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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 61/567,458 | 12/06/2011 | Ali Shahriari | 58330-221640 |

**CONFIRMATION NO. 7902**

23643
Barnes & Thornburg LLP (IN)
11 S. Meridian Street
Indianapolis, IN 46204

**POWER OF ATTORNEY NOTICE**

*OC000000066549536*

Date Mailed: 02/19/2014

## NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

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

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(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 11,497,634
**Edwards Ex. 1005**

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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 61/567,458 | 12/06/2011 | Ali Shahriari | 58330-221640 |

**CONFIRMATION NO. 7902**

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

**POA ACCEPTANCE LETTER**

*OC000000066549663*

Date Mailed: 02/19/2014

## 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

## 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 | 032145/0006 | 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 | 032145/0110 | 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:** | 18141409 |
| **Application Number:** | 61567458 |
| **International Application Number:** | |
| **Confirmation Number:** | 7902 |
| **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:** | 58330-221640 |
| **Receipt Date:** | 07-FEB-2014 |
| **Filing Date:** | 06-DEC-2011 |
| **Time Stamp:** | 09:54:15 |
| **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 | 426-2-2replacementADS.pdf | 119937<br>66d18ae91f8c0cacf5508f9151ede594a9586791 | no | 7 |

| | |
|---|---|
| **Warnings:** | |
| **Information:** | |

| This is not an USPTO supplied ADS fillable form | | | | | |
|---|---|---|---|---|---|
| 2 | Power of Attorney | AorticInnovationsPOAexecuted.pdf | 279772<br>415c50a1001cae2102c68cea76c5bde165dc3599 | no | 1 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | | **Total Files Size (in bytes):** | 399709 | |

**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 | 61/567,458 |
| 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 i | 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 :**

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
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| 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:

PTO/AIA/14 (12-13)
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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 | |

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

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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.

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| 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
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 61/567,458 | 12/06/2011 | Ali Shahriari | 67306-0001 |

**CONFIRMATION NO. 7902**

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

**POA ACCEPTANCE LETTER**

*OC000000056814941*

Date Mailed: 10/01/2012

## NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/24/2012.

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.

/hchristian/

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

PTO/SB/80 (11-08)
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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(b).

I hereby appoint:

☑ Practitioners associated with the 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 assignment documents attached to this form in accordance with 37 CFR 3.73(b).

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

☑ The address associated with Customer Number: 23643

*OR*

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

Assignee Name and Address:

Aortic Innovations
9221 Anchor Mark Drive
Indianapolis, In 46236

**A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, 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. Shahriari | Date | 9/13/12 |
| Name | Ali Shahriari | Telephone | 617-839-8525 |
| Title | Chief Executive Officer, CEO | | |

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.**

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## STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Ali Shahriari / Aortic Innovations LLC

Application No./Patent No.: 61/567,458 Filed/Issue Date: Filed: December 6, 2011

Titled:
Transcatheter 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 it is:

1. ☒ the assignee of the entire right, title, and interest in;

2. ☐ an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or

3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

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 029005, Frame 0233, or for which a copy therefore is attached.

**OR**

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
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2. From: _____ To: _____
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3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
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☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(b)(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.

/Bradford G. Addison/ 24 September 2012
Signature Date

Bradford G. Addison 41486
Printed or Typed Name Title

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.**

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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.
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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.
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.
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| Electronic Acknowledgement Receipt | |
|---|---|
| **EFS ID:** | 13816157 |
| **Application Number:** | 61567458 |
| **International Application Number:** | |
| **Confirmation Number:** | 7902 |
| **Title of Invention:** | TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR |
| **First Named Inventor/Applicant Name:** | Ali Shahriari |
| **Customer Number:** | 10291 |
| **Filer:** | Bradford G. Addison/Garla Twyman |
| **Filer Authorized By:** | Bradford G. Addison |
| **Attorney Docket Number:** | 67306-0001 |
| **Receipt Date:** | 24-SEP-2012 |
| **Filing Date:** | 06-DEC-2011 |
| **Time Stamp:** | 11:32:07 |
| **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 | Power of Attorney | Aortic_Innovations_POA.pdf | 660673<br>aa31089d634a8e91652d0518c6ba68d8dedcc8ec | no | 1 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |

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|---|---|---|---|---|---|
| 2 | Assignee showing of ownership per 37 CFR 3.73(b). | sb0096.pdf | 423509<br>a531baa972f0bd0f78e735ebf23779bf55d963d5 | no | 2 |

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| **Warnings:** | |
| **Information:** | |
| **Total Files Size (in bytes):** | 1084182 |

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**New International Application Filed with the USPTO as a Receiving Office**
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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 |
|---|---|---|---|---|---|---|
| 61/567,458 | 12/06/2011 | | 125 | 67306-0001 | | |

**CONFIRMATION NO. 7902**

10291
RADER, FISHMAN & GRAUER PLLC
39533 WOODWARD AVENUE
SUITE 140
BLOOMFIELD HILLS, MI 48304-0610

**FILING RECEIPT**

*OC000000051526259*

Date Mailed: 12/21/2011

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**

**Applicant(s)**

Ali Shahriari, Indianapolis, IN;

**Power of Attorney:**
Kristin Murphy--41212

**If Required, Foreign Filing License Granted:** 12/16/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/567,458**

**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

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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

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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

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

**Express Mail Label No.** _____

| INVENTOR(S) | | |
|---|---|---|
| Given Name (first and middle [if any] ) | Family Name or Surname | Residence (City and either State or Foreign Country) |
| Ali | Shahriari | Indianapolis, Indiana |
| | | |
| | | |
| | | |
| | | |

*Additional inventors are being named on the* _____ *separately numbered sheets attached hereto.*

**TITLE OF THE INVENTION (500 characters max):**

TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

*Direct all correspondence to:* **CORRESPONDENCE ADDRESS**

[X] The address corresponding to Customer Number: 10291

**OR**

[ ] Firm or Individual Name: Kristin L. Murphy, RADER, FISHMAN & GRAUER PLLC

Address: 39533 Woodward Avenue, Suite 140

| City | Bloomfield Hills | State | MI | Zip | 48304 |
|---|---|---|---|---|---|
| Country | US | Telephone | (248) 594-0600 | Email | |

**ENCLOSED APPLICATION PARTS (*check all that apply*)**

[X] Application Data Sheet. See 37 CFR 1.76 [ ] CD(s), Number of CDs _____

[X] Drawing(s) *Number of Sheets* 7 [ ] Other (specify) _____

[X] Specification (e.g. description of the invention) *Number of Pages* 12

**Fees Due:** Filing Fee of $250 ($125 for small entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which 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).

**METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT**

[X] Applicant claims small entity status. See 37 CFR 1.27.

[ ] A check or money order made payable to the *Director of the United States Patent and Trademark Office* is enclosed to cover the filing fee and application size fee (if applicable).

[ ] Payment by credit card. Form PTO-2038 is attached.

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**TOTAL FEE AMOUNT ($)**

[X] The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: 18-0013 .

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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: December 6, 2011 Electronic Signature for Kristin L. Murphy: /Kristin L. Murphy/

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

[X] No.

[ ] Yes, the name of the U.S. Government agency and the Government contract number are:

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SIGNATURE /Kristin L. Murphy/ Date December 6, 2011

TYPED or PRINTED NAME Kristin L. Murphy REGISTRATION NO. *(if appropriate)* 41,212

TELEPHONE (248) 594-0647 Docket Number: 67306-0001

**Application Data Sheet**

**Application Information**

| | |
|---|---|
| Application Type:: | Provisional |
| Subject Matter:: | Utility |
| Suggested Group Art Unit:: | N/A |
| CD-ROM or CD-R?:: | None |
| Sequence submission?:: | None |
| Computer Readable Form (CRF)?:: | No |
| Title:: | TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR |
| Attorney Docket Number:: | 67306-0001 |
| Request for Early Publication?:: | No |
| Request for Non-Publication?:: | No |
| Total Drawing Sheets:: | 7 |
| Small Entity?:: | Yes |
| Petition included?:: | No |
| Secrecy Order in Parent Appl.?:: | No |

**Applicant Information**

| | |
|---|---|
| Applicant Authority Type:: | Inventor |
| Primary Citizenship Country:: | US |
| Status:: | Full Capacity |
| Given Name:: | Ali |

| | |
|---|---|
| Family Name:: | Shahriari |
| City of Residence:: | Indianapolis |
| State or Province of Residence:: | IN |
| Country of Residence:: | US |
| Street of mailing address:: | 9221 Anchor Mark Dr. |
| City of mailing address:: | Indianapolis |
| State or Province of mailing address:: | IN |
| Postal or Zip Code of mailing address:: | 46236 |

**Correspondence Information**

| | |
|---|---|
| Correspondence Customer Number:: | 10291 |

**Representative Information**

| | |
|---|---|
| Representative Customer Number:: | 10291 |

**Domestic Priority Information**

**Foreign Priority Information**

**Assignee Information**

Application No. (if known): Attorney Docket No.: 67306-0001

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on December 6, 2011
Date

/Kristin L. Murphy/
Signature

Kristin L. Murphy
Typed or printed name of person signing Certificate

41,212
Registration Number, if applicable

(248) 594-0647
Telephone Number

Note: Each paper must have its own certificate of mailing.

Application Data Sheet (2 pages)

# TRANSCATHETAR AORTIC VALVE FOR ENDOVASULAR AORTIC REPAIR

## TECHNICAL FIELD

**[0001]** The present disclosure relates to a device and method of using same for endovascular repair of ascending aortic aneurysms.

## BACKGROUND

**[0002]** 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.

**[0003]** 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.

**[0004]** The anatomical characteristics of type B aneurysms is 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. 1B.

**[0005]** 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.

**[0006]** 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 ascending aortic aneurysms. Indeed, a device is needed that that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones, and have a durable valve, but allow future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variation, allow future coronary re-intervention, but avoid coronary compression, and allow treatment of possible paravalvular leaks.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0007]** Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

**[0008]** FIG. 1A is an example of a Type A aneurysm;

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

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

**[0011]** FIG. 2 is an exemplary endovascular device, disposed in the ascending aorta;

**[0012]** FIG. 3 is a first component of the endovascular device shown in FIG. 2;

**[0013]** FIG. 4 is a second component of the endovascular device shown in FIG. 2;

**[0014]** FIGS. 5-6 are schematic images of a transcatheter valve positioned with the aorta.

**[0015]** FIG. 7 is an exemplary transcatheter valve.

## DETAILED DESCRIPTION OF THE INVENTION

**[0016]** Referring to FIGS. 2-4, the present disclosure illustrates an exemplary design of an endovascular device 10 intended for the treatment of most ascending aortic aneurysms. The device 10 is intended to be configured to treat any type of ascending aneurysm regardless of involvement of the aortic valve and the sinuses of Valsalva. The device 10 allows for future coronary and aortic valve interventions as well as extension of a fenestrated/ branch graft into the aortic arch. With slight modification, part of this device 10 may also be used as a transcatheter valve that could be introduced transfemorally or through the subclavian artery or the apex of the heart.

**[0017]** The device 10 may be configured as a modular device with a proximal valved component and a distal seal component that also carries conduits for coronary blood flow. In the exemplary embodiment depicted, device 10 is composed of first and second components 12, 14, shown in FIGS. 3 and 4, respectively. First component 12 may be constructed from treated bovine pericardium or other suitable proven biological or synthetic material, and includes a valve 16 (shown in phantom) that is housed within a balloon-expandable stent 18. In one exemplary arrangement, valve 16 is configured as a bicuspid valve but may be tricuspid or quadracuspid. Balloon-expandable stent 18 may be configured as a metallic stent. In one exemplary configuration, stent 18 may be formed in an open cell fashion. In one particular, non-limiting example, stent 18 is constructed to be approximately 15mm in height and has a diameter of approximately 26 mm.

**[0018]** Stent 18 is attached to a self-expanding covered Z-stent frame 20, which is configured to have a generally hourglass shape. The stent frame 20 is configured with a first inwardly tapered section 22, a second outwardly tapered section 24 and an elongated section 26. In one particular, non-limiting example, stent frame 20 first inwardly tapered section 22 is constructed to be approximately 10mm in length, and the diameter tapers from a distal end of section 22 of approximately 26mm to approximately 22mm at a proximal end of section 22. The second tapered section 24 is constructed to be approximately 10mm in length, and tapers outwardly from proximal

end of section 22 to a distal end. More specifically, in one particular non-limiting example, second tapered section 24 expands from a diameter of approximately 22mm to a diameter of approximately 28 mm. The entire component 12 is covered with low profile polyester or other synthetic material. Stent 18 may also be covered with hydrogel or other sealing material.

**[0019]** Second tapered section 24 mates with elongated section 26. Elongated section is configured with a length that is greater than the length of first and second tapered sections 22, 24. In one particular non-limiting example, the length of elongated section 26 is approximately 25mm and has a diameter of approximately 28mm. As will be explained in greater detail below, the elongated section serves as connection to second component 14 of device 10.

**[0020]** The tapered design of first component 12 allows for placement of "endo-Cabrol conduits" attached on second component 14, to the coronary arteries. The entire exterior surface of first component 12 may be covered with low-profile Dacron or other synthetic material. The Dacron immediately above the balloon-expandable segment 18 is equipped with a "trap door" for embolization of possible paravalvular leaks.

**[0021]** The self-expanding portion of first component 12 will significantly improve the accuracy and control of the deployment of the device 10. The bicuspid configuration of the valve 16 serves three distinct purposes: 1) by reducing the number of valve commissures to two, the profile will be reduced, 2) the valve 16 may conform better to the aortic annulus, 3) when the annulus is asymmetrical, the incidence of aortic insufficiency may be reduced. The German TAVI registry recorded 17% incidence of aortic regurgitation using transcatheter valves. This leak for an ascending endovascular device would translate into a paravalvular leak potentially into the aneurysm sac and must be improved upon with the new generation devices.

**[0022]** With slight modification, first component 12 may be used as a transcatheter valve deployed via a transfemoral or trans-axillary route, as will be explained in further detail below.

**[0023]** Second component 14 is depicted in FIG. 4. Second component 14 is configured as a covered z-stent frame and comprises a proximal section 28, a tapered section 30 and a distal section 32. In one particular non-limiting example, proximal section 28 is configured with a length of

approximately 25mm and has a diameter of approximately 26mm. The tapered section 30 expands from proximal section 28 to distal section 32. In one particular non-limiting example, tapered section 30 has a length of approximately 10mm and tapers from a diameter of 26mm to diameter between approximately 44 and 48mm. Distal section 32 has a diameter of approximately 44mm to 48mm and a length of approximately 20mm.

**[0024]** A "Cabrol endo-conduit" 34 is constructed on each side of the tapered section 30 of the covered graft. In one exemplary and non-limiting configuration, the endo-conduit 34 measures approximately 8mm in diameter over a distance of approximately 5mm tapering smoothly into an approximately 5mm diameter component measuring approximately 2cm in length. The endo-conduit 34 is wire reinforced and allows for passage of catheters and easier cannulation of the coronary ostia, regardless of deployment orientation. This configuration allows stenting of the coronary arteries prior to the deployment of first component 12. The purpose of the tapered proximal portion 30 is to allow space for uncompromised passage of stents into the coronary arteries in such a way that the stents are not compressed between the sinutubular junction and the device 10 itself.

**[0025]** The covered portion of second component 14 is attached to an uncovered self-expanding stent portion 36. In one particular non-limiting example, stent portion 36 has a length of approximately 10cm, sufficient to cover the aortic arch, when installed. Stent portion 36 allows for accurate deployment of second component 14 without covering the supra-aortic branches. It also allows for cannulation of the supra-aortic branches, if placement of a fenestrated/ branch arch device would become necessary.

**[0026]** In operation, elongated section 26 of first component 12 is received within proximal section 28 of second component 14. This design would treat all ascending aneurysms (B and C) with dilated sinutubular junctions measuring > 35mm in diameter. This diameter is chosen based on the diameter of first component 12 and the endo-conduits.

**[0027]** Referring to FIGS. 5-7, a transcatheter valve 40 is depicted. The transcatheter valve 40 is composed of four main components: a valve 42, a covered balloon-expandable stent portion 44, an uncovered stent portion 46 and a covered stent portion 48.

**[0028]** The valve 42 is bicuspid in design but may be tri- or quadracuspid, and may be configured from treated bovine pericardium or other suitable proven biological or synthetic material. Valve 42 is housed within balloon-expandable stent portion 44. Stent portion 44 may be constructed of a metallic material. The stent portion 44 is formed in an open cell fashion. In one particular non-limiting example, stent portion 44 is configured with a length of approximately 15mm. Stent portion 44 is covered with low-profile polyester or other suitable material including, but not limited to hydrogel to prevent leakage around the stent portion 44. The stent portion 44 is attached to uncovered stent portion 46, which is configured as a self-expanding open-cell design stent. In one non-limiting example, stent portion 46 is configured to have a length of approximately 10mm and tapers down to approximately 22mm diameter. Covered stent portion 48 includes a tapered section that extends from stent portion 46 and an elongated section. In one exemplary, non-limiting embodiment, tapered section is configured with a length of approximately 10mm, and has a diameter that extends from approximately 22mm to approximately 34mm. The elongated section is approximately 30 mm in length.

**[0029]** The uncovered, open cell stent portion 46, is configured to allow for coronary artery perfusion. Covered stent portion 48 serves to stabilize the valve 42 against the aorta. It is also covered with low profile polyester (or other suitable material) to be able to serve as a docking station to ascending aortic extensions or fenestrated/ branch arch grafts. The covered stent portion 48 would allow for endograft extension of the device 40 for suitable type B aneurysms without dilation of the sinutubular junction. The valve 40 would be offered in sizes 23, 26, and 29.

**[0030]** Delivery and deployment of endovascular device 10 and transcatheter device 40 will now each be described.

**[0031]** With respect to endovascular device 10, a proposed delivery system is composed of a 100-105 cm large bore hydrophilic sheath. Second component 14 is delivered first. After

performing a lateral oblique thoracic aortogram, second component 14 is deployed immediately proximal to the innominate artery, ensuring opening of the Cabrol endo-conduits at 12 and 6 o'clock with relationship to the innominate artery. Next, the Cabrol conduits are cannulated with standard coronary guide catheters, guidewires are placed and covered stents are placed connecting each coronary artery to its respective Cabrol conduit. Having secured the coronary circulation, the valved portion of the device, first component 12 is now deployed into position across the native aortic valve to complete the repair.

**[0032]** The delivery of the transcatheter valve 40 begins by gaining access to the left ventricle across the native aortic valve. An ascending aortogram is performed to locate the right and left coronary arteries. The device 40 is delivered via the common femoral artery and passed across the native valve. The balloon expandable portion 44 of the valve is unsheathed. After optimal positioning of device markers against the native valve annulus, the heart is rapidly paced (RVP) to minimize ejection during a short period of time while the valvular portion 42 of the device 40 is deployed inside the native annulus, after which the rest of the device 40 can rapidly be unsheathed and the RVP can be terminated.

**[0033]** The design of first and second components 12, 14, and the transcatheter valve 40 has intentionally taken into account the potential failure modes of the device 40 and allows for correction of any such failure modes. For example, with respect to first and second components 12, 14, paravalvular leaks may be corrected. More specifically, with respect to a paravalvular leak (type Ia endoleak), leakage around the valve 16 would act as a type Ia endoleak. A trapdoor mechanism in first component 12 would allow for coil embolization of the area of the leak. Two trapdoors at 180 degree location would allow access to the entire area above the aortic annulus. Since the coronary arteries are protected by the Cabrol endo-conduits, coil embolization of this area would not compromise the coronary blood flow. Coil embolization of paravalvular leaks are already being performed clinically after heart valve surgery if there are additional leaks around the valve.

**[0034]** Aortic insufficiency (AI) after implantation may also be corrected. Significant AI has been documented in up to 17% of patients after transcatheter valve implantation. Except heavy annular calcification, the tricuspid morphology of the current valves and the ovoid shape of the

aortic annulus can cause malcoaptation of the valve leaflets causing AI. The bicuspid valve nature of the proposed device potentially eliminates the problem with malcoaptation and AI secondary to that.

[0035] Structural valve degeneration may also be corrected. More specifically, the bicuspid valve design allows for placement of another transcatheter valve across the first device without compromising valvular flow area.

[0036] Coronary insufficiency may also be corrected. The Cabrol endo-conduits 34 in conjunction with the tapered portion 30 of device 14 ensure uninterrupted coronary blood flow. By first deploying second component 14, the operator will be able to work through the Cabrol conduits and using standard catheters and guidewires to cannulate the right and left coronary arteries. Stents are deployed from the coronary arteries into the Cabrol conduits. The first component 12 will only be deployed once the coronary blood flow is secured. The tapered design will mitigate the risk of compression of the coronary stents between the device 10 and the aortic wall.

[0037] For the transcatheter valve 40, paravalvular leaks may also be corrected in that the open cell midsection of the valve allows the cannulation and stenting of the coronary arteries with potential coil embolization of the leak after the protection of the coronary artery if necessary.

[0038] Structural valve degeneration in the transcatheter valve 40 may be corrected in that the bicuspid valve design allows for placement of another transcatheter valve across the first device without compromising valvular flow area.

[0039] 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.

**[0040]** 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. 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

What is claimed is:

1. An endograft device for endovascular repair of ascending aortic aneurysms, comprising:

a first component comprising a valve, a balloon expandable stent portion, and a stent frame, wherein the valve is disposed in the balloon expandable stent potion and the stent frame extends from a distal end of the balloon expandable stent portion; and

a second component comprising a proximal section connected to a tapered section and a distal section connected to the tapered section, at least one conduit is positioned adjacent the proximal section, a self-expanding stent portion extends from the distal section.

2. The endograft device of claim 1, wherein the valve is configured as a bicuspid valve.

3. The endograft device of claim 1, wherein the balloon expandable stent portion is configured with an open cell design.

4. The endograft device of claim 1, wherein the stent frame has an hourglass shape.

5. The endograft device of claim 1, wherein the second component includes a pair of conduits diametrically opposed to one another.

6. The endograft device of claim 1, wherein the second component further comprises an uncovered self-expanding stent portion that is fixedly secured to the distal section of the second component.

7. A transcatheter valve, comprising:

a valve element;

a balloon expandable stent portion; and

a self-expanding stent portion;

wherein the valve element is disposed in the balloon expandable stent portion and wherein the self-expanding stent portion further comprises a tapered section and an elongated section.

8. The transcatheter valve of claim 7, wherein the valve element is a bicuspid valve.

9. The transcatheter valve of claim 7, wherein self-expanding stent portion includes an uncovered portion and a covered portion.

10. The transcatheter valve of claim 9, wherein the uncovered portion has a first diameter that is smaller than a portion of the covered portion.

## ABSTRACT

An endograft device and a transcatheter valve are disclosed for treating aortic aneurysms.

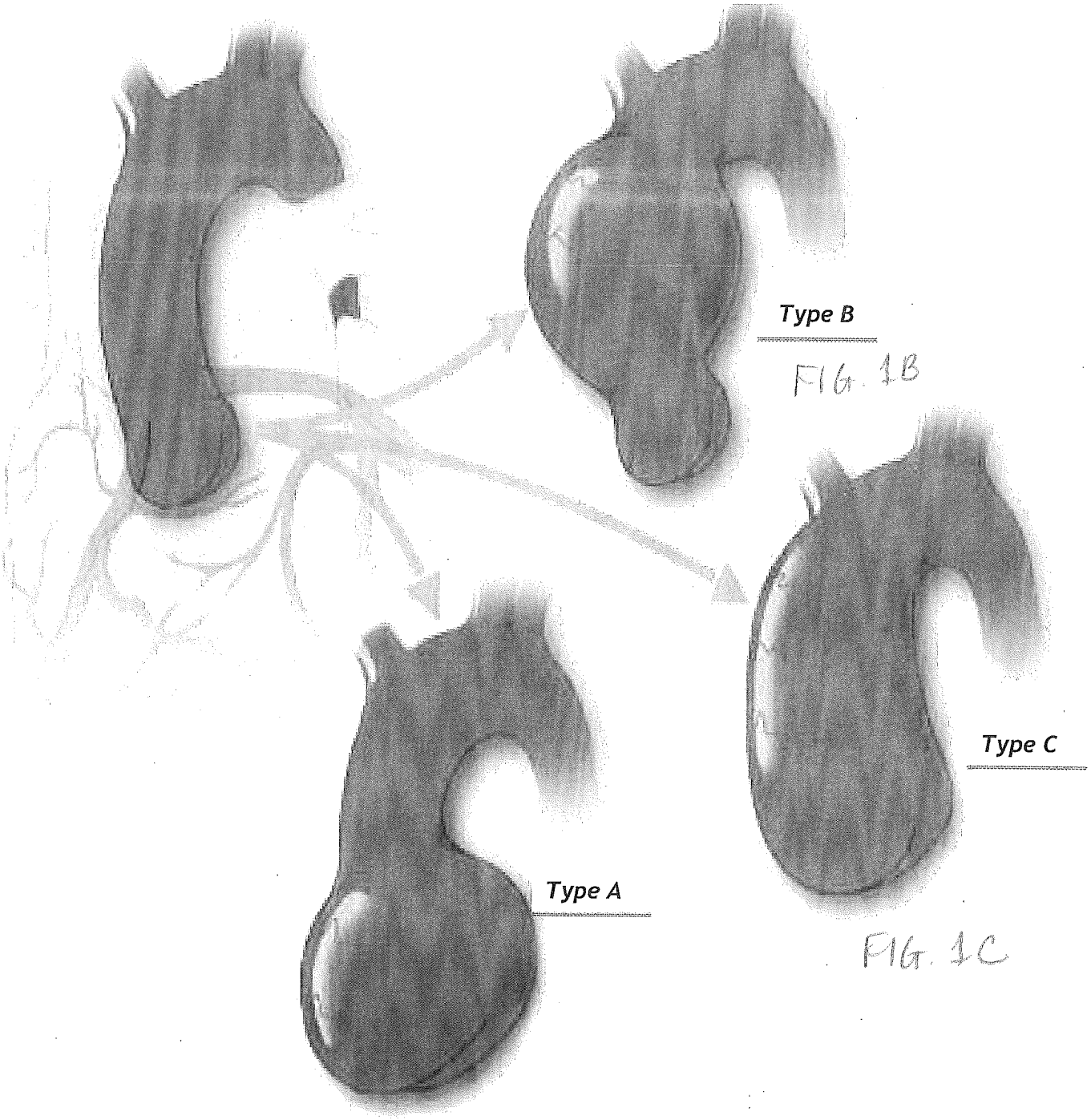


FIG. 1B

FIG. 1C

FIG. 1A

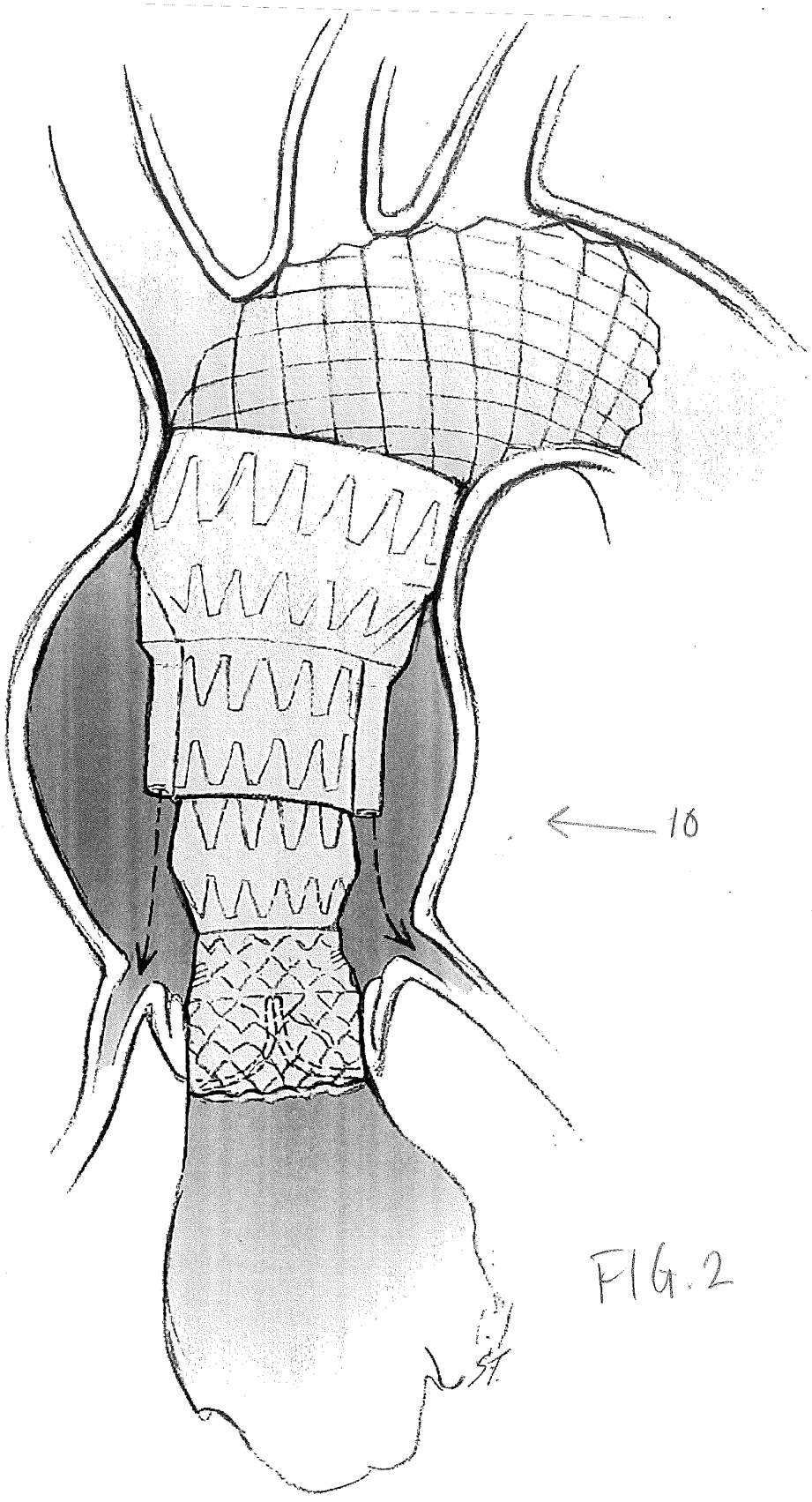


FIG. 2

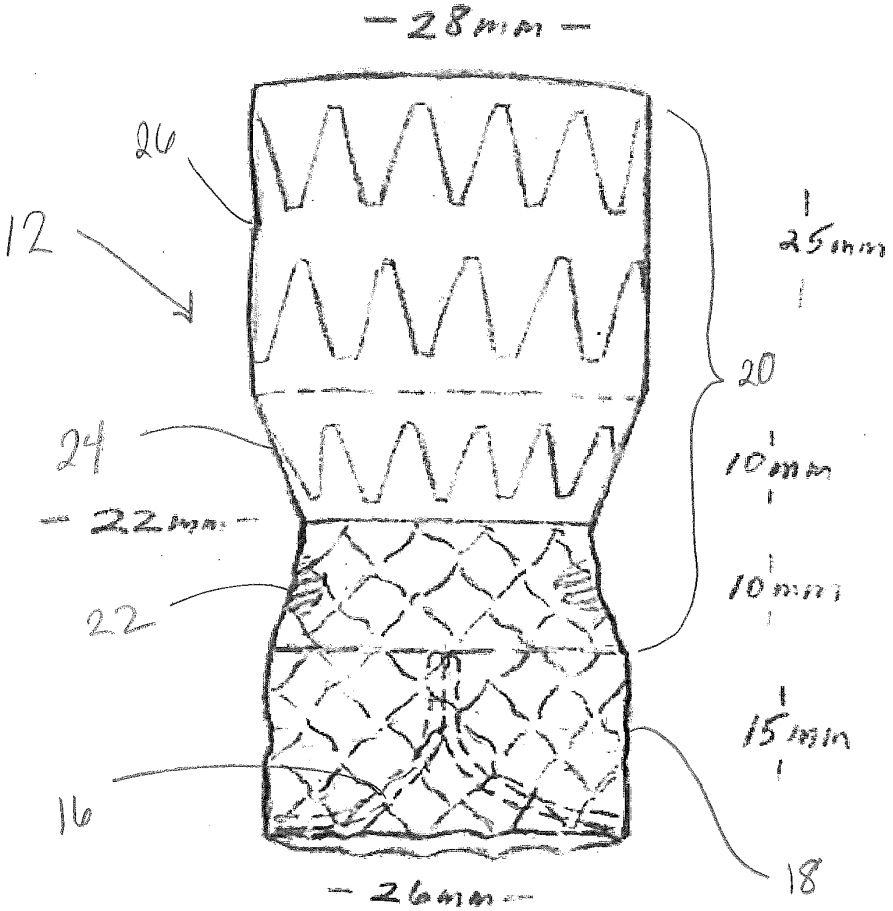


FIG. 3

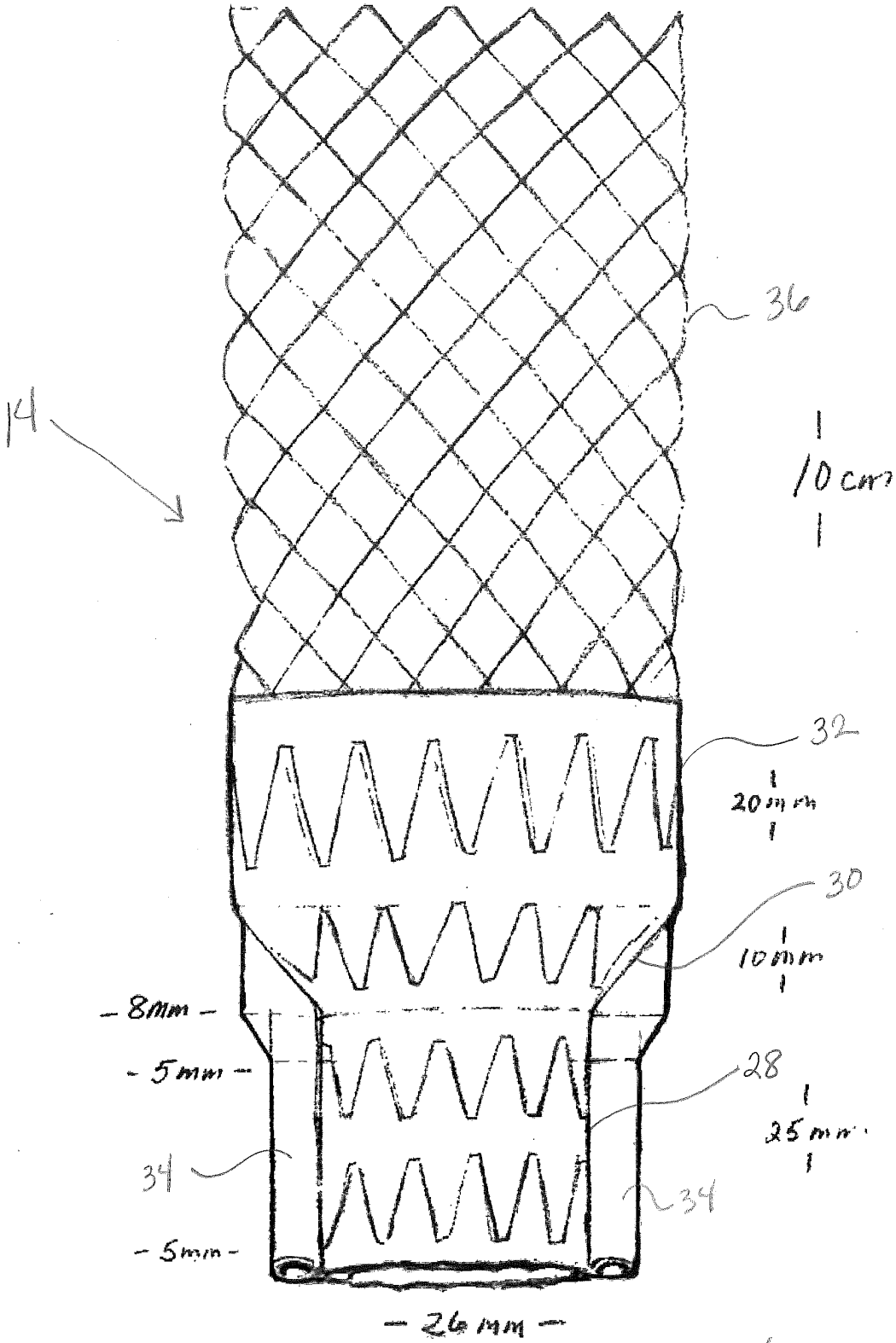


FIG. 4

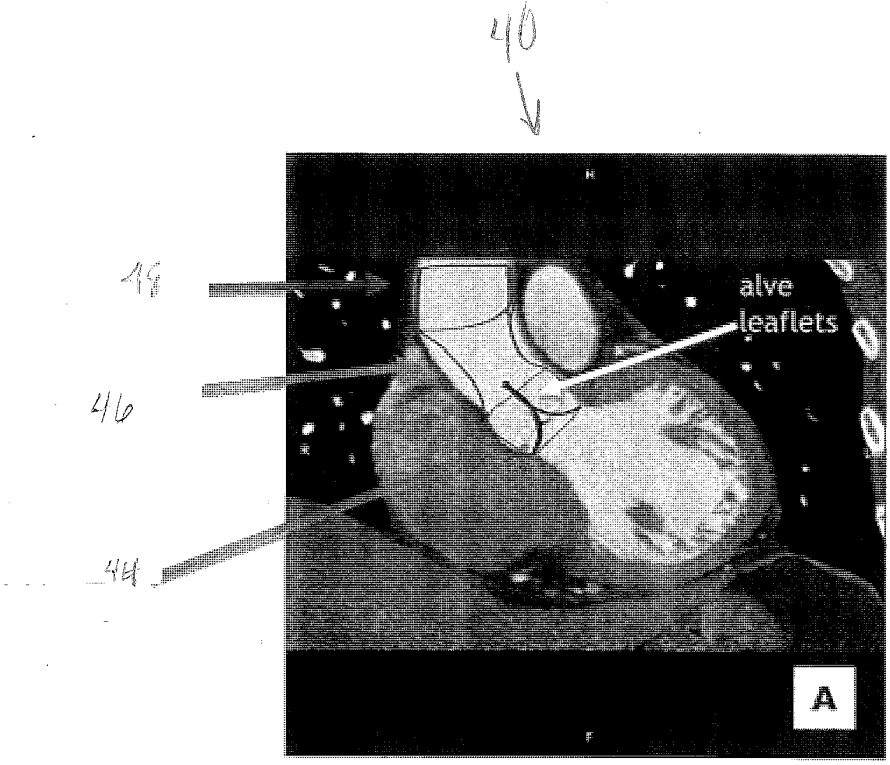


FIG. 5

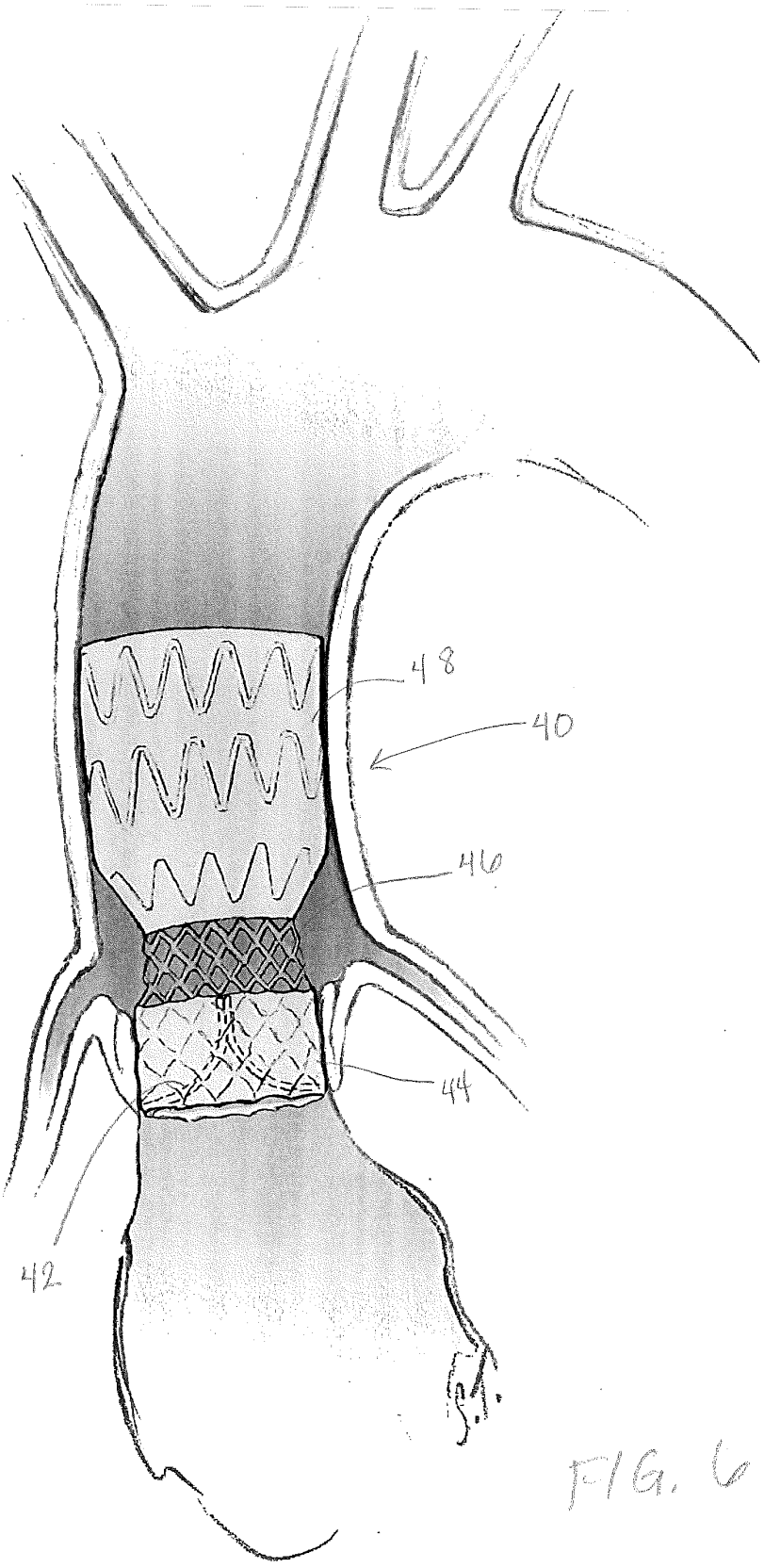


FIG. 6

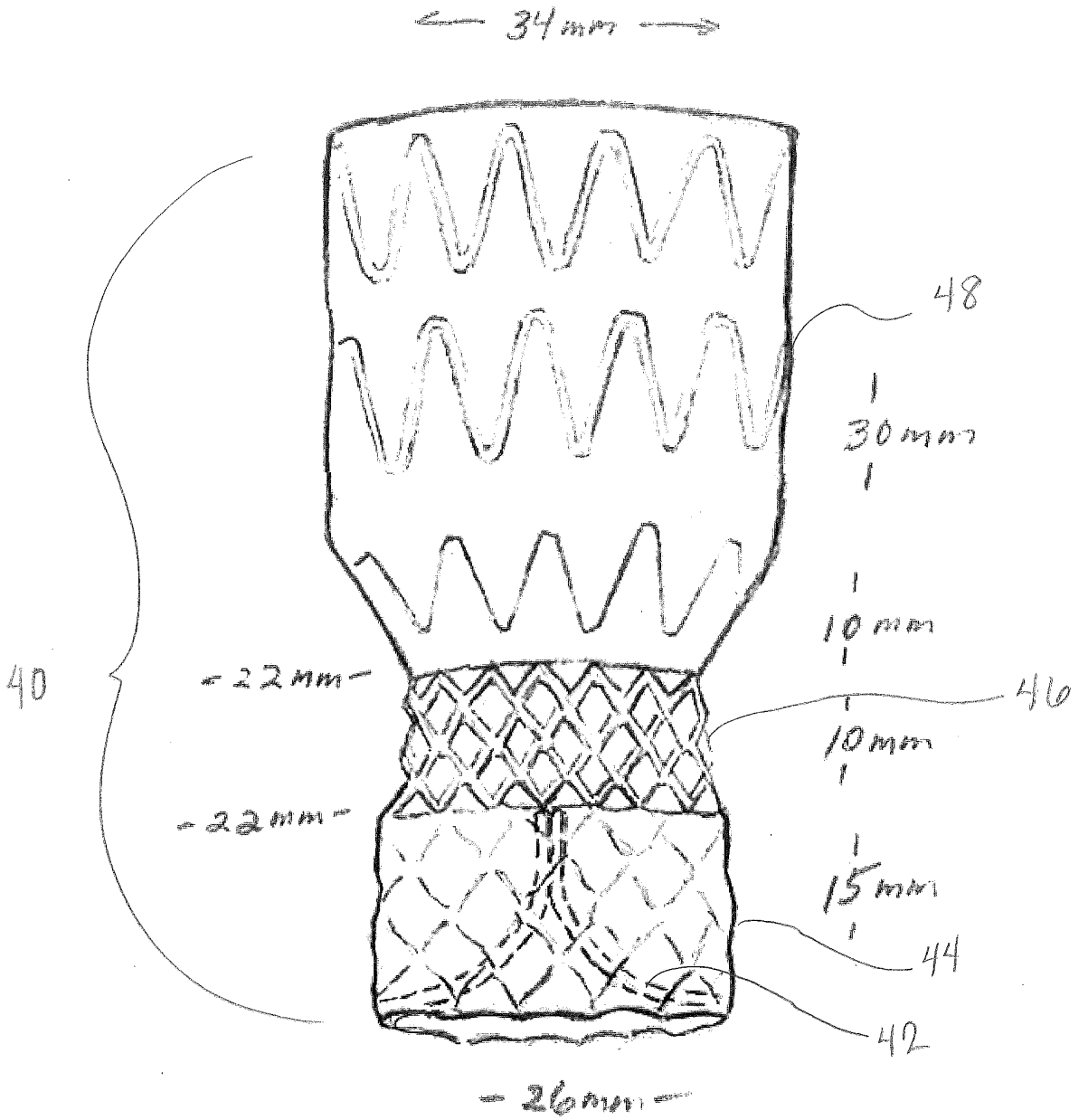


FIG. 7

| 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:** | Kristin Lee Murphy/Kathryn Nash |
| **Attorney Docket Number:** | 67306-0001 |
| 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($) |
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| **Miscellaneous:** | | | | |
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| Electronic Acknowledgement Receipt | |
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| **EFS ID:** | 11554820 |
| **Application Number:** | 61567458 |
| **International Application Number:** | |
| **Confirmation Number:** | 7902 |
| **Title of Invention:** | TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR |
| **First Named Inventor/Applicant Name:** | Ali Shahriari |
| **Customer Number:** | 10291 |
| **Filer:** | Kristin Lee Murphy/Kathryn Nash |
| **Filer Authorized By:** | Kristin Lee Murphy |
| **Attorney Docket Number:** | 67306-0001 |
| **Receipt Date:** | 06-DEC-2011 |
| **Filing Date:** | |
| **Time Stamp:** | 16:49:38 |
| **Application Type:** | Provisional |

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## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | | R0957138.PDF | 2658404<br>4f64f859f2b4349a8514872e078981811ac9d46d | yes | 24 |

| Multipart Description/PDF files in .zip description | | |
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| **Document Description** | **Start** | **End** |
| Provisional Cover Sheet (SB16) | 1 | 2 |
| Application Data Sheet | 3 | 5 |
| Specification | 6 | 14 |
| Claims | 15 | 16 |
| Abstract | 17 | 17 |
| Drawings-only black and white line drawings | 18 | 24 |

**Warnings:**

**Information:**

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| 2 | Fee Worksheet (SB06) | fee-info.pdf | 29491<br>ba0c76d726a7d1b8de62821e8f95b8679c983328 | no | 2 |

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