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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
61/723,446	11/07/2012	Ali Shahriari	58330-221639

CONFIRMATION NO. 5732

115007
NK Patent Law
4917 Waters Edge Drive
Suite 275
Raleigh, NC 27606

POA ACCEPTANCE LETTER

OC000000066548416

Date Mailed: 02/25/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/07/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/hchristian/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Edwards v. Aortic Innovations
U.S. Patent 11,337,834
Edwards Ex. 1006

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
61/723,446	11/07/2012		125	426/2 PROV		

CONFIRMATION NO. 5732

REPLACEMENT FILING RECEIPT

115007
NK Patent Law
4917 Waters Edge Drive
Suite 275
Raleigh, NC 27606

OC000000066548465

Date Mailed: 02/25/2014

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. 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)

Ali Shahriari, Indianapolis, IN;

Applicant(s)

Aortic Innovations, LLC, Boca Raton, FL

Power of Attorney: The patent practitioners associated with Customer Number 115007

If Required, Foreign Filing License Granted: 11/27/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/723,446**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

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

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).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

POWER OF ATTORNEY FOR PATENT APPLICATIONS

Under 37 CFR § 3.73(b) and/or (c), Aortic Innovations, LLC, hereby certifies that it is the Assignee of the entire right, title, and interest in and to the patent applications listed below. Each of the patent applications listed below is assigned to Aortic Innovations, LLC. As required by 37 CFR § 3.73(b)(1)(i) and/or (c)(1)(i), the documentary evidence of the chain of title from the original owner to the Assignee was submitted for recordation pursuant to 37 § CFR 3.11 as shown in the Reel/Frame numbers listed below.

Title	Serial No.	Filing Date	Assignment	Date
Transcathetor Arotic Valve for Endovascular Aortic Repair	61/723,446	11/7/2012	029574/0731	1/7/2013
Transcathetor Aortic Valve for Endovascular Aortic Repair	61/567,458	12/6/2011	029005/0233	9/19/2012
Branched Aortic Graft and Method of Using the Same	61/777,918	3/12/2013	030346/0253	5/3/2013
Device for Endovascular Aortic Repair and Method of Using the Same	13/706,896	12/6/2012	032145/0696	2/5/2014
Device for Endovascular Aortic Repair and Method of Using the Same	US2012/068165	12/6/2012	029574/0887	1/7/2013
Transcatheral Mitral Valve and Delivery System	61/780,242	3/13/2013	030346/0233	5/3/2013
Device for Transcatheter Mitral Valve Repair and Replacement	61/817,118	4/29/2013	032145/0696	2/5/2014

The undersigned, acting as the Assignee, hereby revokes all prior powers of attorney, if applicable, and appoints the practitioners associated with the customer number 115007 as my/our attorney(s) or agent(s) to prosecute the patent(s) and/or patent application(s) and transact all business in the United States Patent and Trademark Office connected therewith.

By: _____ Date: 2/4/14

Ali Shahriari, Owner

Aortic Innovations, LLC

1

Electronic Acknowledgement Receipt

EFS ID:	18141375
Application Number:	61723446
International Application Number:	
Confirmation Number:	5732
Title of Invention:	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	23643
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	58330-221639
Receipt Date:	07-FEB-2014
Filing Date:	07-NOV-2012
Time Stamp:	09:51:07
Application Type:	Provisional

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	Application Data Sheet	426-2replacementADS.pdf	131324 73c905f5db45fc3fa9419096a6569712d4f10694	no	7

Warnings:	
Information:	

This is not an USPTO supplied ADS fillable form					
2	Power of Attorney	AorticInnovationsPOAexecuted.pdf	279772 415c50a1001cae2102c68cea76c5bde165dc3599	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	411096	

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

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2 PROV
	Application Number	61/723,446
Title of Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR	

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
	Ali		Shahriari	

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

City	Boca Raton	State/Province	FL	Country of Residence	US

Mailing Address of Inventor:

Address 1	839 Enfield Street		
Address 2			
City	Boca Raton	State/Province	FL
Postal Code	33487	Country	US

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.**

Customer Number	115007		
Email Address	jrnifong@nkpatentlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR		
Attorney Docket Number	426/2 PROV	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Filing By Reference :

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2 PROV
	Application Number	
Title of Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR	

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	115007		

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			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2 PROV
	Application Number	
Title of Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR	

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.

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

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
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2 PROV
	Application Number	
Title of Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR	

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 o f 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.

Applicant 1

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	Aortic Innovations, LLC

Mailing Address Information For Applicant:

Address 1	839 Enfield Street		
Address 2			
City	Boca Raton	**State/Province**	FL
Country	US	Postal Code	
Phone Number		Fax Number	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2 PROV
	Application Number	
Title of Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR	

Email Address	

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

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.

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

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.

Signature:

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

Signature	/Justin R. Nifong/			Date (YYYY-MM-DD)	2014-02-07
First Name	Justin	Last Name	Nifong	Registration Number	59389

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2 PROV
	Application Number	
Title of Invention	TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR	

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.

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 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 C o o p eration 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
61/723,446	11/07/2012	Ali Shahriari	58330-221639

CONFIRMATION NO. 5732

23643
BARNES & THORNBURG LLP
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

POA ACCEPTANCE LETTER

OC00000058138734

Date Mailed: 12/18/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/05/2012.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/atesfai/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/AIA/122 (08-12)
Approved for use through 11/30/2014. OMB 0651-0035
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CHANGE OF CORRESPONDENCE ADDRESS
Application

Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	61/723,446
Filing Date	November 7, 2012
First Named Inventor	Ali Shahriari
Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	58330-221639

Please change the Correspondence Address for the above-identified patent application to:

☒ The address associated with Customer Number: **23643**

OR

☐ Firm or Individual Name

Address

City	State	Zip

Country

Telephone	Email

This form cannot be used to change the data associated with a Customer Number. To change the data associated with an existing Customer Number use "Request for Customer Number Data Change" (PTO/SB/124).

I am the:

☐ Applicant

☒ Attorney or agent of record. Registration Number 63696.

☐ Registered practitioner named in the application transmittal papers who acts in a representative capacity under 37 CFR 1.34. See 37 CFR 1.33(a)(1). Registration Number _____.

Signature /Jeffrey T.G. Kelsey/

Typed or Printed Name Jeffrey T.G. Kelsey

Date	Telephone
December 5, 2012	317-231-6412

NOTE: This form must be signed in accordnace 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, see below*.

☐ *Total of _____forms are submitted.

This collection of information is required by 37 CFR 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.

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/80 (07-12)
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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: 23643

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:

OR

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

Assignee Name and Address: Aortic Innovations LLC
9221 Anchor Mark Drive
Indianapolis, IN 46236 US

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	A Shah	Date	12/5/12
Name	Ali Shahriari	Telephone	(617) 839 8525
Title	CEO Aortic Innovations LLC.		

This collection of information is required by 37 CFR 1.31, 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.

Electronic Acknowledgement Receipt

EFS ID:	14392616
Application Number:	61723446
International Application Number:	
Confirmation Number:	5732
Title of Invention:	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	23634
Filer:	Jeffrey T.G. Kelsey
Filer Authorized By:	
Attorney Docket Number:	58330-221639
Receipt Date:	05-DEC-2012
Filing Date:	07-NOV-2012
Time Stamp:	16:48:36
Application Type:	Provisional

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	Assignee showing of ownership per 37 CFR 3.73.	Combined373c_Assignment.pdf	314763 7c0783ba6127f75c86647e8cfd19faf97649242e	no	5

Warnings:	
Information:	

2	Change of Address	ChangeCorrAddress.pdf	256215 b278049602f78b05e73a5147fea64eef875a7b65	no	2
Warnings:					
Information:					
3	Power of Attorney	PowerOfAttorney.pdf	82505 27d3b0c9f1ecc95bb1411ddbce31bf9b4a661c0e	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	653483	

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/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Ali Shahriari

Application No./Patent No.: 61/723,446 Filed/Issue Date: November 7, 2012

Titled: TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

Aortic Innovations 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: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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 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/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, 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.

/Jeffrey T.G. Kelsey/	December 5, 2012
Signature	Date
Jeffrey T.G. Kelsey	Attorney of Record
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

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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 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.

ASSIGNMENT TO BUSINESS CONCERN

Attorney Docket No.: 58330-221639
Client Reference No.: 58330-221639

PATENT ASSIGNMENT

For good and valuable consideration, the sufficiency of which is acknowledged, the undersigned,

Name(s) of Inventor(s): Ali SHAHRIARI

maker(s) of an invention which is the subject of an application for Letters Patent of the United States ("Application") entitled

Title of Application: TRANSCATHETOR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

Serial No.: 61/723,446
Filing Date: November 7, 2012

the undersigned hereby sell(s), assign(s), and set(s) over to

Name of Assignee: Aortic Innovations LLC

Address of principal place of business: 9221 Anchor Mark Drive
Indianapolis, IN 46236

Insert State of Incorporation (if applicable) or "Not Applicable"

a corporation of Indiana

(hereinafter designated as the Assignee) their entire right, title, and interest in, to, and under the Application, including all priority rights for other countries arising therefrom, all inventions therein disclosed, and any and all Letters Patent of the United States and of all other countries, including Canada, which may be granted for such inventions, or any of them, all such inventions and all rights in such Application and Letters Patent to be held and enjoyed by Assignee for its own use and enjoyment to the full end of the term or terms for which such Letters Patent may be granted, as fully and entirely as the same would have been held and enjoyed by them had this assignment and sale not been made.

The undersigned agree(s) to execute all papers necessary in connection with the application(s) in the United States and foreign countries and any continuing, divisional, or reissue applications thereof, and any reexamination of any of such applications, and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

The undersigned agree(s) to execute all papers necessary in connection with any interference which may be declared or litigation concerning the application(s) or continuation, division, reissue, or reexamination thereof, and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such interference or litigation.

The undersigned agree(s) to execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.

ASSIGNMENT TO BUSINESS CONCERN

Attorney Docket No.: 58330-221639
Client Reference No.: 58330-221639

The undersigned agree(s) to do all other acts which, in the opinion of Assignee, may be necessary or desirable to secure the grant of Letters Patent to Assignee or its nominees, in the United States and in all other countries where Assignee may desire to have such inventions, or any of them, patented, with specifications and claims in such form as shall be approved by Assignee and to vest and confirm in Assignee or its nominees the full and complete legal and equitable title to all such Letters Patent.

The undersigned hereby authorize(s) and request(s) the Commissioner of Patents to issue any and all Letters Patent of the United States resulting from said application(s) or any division or divisions or continuing or reissue applications thereof, and any reexamination of any of such applications, to the said Assignee, as Assignee of the entire interest, and hereby covenants that the undersigned has full right to convey the interest herein assigned, and that the undersigned has not executed, and will not execute, any agreement in conflict herewith.

The undersigned hereby grant(s) the attorney of record the power to insert on this assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

IN WITNESS WHEREOF, I have executed this assignment at Indianapolis, In
(city and state or country if outside USA)

this 5TH day of December, 2012.

Outside the USA: Witnesses are required when acknowledgment before a Notary Public is not feasible.

_____
Witness

_____
Witness

_____
Inventor (Signature)

Ali SHAHRIARI
Inventor (Printed Name)

ACKNOWLEDGMENT

STATE OF Indiana }
} SS:
COUNTY OF Marion }

Acknowledged before me, a Notary Public, within and for said County and State. Witness my hand and Notarial Seal this 5TH day of December, 2012.

_____
Notary Public

Kelly Frakes
Printed Name

My Commission Expires: 9-15-13

Resident of Hancock County

INDS02 1249220v1

-2-

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
61/723,446	11/07/2012		125	58330-221639		

CONFIRMATION NO. 5732

23634
OXY SERVICES, INC
5005 LBJ FREEWAY
DALLAS, TX 75244

FILING RECEIPT

OC000000057830049

Date Mailed: 11/28/2012

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. 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)

Ali Shahriari, Indianapolis, IN;

Applicant(s)

Ali Shahriari, Indianapolis, IN;

Power of Attorney:
Jeffrey Kelsey--63696

If Required, Foreign Filing License Granted: 11/27/2012
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/723,446**
Projected Publication Date: None, application is not eligible for pre-grant publication
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

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 (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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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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Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1 Remove

Given Name	Middle Name	Family Name	City	State	Country
Ali		Shahriari	Indianapolis	IN	US

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

Title of Invention	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
Attorney Docket Number (if applicable)	58330-221639

Correspondence Address

Direct all correspondence to (select one):

(•) The address corresponding to Customer Number	( ) Firm or Individual Name
Customer Number	23634

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

(•) No.

( ) Yes, the name of the U.S. Government agency and the Government contract number are:

Doc Code: **TR.PROV**
Document Description: Provisional Cover Sheet (SB16)

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Entity Status

Applicant claims small entity status under 37 CFR 1.27

(•) Yes, applicant qualifies for small entity status under 37 CFR 1.27

( ) No

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Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey T.G. Kelsey/			Date (YYYY-MM-DD)	2012-11-07
First Name	Jeffrey	Last Name	Kelsey	Registration Number (If appropriate)	63696

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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.
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TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Cross-reference is made to co-pending U.S. Provisional Patent Application Serial No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair," which was filed by Ali Shahriari on December 6, 2011 and is expressly incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure relates to a device and method of using same for repair of aortic valve disease, aortic stenosis, ascending aortic aneurysms, aortic insufficiency, aortic regurgitation, ascending aneurysm, bicuspid valve disease, and/or Type A dissections.

BACKGROUND

[0003] The normal aortic root and the ascending aorta are composed of 1) the aortic annulus, 2) sinuses of Valsalva, 3) sinutubular junction, and 4) tubular portion. The challenge facing practitioners of endovascular repair of ascending aortic aneurysms is that there is a very short proximal landing zone at the level of the sinutubular junction, there is variable coronary anatomy from patient to patient, and, in many cases, there is involvement of the aortic

valve with either stenosis or insufficiency. Generally speaking, and as discussed in the article SURGERY INSIGHT: THE DILATED ASCENDING AORTA — INDICATIONS FOR SURGICAL INTERVENTION, by James E. Davies and Thralf M. Sundt published in Nature Clinical Practice Cardiovascular Medicine (2007), the contents of which are incorporated by reference in its entirety, there are three basic types of involvement of the ascending aorta, designated as Type A, B, or C. These will be discussed in further detail below and are shown in FIGS. 1A-1C, which have been reproduced from the referenced article.

[0004] Type A aneurysms are most commonly found in younger patients and patients with connective tissue disorders such as Marfan syndrome. The anatomical characteristics of Type A aneurysms are dilatation of the sinuses of Valsalva with or without dilatation of the aortic annulus. The sinutubular junction is most often dilated. The valve could be normal, stenotic or insufficient. An example of a Type A aneurysm is shown in FIG. 1A.

[0005] The anatomical characteristics of Type B aneurysms are dilatation of the tubular portion. Initially the sinutubular junction may be normal or mildly dilated, however as the aneurysm grows, it stretches the sinutubular junction and may eventually lead to aortic insufficiency. The valve could be normal, stenotic or insufficient. The bulk of the aneurysm is at the level of the tubular aorta. An example of a Type B aneurysm is shown in FIG. lB.

[0006] The anatomical characteristics of Type C aneurysms are dilatation of the sinuses of Valsalva, sinutubular junction and the tubular portion of the aorta. The valve could be normal, stenotic or insufficient. Type B and C aneurysms are most commonly found in an older group of patients. An example of a Type C aneurysm is shown in FIG. 1C.

[0007] Currently there are devices clinically used for endovascular repair of ascending aortic aneurysms. Although transcatheter valves are a clinical reality today, none in clinical use have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms. Indeed, a device is needed that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

[0009] FIG. 1A is an example of a Type A aneurysm;

[0010] FIG. 1B is an example of a Type B aneurysm;

[0011] FIG. 1C is an example of a Type C aneurysm;

[0012] FIG. 2 is a side elevation view of an exemplary transcatheter valve including a dual-frame component and a valve component;

[0013] FIG 3 is a side elevation view of a self-expanding outer frame of the dual-frame component of FIG. 2;

[0014] FIG. 4 is a side elevation view of a balloon-expandable inner frame of the dual-frame component and the valve component of FIG. 2;

[0015] FIG. 5 is a perspective view of the transcatheter valve of FIG. 2;

[0016] FIG. 6 is a cross-sectional elevation view of the balloon-expandable inner frame of the dual-frame component and the valve component of FIG. 2;

[0017] FIG. 7 is a plan view of the transcatheter valve device of FIG. 2 showing the inner frame unexpanded;

[0018] FIG. 8 is a view similar to FIG. 7 showing the inner frame expanded;

[0019] FIG. 9 is a view of the transcatheter valve device of FIG. 2 positioned in the aorta with the balloon-expandable inner frame unexpanded; and

[0020] FIG. 10 is a view of the transcatheter valve device of FIG. 2 positioned in the aorta with the balloon-expandable inner frame expanded.

DETAILED DESCRIPTION OF THE DRAWINGS

[0021] Referring now to FIGS. 2-10, a transcatheter valve device (hereinafter device 10) is shown. The device 10 includes a dual-frame component 14 and a valve component 12 secured to the dual-frame component 14. The dual-frame component 14 includes a self-expanding outer frame 16 and a balloon-expandable inner frame 18 that is secured to the self-expanding outer frame 16. The device 10 may be deployed via a transfemoral or trans-axillary route, as will be described in greater detail below.

[0022] As shown in FIG. 3, the self-expanding outer frame 16 is configured in an open-cell arrangement. The frame 16 is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. The self-expanding outer frame 16 is formed as a single, integral structure. However, the frame 16 may also be formed as separate pieces that are later assembled. The self-expanding frame 16 may be completely or partially covered by polyester, ePTFE or other nonporous covering material.

[0023] In the illustrative embodiment, the outer frame 16 includes an uncovered tubular stent 20 that has a height of approximately 15 mm and a diameter of approximately 32 mm. The height and diameter of the frame 16 may also vary according to the anatomy of the patient. It should be appreciated that in other embodiments the stent 20 may be covered and may have different dimensions to accommodate configuration of a particular patient's aorta. The stent 20 defines a passageway 22 in the outer frame 16.

[0024] In the illustrative embodiment, collagen fibers 24 are attached to the stent 20 to aid in preventing paravalvular leaks and migration of the transcatheter valve device 10 within the aortic walls. The fibers 24 extend outwardly from the stent 20 and inwardly into the passageway 22. It should be appreciated that in other embodiments the outer frame 16 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the stent 20. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

[0025] In the illustrative embodiment, the outer frame 16 has a generally hourglass shape. The outer frame 16 includes a lower inwardly tapered section 26, an upper outwardly tapered section 28 and an elongated section 30. In one particular, non-limiting example, the inwardly tapered section 26 is constructed to be approximately 10 mm in length, and the diameter tapers from a proximal end of section 26 from approximately 32 mm to approximately 22 mm at a distal end of section 26. The inwardly tapered section 26 may be covered or uncovered depending on the indication for which the device 10 will be used. In the illustrative embodiment, the inwardly tapered section 26 of the outer frame 16 is uncovered.

[0026] The upper outwardly tapered section 28 of the outer frame 16 is constructed to be approximately 10 mm in length, and tapers outwardly from proximal end of section 26 to a distal end. More specifically, in one particular

non-limiting example, outwardly tapered section 28 expands from a diameter of approximately 22 mm to a diameter of approximately 34 mm. As shown in the illustrative embodiment, the outwardly tapered section 28 is covered.

[0027] The outwardly tapered section 28 mates with the elongated section 30. The elongated section 30 is configured with a length that is greater than the length of the tapered sections 26, 28. In one particular non-limiting example, the length of the elongated section 30 is approximately 30 mm and has a diameter of approximately 34 mm. As shown in the illustrative embodiment, the elongated section 30 is covered.

[0028] A portion of the outer frame 16, including portions of the sections 26, 28, 30, may be uncovered or covered with polyester, ePTFE or other appropriate material. In the illustrative embodiment, approximately 30 mm to approximately 40 mm of the distal portion of the outer frame 16 is covered.

[0029] As described above, the device 10 also includes a balloon-expandable inner frame 18 that is secured to the outer frame 16. Referring now to FIG. 4, the inner frame 18 includes a tubular stent 32 that has with a length of approximately 15mm and an expanded diameter of 26 mm. In the illustrative embodiment, the tubular stent 32 is constructed of a metallic material in an open-cell fashion. It should be appreciated that in other embodiments the tubular stent 32 may be formed from a polymeric material. In the illustrative embodiment, the tubular stent 32 is covered with low-profile polyester.

However, it should be appreciated that the tubular stent 32 may be covered with standard polyester, ePTFE or other nonporous materials.

[0030] As described above, the device 10 also includes a valve component 12 that is secured to the inner frame 18. In the illustrative embodiment, the valve component 12 is bicuspid, but may be tricuspid, and may be configured from treated bovine pericardium or other suitable proven biological or synthetic material.

[0031] Referring now to FIG. 5, the inner frame 18 of the dual-frame component 14 is secured to the outer frame 16 via a plurality of stitches 34. It should be appreciated that in other embodiments soldering, welding or other fasteners may be used to secure the inner frame 18 to the outer frame 16. As shown in FIGS. 5-8, the inner frame 18 and the valve component 12 are positioned in a passageway 22 defined in the self-expanding frame 16. When the inner frame 18 is unexpanded, the outer surface 36 of the tubular stent 32 is spaced apart from the fibers 24 attached to the outer frame 16. In the illustrative embodiment, a gap 40 is defined therebetween, and the gap 40 has a magnitude of about 2 mm to about 3 mm.

[0032] As shown in FIG. 8, the balloon-expandable inner frame 18 may be expanded in the direction indicated by arrows 44. In that way, the outer surface 36 of the stent 32 engages the fibers 24 (and hence the stent 20 of the outer frame 16) and the gap 40 is closed. The fibers 24 create a seal between the inner frame 18 and the outer frame 16.

[0033] The delivery of the transcatheter valve device 10 may begin by gaining access to the left ventricle across the native aortic valve. An ascending aortogram may be performed to locate the right and left coronary arteries. An over the wire introducer system, including a guidewire, is used to introduce the device 10 into the aorta. After the guidewire has been placed into the left ventricle via the iliofemoral, subclavian, or carotid vessels, the device 10 is delivered through the common femoral artery and passed across the native aortic valve. After performing an angiogram to delineate the location of the coronary arteries, the self-expanding outer frame 16 is deployed, thereby stabilizing the device 10 in place (see FIGS. 9 and 10). The inwardly tapered portion 26 of the self-expanding frame 16 may then be positioned across the origins of the coronary arteries to ensure uninhibited coronary circulation. When the self-expanding frame 16 is fully deployed, the device 10 is stabilized in place.

[0034] As shown in FIGS. 9 and 10, the inner frame 18 is initially unexpanded within the passageway 22 of the self-expanding frame 16. The inner frame 18 is deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 18 compresses the collagen fiber/hydrogel coated stent 20 of the outer frame 16 against the aortic annulus 60, thereby sealing the annulus 60 and the paravalvular areas 62, and thus, prevents paravalvular leakage (see FIG. 10).

[0035] It will be appreciated that the devices and methods described herein have broad applications. The foregoing embodiments were chosen and described in order to illustrate principles of the methods and apparatuses as well as some practical applications. The preceding description enables others skilled in the art to utilize methods and apparatuses in various embodiments and with various modifications as are suited to the particular use contemplated. In accordance with the provisions of the patent statutes, the principles and modes of operation of this disclosure have been explained and illustrated in exemplary embodiments.

[0036] It is intended that the scope of the present methods and apparatuses be defined by the following claims. However, it must be understood that this disclosure may be practiced otherwise than is specifically explained and illustrated without departing from its spirit or scope. It should be understood by those skilled in the art that various alternatives to the embodiments described herein may be employed in practicing the claims without departing from the spirit and scope as defined in the following claims.

[0037] The scope of the disclosure should be determined, not with reference to the above description, but should instead be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. It is anticipated and intended that future developments will occur in the arts discussed herein, and that the disclosed systems and methods will be incorporated into such future examples.

Furthermore, all terms used in the claims are intended to be given their broadest reasonable constructions and their ordinary meanings as understood by those skilled in the art unless an explicit indication to the contrary is made herein. In particular, use of the singular articles such as "a," "the," "said," etc. should be read to recite one or more of the indicated elements unless a claim recites an explicit limitation to the contrary. It is intended that the following claims define the scope of the disclosure and that the method and apparatus within the scope of these claims and their equivalents be covered thereby. In sum, it should be understood that the disclosure is capable of modification and variation and is limited only by the following claims.

CLAIMS

1. A transcatheter valve, comprising:

a dual-frame component including (i) a self-expanding outer frame having a passageway defined therein, and (ii) a balloon-expandable inner frame positioned in the passageway and secured to the self-expanding outer frame,

a valve element secured to the balloon-expandable inner frame, and

a plurality of fibers attached to the self-expanding outer frame and extending into the passageway,

wherein the balloon-expandable inner frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable inner frame is spaced apart from the plurality of fibers and an expanded position in which the balloon-expandable inner frame is engaged with the plurality of fibers.

2. The transcatheter valve of claim 1, wherein the valve element is a bicuspid or tricuspid valve.

3. The transcatheter valve of claim 1, wherein the self-expanding outer frame includes an uncovered portion and a covered portion.

4. The transcatheter valve of claim 3, wherein the uncovered portion has a first diameter that is smaller than a portion of the covered portion.

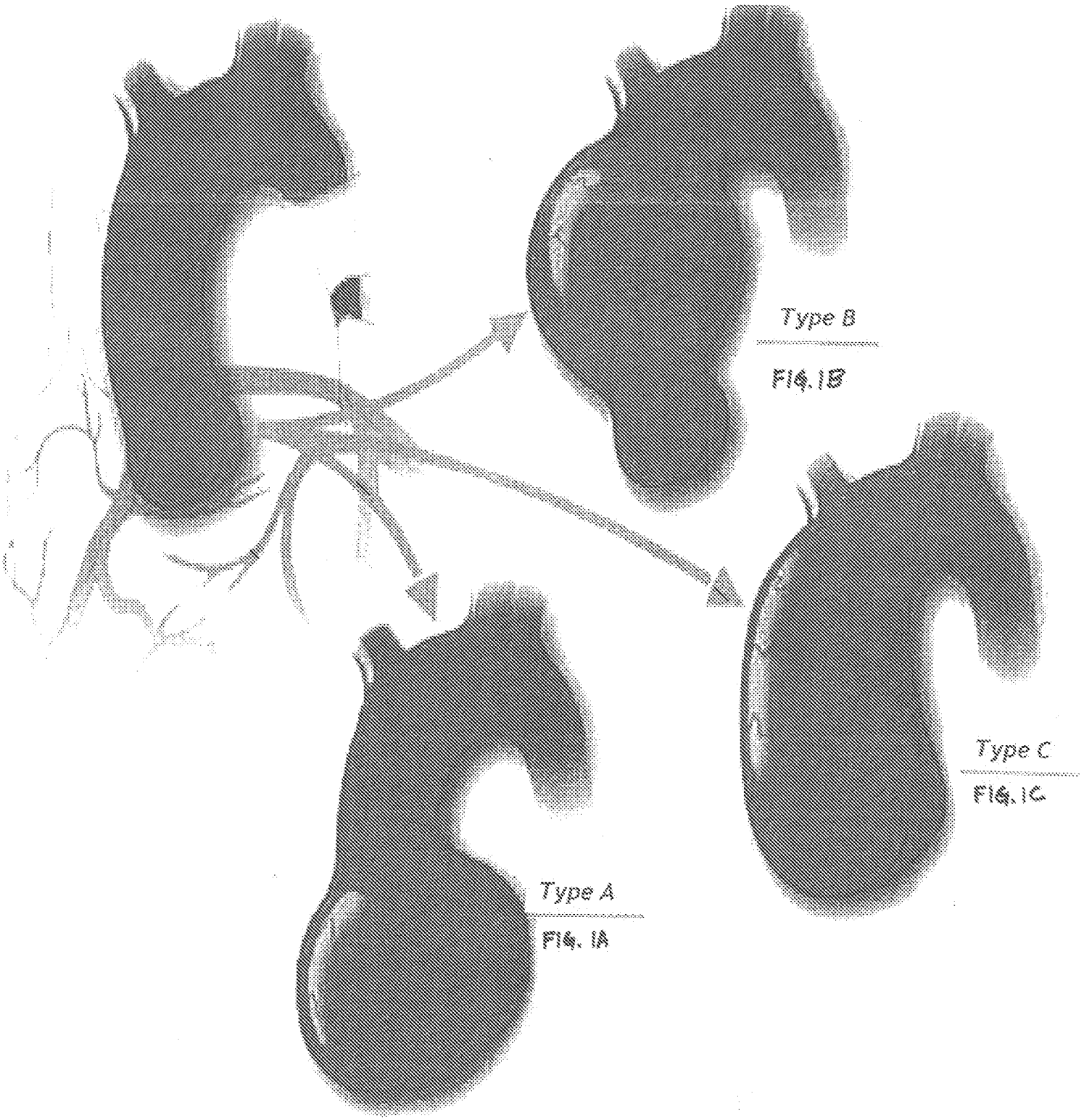
5. The transcatheter valve of claim 1, wherein the self-expanding outer frame is covered with collagen or hydrogel.

6. The transcatheter valve of claim 1, wherein the self-expanding outer frame has an hourglass shape.

7. The transcatheter valve of claim 1, wherein the self-expanding outer frame has a tapered section and an elongated section.

ABSTRACT OF THE DISCLOSURE

A transcathetar valve is disclosed for treating aortic aneurysms and valvular disease.



Type B

FIG. 1B

Type C

FIG. 1C

Type A

FIG. 1A

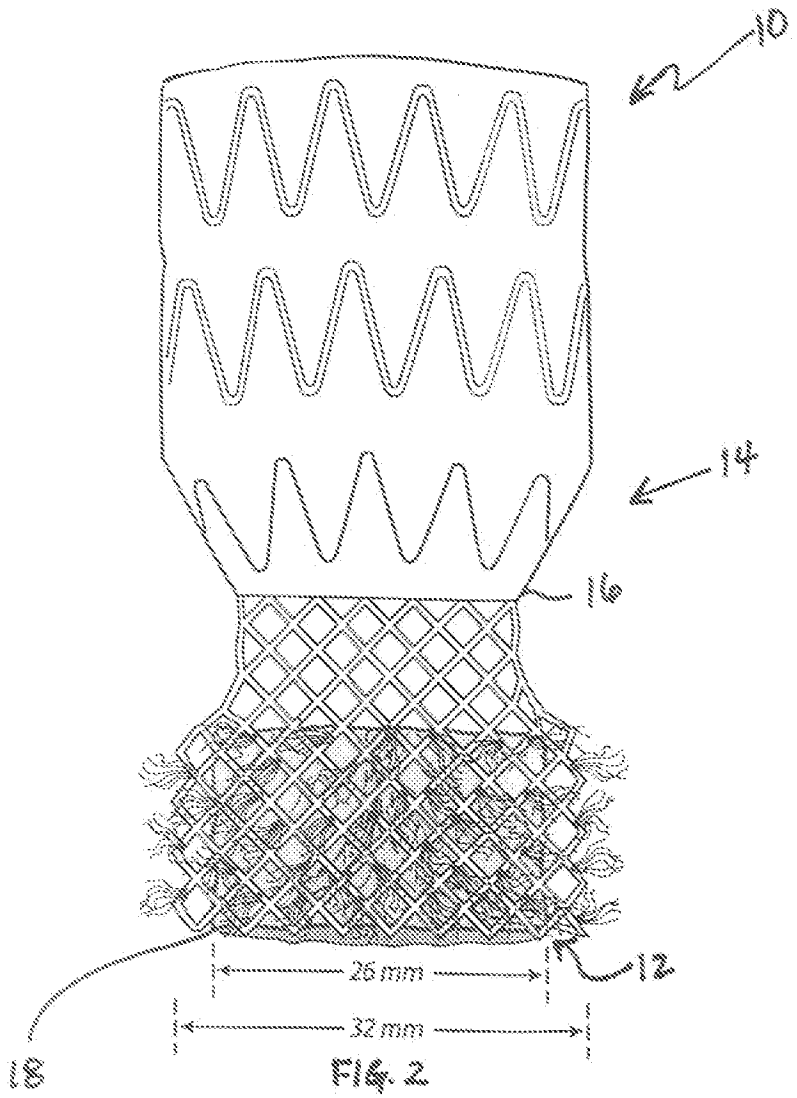


FIG. 2

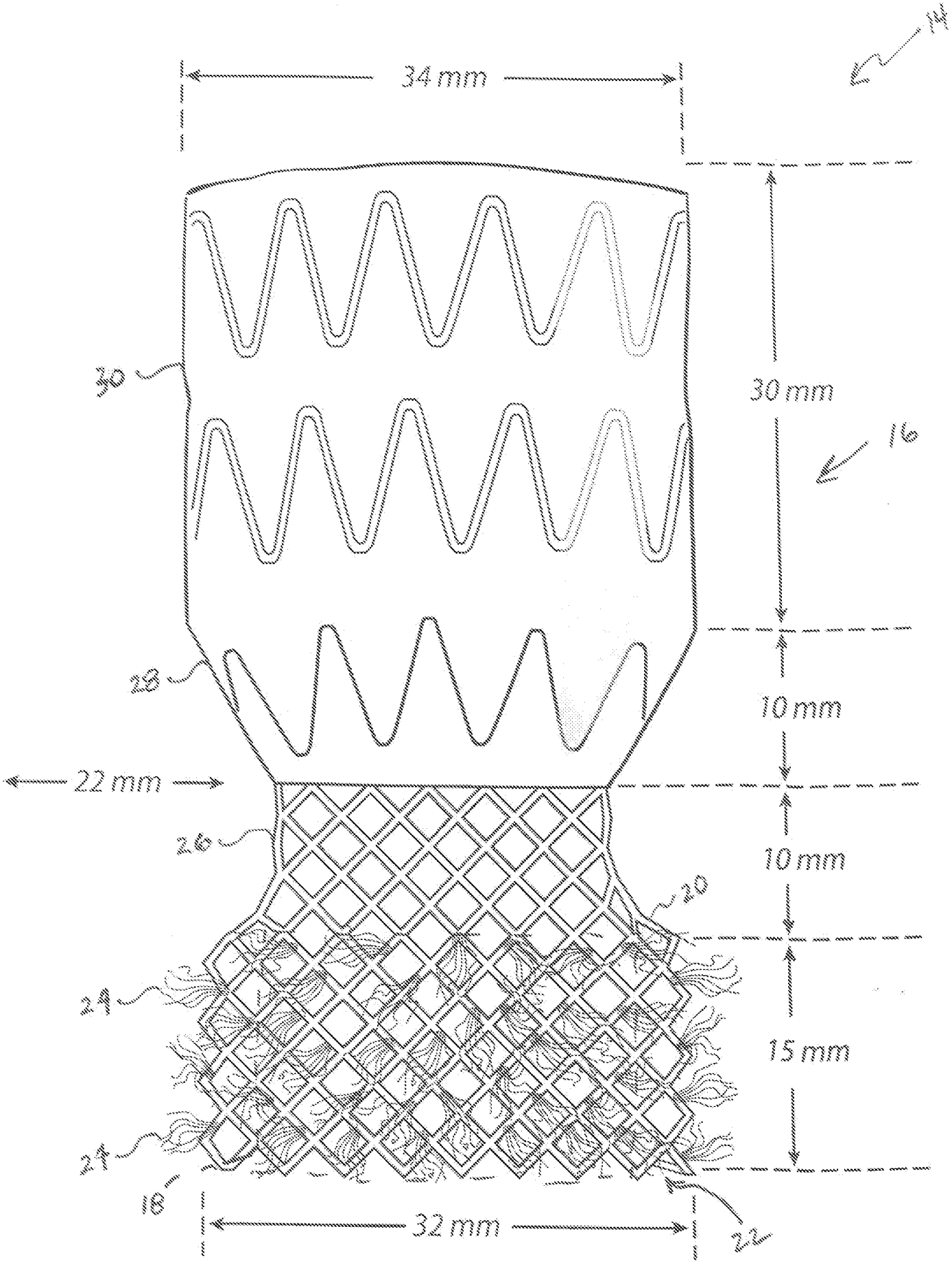


FIG. 3

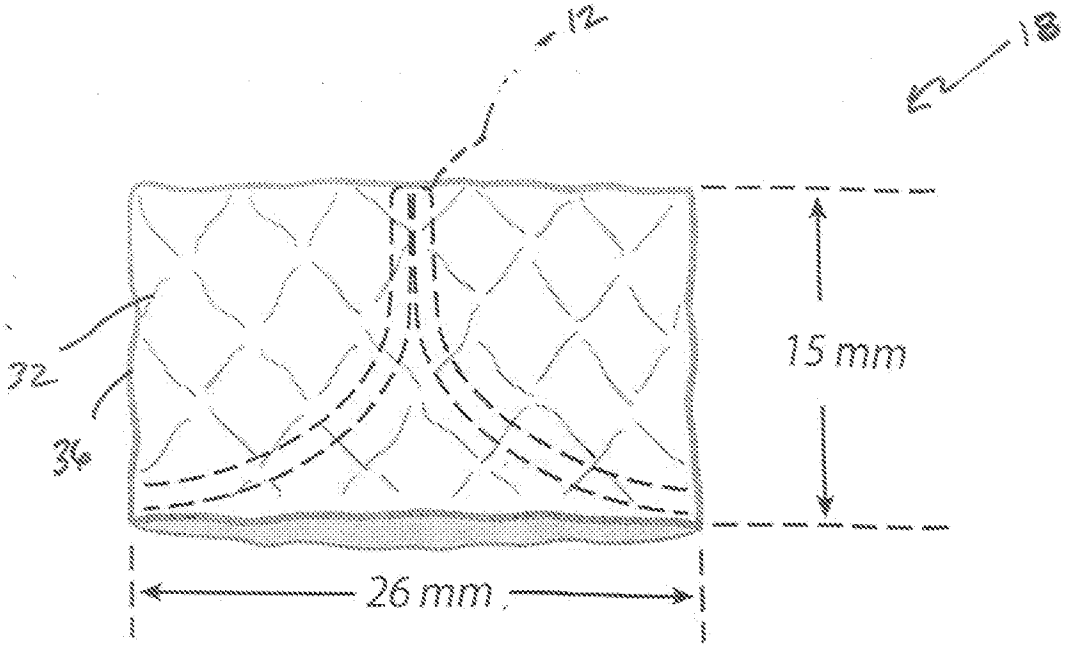


FIG. 4

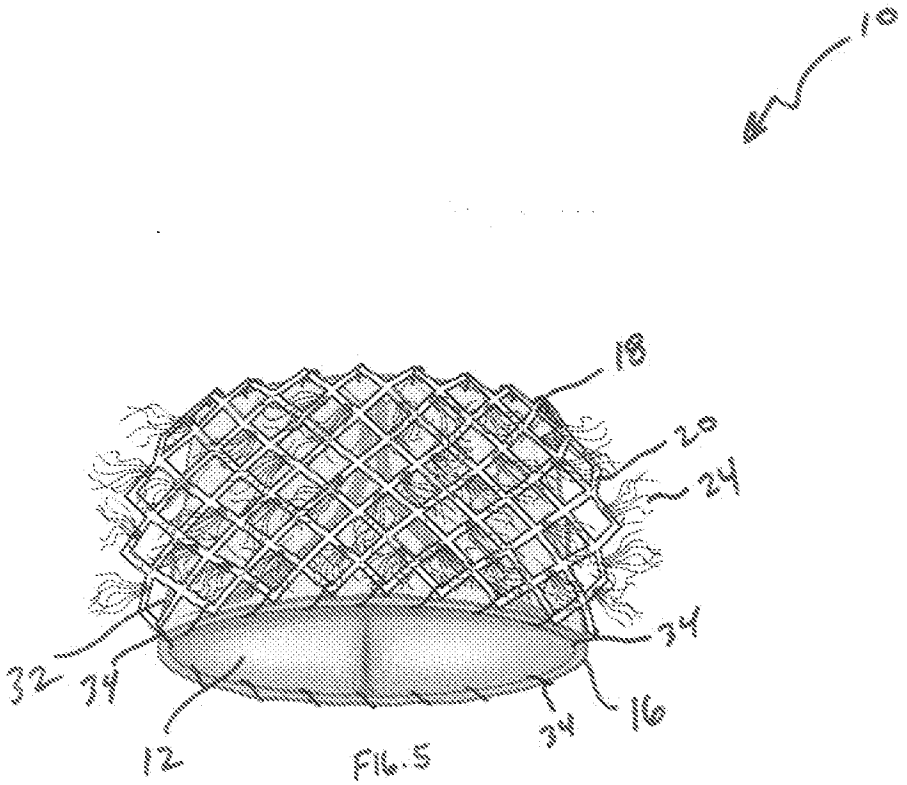


FIG. 5

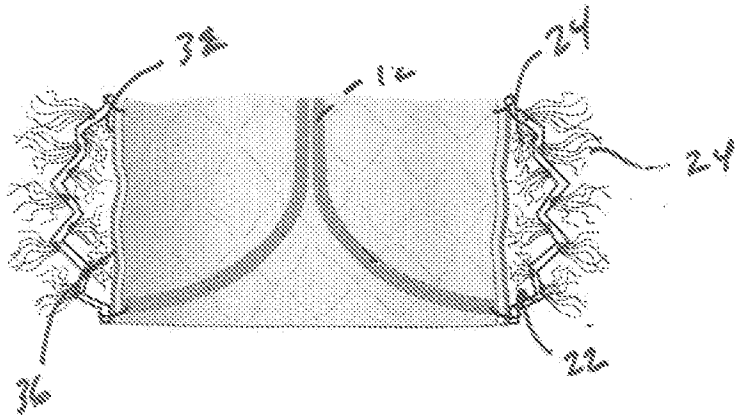
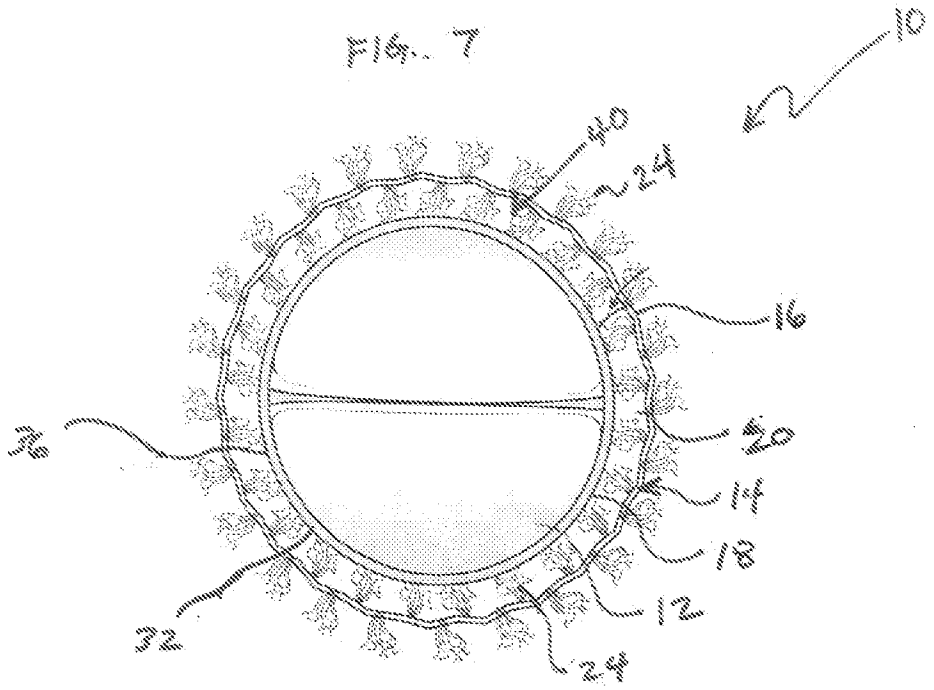


FIG. 6

FIG. 7



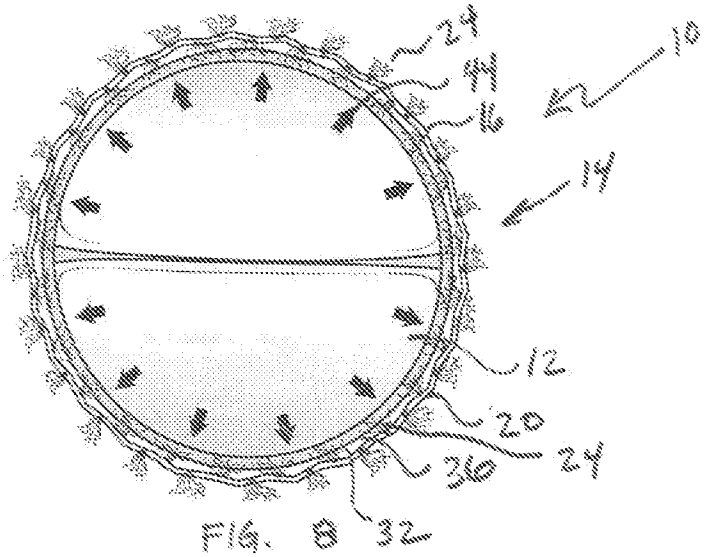


FIG. 8

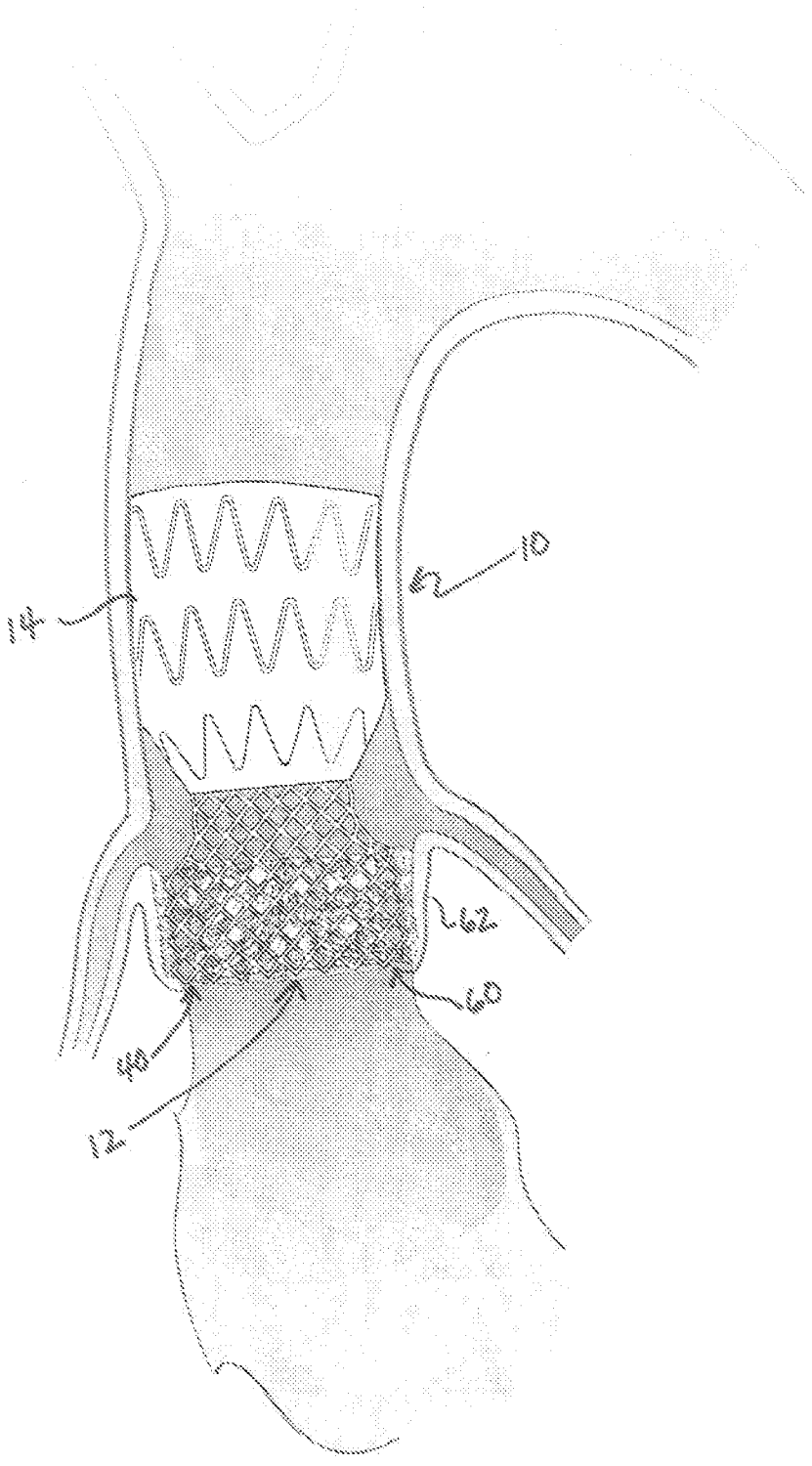


Fig. 9

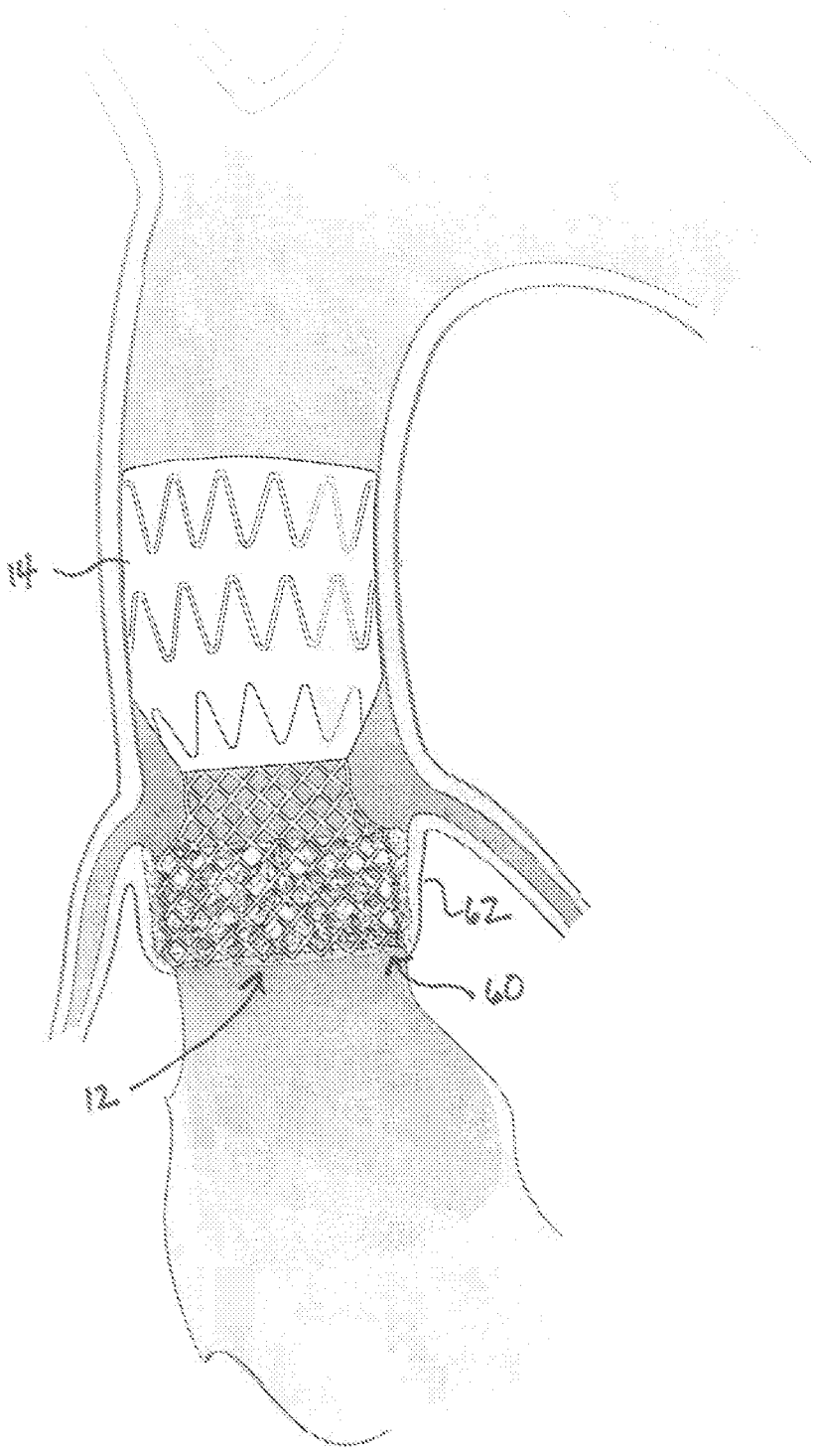


FIG. 10

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Jeffrey T.G. Kelsey
Attorney Docket Number:	58330-221639

Filed as Small Entity

Provisional Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Provisional Application filing fee	2005	1	125	125
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($)
Miscellaneous:				
			Total in USD ($)	**125**

Electronic Acknowledgement Receipt

EFS ID:	14170714
Application Number:	61723446
International Application Number:	
Confirmation Number:	5732
Title of Invention:	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	23643
Filer:	Jeffrey T.G. Kelsey
Filer Authorized By:	
Attorney Docket Number:	58330-221639
Receipt Date:	07-NOV-2012
Filing Date:	
Time Stamp:	14:32:46
Application Type:	Provisional

Payment information:

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1	Provisional Cover Sheet (SB16)	ProvisionalCoverSheet.pdf	2071141 b491926c34fb4c4c46f91826ab6039353c0db4c8	no	3
Warnings:					
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2	Specification	PPAppln.pdf	93279 1c52898abd1fda2efc61c777a9ea683afe7c2221	no	14
Warnings:					
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3	Drawings-only black and white line drawings	Drawings.pdf	1164182 e9f0fdf68c6c8ff2fe060b4532f543c6ae3444e5	no	8
Warnings:					
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4	Fee Worksheet (SB06)	fee-info.pdf	29686 4ccff26083fdaf5571c3a5ad9bc97a0e93d36a7f	no	2
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