve means (6d) including an outer cuff layer (bottom portion of 6d, behind 111, seen in fig.38) and two to four individual leaflets (upper portion of 6d, see fig.38); and a catheter comprising a pusher member (4D) and moveable sheath (116), both the pusher member (4d or 64) and sheath (116 or 10) having a lumen (see fig.31, 37, 2, 3), wherein the pusher member (64

or 4D) is disposed in the sheath lumen, and the prosthetic heart valve (fig.38) is collapsed onto the pusher member (4D or 64; see fig.37, 3) to reside in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the sheath (116 or 10). Garrison discloses the pusher member (4d or 64) to include a controlled release mechanism (balloon 112 or 52) that can be activated (via inflation).

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Gabbay (US 2002/0032481 A1) in view of Garrison (US 6,425,916 B1). Referring to claim 34, Gabbay discloses a percutaneous bioprosthetic heart valve and delivery and implantation system (figs.1-4, 9a-9b) configured for percutaneous use (may be closed chest procedure, P0066, P0069, P0071, P0107, through blood vessel) comprising: a stent member (14) having an inner channel (central lumen), the stent member (14) being collapsible (fig.9a, 9b) and expandable (fig.2, 11) and configured for percutaneous delivery (closed chest procedure, through blood vessel, P0066, P0069, P0071, P0107), the stent member (14) including a tubular structure away from its central portion that flares at both ends (30, 32) in a trumpet-like configuration (see fig.2; P0043), a valve means (12) residing entirely within the inner channel of the stent member (seen in fig.2), the valve means (12) including an outer cuff layer (20) and two to four individual leaflets (22, 24, 26); and a catheter comprising a pusher member (210 or 716) and moveable sheath (208 or 704),

both the pusher member and sheath having a lumen (see fig.9a, 9b, 21; P0105, P0108), wherein the pusher member (210 or 716) is disposed in the sheath lumen (fig.9a, 9b, 21), the prosthetic heart valve restrained in a collapsed configuration by the sheath (fig.9a, 9b, 20). Gabbay discloses the valve and delivery system substantially as claimed, however does not disclose the valve to be collapsed onto the pusher member (210 or 716), to reside in a collapsed configuration on the pusher member (Gabbay's pusher member 210 or 716 is a plunger member with lumen, ending proximally to the valve, which pushes out the valve from behind). Garrison teaches in the same field of prosthetic heart valves and delivery systems therefore (see fig.21 for example), an alternate pusher member (78b) for a self-expanding stent valve (6a) used in catheter delivery systems (fig.21), the alternate pusher member (78a) having a hollow tube (distal end of 78a) extending distally of the plunger (80b and 83b), to which a prosthetic valve is collapsed onto (see fig.21), this aids in assembly, and also allows use of guidewire for positioning (col.8, lines 24-34; col.9, lines 10-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Gabbay's disclosed prosthetic valve and delivery system, with Garrison's teaching of alternate pusher member (78a), in order to provide Gabbay's system with easier loading and positioning.

Gabbay discloses the stent member (14) to be self-expanding and comprising nitinol (P0045). Gabbay discloses the stent member (14) to include two circles of barbs (38, 40; P0048, fig.1b, 3) on an outer surface of the stent member (14). Gabbay as modified by Garrison's pusher (78b) discloses the pusher member to include a controlled release mechanism (80/80b) that can be activated (by being pushed axially).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./
Examiner, Art Unit 3738
/THOMAS J SWEET/

Supervisory Patent Examiner, Art Unit 3738

Notice of References Cited	Application/Control No. 14/253,650	Applicant(s)/Patent Under Reexamination PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,425,916 B1	07-2002	Garrison et al.	623/2.11
*	B	US-2002/0032481 A1	03-2002	Gabbay, Shlomo	623/2.11
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1973	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
L2	410	1 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
L3	430	1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
L4	674	2 3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
L5	8	"09/973,609"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:17
L6	275	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN. OR ("5397351").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:42
L7	11	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
L8	9	("3626518" | "3691567" | "3868956" | "3911502" | "4030142" | "4503569" | "4759758" | "4994077").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
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6/2/2014 11:51:56 AM
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	RE40404		2008-06-24	Schmitt et al.	
	2	RE42395		2011-05-24	Wright et al.	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
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	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
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Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
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Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
(Not for submission under 37 CFR 1.99)	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

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	49	4666442		1987-05-19	Arru et al.	
	50	4728328		1998-03-01	Hughes et al.	
	51	4743231		1988-05-10	Kay et al.	
	52	4759758		1988-07-26	Gabbay	

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	53	4759759		1988-07-26	Walker et al.	
	54	4798611		1989-01-17	Freeman, Jr.	
	55	4801299		1989-01-31	Brendel et al.	
	56	4870966		1989-10-03	Dellon et al.	
	57	4883458		1989-11-28	Shiber	
	58	4892539		1990-01-09	Koch	
	59	4966604		1990-10-30	Reiss	
	60	4976733		1990-12-11	Giradot	
	61	4979939		1990-12-25	Shiber	
	62	5006104		1991-04-09	Smith et al.	
	63	5007896		1991-04-16	Shiber	

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	64	5011488		1991-04-30	Ginsburg	
	65	5026366		1991-06-25	Leckrone	
	66	5032128		1991-07-16	Alonso	
	67	5047041		1991-09-10	Samuels	
	68	5047050		1991-09-10	Arpesani	
	69	5061277		1991-10-29	Carpentier et al.	
	70	5080660		1992-01-14	Buelna	
	71	5052771		1991-10-01	Williams et al.	
	72	5139515		1992-08-18	Robicsek	
	73	5163955		1992-11-17	Love et al.	
	74	5171273		1992-12-15	Silver et al.	

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	75	5226889		1993-07-13	Sheiban	
	76	5261878		1993-11-16	Galindo	
	77	5282847		1994-02-01	Trescony et al.	
	78	5326370		1994-07-05	Love et al.	
	79	5326371		1994-07-05	Love et al.	
	80	5332402		1994-07-26	Teitelbaum	
	81	5336616		1994-08-09	Livesey et al.	
	82	5360443		1994-11-01	Barone et al.	
	83	5374539		1994-12-20	Nimni et al.	
	84	5376110		1994-12-27	Tu et al.	
	85	5383927		1995-01-24	De Goiceochea et al.	

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	86	5411552		1995-05-02	Andersen et al.	
	87	5413601		1995-05-09	Keshelava	
	88	5449384		1995-09-12	Johnson	
	89	5476506		1995-12-19	Lunn	
	90	5480424		1996-01-02	Cox	
	91	5489297		1996-02-06	Duran	
	92	5500015		1996-03-19	Deac	
	93	5509930		1996-04-23	Love	
	94	5522879		1995-06-04	Scopelianos	
	95	5522881		1996-06-04	Lentz	
	96	5545215		1996-08-13	Duran	

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	97	5549664		1996-08-27	Hirata et al.	
	98	5549666		1996-08-27	Hata et al.	
	99	5571170		1996-11-05	Palmaz et al.	
	100	5571173		1996-11-05	Parodi	
	101	5571174		1996-11-05	Love et al.	
	102	5578071		1996-11-26	Parodi	
	103	5578072		1996-11-26	Barone et al.	
	104	5582168		1996-12-10	Samuels et al.	
	105	5591229		1997-01-07	Parodi	
	106	5634928		1997-06-03	Fischell et al.	
	107	5653749		1997-08-05	Love et al.	

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	108	5713953		1998-02-03	Vallana et al.	
	109	5728152		1998-03-17	Mirsch, II et al.	
	110	5733299		1998-03-21	Sheiban et al.	
	111	5741333		1998-04-21	Frid	
	112	5746775		1998-05-05	Levy et al.	
	113	5769780		1998-06-23	Hata et al.	
	114	5782914		1998-07-21	Schankereli	
	115	5787887		1998-08-04	Klingenbeck-Regn	
	116	5840081		1998-11-24	Anderson et al.	
	117	5855601		1999-01-05	Bessler et al.	
	118	5861028		1999-01-19	Angell	

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	119	5862806		1999-01-26	Cheung	
	120	5895420		1999-04-20	Mirsch, II et al.	
	121	5931969		1999-08-03	Carpentier et al.	
	122	5957949		1999-09-28	Leonhardt et al.	
	123	5961539		1999-10-05	Northup et al.	
	124	5961549		1999-10-05	Nguyen et al.	
	125	5972030		1999-10-26	Garrison et al.	
	126	5976179		1999-11-02	Inoue	
	127	6004328		1999-12-21	Solar	
	128	6004330		1999-12-21	Middleman et al.	
	129	6010531		2000-01-04	Donlon et al.	

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	130	6029671		2000-02-29	Stevens et al.	
	131	6045576		2000-04-04	Starr et al.	
	132	6053938		2000-04-25	Goldmann et al.	
	133	6091984		2000-07-18	Perelman et al.	
	134	6102944		2000-08-15	Huynh et al.	
	135	6117169		2000-09-12	Moe	
	136	6124523		2000-09-26	Banas et al.	
	137	6125852		2000-10-03	Stevens et al.	
	138	6126686		2000-10-03	Badylak et al.	
	139	6129756		2000-10-10	Kugler	
	140	6162245		2000-12-19	Jayaraman	

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	141	6168614		2001-01-02	Andersen et al.	
	142	6168619		2001-01-02	Dinh et al.	
	143	6171335		2001-01-09	Wheatley et al.	
	144	6174327		2001-01-16	Mertens et al.	
	145	6186999		2001-02-13	Chen	
	146	6197143		2001-03-06	Bodnar	
	147	6214055		2001-04-10	Simionescu et al.	
	148	6221091		2001-04-24	Khosravi	
	149	6231602		2001-05-15	Carpentier et al.	
	150	6245102		2001-06-12	Jayaraman	
	151	6254629		2001-07-03	Inoue	

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	152	6254630		2001-07-03	Inoue	
	153	6254636		2001-07-03	Peredo	
	154	6264691		2001-07-24	Gabbay	
	155	6269819		2001-08-07	Oz et al.	
	156	6270526		2001-08-07	Cox	
	157	6277397		2001-08-21	Shimizu	
	158	6277555		2001-08-21	Duran et al.	
	159	6287335		2001-09-11	Drasler et al.	
	160	6293970		2001-09-25	Wolfinbarger, Jr. et al.	
	161	6312462		2001-11-06	McDermott et al.	
	162	6312474		2001-11-06	Francis et al.	

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	163	6334873		2002-01-01	Lane et al.	
	164	6342069		2002-01-29	Deac et al.	
	165	6350282		2002-02-26	Eberhardt	
	166	6352554		2002-03-05	De Paulis	
	167	6352708		2002-03-05	Duran et al.	
	168	6358275		2002-03-19	McIlroy et al.	
	169	6358284		2002-03-19	Fearnot et al.	
	170	6371980		2002-04-16	Rudakov et al.	
	171	6376244		2002-04-23	Atala et al.	
	172	6378221		2002-04-30	Ekholm, Jr. et al.	
	173	6383171		2002-05-07	Gifford et al.	

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	174	6391333		2002-05-21	Li et al.	
	175	6409755		2002-06-25	Vrba	
	176	6418339		2002-07-09	Essenpreis et al.	
	177	6425916		2002-07-30	Garrison et al.	
	178	6432712		2002-08-13	Wolfinbarger, Jr. et al.	
	179	6440167		2002-08-27	Shimizu	
	180	6458153		2002-10-01	Bailey et al.	
	181	6461382		2002-10-08	Cao	
	182	6468313		2002-10-22	Claeson et al.	
	183	6471723		2002-10-29	Ashworth et al.	
	184	6482227		2002-11-19	Solovay	

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	185	6482228		2002-11-19	Norred	
	186	6482240		2002-11-19	Echmayer et al.	
	187	6491719		2002-12-10	Fogarty et al.	
	188	6494909		2002-12-17	Greenhalgh	
	189	6503272		2003-01-07	Duerig et al.	
	190	6534004		2003-03-18	Chen et al.	
	191	6540782		2003-04-01	Snyders	
	192	6558418		2003-05-06	Carpentier et al.	
	193	6569200		2003-05-27	Wolfinbarger Jr. et al.	
	194	6565960		2003-05-20	Koob et al.	
	195	6582458		2003-06-24	White et al.	

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	196	6582462		2003-06-24	Andersen et al.	
	197	6582464		2003-06-24	Gabbay	
	198	6599524		2003-07-29	Li et al.	
	199	6624890		2003-09-23	Backman et al.	
	200	6626938		2003-09-30	Butaric et al.	
	201	6652577		2003-11-25	Gianotti	
	202	6652578		2003-11-25	Bailey et al.	
	203	6553681		2003-04-29	Ekholm, Jr. et al.	
	204	6610088		2003-08-26	Gabbay	
	205	6666886		2003-12-23	Tranquillo et al.	
	206	6682559		2001-01-27	Myers et al.	

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	207	6685739		2004-02-03	Dimatteo et al.	
	208	6696074		2004-02-24	Dia et al.	
	209	6719788		2004-04-13	Cox	
	210	6719789		2004-04-13	Cox	
	211	6702826		2004-03-09	Liddicoat et al.	
	212	6736823		2004-05-18	Darios et al.	
	213	6764510		2004-07-20	Vidlund et al.	
	214	6773456		2004-08-10	Gordon et al.	
	215	6773457		2004-08-10	Ivancev	
	216	6790229		2004-09-14	Berreklouw	
	217	6792979		2004-09-21	Konya et al.	

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	218	6802319		2004-10-12	Stevens et al.	
	219	6802806		2004-10-12	McCarthy et al.	
	220	6821297		2004-11-23	Snyders	
	221	6821530		2004-11-23	Koob et al.	
	222	6830584		2004-12-14	Seguin	
	223	6893460		2005-05-17	Spenser et al.	
	224	6908481		2005-06-21	Cribier	
	225	6913608		2005-07-02	Liddicoat et al.	
	226	6916338		2005-07-12	Speziali	
	227	6942694		2005-09-13	Liddicoat et al.	
	228	6951571		2005-10-04	Srivastava	

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	229	6961123		2005-11-01	Wang et al.	
	230	6977231		2005-12-20	Matsuda	
	231	6986735		2006-01-17	Abraham et al.	
	232	7004925		2006-02-28	Navia et al.	
	233	7008763		2006-03-07	Cheung	
	234	7011688		2006-03-14	Gryska et al.	
	235	7018404		2006-03-28	Holmberg et al.	
	236	7018406		2006-03-28	Seguin et al.	
	237	7022348		2006-04-04	Ketharananthan	
	238	7025780		2006-04-11	Gabbay	
	239	7037333		2006-05-02	Myers et al.	

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	240	7039446		2006-05-02	Ruchti et al.	
	241	7041132		2006-05-09	Quijano et al	
	242	7053051		2006-05-30	Hendriks et al	
	243	7060092		2006-06-13	Kuribayashi et al.	
	244	7070616		2006-07-04	Majercak et al.	
	245	7077862		2006-07-18	Vidlund et al.	
	246	7084082		2006-08-01	Shimizu	
	247	7138226		2006-11-21	Vincek et al.	
	248	7153324		2006-12-26	Case et al.	
	249	7160322		2007-01-09	Gabbay	
	250	7164145		2007-01-16	Shakespeare	

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	251	7166570		2007-01-23	Hunter et al.	
	252	7189259		2007-03-13	Simionescu et al.	
	253	7213601		2007-05-08	Stevens et al.	
	254	7214242		2007-05-08	Abraham et al.	
	255	7232461		2007-06-19	Ramer	
	256	7261732		2007-08-28	Justino	
	257	7289211		2007-10-30	Walsh, Jr. et al.	
	258	7309461		2007-12-18	Kujawski et al.	
	259	7311730		2007-12-25	Gabbay	
	260	7318998		2008-01-15	Goldstein et al.	
	261	7331993		2008-02-19	White	

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	262	7329279		2008-02-12	Haug et al.	
	263	7354702		2008-04-08	Dai et al.	
	264	7381218		2008-06-03	Schreck	
	265	7381219		2008-06-03	Salahieh et al.	
	266	7399315		2008-07-15	Iobbi	
	267	7427291		2008-09-23	Liddicoat et al.	
	268	7431725		2008-10-07	Stack et al.	
	269	7468073		2008-12-23	Johnson et al.	
	270	7473237		2009-01-06	Navia et al.	
	271	7481838		2009-01-27	Carpentier et al.	
	272	7503929		2009-03-17	Johnson et al.	

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	273	7510571		2009-03-31	Spiridigliozzi et al.	
	274	7510575		2009-03-31	Spenser et al.	
	275	7524330		2009-04-28	Berreklouw	
	276	7566343		2009-07-28	Jenson et al.	
	277	7585321		2009-09-08	Cribier	
	278	7604661		2009-10-20	Pavcnik et al.	
	279	7618446		2009-11-17	Andersen et al.	
	280	7622276		2009-11-24	Cunanan et al.	
	281	7628805		2009-12-08	Spenser et al.	
	282	7648676		2010-01-19	Mills et al.	
	283	7670368		2010-03-02	Hill et al.	

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	1	Cross-reference is made to U.S. Application No. 14/253,656 filed on April 15, 2014, and its associated Preliminary Amendment (109978.10113)	☐
	2	Cross-reference is made to U.S. Application No. 14/268,184 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10114)	☐
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	1.24, 1.26, 2.12-2.19	6/2/2014	cm

SEARCH NOTES		
Search Notes	Date	Examiner

INTERFERENCE SEARCH			
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	Attorney Docket Number	109978.10104	

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	30	Office Action issued in U.S. Application No. 14/136,516, dated March 10, 2014 (109978.10102)	☐
	31	Notice of Allowance issued in U.S. Application No. 14/136,516, dated March 31, 2014 (109978.10102)	☐
	32	Office Action issued in U.S. Application 10/887,688, dated November 28, 2007 (54813-10100)	☐
	33	Final Office Action issued in U.S. Application 10/887,688, dated July 15, 2008 (54813-10100)	☐

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Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	34	Office Action issued in U.S. Application 10/887,688, dated March 16, 2009 (54813-10100)	☐
	35	Examiner Interview Summary issued in U.S. Application 10/887,688, dated June 12, 2009 (54813-10100)	☐
	36	Final Office Action issued in U.S. Application 10/887,688, dated March 2, 2010 (54813-10100)	☐
	37	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed September 14, 2009 (54813-10100)	☐
	38	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed February 28, 2008 (54813-10100)	☐
	39	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed December 15, 2008 (54813-10100)	☐
	40	Examiner Interview Summary issued in U.S. Application 10/887,688, dated July 26, 2010 (54813-10100)	☐
	41	Office Action issued in U.S. Application 10/887,688, dated February 16, 2012 (54813-10100)	☐
	42	Office Action issued September 29, 2010, issued in U.S. Application 12/228,192 (54813-10110)	☐
	43	Examiner Interview Summary, dated 04/05/2011 in U.S. Application No. 12/228,192 (54813-10110)	☐
	44	Final Office Action issued July 14, 2011, in U.S. Application No. 12/228,192 (54813-10110)	☐

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Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
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	First Named Inventor	David PANIAGUA
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(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	45	Office Action issued in U.S. Application 10/037,266, dated May 8, 2003	☐
	46	Final Office Action issued in U.S. Application 10/037,266, dated March 9, 2004	☐

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EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/02/2014

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14/253,650 filed on 2014-04-15.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: R. David FISH Date (Optional): _____

Signature: RDFish

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: David PANIAGUA Date (Optional) :

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

Electronic Acknowledgement Receipt

EFS ID:	19431497
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	27-JUN-2014
Filing Date:	15-APR-2014
Time Stamp:	10:43:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	Colibri_10104_Fish_Declaration.PDF	342756 1528ee711c85b4924129699d7e6ae385978886e9	no	1

Warnings:	
Information:	

2	Oath or Declaration filed	Colibri_10104_Paniagua_Declaration.PDF	333387 2ec4bb12665cd234c519287fb96bf7a4c0eb161f	no	1
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			Total Files Size (in bytes):	676143	

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	AMENDMENT AND RESPONSE
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on July 24, 2014.
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Registration Number: 45,246

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

In response to the June 9, 2014 Office Action (the "Office Action"), please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

AMENDMENTS TO THE SPECIFICATION

Please amend the Title as follows:

PERCUTANEOUS ~~BIOPROSTHETIC~~ REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-33. (Cancelled)

34. (Currently Amended) ~~A percutaneous bioprosthetic heart valve and a delivery and implantation system configured for percutaneous use where a bioprosthetic heart valve is indicated,~~ An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration; and

a valve means residing entirely within the inner channel of the stent member, the valve means including ~~an outer cuff layer and~~ two to four individual leaflets made of fixed pericardial tissue, wherein the valve means is attached to a proximal and wider part of the stent member;

a ~~catheter~~ delivery system including a pusher member and a moveable sheath, [[both]] the pusher member including a guidewire lumen ~~and the moveable sheath each including a lumen~~, wherein the pusher member is disposed within [[the]] a lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed

configuration on the pusher member and is restrained in [[a]] the collapsed configuration by the moveable sheath.

35. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 34, wherein the stent member is self-expanding.

36. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 35, wherein the stent member comprises nitinol.

37. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicants' reply to the Examiner's June 9, 2014 Office Action. No claims are cancelled. Claims 34-38 are amended. No new claims have been added. Accordingly, Claims 34-38 are now pending in view of the above amendments.

Applicants believe that no new matter has been added with regard to the claim amendments provided herein. Applicants do not donate or disclaim any claims or subject matter with the claim amendments made herein, and the Applicants expressly reserve the right to prosecute the original claims, previously pending claims, or any unclaimed subject matter in one or more future filed continuing applications.

Applicants have amended the "stent member" limitation to further recite that the stent member is "configured for transluminal percutaneous delivery." The Applicants have also amended the title. Support for these amendments can be found in Paragraph [0057] of U.S. Pat. App. Pub. No. 2003/0130729 (filed January 4, 2002) from which the present application claims priority.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited reference and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the

references, if any, is consistent with the Examiner's understanding. Also, Applicants' arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Rejection Under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), Second Paragraph

The Examiner rejected Claims 34-38 under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), Second Paragraph for indefiniteness on the grounds that the claims fail to particularly point out and distinctly claims the subject matter of the invention.

The Applicants have amended the preamble of Claim 34. Applicants believe that the amended preamble addresses any indefiniteness issue previously asserted by the Examiner.

The Applicants have also adopted the Examiner's suggestion for addressing the last line of Claim 34 (changing "a collapsed configuration" to "the collapsed configuration.") Applicant notes with appreciation the Examiner's suggestion.

Based on the foregoing, the Examiner is respectfully requested to withdraw the 35 U.S.C. § 112 rejections.

II. Prior Art Rejections

A. Rejection Under 35 U.S.C. § 102(e)

The Examiner rejected Claims 34 and 38, under pre-AIA 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,425,916 to Garrison et al. ("Garrison"). The Applicants have addressed Garrison in the present reply, however, if necessary, the Applicants reserve the right to "swear behind" Garrison if the Applicants choose to do so at a later time.

It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Vertegaal Bros. v. Union Oil Co. of

Calif., 814 F.2d 628, 631 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as a complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 U.S.P.Q. 344 (C.C.P.A. 1978). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1999).

Applicants have amended independent Claim 34 to now read as follows:

> An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:
> a prosthetic heart valve including:
> a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration; and
> a valve means residing entirely within the inner channel of the stent member, the valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means is attached to a proximal and wider part of the stent member;
> a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath.

As amended, Claim 34 now recites "a valve means residing entirely within the inner channel of the stent member, the valve means including two to four individual leaflets made of fixed pericardial tissue." Support for this amended claim wording can be found at least in Paragraphs [0048]-[0053] of U.S. Pat. App. Pub. No. 2003/0130729 (filed January 4, 2002) from which the present application claims priority.

Turning now to Garrison, while Garrison mentions synthetic materials (Garrison, col. 5, ll. 50-60), the only written description of a "tissue" material of Garrison is found at col. 5, ll. 42-48, wherein Garrison states:

> The posts 32 support a valve portion 38 which performs the functions of the patient's malfunctioning native valve. Referring to FIGS. 10 and 11, the valve portion 38 is preferably a stentless tissue valve such as a tri-leaflet 39 stentless porcine valve. The valve portion 38 has a base 41 which is secured to the support structure 26 with sutures (not shown).

Thus, review of Garrison reveals that Garrison uses "a trileaflet 39 stentless porcine valve." That is, Garrison does not disclose *"two to four individual leaflets made of fixed pericardial tissue,"* as claimed in amended Claim 34. Accordingly, Garrison fails to anticipate the amended wording of Claim 34.

As amended, Claim 34 further recites that "the valve means is attached to a proximal and wider part of the stent member." Support for this amended claim wording can be found in the last sentence of Paragraph [0052] of U.S. Pat. App. Pub. No. 2003/0130729 (filed January 4, 2002) from which the present application claims priority. Such structure is not disclosed in the cited references, including Garrison. More particularly, at least one embodiment of Garrison does not attach commissures to the frame as is evidenced by the inverted valve structure shown in Figures 35 and 38.

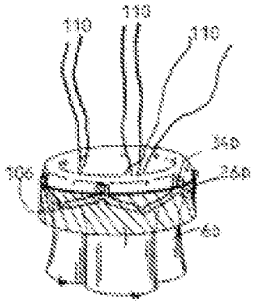

FIG. 35

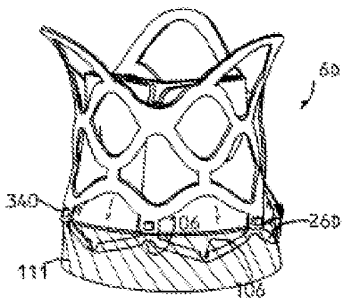

FIG. 38

With regard to Garrison, the valve 6D is attached to a circumferential ring 111 around the support structure 26D. (Garrison, col.10, ll. 51-62.) This is at the distal end of the construct. Accordingly, Garrison does not disclose that "the valve means is attached to a proximal and wider part of the stent member" as recited in amended Claim 34. Moreover, by the inverted structure shown, which is the only method that Garrison discloses as the union of Garrison's various elements, the valve displacer and valve are joined outside the patient's body *prior to* advancing as a system. Indeed, Garrison states that "[t]he valve 6D is coupled to a valve displacer 8D prior to introduction into the patient." (Garrison, col. 10, ll. 40-42.) Thus, when connected together for insertion, the valve is *inverted* as shown above. This is the only method that Garrison discloses and describes when the components are together *before* implantation. Accordingly, Garrison cannot disclose that the "prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath," wherein "the valve means is attached to a proximal and wider part of the stent member," as claimed in amended Claim 34, if the proximal end of the valve 6D is never attached to any structure other than the sutures 110 that are removed after inverting the valve 6D. "The catheter 4D is then removed and the sutures 110 are pulled to invert the valve 6D as shown in FIG. 33. An end of each suture 110 is then pulled to remove the sutures 110." (Garrison, col. 11, ll. 29-32.)

With regard to the Garrison embodiment shown in Fig. 10, the valve portion 38 is connected to a support structure 26.

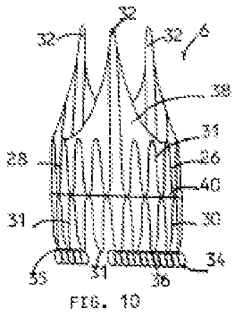

FIG. 10

However, the support structure 26 is not a "stent member" that "includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration," as claimed in Claim 34. If one considers the valve displacer 8 shown in Fig. 9 of Garrison, then the support structure 26 is attached to the valve displacer 8 along its distal end using protrusions 34.

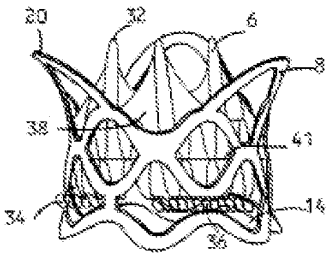

FIG. 9

However, Garrison discloses that the valve displacer 8 and support structure 26 are separate components that are only combined in the body following the valve displacer deployment. Moreover, the support structure 26 contains a porcine valve per Garrison, but the support structure 26, not the valve, is attached to the *distal* end of the valve displacer 8.

MPEP §2131 clearly states that to anticipate a claim, the reference must teach every element of the claim. In addition, The United States Court of Appeals for the Federal Circuit has held "that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus,

cannot anticipate under 35 U.S.C. § 102." Net Moneyin, Inc., v. Verisign, Inc., 2008 U.S. App. LEXIS 21827 (CAFC 2008).

For the foregoing reasons, Garrison does not disclose the claim limitations as recited in amended Claim 34 presented herein. Accordingly, the Examiner is respectfully requested to withdraw the 35 U.S.C. § 102(e) rejection of Claim 34, as well as its dependent Claim 38.

B. Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0032481 to Gabbay ("Gabbay") in view of Garrison. The Applicants have addressed Gabbay in the present reply, however, if necessary, the Applicants reserve the right to "swear behind" Gabbay if the Applicants choose to do so at a later time.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit). See MPEP § 2142. "Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See MPEP § 2142 and In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a § 103(a) rejection, the Examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

Referring now to Gabbay, as noted above, amended Claim 34 now recites "the valve means is attached to a proximal and wider part of the stent member." However, Gabbay discloses that the valve is attached to a portion of the sent that is spaced apart from both ends of the frame. Figure 2 of Gabbay is shown below.

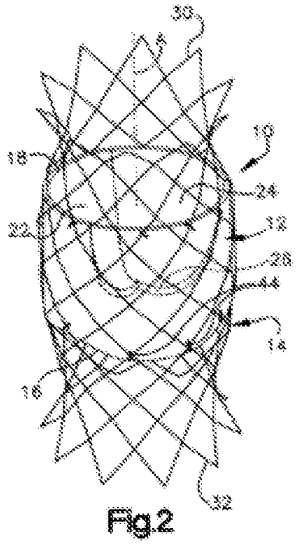

Fig.2

When referring to Fig. 2, Gabbay states that the "[t]he valve 12 may be affixed relative to the stent portion 14, such as by one or more sutures 44. The sutures 44 may be located at the inflow

and outflow ends 16 and 18 of the valve 12 to connect the valve to the stent 14 to inhibit axial movement of the valve relative to the stent." (Gabbay, ¶ [0049].) Accordingly, Gabbay does not disclose that "the valve means is attached to a proximal and wider part of the stent member," as now recited in amended Claim 34. In addition, based on the discussion above pertaining to Garrison, either alone or in combination with Garrison, Gabbay does not disclose the foregoing recited claim limitation.

In addition to the foregoing, Claim 34 further recites the following:

> a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath.

As stated by the Examiner on page 5 of the Office Action, "Gabbay does not disclose the valve to be collapsed onto the pusher member (210 or 716), to reside in a collapsed configuration on the pusher member." The Examiner then goes on to modify Gabbay with Garrison, stating, in part, that Garrison provides "an alternate pusher member (78a) having a hollow tube (distal end of 78a) extending distally of the plunger (80a and 83b), to which a prosthetic valve is collapsed onto," and that Garrison "allows use of guidewire for positioning." While it is true that Garrison discloses a guidewire, the problem is that Gabbay does not include a "pusher member including a guidewire lumen," as recited in amended Claim 34, and the structure of Gabbay is not consistent with being altered as suggested by the Examiner. More particularly, Gabbay does not use a guidewire and will not work with a guidewire because Gabbay uses a trigger mechanism 206 associated with a plunger mechanism 210. Figure 9A of Gabbay is provided below:

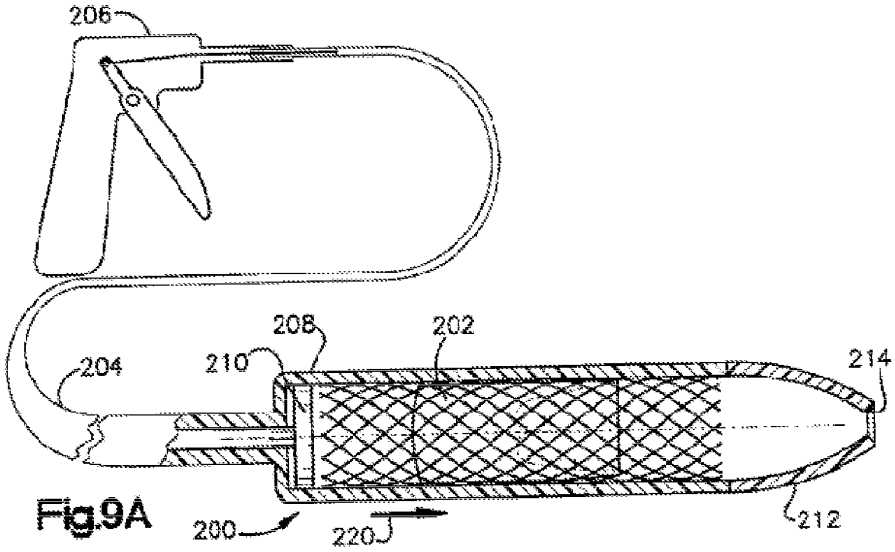

Fig.9A

Gabbay states that "[a] plunger mechanism 210 is located at a proximal end of the enclosure 208 for urging the prosthesis 202 generally axially from the enclosure 208." (Gabbay, ¶ [0064].) Therefore, to combine Garrison with Gabbay as suggested by the Examiner causes a change in the principle of operation of the Gabbay device, because the entire trigger mechanism 206 and plunger mechanism 210 (that is, Gabbay's delivery structure) would no longer operate to deliver the valve if a guidewire exists instead of the plunger linkage. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP § 2143.02; citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Moreover, as cited on page 10 in Appeal 2011-001382 (*Ex Parte* Mueller et al., App. No. 10/348,306) by the PTAB, "[i]f references taken in combination would produce a 'seemingly inoperative device,' such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness." McGinley v. Franklin Sports, Inc., 262 F3d. 1339, 1354 (Fed. Cir. 2001).

Based on the foregoing, Gabbay alone or in combination with Garrison fails to render amended Claim 34 obvious. Accordingly, the Examiner is respectfully requested to withdraw the 35 U.S.C. §103 rejection of amended independent Claim 34.

With regard to dependent Claims 35-38, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). See MPEP §2143.03. Accordingly, the Examiner is requested to withdraw the rejection of dependent Claims 35-38.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds a remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/ Mark L. Yaskanin /

Mark L. Yaskanin
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Dated: July 24, 2014

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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	1	20030027332		2003-02-06	Lafrance et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Attorney Docket Number	109978.10104

	1	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

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	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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☐ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-07-24
Name/Print	Mark L. Yaskanin	Registration Number	45246

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Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin
Filer Authorized By:	
Attorney Docket Number:	109978.10104
Receipt Date:	24-JUL-2014
Filing Date:	15-APR-2014
Time Stamp:	14:52:14
Application Type:	Utility under 35 USC 111(a)

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File Listing:

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1		Reply_to_6-9-14_OA.pdf	236614 42180b0d39864074c36785d4cf3b74170ec33590	yes	15

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	Specification	2	2
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/253,650	Filing Date 04/15/2014	☐ To be Mailed

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APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
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☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
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AMENDMENT 07/24/2014

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Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
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					TOTAL ADD'L FEE	

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14/253,650	04/15/2014	David PANIAGUA	109978.10104

CONFIRMATION NO. 5427

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

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Title:PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

Publication No.US-2014-0228944-A1
Publication Date:08/14/2014

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First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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	1	Office Action issued July 8, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐
	2	Office Action issued August 15, 2014, in U.S. Application No. 14/284,063 (File: 109978.10117)	☐
	3	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

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	Attorney Docket Number	109978.10104

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-08-21
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	19930554
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	21-AUG-2014
Filing Date:	15-APR-2014
Time Stamp:	16:10:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS.PDF	643473 5b32c557b249c6507a6252947d92fb0bd8460fbd	no	4

Warnings:	
Information:	

2	Non Patent Literature	10113_US_14-253656_Office_Action_2014-07-08.PDF	437014 37dc712effb927478d8a4a3f745f32f2fabbfcb2	no	11
Warnings:					
Information:					
3	Non Patent Literature	10117_US_14-284063_Office_Action_2014-08-15.PDF	405746 767cb51c75a56970fcae19c2c2d9362f0c07ac12	no	10
Warnings:					
Information:					
4	Non Patent Literature	Hilbert_Biomechanics.PDF	411710 b4851a8736a6654787e31c40da105c179fcf1302	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	1897943	

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6676698		2004-01-13	McGuckin, Jr.	
	2	6733525		2004-05-11	Yang et al.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action issued September 11, 2014, in U.S. Application No. 14/268,190 (File: 109978.10115)	☐
	2	Office Action issued September 3, 2014, in U.S. Application No. 14/284,049 (File: 109978.10116)	☐
	3	Office Action issued September 12, 2014, in U.S. Application No. 14/268,184 (File: 109978.10114)	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-09-12
Name/Print	Mark L. Yaskanin	Registration Number	45246

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Electronic Acknowledgement Receipt

EFS ID:	20123129
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	12-SEP-2014
Filing Date:	15-APR-2014
Time Stamp:	13:40:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2014-09-12.PDF	649155 3e7a857f9eb78a275667c3e5b40e0f3a4cac0ea4	no	4

Warnings:	
Information:	

2	Non Patent Literature	10115_US_14-268190_Office_Action_2014-09-11.PDF	789645 6113f5cb5892a4df0d3c7c1a6375cda9a03c1a5d	no	19
Warnings:					
Information:					
3	Non Patent Literature	10116_US_14-284049_Office_Action_2014-09-03.PDF	416178 b343786491136eddbbad5222e392024a2a80ebde	no	11
Warnings:					
Information:					
4	Non Patent Literature	10114_US_14-264184_Office_Action_2014-09-12.PDF	459730 b11ce91ce36a866c33d03b2a7d3360d4ff025cfc	no	12
Warnings:					
Information:					
		Total Files Size (in bytes):	2314708		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6530952		2003-03-11	Vesely	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Final Office Action issued September 25, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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☐ A certification statement is not submitted herewith.

SIGNATURE

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-09-26
Name/Print	Mark L. Yaskanin	Registration Number	45246

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EFS ID:	20252523
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
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First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	26-SEP-2014
Filing Date:	15-APR-2014
Time Stamp:	10:56:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	10113_US_14-253656_Final_Office_Action_2014-09-25.PDF	538987 cb00303b193a23cd9bb73177ceeba6167d2b91a4	no	14

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2014-09-26.PDF	626847 61082b383f5b6d924ba6b9532246b90838e132ba	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	1165834

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5484444		1996-01-16	Braunschweiler et al.	
	2	5645559		1997-07-08	Hachtman et al.	
	3	5683451		1997-11-04	Lenker et al.	
	4	5876448		1999-03-02	Thompson et al.	
	5	6350278		2002-02-26	Lenker et al.	
	6	6682537		2004-01-27	Ouriel et al.	
	7	6896690		2005-05-24	Lambrecht et al.	
	8	7556646		2009-07-07	Yang et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Notice of Allowance issued October 7, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

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EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-10-07
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Electronic Acknowledgement Receipt

EFS ID:	20354902
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	07-OCT-2014
Filing Date:	15-APR-2014
Time Stamp:	18:10:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2014-10-07.PDF	648570 5d6497751aa0165bda4e56aa23ed53b099d30a12	no	4
Warnings:					
Information:					

2	Non Patent Literature	10113_US_14-253656_Notice_of_Allowance_2014-10-07.PDF	240537 a0f5ed8b9f3c8355dca4c8e4728a4283e7b525c3	no	6
Warnings:					
Information:					
			Total Files Size (in bytes):	889107	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	SUPPLEMENTAL AMENDMENT
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	**Certificate of EFS-Web Transmission** I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 16 October 2014. Typed or printed name of person signing this certificate: Carol Donahue Signature: / Carol Donahue /

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Applicants submit the enclosed claim amendments for the Examiner's consideration.

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-33. (Cancelled)

34. (Currently Amended) An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from [[its]] a central portion that flares at both ends in a trumpet-like configuration; and

a valve means residing entirely within the inner channel of the stent member, the valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means is attached to a proximal ~~and wider part~~ portion of the stent member;

a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, [[and]] wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, and wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath.

35. (Previously Presented) The assembly of Claim 34, wherein the stent member is self-expanding.

36. (Previously Presented) The assembly of Claim 35, wherein the stent member comprises nitinol.

37. (Previously Presented) The assembly of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (Previously Presented) The assembly of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

REMARKS/ARGUMENTS

The present filing is a Supplemental Amendment to Applicants' reply dated July 24, 2014 to the USPTO Office Action dated June 9, 2014. An Examiner's Interview (discussed below) was conducted on October 14, 2014, and this Supplemental Amendment has been prepared to place the application in a condition for allowance. No claims are cancelled. Claim 34 is amended, with support for the amendments found in Fig. 8 of the present application. No new claims have been added. Accordingly, Claims 34-38 are now pending in view of the above amendments.

Applicants believe that no new matter has been added with regard to the claim amendments provided herein. Applicants do not donate or disclaim any claims or subject matter with the claim amendments made herein, and the Applicants expressly reserve the right to prosecute the original claims, previously pending claims, or any unclaimed subject matter in one or more future filed continuing applications.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited reference and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicants' arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Examiner's Interview

Applicants' Attorney and Applicants express their sincere appreciation to Examiner Cheryl L. Miller for conducting a telephone interview with the undersigned Applicants' Attorney and Joseph B. Horn (CEO and President of Colibri Heart Valve LLC (the assignee of the present application)) on October 14, 2014. Applicants will provide a reply upon receiving the Examiner's Interview Summary.

Again, the Applicants and the Applicants' Attorney thank the Examiner for participating in the Examiner's Interview.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds a remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/ Mark L. Yaskanin /

Mark L. Yaskanin
Registration No. 45,246
Customer No. 29880
Phone: (303) 446-3852
Facsimile: (303) 292-1300

Dated: October 16, 2014

Electronic Acknowledgement Receipt

EFS ID:	20433382
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	16-OCT-2014
Filing Date:	15-APR-2014
Time Stamp:	14:24:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Colibri_10104_Supplemental_Amendment_2014-10-16.PDF	130990 00caee70f0fd5c021339f6212a993066305405e5	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	5
Warnings:			
Information:			
	Total Files Size (in bytes):	130990	

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/253,650	Filing Date 04/15/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 10/16/2014

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 5	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/TERRY MALLOY/

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 10/24/2014

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

NOTIFICATION DATE	DELIVERY MODE
10/24/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Applicant-Initiated Interview Summary	**Application No.** 14/253,650	**Applicant(s)** PANIAGUA ET AL.	
	Examiner CHERYL MILLER	**Art Unit** 3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) *CHERYL MILLER (Examiner)*. (3)*Joe Horn (Assignee)*.

(2) *Mark Yaskanin (Reg. No.45,246)*. (4)_____.

Date of Interview: *14 October 2014*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☒112 ☒102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *34*.

Identification of prior art discussed: *Gabbay (US 2002/0032481 A1) and Garrison (6,425,916 B1)* .

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

See Continuation Sheet.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHERYL MILLER/ Examiner, Art Unit 3738	/THOMAS J SWEET/ Supervisory Patent Examiner, Art Unit 3738

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The official amendment filed July 24, 2014 was discussed. The amendment appears to overcome the previous indefinite issues. Although it was suggested by examiner to remove "its" from the claim to make more clear what "its" refers to. The limitation of the valve means attached to a proximal and wider part of the stent member was discussed. Examiner noted that Gabbay's valve of figure 2 for example, although centered on the stent member, is attached to the proximal portion at one suture line and the distal portion at another suture line, and thus, claiming the positioning of the valve more proximally than distally, or the valve itself, as a whole, is positioned closer to the proximal end of the stent member than the distal end, may be needed to overcome such interpretations discussed above. Such language would appear to be more close to that recited in the specification as well, thus would avoid any new matter issues, as the examiner had concern for lack of support of the valve attached to the wider portion, as this detail does not appear to be shown in the drawings. Also, the proximal part of the stent member has no reference point, thus any end of a stent member in the prior art may be considered a proximal end. Applicant may consider defining where the proximal end is, possibly by the inflow/outflow of leaflets or blood flow, or alternately, by the prosthetic valve's orientation/positioning on the pusher member (which end is where on the pusher). Applicant plans to file a supplemental amendment in next week or so, which the examiner has agreed to have entered and will conduct a new search and consideration at that point in time.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	REPLY TO APPLICANT-INITIATED INTERVIEW SUMMARY
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 31 October 2014.
Typed or printed name of person signing this certificate:
Carol Donahue
Signature: /Carol Donahue/

Dear Sir:

Applicants submit the following reply to the October 24, 2014 Applicant-Initiated Interview Summary. The participants in the Interview were Examiner, Cheryl Miller, Joseph Horn (for the Assignee), and Applicants' undersigned counsel. Applicants' Attorney expresses his sincere appreciation to the Examiner for conducting the telephone interview on October 14, 2014.

An Interview Summary was prepared by the Examiner and mailed on October 24, 2014. The Applicants' Attorney is in agreement with the Examiner's Summary as set forth in the Interview Summary, regarding the claim and prior art discussed. While there was not a resolution reached regarding the exact wording needed for claim amendments, the Examiner offered guidance to the Applicants possible amendments to put the claims in condition for allowance. Applicants filed claim amendments on October 16, 2014 in a Supplement Amendment. In the Supplemental Amendment, the Applicants endeavored to provide claim

wording supported by the application that would place the application in a condition for allowance.

Notwithstanding the Applicants' amendments set forth in the Supplemental Amendment, which Applicants believes places the application in a condition for allowance, the Applicants' Attorney nonetheless invites the Examiner to contact Applicants' Attorney directly by phone at (303) 446-3852 if an Examiner's Amendment is needed to place the application in a condition for allowance.

Applicant believes no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/ Mark L. Yaskanin /

Mark L. Yaskanin
Registration No. 45,246
Customer No. 29880
Phone: (303) 446.3852
Facsimile: (303) 292.1300

Dated: 31 October 2014

Electronic Acknowledgement Receipt

EFS ID:	20577188
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	31-OCT-2014
Filing Date:	15-APR-2014
Time Stamp:	15:25:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	Colibri_10104_Reply_to_Interview_Summary.PDF	87454 025eae7243aea2f1b98e9dd46b47566dbac1b48d	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	87454

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

OK TO ENTER: /CM/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	
Atty. File No.: 109978.10104	SUPPLEMENTAL AMENDMENT
	Filed Electronically
Entitled: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	**Certificate of EFS-Web Transmission** I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 16 October 2014. Typed or printed name of person signing this certificate: Carol Donahue Signature: / Carol Donahue /

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Applicants submit the enclosed claim amendments for the Examiner's consideration.

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030027332		2003-02-06	Lafrance et al.	

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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Receipt date: 07/24/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

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EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	1.24, 1.26, 2.12-2.19	6/2/2014	cm
update		11/1/2014	cm

SEARCH NOTES		
Search Notes	Date	Examiner
East text search	11/2/2014	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.M./ Examiner.Art Unit 3738	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030027332		2003-02-06	Lafrance et al.	
	2	20070061008		2007-03-15	Salahieh et al.	
	3	20100043197		2010-02-25	Abbate et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Receipt date: 08/21/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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NON-PATENT LITERATURE DOCUMENTS **Remove**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action issued July 8, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐
	2	Office Action issued August 15, 2014, in U.S. Application No. 14/284,063 (File: 109978.10117)	☐
	3	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"7556646".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 13:32
L2	1	"6733525".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 14:12
S1	1973	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
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S3	430	S1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S4	674	S2 S3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S5	8	"09/973,609"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:17
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S7	11	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
S8	9	("3626518" | "3691567" | "3868956" | "3911502" | "4030142" | "4503569" | "4759758" | "4994077").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
S9	2	("4038703" | "4106129").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:45
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			USOCR			
S11	0	a61f2002/3601.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S12	4	"4759758".pn. or "5935163".pn. or "5861028".pn. or "5855602".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 15:29
S13	4	S12 and pericardium	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 15:29
S14	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
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S16	430	S14 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S17	680	S15 S16	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S18	199	S17 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:26
S19	1	"6579307".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:34
S20	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S21	416	S20 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S22	430	S20 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S23	680	S21 S22	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S24	279	S23 and (valve with pericardi$3)	US-PGPUB;	OR	ON	2014/11/02 20:44

			USPAT; USOCR			
S25	199	S23 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S26	85	S24 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S27	364	S23 and (pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:59
S28	85	S27 not S24	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S29	80	S28 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
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S31	1	"6652578".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 10:38

11/3/2014 2:17:15 PM
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5484444		1996-01-16	Braunschweiler et al.	
	2	5645559		1997-07-08	Hachtman et al.	
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Receipt date: 10/07/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Notice of Allowance issued October 7, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

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EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 11/07/2014

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LAWRENCEVILLE, NJ 08648

EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

NOTIFICATION DATE	DELIVERY MODE
11/07/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 14/253,650	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/16/2014 and 7/24/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *34-38* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *34-38* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *10/7/2014, 9/26/2014, 9/12/2014, 8/21/2014, 7/24/2014*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Supplemental Amendment

The supplemental amendment filed October 16, 2014 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 34-38 have been considered but are moot because the arguments do not apply to any of the specific combination of references being used in the current rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,652,578 B2) in view of Cribier (US 6,908,481 B2). Bailey discloses an assembly to treat a native heart valve, the assembly comprising: a prosthetic heart valve (figs.7-12) including a stent member (12) having an inner channel, the stent member (12) collapsible, expandable, and configured for transluminal percutaneous delivery (fig.20a-20i; col.63-67), wherein the stent member (12) includes a tubular structure away from a central portion that flares at both ends (42, 44) in a trumpet-like configuration (see fig.12a and 12b, wherein flanges 42 and 44 appear to be more trumpet shaped when placed in the body and surrounding the annulus, as

opposed to the perpendicular shape in fig.7) and a valve means (11b+28) residing entirely within the inner channel of the stent member (see fig.10), the valve means including two to four individual leaflets (26) of tissue (biologically derived membranes col.8, lines 47-49; col.9, lines 20-25; col.5, lines 53-60), the valve means (11b+28) attached to a proximal portion of the stent member (as the valve means is attached along the majority of the inner surface of stent, 11b is coplanar with stent length and leaflets 26 are attached to stent at seams 29 which extend from a proximal portion to a distal portion, thus the valve is attached to *both* a proximal portion and a distal portion of the stent member, which includes attachment at the proximal portion and thus meets the claim limitation); a delivery system (fig.19) including a pusher member (222) and a moveable sheath (217), the pusher member (222) including a guidewire lumen (see fig.19), the pusher member (222) disposed within a lumen (216) of the moveable sheath (217), wherein the prosthetic valve (40; fig.7-11) is collapsed onto the pusher member (222) to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath (217; see fig.19; wherein valve 10 is shown, however applies also to valve 40; col.14, lines 63-67), and wherein a distal end of the prosthetic valve is located at a distal end of the moveable sheath (see fig.19; col.14, lines 63-67; Baileys valve is attached to both proximal and distal portions of the stent member; thus, either end of the stent member may be considered the proximal end, and the opposite end would be the distal end, both of which are located at the distal end of the moveable sheath). Bailey discloses the assembly substantially as claimed, having leaflets (26) of biological tissue (biologically derived membranes col.8, lines 47-49), however is silent to mention what type of tissue specifically. Cribier teaches in the same field of prosthetic heart valves, use of fixed pericardial tissue (col.5, lines 20-30) for the leaflets that are

attached to an expandable stent in a similar manner as Bailey (see fig.6a-6c and col.5, lines 30-46 of Cribier compared to figs.10 of Bailey), fixed pericardial tissue taught by Cribier to be an example of a biologically derived membrane material used for leaflets attached to expandable stent structures (col.5, lines 20-30; col.15, lines 5-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Baileys assembly with Cribier's alternate choice of material for leaflets, as such would be an obvious alternate material choice known in the art.

Bailey discloses the stent member to be self-expanding and comprising nitinol (col.5, lines 44-53; col.8, lines 13-17). Bailey discloses two circles of barbs on the stent member (pointed ends of triangles in flanges 42 and 44 may be considered barbs as the project and anchor to tissue). Bailey discloses the pusher member (222) to include a control release mechanism (220 and 218; function to hold valve in place longitudinally on pusher while sheath is withdrawn slowly, to control deployment by longitudinal restraint).

In the alternative to the above rejection, claims 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,652,578 B2) in view of Cribier (US 6,908,481 B2). Bailey discloses an assembly to treat a native heart valve, the assembly comprising: a prosthetic heart valve (figs.7-12 or figs.1-6) including a stent member (12) having an inner channel, the stent member (12) collapsible, expandable, and configured for transluminal percutaneous delivery (fig.20a-20i; col.63-67), wherein the stent member (12) includes a tubular structure away from a central portion that flares at both ends (42, 44 fig.10,12 or alternately 22, 18 fig.4, 6) and a valve means (11b+28) residing entirely within the inner channel of the stent

member (see fig.10 and 4), the valve means including two to four individual leaflets (26) of tissue (biologically derived membranes col.8, lines 47-49; col.9, lines 20-25; col.5, lines 53-60), the valve means (11b+28) attached to a proximal portion of the stent member (as the valve means is attached along the entire inner surface of stent, 11b is coplanar with stent and leaflets 26 are attached to stent at seams 29 which extend from a proximal portion to a distal portion, thus the valve is attached to both a proximal portion and a distal portion of the stent member, which includes attachment at the proximal portion and thus meets the claim limitation; in the embodiment of fig.4, the leaflets are positioned closer to the bottom of the stent member, which is disclosed to be the proximal portion); a delivery system (fig.19) including a pusher member (222) and a moveable sheath (217), the pusher member (222) including a guidewire lumen (see fig.19), the pusher member (222) disposed within a lumen (216) of the moveable sheath (217), wherein the prosthetic valve (40; fig.7-11) is collapsed onto the pusher member (222) to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath (217; see fig.19; wherein valve 10 is shown, however applies also to valve 40; col.14, lines 63-67), and wherein a distal end of the prosthetic valve is located at a distal end of the moveable sheath (see fig.19; col.14, lines 63-67; Baileys valve is attached to both proximal and distal portions of the stent member; thus, either end of the stent member may be considered the proximal end, and the opposite end would be the distal end, both of which are located at the distal end of the moveable sheath). Bailey discloses the assembly substantially as claimed, having leaflets (26) of biological tissue (biologically derived membranes col.8, lines 47-49), however is silent to mention what type of tissue specifically. Bailey also shows two ends flared (18 and 20 in fig.4 and 42 and 44 in fig.10), and discloses these may be at an acute, right,

or perpendicular angle (col.5 line 64-col.6 line 4), however does not recite that the flared ends are specifically "trumpet" shaped. Cribier teaches in the same field of prosthetic heart valves, use of fixed pericardial tissue (col.5, lines 20-30) for the leaflets that are attached to an expandable stent in a similar manner as Bailey (see fig.6a-6c and col.5, lines 30-46 of Cribier compared to figs.10 of Bailey), fixed pericardial tissue taught by Cribier to be an example of a biologically derived membrane material used for leaflets attached to expandable stent structures (col.5, lines 20-30; col.15, lines 5-9) and Cribier also teaches a stent (10) with flared ends (12) similar to Bailey (see Cribier fig.3a, 3b), for the same purpose of anchoring against the native valve annulus (col.8, lines 62-67; col.9, lines 21-29), however more of a trumpet shaped flare (concave, col.5, lines 64-67; fig.3a, 3b). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Baileys assembly with Cribier's alternate choice of material for Baileys leaflets, as such would be an obvious alternate material choice known in the art and with Cribier's alternate trumpet shaped flares, as such is an obvious alternate flare shape that serves the same purpose as Baileys flared ends (anchoring above and below the native valve annulus).

Bailey discloses the stent member to be self-expanding and comprising nitinol (col.5, lines 44-53; col.8, lines 13-17). Bailey discloses two circles of barbs on the stent member (pointed ends of triangles in flanges 42 and 44 may be considered barbs as the project and anchor to tissue). Bailey discloses the pusher member (222) to include a control release mechanism (220 and 218; function to hold valve in place longitudinally on pusher while sheath is withdrawn slowly, to control deployment by longitudinal restraint).

Claims 34 and 38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US 6,425,916 B1, cited previously) in view of Cribier (US 6,908,481 B2) and Gabbay (US 2002/0032481 A1, cited previously). Garrison discloses an assembly to treat a native heart valve in a patient comprising: a prosthetic heart valve (figs.31-38) including configured for percutaneous use (see fig.31, 38; other delivery methods may also be used, col.11, lines 10-12; for example fig.3-6) comprising: a stent member (111+26d+8d; see fig.38) having an inner channel (central lumen), the stent member (8d+26d+111) being collapsible (seen in fig.31, 36, 37) and expandable (seen in fig.32, 33, 38) and configured for percutaneous delivery (see fig.31; other delivery methods may be used, col.11, lines 10-12; figs.3-6), the stent member (111+26d+8d) including a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.38), a valve means (6d) residing entirely within the inner channel (see fig.38; valve does reside entirely within inner channel in the implanted state; noting that the claims do not require valve to reside entirely within the inner channel of the stent member when the prosthetic heart valve is collapsed on the pusher member *and* when the prosthetic heart valve is in the released from the delivery system; such a claim limitation would seemingly overcome this rejection) of the stent member (111+26d+8d), the valve means (6d) including two to four individual leaflets (upper portion of 6d, see fig.38) of biological tissue material (membrane material that is preserved/fixed prior to implantation as seen in fig.34; col.11, lines 4-5, thus assumingly tissue, however not specific as to what type); the valve attached to one end of the stent member (bottom, inflow end, see fig.36, 37) and a delivery system including a pusher member (4D) and moveable sheath (116), both the pusher member (4d or 64) and sheath (116 or 10) having a lumen (see fig.31, 37, 2, 3), wherein the pusher member

(64 or 4D) is disposed in the sheath lumen, and the prosthetic heart valve (fig.38) is collapsed onto the pusher member (4D or 64; see fig.37, 3) to reside in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the sheath (116 or 10), a distal end of the valve is located at the distal end of the sheath (both proximal and distal ends of the prosthetic valve are positioned in the distal end of the sheath). Garrison discloses the assembly substantially as claimed, however does not disclose 1) pericardium to be the specific type of fixed tissue used for leaflets and 2) the valve attached to the proximal end of the stent when in the distal end of the sheath (Garrison discloses that when the prosthetic valve is in the distal end of the sheath, it is positioned/oriented such that the attachment of the stent to the valve is at the distal end instead of the proximal end). Cribier teaches in the same field of prosthetic heart valves, use of fixed pericardial tissue (col.5, lines 20-30) for the leaflets that are attached to an expandable stent (fig.6a-6c and col.5, lines 30-46 of Cribier), fixed pericardial tissue taught by Cribier to be an example of a biologically derived membrane material used for leaflets attached to expandable stent structures (col.5, lines 20-30; col.15, lines 5-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Garrison's assembly of figs.31-38 with Cribier's alternate choice of material (pericardium) for Garrisons leaflets, as such would be an obvious alternate material choice known in the art. Further, Gabbay teaches in the same field of expandable prosthetic heart valves and percutaneous delivery systems therefor, positioning a prosthetic heart valve such that the outflow end is closer to the distal end of the sheath than the inflow end (seen in figure 11) or alternately, positioning such that the inflow end of the valve is closer to the distal end of sheath than the outflow end (seen in figure 19, 22) and that such are obvious alternative positions of the heart valve within

the sheath, depending on which valve in the heart is being replaced and the direction in which the delivery system is inserted (P0071, P0106). It would have been obvious to one having ordinary skill in the art at the time the invention was made also combine Garrison's assembly with Gabbay's teaching of alternate orientation of the prosthesis within the sheath, as such is shown by Gabbay to be an obvious alternate positioning providing for different delivery routes and positioning at different valves within the heart.

Garrison discloses the pusher member (4d or 64) to include a controlled release mechanism (balloon 112 or 52) that can be activated (via inflation).

Claims 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 6,733,525 B2) in view of Yang et al. (US 7,556,646 B2) and further in view of Gabbay (US 2002/0032481 A1, cited previously). Yang 525' discloses an assembly to treat a native heart valve in a patient comprising: a prosthetic heart valve (fig.21a-21c embodiment) including configured for percutaneous use (compressible, see fig.21b; col.4, lines 5-17; col.6, lines 23-40) comprising: a stent member (602) having an inner channel (central lumen seen in fig.21b, 21c), the stent member (602) being collapsible (seen in fig.21b) and expandable (seen in fig.21c) and configured for percutaneous delivery (col.16, lines 7-11; col.4, lines 5-17), the stent member (602) including a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.21a; flared out outflow **and** overlapped sides at inflow, col.16, liners 10-11), a valve means (626) residing entirely within the inner channel (fig.21a-21c, fig.2a, 2b) of the stent member (602), the valve means (626) including two to four individual leaflets (626) of fixed pericardium (col.1, lines 22-40; col.6, lines 14-16); the valve

attached to one end of the stent member (inflow end, see fig.21a-21c) and a delivery system comprising a moveable outer sheath and pusher (col.16, lines 43-59; col.12, lines 41-50), however does not disclose specific details of the delivery system. Yang 646' teaches in the same field of delivery of Yang 525 type of prosthetic heart valves. Yang 646' teaches the delivery system particulars to include an outer moveable sheath (disclosed percutaneous catheter tube; col.5 line 65-col.6 line 2) and a pusher member (end of 24, at 26 in fig.1 for example) having a lumen for a guidewire (28) and the prosthetic heart valve (30) is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member (fig.1) and is restrained in a collapsed configuration by the sheath (col.5 lines 65-col.6 line 2), a distal end of the valve (30) is located at the distal end of the sheath (both proximal and distal ends of the prosthetic valve are positioned in the distal end of the sheath). Further, Gabbay teaches in the same field of expandable prosthetic heart valves and percutaneous delivery systems therefor, positioning a prosthetic heart valve such that the outflow end is closer to the distal end of the sheath than the inflow end (seen in figure 11) or alternately, positioning such that the inflow end of the valve is closer to the distal end of sheath than the outflow end (seen in figure 19, 22) and that such are obvious alternative positions of the heart valve within the sheath, depending on which valve in the heart is being replaced and the direction in which the delivery system is inserted (P0071, P0106). It would have been obvious to one having ordinary skill in the art at the time the invention was made also combine Yang525's prosthetic heart valve with Yang 646's teaching of a delivery system for heart valves of Yang 525', also with Gabbay's teaching of alternate orientations of a heart valve on the distal ends of delivery systems, in order to provide Yang

525's prosthetic valve with a delivery system that may be introduced through various routes and to various valves within the heart.

Yang 525' discloses the stent (602) to be self-expandable and to comprise nitinol (col.6, lines 5-14; col.6, lines 23-34; col.8, lines 35-38; col.14, lines 30-43) and two circles of barbs (fig.11e for example, col.15, lines 45-53). Yang 525' (as modified by Yang 646 delivery system and Gabbay's orientation on a delivery system) discloses the pusher member (24/26 of Yang 646') to include a controlled release mechanism (balloon or pivoting arms) that can be activated (via inflation or turning gears).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./
Examiner, Art Unit 3738
/THOMAS J SWEET/

Supervisory Patent Examiner, Art Unit 3738

Notice of References Cited	Application/Control No. 14/253,650	Applicant(s)/Patent Under Reexamination PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,652,578 B2	11-2003	Bailey et al.	623/1.24
*	B	US-6,908,481 B2	06-2005	Cribier, Alain	623/2.11
*	C	US-6,733,525 B2	05-2004	Yang et al.	623/2.18
*	D	US-7,556,646 B2	07-2009	Yang et al.	623/2.11
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6676698		2004-01-13	McGuckin, Jr.	
	2	6733525		2004-05-11	Yang et al.	
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Receipt date: 09/12/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action issued September 11, 2014, in U.S. Application No. 14/268,190 (File: 109978.10115)	☐
	2	Office Action issued September 3, 2014, in U.S. Application No. 14/284,049 (File: 109978.10116)	☐
	3	Office Action issued September 12, 2014, in U.S. Application No. 14/268,184 (File: 109978.10114)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Application Number	14253650
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Attorney Docket Number	109978.10104

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6530952		2003-03-11	Vesely	

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Receipt date: 09/26/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Final Office Action issued September 25, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Cross-reference is made to U.S. Application No. 14/502,453 filed on September 30, 2014, and its associated Preliminary Amendment (109978.10106)	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-11-20
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Electronic Acknowledgement Receipt

EFS ID:	20752868
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	20-NOV-2014
Filing Date:	15-APR-2014
Time Stamp:	13:34:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	10106_US_14-502453_Preliminary_Amendment.PDF	138042 d392693ca35db7c7c7b2f546ead31db8e20a94d8	no	10
Warnings:					
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2	Non Patent Literature	10106_US_14-502453_2nd_Prelim_Amendment_2014-11-19.PDF	119965 2a3ff524e287df719fa75fdd883fb94f44d0285f	no	5
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2014-11-20.PDF	703510 73bf8281af7e7c03b2d19117991bbb1782cc82de	no	4
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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	1	20030209835		2003-11-13	Chun et al.	

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	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Office Action issued December 5, 2014 in U.S. Application No. 14/502,453 (109978.10106)	☐
	2	Declaration Under 37 CFR 1.131 as filed in U.S. Patent Application No. 10/887,688 on December 15, 2008, by co-inventors of that application. (Best available copy)	☐

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Examiner Signature		Date Considered	

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-05-07
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	AMENDMENT AND RESPONSE
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

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Alexandria, VA 22313

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Carol Donahue
Signature: / Carol Donahue /

Dear Sir:

In response to the November 7, 2014 Final Office Action (the "Office Action"), please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

A Request for Continued Examination and a 3-month extension are submitted herewith along with the associated fees. Applicants believe no additional fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-33. (Cancelled)

34. (Currently Amended) An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and

a valve means ~~residing entirely within the inner channel of the stent member, the valve means~~ including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member, wherein the valve means is attached closer to a proximal and wider part ~~portion~~ of the stent member;

a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, [[and]] wherein a distal end of the prosthetic heart valve is

located at a distal end of the moveable sheath, and wherein the valve means resides entirely within the inner channel of the stent member when the stent member is collapsed onto the pusher member and further resides entirely within the inner channel of the stent member when the stent member is unrestrained from the moveable sheath upon deployment in the patient.

35. (Previously Presented) The assembly of Claim 34, wherein the stent member is self-expanding.

36. (Previously Presented) The assembly of Claim 35, wherein the stent member comprises nitinol.

37. (Previously Presented) The assembly of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (Previously Presented) The assembly of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicant's reply to the Examiner's November 7, 2014 Final Office Action. No claims have been cancelled. Claim 34 has been amended. No new claims have been added. Accordingly, Claims 34-38 remain pending in view of the above amendments.

Claim 34 has been amended to recite, in part: "wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member." In addition, Claim 34 has been further amended to recite "wherein the valve means resides entirely within the inner channel of the stent member when the stent member is collapsed onto the pusher member and further resides entirely within the inner channel of the stent member when the stent member is unrestrained from the moveable sheath upon deployment in the patient." Support for the foregoing amendments can be found, in part, in the Abstract, as well as in Figures 5 and 6 of the present application. Claim 34 has also been amended to recite "the valve means is attached closer to a proximal and wider part of the stent member." Support for this claim amendment can be found in the last sentence of Paragraph [0052] of Patent Application Publication No. 2003/0130729, which corresponds to U.S. Patent Application No. 10/037,266 from which priority is claimed. Accordingly, Applicants believe that no new matter has been added with regard to the claim amendments provided herein and that support for all claimed subject matter can be found in U.S. Patent Application No. 10/037,266 filed on January 4, 2002.

Applicants do not donate or disclaim any claims or subject matter with the claim amendments made herein, nor do the Applicants acquiesce to any rejections. The Applicants

expressly reserve the right to prosecute the original claims, previously pending claims, or any unclaimed subject matter in one or more future filed continuing applications.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited reference and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicants' arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Prior Art Rejections

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,652,578 to Bailey et al. ("Bailey") in view of U.S. Patent No. 6,908,481 to Cribier ("Cribier"); rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,425,916 to Garrison et al. ("Garrison") in view of Cribier and U.S. Patent Application Publication No. 2002/0032481 to Gabbay ("Gabbay"); and rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,733,525 to Yang et al. ("Yang '525") in view of U.S. Patent No. 7,556,646 to Yang et al., ("Yang '646") and further in view of Gabbay.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined. When making any obviousness rejection, the Examiner must first acquire a thorough understanding of the claimed invention by reading the specification and claims to understand what the Applicant is claiming as his or her invention. MPEP § 904.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit). See MPEP § 2142. "Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See MPEP § 2142 and In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a § 103(a) rejection, the Examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

The following sections address the various 35 U.S.C. § 103(a) rejections.

35 U.S.C. § 103(a) Rejections As Being Unpatentable Over Bailey In View Of Cribier

Claims 34-38 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Bailey in view of Cribier.

The Applicants have amended Claim 34 to recite, in part:

> a valve means including two to four individual leaflets made of fixed pericardial tissue, *wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member, wherein the valve means is attached closer to a proximal and wider part of the stent member*;

Bailey fails to disclose at least the limitations shown above in italics. More particularly, Bailey discloses that the tissue is located on an abluminal side of the frame. This is shown in Figures 4, 10 and 16 of Bailey, as reproduced below:

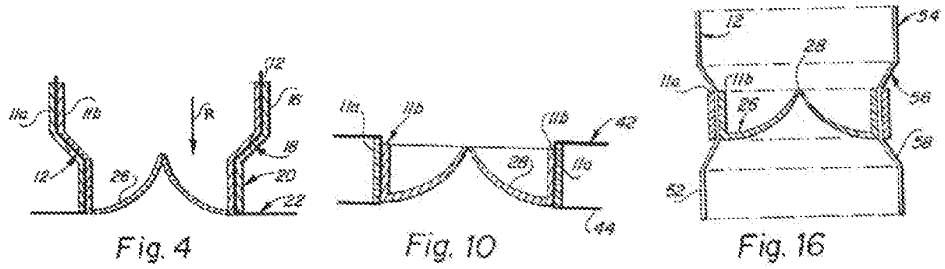


Fig. 4 Fig. 10 Fig. 16

In addition, Bailey states "[i]t should be appreciated, that **the graft member 11 should cover at least a portion of the ablumenal surface of the stent body member 12** in order to exclude the anatomic valves. . . ." (Bailey, col. 9, ll. 59-62.) (Emphasis added.) Accordingly, Bailey teaches away from a configuration where tissue is limited to the interior of the stent member, as recited in amended Claim 34, which states "*wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member.*"

In addition to the foregoing, the Applicants assert that Bailey does not enable a device that does not include the valve arms or blood flow regulator struts. There is no question that Bailey insists on the valve regulator arms being present. Reference here is made to Figs. 3, 9 and 15 of Bailey shown below. Each of the embodiments described in Bailey uses valve leaflets 26 that are biased using valve arms 24.

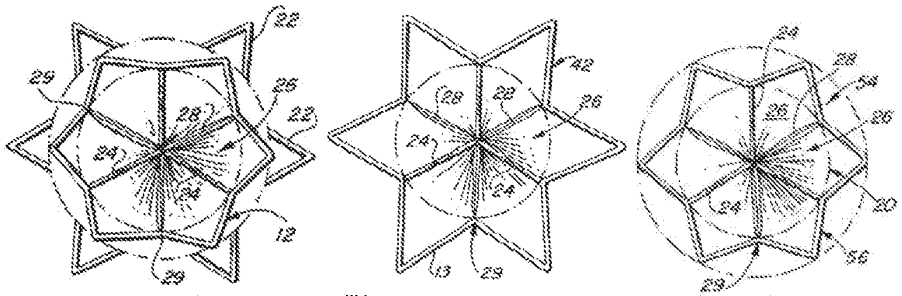


Fig. 3 Fig. 9 Fig. 15

In addition, the specification of Bailey states: "The stent body member is shaped to include the following stent sections: ... **and at least one valve arm or blood flow regulator struts"** (Bailey, col. 5, ll. 51-54)(emphasis added); "[f]low regulation in the inventive stent valve prosthesis is provided by the combination of the prosthetic valve leaflets **and the valve arms** and is biased closed..." (Bailey, col. 6,11. 10-12)(emphasis added); and **"[c]ertain elements are common to each of the preferred embodiments of the invention, specifically, each embodiment includes ... at least one biasing arm []** [that] projects from the stent body member and into the central annular opening of the stent body member." (Bailey, col. 7, ll. 58-67.) (Emphasis added.) Accordingly, Bailey requires use of at least one biasing arm within the inner channel of the stent body member.

Applicants further direct the Examiner's attention to Bailey, wherein when discussing the struts, Bailey states:

> The struts of the stent are encapsulated by the outer graft-membrane. **The valve regulator-struts** are encapsulated by the inner leaflet-membrane **and serve to bias the valve to the closed position**. The regulator-struts also prevent inversion or prolapse of the otherwise unsupported leaflet-membrane during increased supra-valvular pressure.

(Bailey, col. 6, ll. 23-26.) (Emphases added.) Here, it is clear that Bailey recognized the necessity to provide some type of mechanism to prevent prolapse of the leaflet membrane when closing. However, if the valve arms or blood flow regulator struts "serve to bias the valve to the closed position," then such biasing force must be overcome by the heart when attempting to pump blood through the valve. Accordingly, the valve arms or blood flow regulator struts of Bailey not only cause resistance to blood flow, but they add a level of complexity associated with interconnecting the leaflet-membrane to the valve arms or blood flow regulator struts, as well as crimping and deploying the valve.

Bailey also makes it clear that the valve arms or blood flow regulator struts are part of the stent member. More particularly, Bailey states:

> Valve arms or regulator struts 24 **are coupled or formed integral with the stent body member 12** and are positioned adjacent the junction point between intermediate annular section 20 and the proximal anchor flange 22 of the stent body member 12.

(Bailey, col. 9, ll. 25-29.) (Emphasis added.) Bailey does not enable its tissue assembly to operate properly as a valve *without* the valve arms or blood flow regulator struts. Accordingly, while Bailey discloses a construct that uses a plurality of valve arms or flow regulator struts 24, Bailey provides information insufficient to enable one of ordinary skill in the art to practice the invention without undue experimentation *if* the

valve arms or regulator struts are *not* present. In the present application, valve arms or regulator struts are not used, and therefore, Bailey does not disclose or enable a device that lacks these structures.

In addition to the foregoing, Cribier has been cited by the Examiner as disclosing fixed pericardial tissue for the leaflets. However, Cribier is only deployed using a balloon catheter (contrary to the limitations recited in current independent Claim 34) and more importantly, requires the valvular structure to include strengthening struts 14a, pleats 22 or other reinforcing feature. Cribier states:

> The **valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, creating stiffened zones** which induce the valvular structure to follow a patterned movement from its open position to its closed state and vice-versa, **providing therefore a structure sufficiently rigid to prevent diversion**, in particular into the left ventricle and thus preventing any regurgitation of blood into the left ventricle in case of aortic implantation.

(Cribier, col. 3, l. 67 to col. 4, l. 8.) (Emphasis added.) Accordingly, there is no disclosure in Cribier of fixed pericardial tissue (as recited in Claim 34 herein) without the use of the reinforcing features taught by Cribier. Indeed, Cribier further states "[t]hese reinforcing pleats and/or struts, rectilinear or inclined, have the advantage to impart a reproducible movement and, accordingly, **to avoid the valvular structure from closing to a nonstructurized collapse on the frame base**." (Cribier, col. 15, ll. 49-52.) (Emphasis added.) The use of fixed pericardial tissue from Cribier without reinforcing structure is not enabled.

Based on the foregoing, the Examiner is requested to withdraw the 35 U.S.C. § 103(a) rejections of Claims 34-38 as being unpatentable over Bailey in view of Cribier.

35 U.S.C. § 103(a) Rejection As Being Unpatentable Over Garrison In View Of Cribier And Gabbay

Claims 34-38 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Garrison in view of Cribier and Gabbay.

As suggested by the Examiner on page 7 of the Office Action dated November 7, 2014, the Applicants have amended the wording of Claim 34 to now recite, in part:

> wherein the valve means resides entirely within the inner channel of the stent member when the stent member is collapsed onto the pusher member and further resides entirely within the inner channel of the stent member when the stent member is unrestrained from the moveable sheath upon deployment in the patient.

Garrison clearly fails to disclose the above recited limitations. Indeed, Garrison does not attach commissures to the frame as is evidenced by the inverted valve structure shown in Figures 35 and 38.

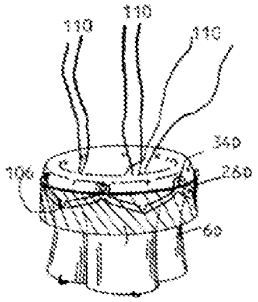


FIG. 35

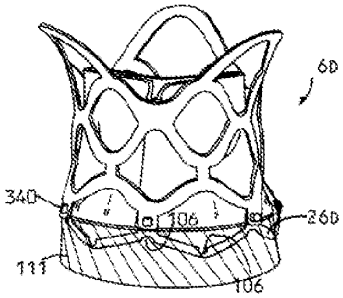


FIG. 38

With regard to Garrison, the valve 6D is attached to a circumferential ring 111 around the support structure 26D. (Garrison, col.10, ll. 51-62.) This is at the distal end of the construct. Accordingly, Garrison also does not disclose that "the valve means is attached closer to a proximal and wider part of the stent" as recited in amended Claim 34.

Moreover, by the inverted structure shown, which is the only method that Garrison discloses as the union of Garrison's various elements, the valve displacer and valve are joined outside the patient's body *prior to* advancing as a system. Indeed, Garrison states that "[t]he valve 6D is coupled to a valve displacer 8D prior to introduction into the patient." (Garrison, col. 10, ll. 40-42.) Thus, when connected together for insertion, the valve is *inverted* as shown above. This is the only method that Garrison discloses and describes when the components are together *before* implantation. Accordingly, Garrison cannot disclose that the "prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath," wherein "the valve means is attached closer to a proximal and wider part of the stent," as claimed in amended Claim 34, if the proximal end of the valve 6D is never attached to any structure other than the sutures 110 that are removed after inverting the valve 6D. "The catheter 4D is then removed and the sutures 110 are pulled to invert the valve 6D as shown in FIG. 33. An end of each suture 110 is then pulled to remove the sutures 110." (Garrison, col. 11, ll. 29-32.)

With regard to the Garrison embodiment shown in Fig. 10, the valve portion 38 is connected to a support structure 26.

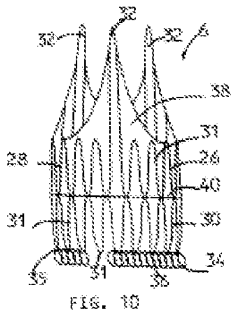


FIG. 10

However, the support structure 26 is not a "stent member" that "includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration," as claimed in Claim 34. If one considers the valve displacer 8 shown in Fig. 9 of Garrison, then the support structure 26 is attached to the valve displacer 8 along its distal end using protrusions 34.

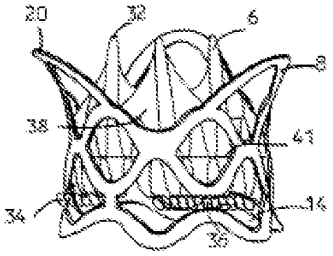


FIG. 9

However, Garrison discloses that the valve displacer 8 and support structure 26 are separate components that are only combined in the body following the valve displacer deployment. Moreover, the support structure 26 contains a porcine valve per Garrison, but the support structure 26, not the valve, is attached to the *distal* end of the valve displacer 8.

In addition to the foregoing, the Applicants reference their remarks above regarding the tissue disclosed in Cribier. Again, there is no disclosure in Cribier of fixed pericardial tissue (as recited in Claim 34 herein) without the use of the reinforcing features taught by Cribier. Moreover, the reinforcing features of Cribier would be required if the tissue is going to be combined with Garrison, because Garrison discloses the inverted leaflet configuration for deployment without attaching the proximal portion of the leaflets to the frame. Thus, Cribier does not facilitate a working embodiment when combined with Garrison.

Based on the foregoing, the Examiner is requested to withdraw the 35 U.S.C. § 103(a) rejection of Claims 34-38 as being unpatentable over Garrison in view of Cribier and Gabbay.

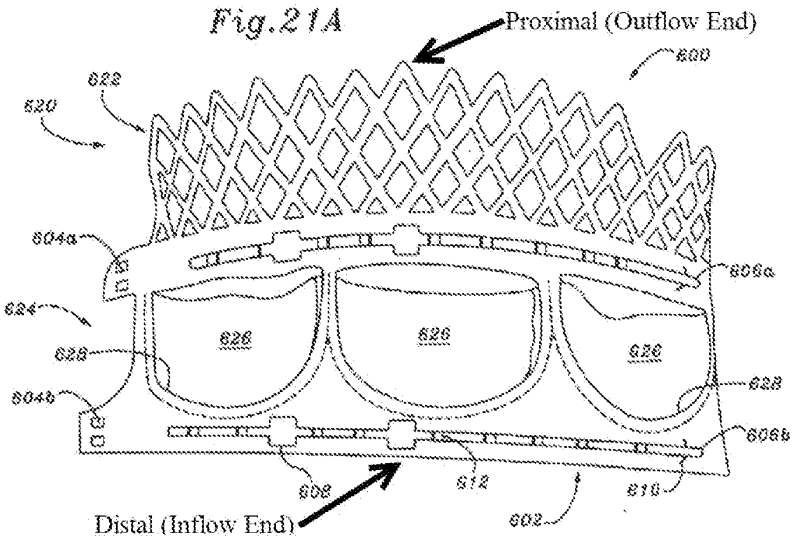
35 U.S.C. § 103(a) Rejection As Being Unpatentable Over Yang '525 In View Of Yang '646 And Further In View Of Gabbay

Claims 34-38 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Yang '525 in view of Yang '646 and further in view of Gabbay.

In the Office Action, the Examiner has stated that Yang '525 discloses "a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.21A; flared out outflow **and** overlapped sides at inflow, col. 16, line[]s 10-11)." (Office Action, pg. 7.) (Emphasis in original.) Yang '525 states: "FIG. 21B illustrates the stent 602 by itself in a partial state of unrolling, while FIG. 21C shows the stent fully unrolled. Note the flared configuration of the mesh 622 on the outflow section 620 and the overlapped sides of the stent." There is no disclosure within Yang '525 that the stent member is flared "at both ends in a trumpet-like configuration," as recited in Claim 34 herein. Moreover, even within Yang '646, the specification states "in the aortic position, **an outflow portion** of the valve may extend upward into and even flare out and contact the aorta to better stabilize the commissure regions of the valve." (Yang '646, col. 6, ll. 7-9.) Therefore, even Yang '646 only supports that the outflow end of the frame is flared. Moreover, the text of Yang '646 quoted above identifies not only what part of the valve is flared but why; that is, to "contact the aorta to better stabilize the commissure regions of the valve." Id.

Accordingly, although the text states of Yang '525 states that there are "overlapped sides of the stent," this is associated with the rolled configuration of the stent, whereas Claim 34 recites "a central portion that flares at both ends in a trumpet-like configuration." Accordingly, Yang '525 and Yang '646 fail to disclose this limitation.

In addition to the foregoing, Yang '525 fails to disclose the limitation "wherein the valve means is attached closer to a proximal and wider part of the stent member," as currently recited in independent Claim 34. Indeed, Yang '525 discloses the opposite. That is, Yang '525 discloses that the valve is attached closer to the inflow end. See Figure 21A of Yang '525 reproduced below (with Applicants' annotations as to the inflow and outflow ends):



Turning now to the delivery system, the Examiner stated on page 10 of the Office Action that Yang '525 "does not disclose specific details of the delivery system." The Applicants agree with this assessment. However, the Applicants respectfully disagree with the Examiner's assertions concerning the delivery system allegedly disclosed in Yang '646. More particularly, the Examiner has stated that Yang '646 discloses "a pusher member (end of 24, at 26 in fig. 1 for example)." (Office Action, pg. 10, l. 6.) Upon Review, Yang '646 identifies structure 24 as the catheter shaft. (Yang '646, col. 6, l. 33.) The Examiner further states in the Office Action that "the prosthetic heart valve (30) is collapsed onto the pusher member to reside in a collapsed

configuration on the pusher member (fig. 1)." (Office Action, pg. 10, ll. 7-8.) However, as can be seen in Fig. 1 of Yang '646, the catheter shaft 24 *terminates* proximal (to the right in Fig. 1) of the valve 30. Fig. 1 of Yang '646 is reproduced below.

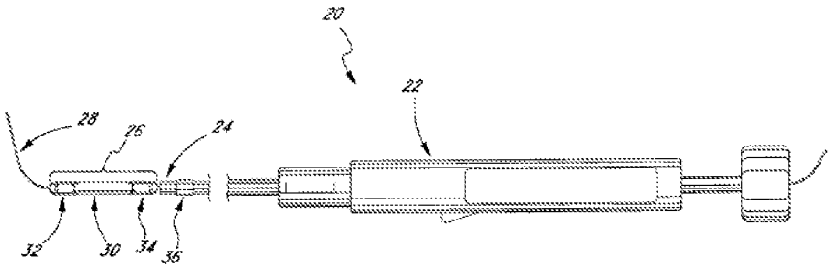


FIG.1

Accordingly, the expandable heart valve 30 cannot be collapsed onto the catheter shaft 24 because the catheter shaft carries stabilization balloon 36 and the catheter shaft 24 terminates proximally of the valve 30. Indeed, Yang '646 states "[t]he system may further include a stabilization balloon 36 provided on the catheter shaft 24 just proximal of the deployment mechanism 26." (Yang '646, col. 6, ll. 39-41.)

Assuming, *arguendo*, that the Examiner is asserting that deployment mechanism 26 is a "pusher member" corresponding to structure claimed by the Applicants, the Applicants respectfully note that Yang '646 discloses structure different than a pusher member. More particularly, when referring to Fig. 1, Yang '646 states that "[t]he expandable heart valve 30 is seen **held in a contracted configuration between a distal collet body 32 and a proximal collet body 34** of the deployment mechanism 26." (Yang '646, col. 6, ll. 36-39.) (Emphasis added.) It is clear from Yang '646 that the deployment mechanism 26 is a mechanical device for both *holding* and *causing the expansion* of the valve 30. Indeed, the description of Fig. 3A states "FIG. 3A is a longitudinal sectional view through a portion of the **distal end of the delivery and deployment system of FIG. 1 illustrating part of a mechanism for controlling the expansion**

of a heart valve, which is shown in its contracted configuration." (Yang '646, col. 4, ll. 47-51.) (Emphasis added.)

Applicants further reference Fig. 7A. Yang '646 states that "FIGS. 7A-7F are perspective views showing a number of steps in the delivery and deployment of an expandable heart valve using the system of FIG. 4." (Yang '646, col. 5, ll. 1-3.) Fig. 7A is reproduced below.

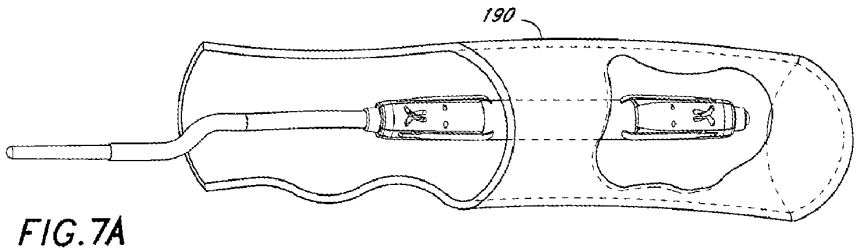


FIG. 7A

When viewing Fig. 7A, it can be seen that the deployment mechanism resides within vessel 190 *without* use of a sheath to restrain the valve. This is contrary to the limitation of Claim 34 of the present application, which recites, in part, that "the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath." Accordingly, neither the embodiment shown in Fig. 1 nor the embodiment shown in Figs. 4 and 7A of Yang '646 use a moveable sheath to restrain the prosthetic heart valve in a collapsed configuration.

Based on the foregoing, the Examiner is requested to withdraw the 35 U.S.C. § 103(a) rejection of Claims 34-38 as being unpatentable over Yang '525 in view of Yang '646 and further in view of Gabbay.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds a remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

A Request for Continued Examination and a 3-month extension are submitted herewith along with the associated fees. Applicants believe no additional fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

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Dated: May 7, 2015

Electronic Patent Application Fee Transmittal

Application Number:	14253650
Filing Date:	15-Apr-2014
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Filer:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	2253	1	700	700
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
		Total in USD ($)		**1300**

Electronic Acknowledgement Receipt	
EFS ID:	22281169
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	07-MAY-2015
Filing Date:	15-APR-2014
Time Stamp:	18:11:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1300
RAM confirmation Number	4275
Deposit Account	501943
Authorized User	YASKANIN, MARK L.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	Colibri_10104_Extension_2015-05-07.PDF	154424 0a121865ee9d08f32b2061d4f0685039e5cd568d	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	Colibri_10104_RCE_2015-05-07.PDF	116796 184a29617eed6cfadb3355c4de191a65c0ec7c70	no	1
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2015-05-07.PDF	744536 433399b3c0c1ebff850dad3448be57723b5ec0df	no	4
Warnings:					
Information:					
4	Non Patent Literature	10100_US_10-887688_Declaration_of_Inventors_2008-12-15.pdf	1899083 359d55c2c06023369ab2c36187e7f03b2a9d5982	no	46
Warnings:					
Information:					
5	Non Patent Literature	10106_Office_Action_App_14-502453_2014-12-05.PDF	355935 7619eb689048f7c7147d8b4d3ca70dab4e83dd23	no	9
Warnings:					
Information:					
6		Colibri_10104_Final_OA_Reply_2015-05-07.PDF	921118 3a8d23275d9651414604c0f788e0d0979f4bcc05	yes	18

Multipart Description/PDF files in .zip description

Document Description	Start	End
Response After Final Action	1	1
Claims	2	3

	Applicant Arguments/Remarks Made in an Amendment		4	18	
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	32535 5fd928f93693f04067ca0824fa3a334f8ec1bf6f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4224427		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/22 (03-13)
Approved for use through 7/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 109978.10104
Application Number 14/253,650	Filed 2014-04-15
For Percutaneously Bioprosthetic Heart Valve and a Delivery and Implantation System	
Art Unit 3738	Examiner Cheryl L. MILLER

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	Micro Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐	Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑	Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700
☐	Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐	Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-1943.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45,246.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/ Mark L. Yaskanin / — Signature

7 May 2015 — Date

Mark L. Yaskanin — Typed or printed name

303.446.3852 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	14/253,650
Filing Date	2015-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☑ Other Request for Extension of Time

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-1943.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☑ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/ Mark L. Yaskanin /	Date	7 May 2015
Name (Print/Type)	Mark L. Yaskanin	Registration No.	45,246

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature			
Name (Print/Type)		Date	

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/253,650	Filing Date 04/15/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 05/07/2015

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 5	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/Ruby Johnson/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5554184		1996-09-10	Machiraju	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020052651		2002-05-02	Myers et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	9-501594	JP		1997-02-18		Equivalent to WO/1995/005207	☐
	2	2001-500761	JP		2001-01-23		Equivalent to WO/1998/011935	☐
	3	2005-103321	JP		2005-04-21		Equivalent to EP0696447	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	4	2009/149462	WO		2009-12-10	Edwards Lifesciences Corporation		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Final Office Action issued May 8, 2015 in U.S. Application No. 14/502,453 (109978.10106)	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-06-11
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	22603655
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	11-JUN-2015
Filing Date:	15-APR-2014
Time Stamp:	14:47:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2015-06-11.PDF	650688 6232b4feacc017f9fc2a0a3556537d15dd044807	no	4
Warnings:					
Information:					

2	Foreign Reference	WO-1995-005207.PDF	1830719 8d8439b132e183e99b8eda6fd6531f7684b0a3a4	no	41
Warnings:					
Information:					
3	Foreign Reference	WO-1998-011935.PDF	1276360 d4659ecbc9a09de2a741cfbbcb9be6362273c67d	no	31
Warnings:					
Information:					
4	Foreign Reference	EP0696447.PDF	1289143 204e7402d972b324e6b9aa99c82edefdae4bfc93	no	32
Warnings:					
Information:					
5	Foreign Reference	WO-2009-149462.PDF	1394005 4d484e54c510d8718b3cce46f5897bbedccd6466	no	40
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
6	Non Patent Literature	10106_US_14-502453_Final_Office_Action_2015-05-08.PDF	358607 844085e2edd2b6b6f5b143d67cd866c8be0b4695	no	9
Warnings:					
Information:					
		Total Files Size (in bytes):	6799522		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

29880 7590 07/16/2015

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/16/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

TITLE OF INVENTION: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	10/16/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

29880 7590 07/16/2015
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
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LAWRENCEVILLE, NJ 08648

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

TITLE OF INVENTION: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	10/16/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MILLER, CHERYL L	3738	623-001260

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 07/16/2015

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/16/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/253,650	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *5/7/2015*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *34-38*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/C. M./	/THOMAS J SWEET/
Examiner, Art Unit 3738	Supervisory Patent Examiner, Art Unit 3738

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Yaskanin (Reg. No. 45,246) on July 1, 2015. The amendment was agreed upon in order to overcome potential indefiniteness as well as more clearly overcome the previous Bailey rejection, and place the application in condition for allowance.

The application has been amended as follows:

Claim 1, lines 10-12 have been amended as such:

pericardial tissue, wherein the valve means ~~and all fixed pericardial tissue~~ resides entirely within the inner channel of the stent member, ~~wherein the valve means is attached closer to a proximal and wider part of the stent member~~ and wherein no reinforcing members reside within the inner channel of the stent member;

Claim 1, lines 19-21 have been amended as such:

within the inner channel of the stent member ~~when the stent member is collapsed onto the pusher~~

~~member and further resides entirely within the inner channel of the stent member when the stent~~

~~member is unrestrained from the moveable sheath~~ in said collapsed configuration and is configured

to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./
Examiner, Art Unit 3738
/THOMAS J SWEET/
Supervisory Patent Examiner, Art Unit 3738

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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BIB DATA SHEET

CONFIRMATION NO. 5427

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/253,650	04/15/2014	623	3738	109978.10104

APPLICANTS
Colibri Heart Valve LLC, Broomfield, CO;

INVENTORS
David PANIAGUA, Houston, TX;
R. David FISH, Houston, TX;

**** CONTINUING DATA ***************************
This application is a CON of 13/675,665 11/13/2012
which is a CON of 10/887,688 07/10/2004 PAT 8308797
which is a CIP of 10/037,266 01/04/2002 ABN

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/01/2014

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /CHERYL L MILLER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		TX	12	5	1

ADDRESS
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648
UNITED STATES

TITLE
PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

FILING FEE RECEIVED		
800	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1973	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
S2	410	S1 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
S3	430	S1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S4	674	S2 S3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S5	8	"09/973,609"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:17
S6	275	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN. OR ("5397351").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:42
S7	11	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
S8	9	("3626518" | "3691567" | "3868956" | "3911502" | "4030142" | "4503569" | "4759758" | "4994077").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
S9	2	("4038703" | "4106129").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:45
S10	0	"a61f2002.""3601".cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S11	0	a61f2002/3601.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S12	4	"4759758".pn. or "5935163".pn. or "5861028".pn. or "5855602".pn.	US-PGPUB; USPAT;	OR	ON	2014/11/02 15:29

			USOCR			
S13	4	S12 and pericardium	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 15:29
S14	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S15	416	S14 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S16	430	S14 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S17	680	S15 S16	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S18	199	S17 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:26
S19	1	"6579307".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:34
S20	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S21	416	S20 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S22	430	S20 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S23	680	S21 S22	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S24	279	S23 and (valve with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S25	199	S23 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S26	85	S24 not S25	US-PGPUB;	OR	ON	2014/11/02 20:44

			USPAT; USOCR			
S27	364	S23 and (pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:59
S28	85	S27 not S24	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S29	80	S28 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S30	1	"6676698".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:32
S31	1	"6652578".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 10:38
S32	1	"7556646".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 13:32
S33	1	"6733525".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 14:12
S34	1	bessler.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 13:59
S35	2	"6197143".pn. or "20030060875".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:53
S36	2	"20020052651".pn. or "5554184".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:55
S37	1	"20030209835".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:57
S38	19	"10/037,266"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:10
S39	2463	A61F2/2412.cpc. or A61F2/2436.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S40	264	A61F2/2412.cpc. and A61F2/2436.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09

S41	46	S40 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S42	11	S40 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S43	54	S41 S42	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S44	1424	S39 and pericardi$3	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:11
S45	261	S44 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S46	180	S44 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S47	361	S45 S46	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S48	348	S47 not S43	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S49	172	S48 and (taper$4 or flar$3 or conical)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5554184		1996-09-10	Machiraju	

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	1	20020052651		2002-05-02	Myers et al.	

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	1	9-501594	JP		1997-02-18		Equivalent to WO/1995/005207	☐
	2	2001-500761	JP		2001-01-23		Equivalent to WO/1998/011935	☐
	3	2005-103321	JP		2005-04-21		Equivalent to EP0696447	☐

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Receipt date: 06/11/2015	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	4	2009/149462	WO		2009-12-10	Edwards Lifesciences Corporation		☐

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	1	Final Office Action issued May 8, 2015 in U.S. Application No. 14/502,453 (109978.10106)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	06/30/2015

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Receipt date: 06/11/2015	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

CERTIFICATION STATEMENT

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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-06-11
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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/Cheryl Miller/ 06/30/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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	1	20030209835		2003-11-13	Chun et al.	
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Receipt date: 05/07/2015	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Office Action issued December 5, 2014 in U.S. Application No. 14/502,453 (109978.10106)	☐
	2	Declaration Under 37 CFR 1.131 as filed in U.S. Patent Application No. 10/887,688 on December 15, 2008, by co-inventors of that application. (Best available copy)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	06/30/2015

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Receipt date: 05/07/2015	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-05-07
Name/Print	Mark L. Yaskanin	Registration Number	45246

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
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	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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Receipt date: 11/20/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

	1	Cross-reference is made to U.S. Application No. 14/502,453 filed on September 30, 2014, and its associated Preliminary Amendment (109978.10106)	☐

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-11-20
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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/Cheryl Miller/ 06/30/2015

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/2412, 2436	6/30/2015	cm

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	1.24, 1.26, 2.12-2.19	6/2/2014	cm
update		11/1/2014	cm

SEARCH NOTES		
Search Notes	Date	Examiner
East text search	11/2/2014	cm
East text search	6/30/2015	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61F2	2412	6/30/2015	cm

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-05-23
Name/Print	Mark L. Yaskanin	Registration Number	45246

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Symbol					**Type**	**Version**
A61F		2	/	2412	F	2013-01-01
A61F		2002	/	9534	A	2013-01-01
A61F		2	/	2439	A	2013-01-01
Y10T		29	/	49412	A	2015-01-15
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/C.M./ Examiner.Art Unit 3738	06/30/2015	**Total Claims Allowed:**	
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/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738	07/07/2015	O.G. Print Claim(s)	O.G. Print Figure
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

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997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
07/28/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	14/253,650	PANIAGUA ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) *CHERYL MILLER (Examiner)*. (3)_____.

(2) *Mark Yaskanin (Reg.No.45,246)*. (4)_____.

Date of Interview: *16 July 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1/34*.

Identification of prior art discussed: *n/a*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Attorney for Applicant contacted Examiner to bring to attention a typographic error in the examiners amendment in notice of allowance dated July 16, 2015. The examiners amendment makes changes to "claim 1". This is a typographical error, and the examiners amendment should have referenced independent claim 34. It is noted that the examiners amendment to claim 1 is intended to refer to claim 34, which has been renumbered as claim 1 upon issue.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHERYL MILLER/ Examiner, Art Unit 3738	/THOMAS J SWEET/ Supervisory Patent Examiner, Art Unit 3738

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/253,650	04/15/2014	3738	800	109978.10104	5	1

CONFIRMATION NO. 5427

CORRECTED FILING RECEIPT

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

OC000000078320723

Date Mailed: 07/28/2015

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

David PANIAGUA, Houston, TX;
R. David FISH, Houston, TX;

Applicant(s)

Colibri Heart Valve LLC, Broomfield, CO;

Assignment For Published Patent Application

Colibri Heart Valve LLC, Broomfield, CO

Power of Attorney: The patent practitioners associated with Customer Number 29880

Domestic Priority data as claimed by applicant

This application is a CON of 13/675,665 11/13/2012
which is a CON of 10/887,688 07/10/2004 PAT 8308797
which is a CIP of 10/037,266 01/04/2002 ABN

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 05/01/2014
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/253,650**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

Preliminary Class

623

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

29880 7590 07/16/2015
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

TITLE OF INVENTION: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	10/16/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MILLER, CHERYL L	3738	623-001260

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 FOX ROTHSCHILD LLP
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: COLIBRI HEART VALVE LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Broomfield, Colorado

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ☒ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-1943 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Mark L. Yaskanin/ Date 29 July 2015
Typed or printed name Mark L. Yaskanin Registration No. 45,246

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	14253650
Filing Date:	15-Apr-2014
Title of Invention:	PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Filer:	Mark Lauren Yaskanin/Carol Donahue
Attorney Docket Number:	109978.10104

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**480**

Electronic Acknowledgement Receipt	
EFS ID:	23057469
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104
Receipt Date:	29-JUL-2015
Filing Date:	15-APR-2014
Time Stamp:	14:14:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$480
RAM confirmation Number	371
Deposit Account	501943
Authorized User	YASKANIN, MARK L.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	Colibri_10104_Statement_Re_Interview_Summary_2015-07-29.PDF	94490 0eaeb412c27dffd8efbc380d089dd074d6ed9f40	no	2
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	Colibri_10104_Issue_Fee_Transmittal_2015-07-29.PDF	87492 3a7a74d001a82e25751912834785dd61a4437baf	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30569 6344efc6750064c9c577d657f5b194fc99297743	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	212551		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:		)	Group Art Unit: 3738
	PANIAGUA et al.	)	Examiner: Cheryl L. MILLER
Application No.:	14/253,650	)	Confirmation No.: 5427
Filed:	April 15, 2014	)	**STATEMENT OF THE SUBSTANCE OF EXAMINER'S INTERVIEW**
Atty. File No.:	109978.10104	)	
For: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM		)	**(FILED ELECTRONICALLY)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 29 July 2015.
Typed or printed name of person signing this certificate: Carol Donahue
Signature: /Carol Donahue/

Dear Madam:

Applicants' Attorney confirms that Applicants' Attorney called Examiner Cheryl Miller on July 16, 2015 to notify the Examiner that the Examiner's Amendment in the matter of U.S. Pat. App. No. 14/253,650 contained a typographic error as described in the Applicant-Initiated Interview Summary. Applicants' Attorney agrees with the content of the interview of July 16, 2015 as set forth and described in the Applicant-Initiated Interview Summary dated July 28, 2015.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/ Mark L. Yaskanin /

Mark L. Yaskanin
Registration No. 45,246
Customer No. 29880
Phone: (303) 446-3852
Facsimile: (303) 292-1300

Dated: July 29, 2015

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
Change(s) applied to document,	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

/J.E.B./
7/30/2015

	20	4055861		1977-11-01	Carpentier et al.	
	21	4056854		1977-11-08	Boretos et al.	
	22	4060081		1977-11-29	Yannas et al.	
	23	4082507		1978-04-04	Sawyer	
	24	4084268		1978-04-18	Ionescu et al.	
	25	4106129		1978-08-15	Carpentier et al.	
	26	4164045		1979-08-14	Bokros et al.	
	27	4172295		1979-10-30	Batten	
	28	4218782		1980-08-26	Rygg	
	29	4222126		~~1978-09-16~~	Boretos et al.	September 16, 1980
	30	4233493		1980-11-11	Nath et al.	

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
Change(s) applied	Art Unit	3738	
to document,	Examiner Name	Not assigned yet	
/J.E.B./	Attorney Docket Number	109978.10104	
7/30/2015			

	86	5411552		1995-05-02	Andersen et al.	
	87	5413601		1995-05-09	Keshelava	
	88	5449384		1995-09-12	Johnson	
	89	5476506		1995-12-19	Lunn	
	90	5480424		1996-01-02	Cox	
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Application Number	14253650 14253650 - GAU: 3738
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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