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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
62/554,931	09/06/2017	Benjamin E. Merritt	111552-8016.US00

CONFIRMATION NO. 3223

POA ACCEPTANCE LETTER



25096
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

Date Mailed: 06/11/2018

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/07/2018.

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.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/sleutchit/

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

PTO/AIA/82A (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

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

Application Number	62/554,931 - Conf. No. 3223		
Filing Date	September 6, 2017		
First Named Inventor	Benjamin E. Merritt		
Title	HEMOSTASIS VALVES AND METHODS OF USE		
Art Unit	NA		
Examiner Name	NA		
Attorney Docket Number	111552-8016US00		
SIGNATURE of Applicant or Patent Practitioner			
Signature	/Paul T. Parker/	Date (Optional)	6 June 2018
Name	Paul T. Parker	Registration Number	38,264
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Inari Medical, Inc.		
NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.			
☒	Total of <u>1</u> forms are submitted.		

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

25096

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name				
Address				
City	State	Zip		
Country				
Telephone	Email			

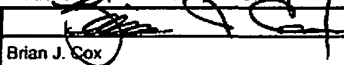
I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Inari Medical, Inc.

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Brian J. Cox		
Title	Vice President, Inari Medical, Inc.		

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

☐ Total of _____ forms are submitted.

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

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

CORRECTED APPLICATION DATA SHEET

PTO/AIA/14 (11-15)

Approved for use through 04/30/2017. 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	401504-000300US-1048388
		Application Number	111552-8016.US00
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		
<p>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.</p> <p>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.</p>			

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		
	Benjamin	E.	Merritt			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	San Clemente	State/Province	CA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		c/o Inari Medical, Inc.				
Address 2		9272 Jeronimo Road, Suite 124				
City	Irvine	State/Province	CA			
Postal Code	92618	Country	US			
Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	John	C.	Thress			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Capistrano Beach	State/Province	CA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		c/o Inari Medical, Inc.				
Address 2		9272 Jeronimo Road, Suite 124				
City	Irvine	State/Province	CA			
Postal Code	92618	Country	US			
Inventor 3					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Paul		Lubbock			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						

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	101594-000300US-1046388		
		Application Number			
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE				
City	Monarch Beach	State/Province	CA	Country of Residence	US
Mailing Address of Inventor:					
Address 1	c/o Inari Medical, Inc.				
Address 2	9272 Jeronimo Road, Suite 124				
City	Irvine	State/Province	CA		
Postal Code	92618	Country	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					

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 20350 25096

Email Address ecfiling@kilpatricktownsend.com

Add Email

Remove Email

patentprocurement@perkinscoie.com

Application Information:

Title of the Invention	HEMOSTASIS VALVES AND METHODS OF USE		
Attorney Docket Number	101594-000300US-1046388	Small Entity Status Claimed	☒
Application Type	Provisional <u>111552-8016.US00</u>		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	Suggested Figure for Publication (if any)	

Filing By Reference:

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

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

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

Publication Information:

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

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

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	101594-000300US-1046388
		Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		

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	20360 25096		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

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

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)¹ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(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).

Application Number	Country ¹	Filing Date (YYYY-MM-DD)	Remove
			Access Code ¹ (if applicable)

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

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	101594-000300US-1046388
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

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.
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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	101594-000300US-1046388
		Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant must opt-out of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is 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 State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	101594-000300US-1046388
	Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE	

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

Inari Medical, Inc.

Mailing Address Information For Applicant:

Address 1 9272 Jeronimo Road, Suite 124

Address 2

City

Irvine

State/Province

CA

Country

US

Postal Code

92618

Phone Number

Fax Number

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 substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	101594-000300US-1046388	
		Application Number		
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE			
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 Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is **not** checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Richard B. Christiansen/		Date (YYYY-MM-DD)	2017-09-06
First Name	Richard	Last Name	Christiansen	Registration Number 69493
Additional Signature may be generated within this form by selecting the Add button.				

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	101594-000300US-1046388
		Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		

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 Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	32832809
Application Number:	62554931
International Application Number:	
Confirmation Number:	3223
Title of Invention:	HEMOSTASIS VALVES AND METHODS OF USE
First Named Inventor/Applicant Name:	Benjamin E. Merritt
Customer Number:	20350
Filer:	Paul T Parker/JiYoung Anderson
Filer Authorized By:	Paul T Parker
Attorney Docket Number:	101594-000300US-1046388
Receipt Date:	07-JUN-2018
Filing Date:	06-SEP-2017
Time Stamp:	14:14:43
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	2018-6-6- POA-111552-8016US00.PDF	132423	no	2
			6c74df6c32a76e58a8571e06fc1114661b9b9879		
Warnings:					

Information:					
2	Application Data Sheet	Corrected- ADS-111552-8016US00-pto. PDF	670969	no	9
			f7181f93b5decea784dd151e840fdae857596247		
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
Total Files Size (in bytes):			803392		
<p>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.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



UNITED STATES PATENT AND TRADEMARK OFFICE

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**** SMALL ENTITY ****

Title

HEMOSTASIS VALVES AND METHODS OF USE

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PATENT APPLICATION
HEMOSTASIS VALVES AND METHODS OF USE

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HEMOSTASIS VALVES AND METHODS OF USE

BACKGROUND

5 **[0001]** During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a desired intervention or treatment. During such surgical procedures, it is desired to minimize patient blood loss, prevent delivery of air into the vasculature, and to maintain the sterility of the accessed portions or sites of the patient's body so as to prevent issues such as infection. Further, the desire for improved patient outcomes has led
10 to the development of hemostasis valves that facilitate minimally invasive surgery.

[0002] In minimally invasive surgery, small incisions are created through a blood vessel which one or several catheters are inserted. Each of these one or several catheters can define a lumen extending longitudinally through that catheter. These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing
15 the procedure are inserted through the lumens of some or all of these catheters.

[0003] To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient's body (e.g., blood vessel), these catheters are equipped with hemostasis valves. These valves seal or selectably seal the lumens of the catheters. In many instances, these valves can seal the lumen of the catheter when a tool extends through
20 the catheter, and specifically through the valve. Additionally the valves can seal the lumen when a tool is removed or does not extend through the catheter.

[0004] While such traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for
25 operator use. The drawbacks of such valve designs may in turn increase the complexity of any surgery performed therewith and/or reduce patient safety (e.g., bleeding, infection, and/or other detrimental complications). Accordingly, new and improved hemostasis valves and methods of use are desired.

BRIEF SUMMARY

5 [0005] The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms. The tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member. The filament can interact with the tubular member to constrict, collapse, and/or seal the tubular member via manipulation of the tensioning mechanism(s). A tool can be inserted through the valve to gain
10 access to a patient's body and specifically to gain access to a blood vessel. Through the use of the tensioning mechanism and filament to constrict, collapse, and/or seal the tubular member, the valve can seal around a wide range of tool sizes and shapes, as well as multiple tools of differing sizes simultaneously. Additionally, such a valve creates a robust seal that maintains its seal when a vacuum is applied such as occurs during aspiration.

15 [0006] Aspects of the present disclosure relate to a hemostatic valve for sealing a medical device. The hemostatic valve includes an elongate member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the elongate member is pliable. The hemostatic valve can include a reinforcement structure extending along at least a portion of the elongate member, such that the reinforcement structure is coupled to the elongate member.
20 The hemostatic valve includes an active tensioning mechanism coupled to the elongate member. In some embodiments, the tensioning mechanism is moveable between a first configuration in which the central lumen is constricted and sealed and a second configuration in which the central lumen is open. Optionally, the valve may be manually adjusted by the user to intermediate positions between fully open and fully closed. Additionally, an instrument (e.g. catheter) may
25 provide an intermediate position where the valve creates hemostasis without user adjustment.

[0007] In some embodiments, the elongate member can be a compliant polymer tube. In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the elongate member. In some embodiments, the reinforcement structure is positioned between the at least one filament and the elongate member. In some embodiments, the
30 reinforcement structure can be a braided mesh. In some embodiments, the reinforcement

structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member. In some embodiments, the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member. In
5 some embodiments, the central portion of the compliant polymer tube that is constrained or collapsed by the tensioning mechanism, and at least one filament, is not coupled to the reinforcement structure.

[0008] In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments there are two tensioning mechanisms coupled to the
10 at least one filament that operate in opposite directions. In some embodiments the two tensioning mechanisms are attached to the same filament. In some embodiments the two tensioning mechanisms are attached to opposing filaments. In some embodiments, the actuator can be moveable to control movement of the at least one filament from a first position in which the central lumen is constricted and sealed to a second position in which the central lumen is open.
15 In some embodiments, the at least one filament is in the first position when the tensioning mechanism is in the first configuration. In some embodiments, the actuator is biased towards the first position. In some embodiments, the actuator is biased toward the second position. In some embodiments, the actuator can be a manual actuator.

[0009] In some embodiments, the at least one filament forms a loop around the elongate
20 member. In some embodiments, the at least one filament forms a bight around a portion of the elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some embodiments, each of the first filament and the second
25 filament are coupled to different actuators. In some embodiments, the first filament and the second filament are moveable from the first position to the second position. In some embodiments, each of the first filament and the second filament form a loop around the elongate member. In some embodiments, the first filament forms a first bight around a first portion of the elongate member, and the second filament forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

[0010] In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some embodiments, the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture. In some embodiments, the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve. In some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

[0011] One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a patient's body. The delivery system includes a catheter having a first end, a second end, and a catheter lumen extending therebetween and a hemostatic valve coupled to the first end of the catheter. The hemostatic valve includes a tubular member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the central lumen of the tubular member is fluidly coupled with the catheter lumen. The hemostatic valve includes an active tensioning mechanism coupled to the tubular member, the tensioning mechanism can be moveable between a first configuration in which the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration in which the central lumen is open.

[0012] In some embodiments, the hemostatic valve further includes a reinforcement structure extending along at least a portion of the tubular member. In some embodiments, the reinforcement structure is located between the tensioning mechanism and the tubular member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member. In some embodiments, the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member. In some embodiments, the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

[0013] In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments,

moving the tensioning mechanism from the first configuration to the second configuration can include moving the actuator and the thereto coupled at least one filament from a first position to a second position. In some embodiments, the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

5 **[0014]** In some embodiments, the actuator can be a manual actuator. In some embodiments, the actuator can include a pair of opposing and depressable buttons, which buttons can be biased towards an undepressed position. In some embodiments, the central lumen is sealed when the buttons are in the undepressed position. In some embodiments, the filament can be a monofilament. In some embodiments, the filament can be at least one of: a polymer filament; or
10 a metallic filament. In some embodiments, the catheter can include a thrombus extraction device.

[0015] One aspect of the present disclosure relates to a method of sealing a delivery device accessing a blood vessel of a patient. The method includes inserting the delivery device including a catheter and a hemostatic valve into the blood vessel of the patient. In some embodiments, the catheter can have a first end, a second end, and a catheter lumen extending
15 therethrough. In some embodiments, the hemostatic valve can be coupled to the first end and can have a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member. In some embodiments, the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel. The method can include moving the tensioning mechanism of the hemostatic
20 valve to a second configuration. In some embodiments, the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration. The method can include advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member. The method can include returning the
25 tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

[0016] In some embodiments, the method includes retracting the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device. In
30 some embodiments, the tensioning mechanism is moved to the second configuration during the

retracting of the shaft of the tool from the delivery device, and the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

- 5 **[0017]** In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the hemostatic valve can include a reinforcement structure located between the at least one filament and the tubular member.
- 10 **[0018]** In some embodiments, the at least one filament forms a loop around the elongate member, and moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop. In some embodiments, the filament forms at least one bight around a portion of the elongate member. In some embodiments, the filament can include a first filament and a second filament.
- 15 In some embodiments, the at least one bight can include a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament. In some embodiments, the first and second bights overlap to encircle a portion of the tubular member within a constricting area.

- [0019]** In some embodiments, moving the tensioning mechanism from the second configuration to the first configuration can include moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member. In some embodiments, the tensioning mechanism can include an actuator. In some embodiments, moving the tensioning mechanism to the second configuration can include manipulating the actuator. In some embodiments, the method includes
- 20 applying a vacuum to the delivery device and/or delivery system to aspirate material through the catheter. In some embodiments, the central lumen remains sealed during the aspiration. In some embodiments, the tool can include a thrombus extraction device.
- 25

BRIEF DESCRIPTION OF THE DRAWINGS

- [0020]** Figure 1 is a perspective view of one embodiment of a delivery device.

- [0021]** Figure 2 is a side-section view of one embodiment of a hemostasis valve in a first configuration.
- [0022]** Figure 3 is a side-section view of one embodiment of the valve in a second configuration.
- 5 **[0023]** Figure 4 is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.
- [0024]** Figure 5 is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.
- [0025]** Figure 6 is a perspective view of a filament of a valve forming a loop.
- 10 **[0026]** Figure 7 is a perspective view of two filaments of a valve, each of the filaments forming a loop.
- [0027]** Figure 8 is a perspective view of two overlapping and interlocked bights in an open configuration.
- [0028]** Figure 9 is a perspective view of two overlapping and interlocked bights in a closed configuration.
- 15 **[0029]** Figure 10 is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.
- [0030]** Figure 11 is a side view of one embodiment of a thrombectomy system including the delivery device.
- 20 **[0031]** Figure 12 is a side-section view of another embodiment of a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

- [0032]** The present disclosure relates to a valve that can be used a hemostasis valve. This valve, also referred to herein as a garrote valve can seal with or without a tool extending through the valve. The garrote valve provides convenient, single-handed operation for a wide range of
- 25

medical devices including catheters, wires, embolectomy systems, or the like. This single-handed operation of the garrote valve allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in applications with a pressure differential on different sides of the valve. This pressure differential can arise, for example, during the application of vacuum aspiration in a procedure. Even under such conditions, as well as under other conditions, the garrote valve maintains seal integrity and prevents leakage in one or both directions.

[0033] The garrote valve includes a tubular member. The tubular member is a flexible member that defines a central lumen, which can, in some embodiments, define a single lumen, and in some embodiments, defines a plurality of lumens. In some embodiments, each of the plurality of lumens can comprise the same size and shape, and in some embodiments, some or all of the plurality of lumens can comprise different sizes and shapes. In some embodiments, for example, the plurality of lumens can comprise a lumen sized and/or shaped to receive a guide wire and a lumen sized and/or shaped to receive a tool. The tubular member extends at least partially through a constricting mechanism. The constricting mechanism can be moved from a first configuration to a second configuration, and the constricting mechanism can collapse and/or seal the central lumen of the tubular member when the constricting mechanism is in the first configuration. The constricting mechanism creates the above-discussed robust seal of the tubular member and thus of the valve.

[0034] With reference now to **Figure 1**, a perspective view of one embodiment of a delivery system 100, also referred to herein as a delivery device 100, is shown. The delivery system 100 can include a catheter 102 and a garrote valve 104, also referred to herein as valve 104. The catheter 102 can comprise a shaft 106, also referred to herein as an elongate sheath 106, having a proximal end 108, also referred to herein as a first end 108, that can connect to the valve 104 and a distal end 110, also referred to herein as a second end 110. The shaft 106 can define a catheter lumen 112 extending from the proximal end 108 of the shaft 106 to the distal end 110 of the shaft 106. The catheter 102 and specifically the shaft 106 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the catheter 102 can be

flexible and/or can be made from a biocompatible material. The elongate sheath 106 can have an outer diameter of at least 4 French, at least 6 French, at least 8 French, at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 4 French and 30 French, between 8 French and 24 French, between 12 French and 20 French,
5 and/or any other or intermediate size.

[0035] The valve 104 can include an outer shell 114. The outer shell 114 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the outer shell 114 can be made from one or several polymers or composites. The outer shell 114 can include features that allow interaction with and/or control of the valve 104 to move the valve
10 104 between the first configuration and the second configuration.

[0036] The outer shell 114 can include a proximal cap 116 located at a proximal end 118 of the outer shell 114 and a distal cap 120 located at a distal end 122 of the shell 114. The proximal cap 116 can include and/or house a proximal aperture 124, also referred to herein as a proximal channel 124, a first channel 124, or a first aperture 124, that extends through the proximal cap
15 116, and the distal cap 120 can include and/or house a distal aperture 126, also referred to herein as a distal channel 126, a second channel 126, or second aperture 126, that extends through the distal cap 120. As seen in Figure 1, the distal cap 120 connects to the shaft 106 of the catheter 102 at the distal end 122 of the valve 104.

[0037] The proximal cap 116 and the distal cap 120 are connected via a housing 128. The
20 housing 128 can be a one-piece housing 128 or a multi-piece housing 128. In the embodiment depicted in Figure 1, the housing comprises a two-piece housing 128. The housing 128 can be configured to receive and couple with each of the proximal cap 116 and the distal cap 120, and as seen in Figure 1, the housing 128 is coupled with each of the proximal cap 116 and the distal cap 120 to secure the relative position of the proximal cap 116 and the distal cap 120 with
25 respect to each other.

[0038] The housing 128 can define an interior channel 130 through which an elongate member 132, also referred to herein as a tubular member 132, a septum 132, or a tubular septum 132, can extend and connect the proximal cap 116 and the distal cap 120. The elongate member 132 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some

embodiments, the elongate member 132 can comprise a compliant tubular structure that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the elongate member 132 can facilitate the collapse, and specifically the uniform collapse of the elongate member 132 and the sealing of the elongate member 132. In some embodiments, the elongate member 132 is an elastic, resilient material that may comprise a polymer including either a natural or synthetic polymer. In some embodiments, the elongate member can comprise an elastic, resilient material that may comprise silicone, urethane, ethylene-vinyl acetate, natural or synthetic rubber or other elastomers known in the art. In some embodiments, the elongate member 132 can comprise a silicone tube.

[0039] The elongate member 132 can comprise a proximal end 134, also referred to herein as a first end 134, that can couple to the proximal cap 116, and a distal end 136, also referred to herein as a second end 136, that can couple to the distal cap 120. The elongate member 132 can define a central lumen 138 that can extend from the first end 134 to the second end 136 of the elongate member 132. The elongate member 132 can be coupled to the proximal cap 116 such that the central lumen 138 is fluidly coupled with the proximal aperture 124 of the proximal cap 116, and the elongate member 132 can be coupled to the distal cap 120 such that the central lumen 138, as seen in **Figure 2** and in **Figure 3**, is fluidly coupled with the distal aperture 126 of the distal cap 120.

[0040] The central lumen 138 of the elongate member 132 can be defined by a wall of the elongate member 132 that can have a thickness that is uniform along the length of the elongate member 132 between the first end 134 and the second end 136, or that is non-uniform along the length of the elongate member 132 between the first end 134 and the second end 136. In some embodiments, the wall can have a thickness that is approximately between 0.005 inches and 0.05 inches, and/or approximately between 0.010 inches and 0.030 inches. As used anywhere herein, “approximately” refers to a range of +/- 10% of the value and/or range of values for which “approximately” is used.

[0041] In some embodiments, the elongate member 132 can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member 132 can be dog-bone shaped to facilitate, for example, connection to each of the proximal cap 116 and the distal cap 120. In some embodiments, the elongate member 132 can include one or

several outward-extending protuberances that engage with all or portions of a constricting mechanism 141, also referred to herein as a tensioning mechanism 141, of the valve 104 to secure a position of all or portions of the constricting mechanism 141 with respect to the elongate member 132. In some embodiments, the constricting mechanism 141 can be self-adjusting to seal
5 around tools of different sizes extending through the valve 104.

[0042] The constricting mechanism 141 can, in some embodiments, collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150. The constricting mechanism 141 can comprise: an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150
10 that can extend at least partially around the elongate member 132. In some embodiments, the use of the constricting mechanism 141 can facilitate sealing of the valve around tools or instruments of a wide range of sizes and/or diameters, and particularly around tools or instruments that fit through the elongate member 132.

[0043] The housing 128 can further include one or several retention features 140. The one or
15 several retention features 140 of the housing can engage with and retain all or portions of the constricting mechanism 141 of the valve 104. In some embodiments, the one or several retention features 140 of the housing 128 can retain the actuator 142 and/or can couple the actuator 142 to the housing 128. The actuator 142 can comprise any desired type of actuator including, for example, a manual actuator and/or an automated actuator such as, for example, an
20 electromechanical actuator including a solenoid-based actuator. In some embodiments, the actuator can comprise one or several buttons 144, and specifically, as depicted in Figure 1, the actuator 142 can comprise a first button 144-A and a second button 144-B. Alternatively, and as depicted in **Figure 5**, the actuator 142 can comprise a single button 144. In such an embodiment, the filament 150 can be coupled to the single button 144 and to a portion of the housing 128 such
25 as, for example, to grip portion 500 of the housing 128 such that the movement of the single button 144 causes the sealing and/or opening of the elongate member 132 and of the valve 104.

[0044] The actuator 142 can be biased towards a configuration such as, for example, biased towards the first configuration or biased towards the second configuration. As depicted in Figure 2, which shows the constricting mechanism 141 in the first configuration, the actuator 142 can be
30 biased towards the first configuration wherein the elongate member 132 is collapsed and/or

sealed by a bias feature 146. In this first configuration, the buttons 144 can be in a first position, also referred to herein as an undepressed position. This bias feature 146 can, as shown in Figure 2, include a first spring 148-A configured to bias the first button 144-A towards the first position corresponding to the first configuration of the constricting mechanism 141, and a second spring
5 148-B configured to bias the second button 144-B towards a first position corresponding to the first configuration of the constricting mechanism 141. One or both of the first spring 148-A and the second spring 148-B can comprise a tension spring, compression spring, a torsion spring, a coil spring, or any other desired type of spring.

[0045] In some embodiments, one or both of the first spring 148-A and the second spring 148-
10 B can generate sufficient force so as to allow actuation of the actuator 142 with a single hand and so as to collapse and seal the elongate member 132 when the constricting mechanism 141 is in the first configuration. In some embodiments, one or both of the first spring 148-A and the second spring 148-B can generate a force of: at least 0.1 pounds, at least 0.2 pounds, at least 0.3 pounds, at least 0.4 pounds, at least 0.5 pounds, at least 0.6 pounds, at least 0.7 pounds, at least
15 0.8 pounds, at least 0.9 pounds, at least 1 pound, at least 1.5 pounds, at least 2 pounds, at least 3 pounds, at least 5 pounds, and/or at least 10 pounds and in some embodiments one or both of the first spring 148-A and the second spring 148-B can generate a force approximately between: 0.1 and 10 pounds, 0.1 and 5 pounds, 0.1 and 1.5 pounds, 0.2 and 1 pounds, and/or 0.4 and 0.8 pounds.

[0046] The constricting mechanism 141 can include at least one filament 150 that extends at
20 least partially around the elongate member 132. In some embodiments, the at least one filament 150 can circumferentially constrict the elongate member 132 to collapse and seal the elongate member 132 when the constricting mechanism 141 is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a
25 metal. In some embodiments, the filament 150 can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some
30 embodiments, the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

[0047] The filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132, and specifically the central lumen 138 of the elongate member 132 based on the movement and/or position of the actuator 142. In some embodiments, the filament 150 can be connected to one or both of the buttons 144-A, 144-B such that the filament 150 collapses, constricts, and/or seals the elongate member 132 and specifically the central lumen 138 of the elongate member 132 when the buttons 144-A, 144-B are in the first position, and the filament 150 can be connected to one or both of the buttons 144-A, 144-B such that the elongate member 132 and specifically the central lumen 138 of the elongate member 132 is open and uncollapsed when the buttons 144-A, 144-B are in the second position. In some embodiments in which the actuator 142 comprises a single button 144, as depicted in Figure 5, the filament 150 can be connected to the button 144 and to the housing 128 such that the filament 150 is tightened when the button 144 moves to the first position.

[0048] In some embodiments, the at least one filament 150 can extend along an axis 152 that can be perpendicular to a central axis 154 of the elongate member 132 and/or of the apertures 124, 126. In some embodiments, the axis 152 of the at least one filament 150 can intersect and be perpendicular to the central axis 154 of the elongate member 132 and/or of the apertures 124, 126. In some embodiments, the actuator 142, and specifically the buttons 144-A, 144-B can move along this axis 152 when moved from the first position to the second position.

[0049] In Figure 3, an embodiment of the valve 104 with the constricting mechanism 141 in the second configuration is shown. As specifically shown, both of the first and second buttons 144-A, 144-B are in the second position, depressed into the retention features 140 of the housing 128. In this second position, the filament 150 is loosened, thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.

[0050] As further seen in Figure 3, the proximal cap 116 has a proximal end 300 and a distal end 302. The proximal cap 116 can include a funnel portion 301 of the proximal aperture 124, which funnel portion 301 can facilitate insertion of a tool into the proximal aperture 124. The distal end 302 of the proximal cap 116 can partially extend into the interior channel 130 of the housing 128. The proximal cap 116 can include a mating feature 304 that can mate with the proximal end 134 of the elongate member 132. In some embodiments, the proximal end 134 of

the elongate member 132 can fit over the mating feature 304 of the proximal cap 116. The proximal end 134 of the elongate member 132 can be compressed between the mating feature 304 of the elongate member 132 and a portion of the interior channel 130 of the housing 128 into which the mating feature 304 is inserted to thereby secure the proximal end 134 of the elongate member 132 on the mating feature 304. In some embodiments, the proximal end 134 of the elongate member 132 can be further secured on the mating feature 304 by a proximal O-ring 306 that can be compressed between the housing 128 and the mating feature 304 of the proximal cap 116 to sealingly couple the elongate member 132 to the proximal cap 116.

[0051] The distal cap 120 has a proximal end 308 and a distal end 310. The distal cap can include a mating feature 312 located on the proximal end 308 of the distal cap 120, which mating feature 312 can mate with the distal end 136 of the elongate member 132. In some embodiments, the distal end 136 of the elongate member 132 can fit over the mating feature 312 of the distal cap 123. The distal end 136 of the elongate member 132 can be compressed between the mating feature 312 of the elongate member 132 and a portion of the interior channel 130 of the housing 128 into which the mating feature 312 is inserted to thereby secure the distal end 136 of the elongate member 132 on the mating feature 312. In some embodiments, the distal end 136 of the elongate member 132 can be further secured on the mating feature 312 by a distal O-ring 314 that can be compressed between the housing 128 and the mating feature 312 of the proximal cap 116 to sealingly couple the elongate member 132 to the distal cap 120.

[0052] The distal cap 120 can, in some embodiments, further include a side port barb 314 that can extend laterally away from the distal cap 120 and specifically away from the distal aperture 126 of the distal cap 120. The side port barb 314 can define a side port channel 316 that can extend through the side port barb 314 and fluidly connect to the distal aperture 126. In some embodiments, the side port barb 314 can include a securement feature 318 such as a barb that can secure coupling of a hose or tube to the side port barb 314.

[0053] In some embodiments, the side barb 314 can be used to apply a vacuum to the portions of the delivery device 100, and particularly to portions of the delivery device 100 that are distal of the axis 152 along which the elongate member 132 seals. This vacuum can be applied to aspirate a material through the delivery device 100, and specifically through the catheter 102 of the delivery device. This aspirated material can be a biological material including, for example,

bodily fluids, multi-phase bodily materials that can include, for example, a fluidic portion and at least one solid portion, or the like.

5 **[0054]** In some embodiments, due to the narrowing shape of the elongate member 132 when the constricting mechanism 141 is in the first configuration, a vacuum applied to the portions of the delivery device 100 distal to the axis 152 draws the elongate member 132 towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve 104. This attribute of the valve 104 can provide benefits over other valve designs in which a vacuum can compromise the seal of the valve, and thus the ability to draw a vacuum and aspirate can be limited.

10 **[0055]** In some embodiments, the valve 104 can further include a reinforcement structure 320 that can extend along all or portions of the elongate member 132. The reinforcement structure 320 can facilitate the uniform collapse of the elongate member 132, can prevent the at least one filament 150 from cutting through and/or tearing the elongate member 132, and can assist in guiding one or several tools through the elongate member 132. The reinforcement structure 320
15 can be tubular, can extend along and around the elongate member 132, and can be positioned so as to be between the elongate member 132 and the at least one filament 150.

[0056] The reinforcement structure 320 can include a proximal end 322 and a distal end 324. In some embodiments, the reinforcement structure 320 extends along and around the elongate member 132, and is positioned such that the proximal end 322 of the reinforcement structure 320
20 is proximate to the first end 134 of the elongate member 132 and the distal end 324 of the reinforcement structure 320 is proximate to the second end 136 of the elongate member 132.

[0057] The reinforcement structure 320 can be coupled to the elongate member 132. In some embodiments, the reinforcement structure 320 is coupled to the elongate member 132 along the length of the reinforcement structure 320, and in some embodiments, the reinforcement structure
25 320 is coupled to the elongate member 132 and distinct positions along the length of the elongate member 132 and/or the reinforcement structure 320. In one embodiment, for example, the reinforcement structure 320 can be coupled to the elongate member 132 at one or both of the proximal end 322 of the reinforcement structure 320 and the distal end 324 of the reinforcement structure 320 and/or at one or both of the first end 134 and the second end 136 of the elongate

member 132. In some embodiments, the reinforcement structure 320 can be coupled to the elongate member 132 via one or several other components of the valve 104. In some embodiments, the reinforcement structure 320 can be coupled to the elongate member 132 via the compression of the reinforcement structure 320 and the elongate member 132 between the housing 128 and one or both of the proximal 116 and the distal 120.

[0058] In some embodiments, the reinforcement structure 320 can be adhered to the elongate member 132 via, for example, an adhesive such as silicone adhesive. In some embodiments, the adhesive can be circumferentially applied to the reinforcement structure 320 and/or the elongate member 132 in an adhesive ring that can, for example, have a length approximately between: 0.010 inches and 0.5 inches; 0.02 and 0.4 inches; 0.050 inches and 0.0250 inches, or any other or intermediate range.

[0059] In one embodiment, each of the proximal end 322 and the distal end 324 of the reinforcement structure 320 can be adhered via an adhesive to the elongate member 132. In such an embodiment, the reinforcement structure 320 may be uncoupled to the elongate member 132 at positions other than the coupling at one or both of the proximal end 322 and the distal end 324 of the reinforcement structure 320, and thus the reinforcement structure 320 is uncoupled to the elongate member 132 at a position between the first end 134 and the second end 136 of the elongate member 134 and/or between the proximal end 322 and the distal end 324 of the reinforcement structure 320.

[0060] The lack of coupling of the reinforcement structure 320 to the elongate member 132 can facilitate and improve the collapse of the elongate member 132 around a tool 400, also referred to herein as instrument 400 or device 400, inserted through the valve 104 as shown in **Figure 4**. The tool 400 can be any device inserted through the valve 104 including, for example, one or several additional catheters, lines, wires, grippers, punches, cutters, or the like. As seen in **Figure 4**, the tool 400 is inserted through the valve 104 and specifically through the elongate member 132 of the valve. As shown, the constricting mechanism 141 is in the first configuration and the elongate member 132 and the central lumen 138 of the elongate member 132 is collapsed around the tool 400, and specifically around a shaft 402 of the tool 400 to thereby seal the valve 104 around the tool 400 and specifically around the shaft 402 of the tool 400. The constricting

mechanism 141 can seal around tools 400 that fit through the elongate member 132, regardless of the size of the tool 400. Thus, the valve can be used with a wide variety of tools.

[0061] The reinforcement structure 320 can comprise a variety of designs, shapes, sizes, and materials. In some embodiments, the reinforcement structure 320 can be sized and shaped so as to receive elongate member 132 and to be positioned between the elongate member 132 and the at least one filament 150. In some embodiments, the reinforcement structure 320 can be made from a material sufficiently strong to prevent the cutting of the at least one filament 150 through the elongate member 132.

[0062] In some embodiments, the reinforcement structure can comprise a coil or a mesh sheath. The mesh sheath can, in some embodiments, comprise a braided mesh. The braided mesh can be made from any desired number of wires in any desired configuration. In some embodiments, the braided mesh can comprise a 4 wire braided mesh, an 8 wire braided mesh, a 12 wire braided mesh, a 16 wire braided mesh, a 20 wire braided mesh, a 24 wire braided mesh, a 32 wire braided mesh, a 48 wire braided mesh, a 64 wire braided mesh, a 72 wire braided mesh, an 80 wire braided mesh, a 96 wire braided mesh, or any other or intermediate braided mesh. In some embodiments, the braided mesh can comprise a 1x1 configuration. In some embodiments, the wire in the braided mesh can be any desired material including, for example, a metal wire such as a nitinol wire or a stainless steel wire, a polymer wire, or a natural wire. In one embodiment, the braided mesh can comprise a 48 wire mesh in a 1x1 configuration made with a nitinol wire having a diameter of 0.003 inches.

[0063] With reference now to **Figures 6** through **9**, different embodiments and/or configurations of the filament 150 are shown. The filament 150 can comprise a single filament 150 having a first end 600 and a second end 602 as shown in Figure 6. The filament 150, and specifically which first and second ends 600, 602 can be coupled to the actuator 142 to move the filament 150 between the first and second configurations or positions and/or from the first configuration or position to the second configuration or position. In some embodiments, both of the first end 600 and the second end 602 can be coupled to a single button 144, in some embodiments, each of the first end 600 and the second end 602 can be coupled to different buttons 144, and in some embodiments, one of the first end 600 and the second end 602 can be

coupled to a button 144 and the other of the first end 600 and the second end 602 can be coupled to the housing 128 or other portion of the valve 104.

[0064] In some embodiments, the filament 150 can comprise multiple filaments, and specifically, as shown in Figures 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B. In embodiments in which the filament 150 comprises multiple
5 filaments, each of the multiple filaments can have a first end 700 and a second end 702. The first and second filaments 150-A, 150-B can be coupled to the actuator 142. In such embodiments, the first and second ends 700, 702 can be coupled to the actuator 142 to move the filaments 150-A, 150-B between the first and second configurations and/or from the first configuration to the
10 second configuration. In some embodiments, both of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to a single button 144, in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144, and in some embodiments, one of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to
15 one button 144 and the other of the first end 700 and the second end 702 of those one or more filaments 150 can be coupled to the housing 128 or other portion of the valve 104.

[0065] The filament 150 can be arranged in a variety of configurations. In some embodiments, the filament 150 can be configured to form a single loop 604 that can extend around the elongate member 132 and/or through which the elongate member 132 can be received as shown in Figure
20 6, and in some embodiments, the filament 150 can be configured to form multiple loops, and specifically a first loop 704 and a second loop 706 as shown in Figure 7. The first and second loops 704, 706 can each receive the elongate member 132. In some embodiments, a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.

[0066] In some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights. As used herein, a “bight” refers to a U-shaped section between the two ends of the filament 150. As depicted in Figures 8 and 9, the bight 800 can comprise multiple bights, and specifically a first bight 800-A and a second bight 800-B. In some embodiments, the first bight 800-A can extend through the second bight 800-B such that
30 the first and second bights 800-A, 800-B interlock, whereas in other embodiments, the first and

second bights 800-A, 800-B can be non-interlocking. Similarly, in embodiments containing the filament 150 having multiple loops, one or several of the multiple loops can be interlocking.

[0067] In some embodiments, the bight 800, and specifically one or both of the first bight 800-A and the second bight 800-B can be formed around a portion of the elongate member 132 and/or can extend around a portion of the elongate member 132. Each bight 800 can define a partially enclosed receiving area 808 wherein the elongate member 132 can be received. Thus, the first bight 800-A can define a first receiving area 808-A and the second bight 800-B can define a second receiving area 808-B.

[0068] As seen in Figures 8 and 9, multiple bights, and specifically the first and the second bights 800-A, 800-B can be positioned and oriented such that the first bight 800-A has a first orientation or first direction as indicated by arrow 810, and the second bight has a second orientation or second direction as indicated by the arrow 812. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to herein as a constricting area 814. The elongate member 132 can be received within the encircled area 814. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.

[0069] The filament(s) 150 forming the bights 800 can each apply an arcuate line or narrow longitudinal zone of pressure to the elongate member 132. If the filament(s) are circular in cross-section, the zone of pressure can be very small, and can, in some embodiments, be less than the diameter or thickness of the filament. In some embodiments, the filaments have a diameter or width less than about 2.5mm, less than about 2mm, less than about 1.5mm, less than about 1.25mm, less than about 1mm, less than about 0.75mm, less than about 0.5mm, and/or less than about 0.25mm. In some embodiments, the filaments can have a diameter or width of between about 0.01mm and 2.5mm, between about 0.05mm and 2mm, between about 0.1mm and 1mm, and/or between about 0.125mm and 0.70mm. In some embodiments, the arcuate line or zone of

pressure may form two opposing arcs and in other embodiments, the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once. The longitudinal length of the of the line or zone of pressure may be very short compared to other valves known in the art. In some embodiments, the longitudinal length of the zone of pressure applied to the elongate member 132 by the filament(s) 150 may be less than about 2.0mm and in some embodiments less than about 0.5mm. In some embodiments, the filament(s) 150 can have any desired cross-sectional shape including, for example, a circular cross-section, a rectangular cross-section, an oval cross-section, a square cross-section, a polygonal cross-section, a triangular cross-section, or any other desired shape of cross-section.

10 **[0070]** With reference now to **Figure 10**, a flowchart illustrating one embodiment of a process 1000 for sealing a valve 104 and/or catheter 102 accessing a body of a patient is shown. The process 1000 can be performed using the valve 104 and/or the delivery system 100. The process 1000 begins at block 1002, wherein the delivery device 100, and specifically the catheter 102 of the delivery device 100 is inserted into the body of the patient. In some embodiments, this can include inserting the catheter 102 into a portion of the circulator system of the patient such as, for example, a blood vessel including an artery or a venous vessel. In some embodiments, the delivery device 100 can be inserted into the body of the patient directly through an aperture or incision in the patient, and in some embodiments, the delivery device 100 can be inserted into the body of the patient via another catheter or device. In some embodiments, the constricting mechanism 141 can be in the first configuration while the delivery device 100 and/or the catheter 102 is inserted into the patient's body.

25 **[0071]** After the delivery device 100 is inserted into the body of the patient, the process 1000 proceeds to block 1004, wherein the constricting mechanism 141 is moved from the first configuration to the second configuration. As described above, the central lumen 138 of the elongate member 132 is unsealed when the constricting mechanism 141 is in the second configuration. In some embodiments, the moving of the constricting mechanism 141 from the first configuration to the second configuration can include the manipulation of the actuator 142 and/or the control of the actuator 142, and specifically the depressing of the one or several buttons 144 to move the filament 150 from the first position to the second position to allow the expansion and opening of the central lumen 138 of the elongate member 132.

[0072] After the constricting mechanism 141 is moved from the first configuration to the second configuration, the process 1000 proceeds to block 1006, wherein the tool 400, and specifically the shaft 402 of the tool 400 is advanced through the delivery device 100 and specifically through the valve 104 until a first end of the tool reaches a desired position within
5 the body of the patient. In some embodiments, a portion of the shaft 402 can be positioned within the central lumen 138 of the elongate member 132 after the advancing of the tool 400 through the delivery device 100. In some embodiments, after the tool 400 is advanced through the delivery device 100, the desired procedure can be performed with the tool.

[0073] After the tool 400 is advanced through the delivery device 100, or while the tool 400 is
10 being advanced through the delivery device 100, the process 1000 proceeds to block 1008, wherein the constricting mechanism 141 is returned to the first configuration. In some embodiments, the returning of the constricting mechanism 141 to the first configuration can include the release of the one or several buttons 144 and/or the control of the actuator 142 to reconfigure the constricting mechanism 141 to the first configuration. In some embodiments, the
15 return of the constricting mechanism 141 to the first configuration can result in the collapse and/or sealing of the elongate member 132 and specifically the central lumen 138 of the elongate member 132 around the tool 400 and specifically around the shaft 402 of the tool 400. The return of the constricting mechanism 141 to the first configuration, or the movement of the constricting mechanism 141 to the first configuration can include the decreasing of the size and/or diameter
20 of one or several loops formed by the filament 150 and/or the movement of one or several bights 800 such as, for example, the movement of the first bight 800-A in the first direction indicated by arrow 810 and the movement of the second bight 800-B in the second direction indicated by arrow 812 to reduce the size of the constricting area 814. In some embodiments, after the constricting mechanism is returned to the first configuration, the desired procedure can be
25 performed with the tool.

[0074] After the constricting mechanism is returned to the first configuration, the process 1000 proceeds to block 1010, wherein the tool 400, and specifically the shaft 402 of the tool 400 is retracted from the delivery device 100, and more specifically from the valve 104. In some
30 embodiments, the valve 104 can remain sealed during the retracting of the tool 400 and/or the shaft 402 of the tool. In some embodiments, the valve 104 remains sealed during the retracting of

the tool 400 and/or the retracting of the shaft 402 of the tool 400 as the constricting mechanism 141 can remain in the first configuration during the retracing of the tool 400 and/or the shaft 402 of the tool 400.

5 **[0075]** In some embodiments, the constricting mechanism 141 can be moved to the second configuration to allow the retraction of the tool 400 and/or the shaft 402 of the tool 400 from the valve 104, and the constricting mechanism 141 can be returned to the first configuration when the tool 400 and/or the shaft 402 of the tool 400 is removed from the valve 104. In some embodiments, the retraction of the tool 400 and/or shaft 402 of the tool 400 from the valve 104 can be performed with the constricting mechanism 141 left in the first configuration. In some
10 embodiments, the constricting mechanism 141 can be moved to the second configuration, and then returned to the first configuration via the manipulation and/or control of the actuator 142, which manipulation and/or control of the actuator 142 can include the depressing of the one or several buttons 144 to move the constricting mechanism 141 to the second configuration, and the release of the one or several buttons 144 to return the constricting mechanism 141 to the first
15 configuration. In some embodiments, if the procedure is complete, the delivery device 100 can then be removed from the body of the patient, and any incision created for the procedure can be closed.

[0076] With reference now to Figure 11, a side view of one embodiment of a thrombectomy system 1100 including the delivery device 100 and a thrombus extraction device 1102 is shown.
20 In some embodiments, the thrombectomy system 1100 can be used to access a blood vessel 1104 to treat and/or extract a thrombus 1106 from the blood vessel 1104. The thrombus extraction device 1102 can include a self-expanding coring element 206 and expandable cylindrical portion 208. In some embodiments, and as shown in Figure 11, the thrombus extraction device 1102 can be the tool 400 that can extend through the valve 104, and in some embodiments, the valve 104
25 can be a part of the thrombus extraction device 1102. Further details of thrombectomy systems, thrombus extraction devices, and methods of using the same are disclosed in: U.S. Application No. 15/268,296, filed September 16, 2016, and entitled “INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS”; U.S. Application No. 15/498,320, filed April 26, 2017, and entitled “DEVICES
30 AND METHODS FOR TREATING VASCULAR OCCLUSION”; and U.S. Application No.

15/466,740, filed on March 22, 2017, and entitled “DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION”, the entirety of each of which is hereby incorporated by reference herein.

[0077] With reference now to Figure 12, a side-section view of another embodiment of the hemostasis valve 104 having two piece caps 116, 120 is shown. The valve 104 can include a housing 128 defining an interior channel 130 through which the tubular member 132 can extend. The valve 104 can include the proximal cap 116 and the distal cap 120. In some embodiments, the proximal cap 116 can comprise a two piece cap and can include a proximal exterior member 1200 and a proximal channel member 1202. In some embodiments, the distal cap 120 can comprise a two-piece cap and can include a distal exterior member 1204 and a distal channel member 1206. In some embodiments, this coupling between the proximal exterior member 1200 and the proximal channel member 1202 and/or the coupling between the distal exterior member 1204 and the distal channel member 1206 can be a sealed coupling so as to prevent the leakage of material including fluid or gas between the respective ones of the proximal exterior member 1200 and the proximal channel member 1202 and/or the distal exterior member 1204 and the distal channel member 1206. In some embodiments, this sealing coupling can be achieved and/or maintained via a seal such as an O-ring 1208 that can be positioned between the proximal exterior member 1200 and the proximal channel member 1202 and/or between the distal exterior member 1204 and the distal channel member 1206.

[0078] In some embodiments, the proximal exterior member 1200 can be coupled, and in some embodiments, rotatably coupled to the proximal channel member 1202 in a manner to allow the rotation of the proximal exterior member 1200 without rotating the proximal channel member 1202. Similarly, in some embodiments, the distal exterior member 1204 can be rotatably coupled to the distal channel member 1206 in a manner to allow the rotation of the distal exterior member 1204 without the rotating of the distal channel member 1206. In some such embodiments, the channel members 1202, 1206 can be non-rotatable with respect to the housing 128 and/or the tubular member 132, and one or both of the exterior members 1200, 1204 can be rotatable with respect to the housing 128 and/or the tubular member 132. In such an embodiment, the maintaining of the rotational position of the channel members 1202, 1206 with respect to the housing 128 and/or the tubular member 132 can prevent the twisting of the tubular

member 132 which can result in the sealing of the tubular member 132 regardless of the configuration of the constructing mechanism 141.

[0079] The exterior members 1200, 1204 can comprise a variety of shapes and sizes and can include a variety of features. In some embodiments, one or both of the exterior members 1200, 1204 can be coupled to, for example, a shaft similar to the shaft 106 shown in figure 1. In some
5 1204 can be coupled to, for example, a shaft similar to the shaft 106 shown in figure 1. In some
embodiments, for example, the distal exterior member 1204 can be coupled to a shaft 106,
including, for example, can be non-detachably coupled to the shaft 106. In some embodiments,
one or both of the exterior members can include one or several features configured to facilitate
coupling with the valve 104. These one or several features can include, for example, one or
10 several male or female: connectors; couplers; attachment mechanisms; or the like. In some
embodiments, these one or several features can facilitate use of the valve with other existing
components, instruments, tools, or the like. In some embodiments, for example, one or both of
the exterior members 1200, 1204 can comprise either a male or female luer fitting, and
specifically as shown in Figure 12, the distal exterior member 1204 can comprise a male luer
15 fitting 1210.

[0080] Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific
20 form or forms disclosed, but on the contrary, the intention is to cover all modifications,
alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

[0081] In the previous description, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order
25 to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

[0082] The use of the terms “a” and “an” and “the” and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be
5 construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. The term “connected” is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is
10 incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise
15 claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0083] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred
20 embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations
25 thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0084] All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

WHAT IS CLAIMED IS:

- 1 1. A hemostatic valve for sealing a medical device, the hemostatic valve
2 comprising:
3 an elongate member having a first end, a second end, and a central lumen
4 extending therebetween, wherein the elongate member is pliable;
5 a reinforcement structure extending along at least a portion of the elongate
6 member, wherein the reinforcement structure is coupled to the elongate member; and
7 an active tensioning mechanism coupled to the elongate member, wherein the
8 tensioning mechanism is moveable between a first configuration wherein the central lumen is
9 constricted and sealed and a second configuration wherein the central lumen is open.
- 1 2. The hemostatic valve of claim 1, wherein the elongate member comprises
2 a compliant polymer tube.
- 1 3. The hemostatic valve of claim 1, wherein the tensioning mechanism
2 comprises at least one filament extending at least partially around the elongate member.
- 1 4. The hemostatic valve of claim 3, wherein the reinforcement structure is
2 positioned between the at least one filament and the elongate member.
- 1 5. The hemostatic valve of claim 4, wherein the reinforcement structure
2 comprises a braided mesh.
- 1 6. The hemostatic valve of claim 4, wherein the reinforcement structure is
2 coupled to the elongate member at a position proximate to the first end of the elongate member
3 and at a position proximate to the second end of the elongate member.
- 1 7. The hemostatic valve of claim 6, wherein the reinforcement structure is
2 not coupled to the elongate member at a position between the first end of the elongate member
3 and the second end of the elongate member.
- 1 8. The hemostatic valve of claim 3, wherein the tensioning mechanism
2 comprises an actuator coupled to the at least one filament, wherein the actuator is moveable to
3 control movement of the at least one filament from a first position wherein the central lumen is

4 constricted and sealed to a second position wherein the central lumen is open, wherein the at
5 least one filament is in the first position when the tensioning mechanism is in the first
6 configuration.

1 9. The hemostatic valve of claim 8, wherein the actuator is biased towards
2 the first position.

1 10. The hemostatic valve of claim 8, wherein the actuator is biased toward the
2 second position.

1 11. The hemostatic valve of claim 8, wherein the actuator comprises a manual
2 actuator.

1 12. The hemostatic valve of claim 8, wherein the at least one filament forms a
2 loop around the elongate member.

1 13. The hemostatic valve of claim 8, wherein the at least one filament forms a
2 bight around a portion of the elongate member.

1 14. The hemostatic valve of claim 8, wherein the at least one filament
2 comprises a first filament and a second filament, wherein each of the first filament and the
3 second filament are coupled to the actuator, and wherein the first filament and the second
4 filament are moveable from the first position to the second position.

1 15. The hemostatic valve of claim 14, wherein each of the first filament and
2 the second filament form a loop around the elongate member.

1 16. The hemostatic valve of claim 14, wherein the first filament forms a first
2 bight around a first portion of the elongate member, and wherein the second filament forms a
3 second bight around a second portion of the elongate member.

1 17. The hemostatic valve of claim 16, wherein the first bight extends through
2 the second bight.

1 18. The hemostatic valve of claim 1, further comprising a shell defining a first
2 aperture and a second aperture, wherein the elongate member extends from the first aperture to
3 the second aperture and fluidly couples the first aperture and the second aperture.

1 19. The hemostatic valve of claim 1, wherein the tensioning mechanism is
2 self-adjustable to seal around tools of different sizes extending through the hemostatic valve.

1 20. The hemostatic valve of claim 1, wherein the central lumen comprises a
2 single lumen.

1 21. The hemostatic valve of claim 1, wherein the central lumen comprises a
2 plurality of lumens.

1 22. A delivery system for intravascular access of a blood vessel within a
2 patient's body, the delivery system comprising:
3 a catheter having a first end, a second end, and a catheter lumen extending
4 therebetween;
5 a hemostatic valve coupled to the first end of the catheter, the hemostatic valve
6 comprising:
7 a tubular member having a first end, a second end, and a central lumen
8 extending therebetween, wherein the central lumen of the tubular member is fluidly
9 coupled with the catheter lumen; and
10 an active tensioning mechanism coupled to the tubular member, the
11 tensioning mechanism moveable between a first configuration wherein the tensioning
12 mechanism constricts on the central lumen and the central lumen is sealed and a second
13 configuration wherein the central lumen is open.

1 23. The delivery system of claim 22, wherein the hemostatic valve further
2 comprises a reinforcement structure extending along at least a portion of the tubular member.

1 24. The delivery system of claim 23, wherein the reinforcement structure is
2 located between the tensioning mechanism and the tubular member.

- 1 25. The delivery system of claim 24, wherein the reinforcement structure
2 comprises a braided mesh.
- 1 26. The delivery system of claim 24, wherein the reinforcement structure is
2 coupled to the tubular member at a position proximate to the first end of the tubular member and
3 at a position proximate to the second end of the tubular member.
- 1 27. The delivery system of claim 26, wherein the reinforcement structure is
2 adhered to the tubular member at the first end of the tubular member and at the second end of the
3 tubular member.
- 1 28. The delivery system of claim 27, wherein the reinforcement structure is
2 uncoupled to the tubular member between the first end of the tubular member and the second end
3 of the tubular member.
- 1 29. The delivery system of claim 22, wherein the tensioning mechanism
2 comprises at least one filament extending at least partially around the tubular member.
- 1 30. The delivery system of claim 29, wherein the tensioning mechanism
2 comprises an actuator coupled to the at least one filament, wherein moving the tensioning
3 mechanism from the first configuration to the second configuration comprises moving the
4 actuator and the thereto coupled at least one filament from a first position to a second position,
5 wherein the filament constricts and seals the central lumen of the tubular member when the
6 filament is in the first position.
- 1 31. The delivery system of claim 30, wherein the actuator comprises a manual
2 actuator.
- 1 32. The delivery system of claim 31, wherein the actuator comprises a pair of
2 opposing and depressable buttons, wherein the buttons are biased towards an undepressed
3 position.
- 1 33. The delivery system of claim 31, wherein the central lumen is sealed when
2 the buttons are in the undepressed position.

1 34. The delivery system of claim 30, wherein the filament comprises a
2 monofilament.

1 35. The delivery system of claim 30, wherein the filament comprises at least
2 one of: a polymer filament; or a metallic filament.

1 36. The delivery system of claim 22, wherein the catheter comprises a
2 thrombus extraction device.

3 37. A method of sealing a delivery device accessing a blood vessel of a
4 patient, the method comprising:
5 inserting the delivery device comprising a catheter and a hemostatic valve into the
6 blood vessel of the patient, the catheter having a first end, a second end, and a catheter lumen
7 extending therethrough, and the hemostatic valve coupled to the first end and having a tubular
8 member defining a central lumen fluidly coupled with the catheter lumen and a tensioning
9 mechanism coupled with the tubular member, wherein the tensioning mechanism collapses and
10 seals the central lumen in a first configuration and thereby seals access to the blood vessel;
11 moving the tensioning mechanism of the hemostatic valve to a second
12 configuration, wherein the central lumen is open and access to the blood vessel is unsealed when
13 the tensioning mechanism is in the second configuration;
14 advancing a shaft of a tool through the delivery device until a first end of the tool
15 reaches a desired position within the blood vessel of the patient and a portion of the shaft is
16 positioned within the central lumen of the tubular member; and
17 returning the tensioning mechanism of the hemostatic valve to the first
18 configuration such that the tubular member collapses on the shaft of the tool and seals around the
19 shaft of the tool.

1 38. The method of claim 37, further comprising retracting the shaft of the tool
2 from the delivery device.

1 39. The method of claim 38, wherein the tensioning mechanism is maintained
2 in the first configuration during and after the retracting of the shaft of the tool from the delivery
3 device.

1 40. The method of claim 38, wherein the tensioning mechanism is moved to
2 the second configuration during the retracting of the shaft of the tool from the delivery device,
3 and wherein the tensioning mechanism is returned to the first configuration after the shaft of the
4 tool is retracted from the delivery device.

1 41. The method of claim 37, wherein the tensioning mechanism comprises at
2 least one filament extending at least partially around the tubular member, wherein the at least one
3 filament collapses the tubular member when the tensioning mechanism is in the first
4 configuration.

1 42. The method of claim 41, wherein the at least one filament
2 circumferentially constricts the tubular member to collapse the tubular member when the
3 tensioning mechanism is in the first configuration.

1 43. The method of claim 41, wherein the hemostatic valve comprises a
2 reinforcement structure located between the at least one filament and the tubular member.

1 44. The method of claim 41, wherein the at least one filament forms a loop
2 around the elongate member, and wherein moving the tensioning mechanism from the second
3 configuration to the first configuration reduces a size of the loop to thereby constrict the tubular
4 member within the loop.

1 45. The method of claim 41, wherein the filament forms at least one bight
2 around a portion of the elongate member.

1 46. The method of claim 45, wherein the filament comprises a first filament
2 and a second filament, and wherein the at least one bight comprises a first bight oriented in a first
3 direction and formed by the first filament and a second bight oriented in a second direction and
4 formed by the second filament, wherein the first and second bights overlap to encircle a portion
5 of the tubular member within an constricting area.

1 47. The method of claim 46, wherein moving the tensioning mechanism from
2 the second configuration to the first configuration comprises moving the first bight in the first

3 direction and the second bight in the direction to reduce the size of the constricting area and
4 collapse and seal the central lumen of the tubular member.

1 48. The method of claim 37, wherein the tensioning mechanism comprises an
2 actuator, and wherein moving the tensioning mechanism to the second configuration comprises
3 manipulating the actuator.

1 49. The method of claim 37, further comprising applying a vacuum to the
2 delivery device to aspirate material through the catheter, wherein the central lumen remains
3 sealed during the aspiration.

1 50. The method of claim 37, wherein the tool comprises a thrombus extraction
2 device.

1 51. A hemostatic valve for sealing a medical device, the hemostatic valve
2 comprising:

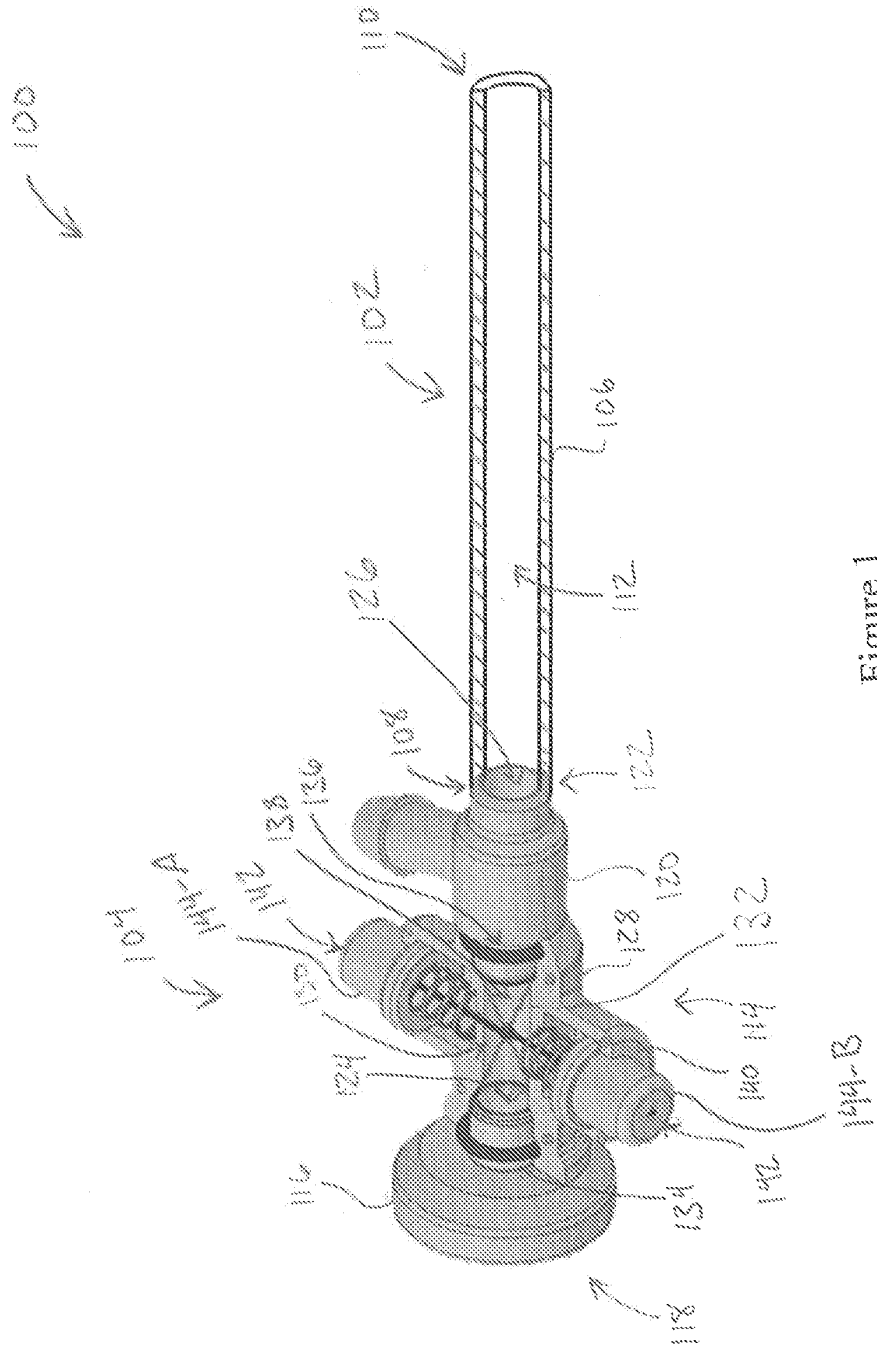
3 an elongate member having a first end, a second end, and a central lumen
4 comprising a plurality of lumens extending therebetween, wherein the elongate member is
5 pliable; and

6 an active tensioning mechanism coupled to the elongate member, wherein the
7 tensioning mechanism is moveable between a first configuration wherein the central lumen is
8 constricted and sealed and a second configuration wherein the central lumen is open.

ABSTRACT OF THE DISCLOSURE

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure extends along at least a portion of the elongate member and is coupled to the elongate member. A shell defining a first aperture and a second aperture may be included, which first and second apertures can be fluidly coupled by the elongate member. A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

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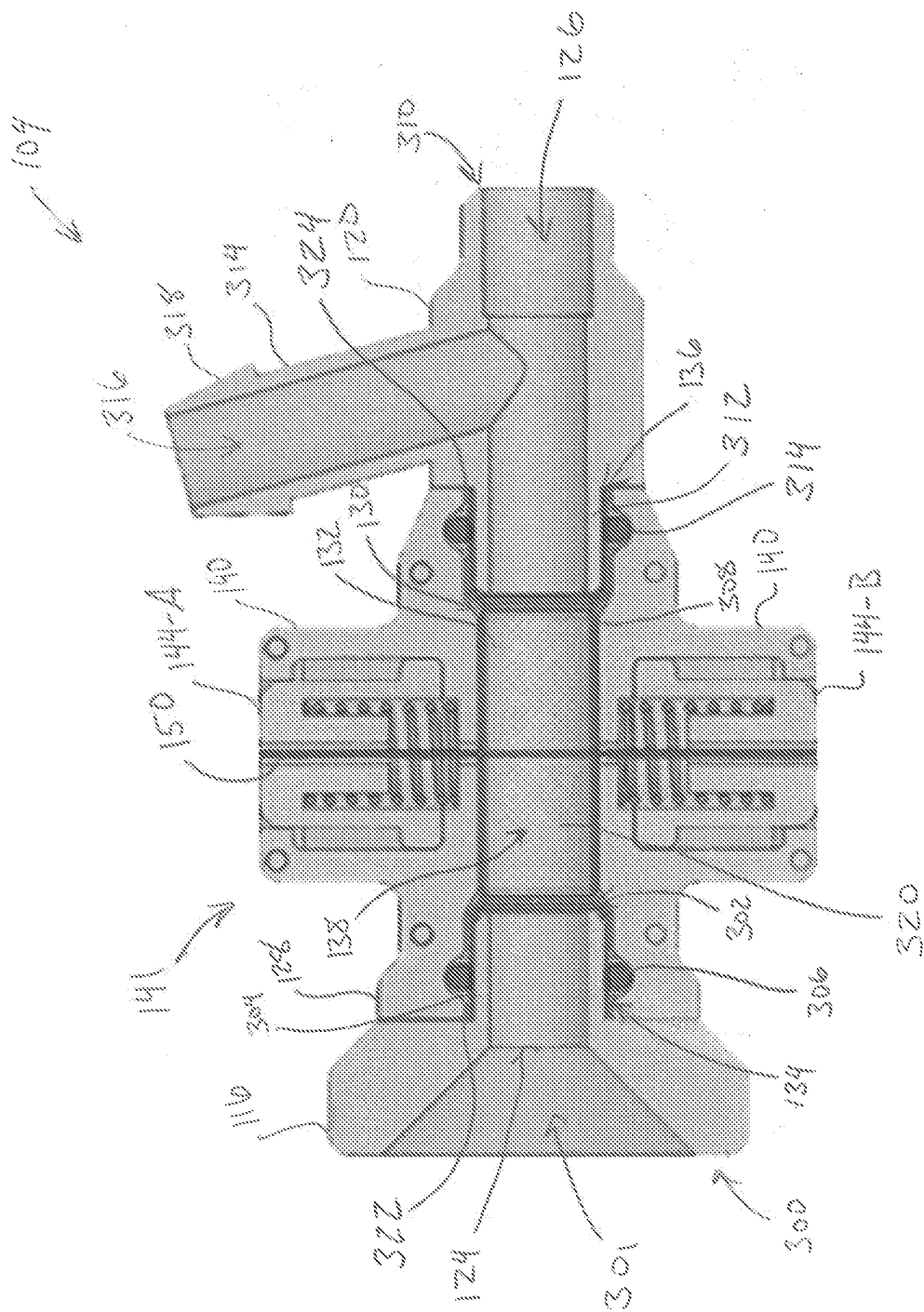


Figure 3

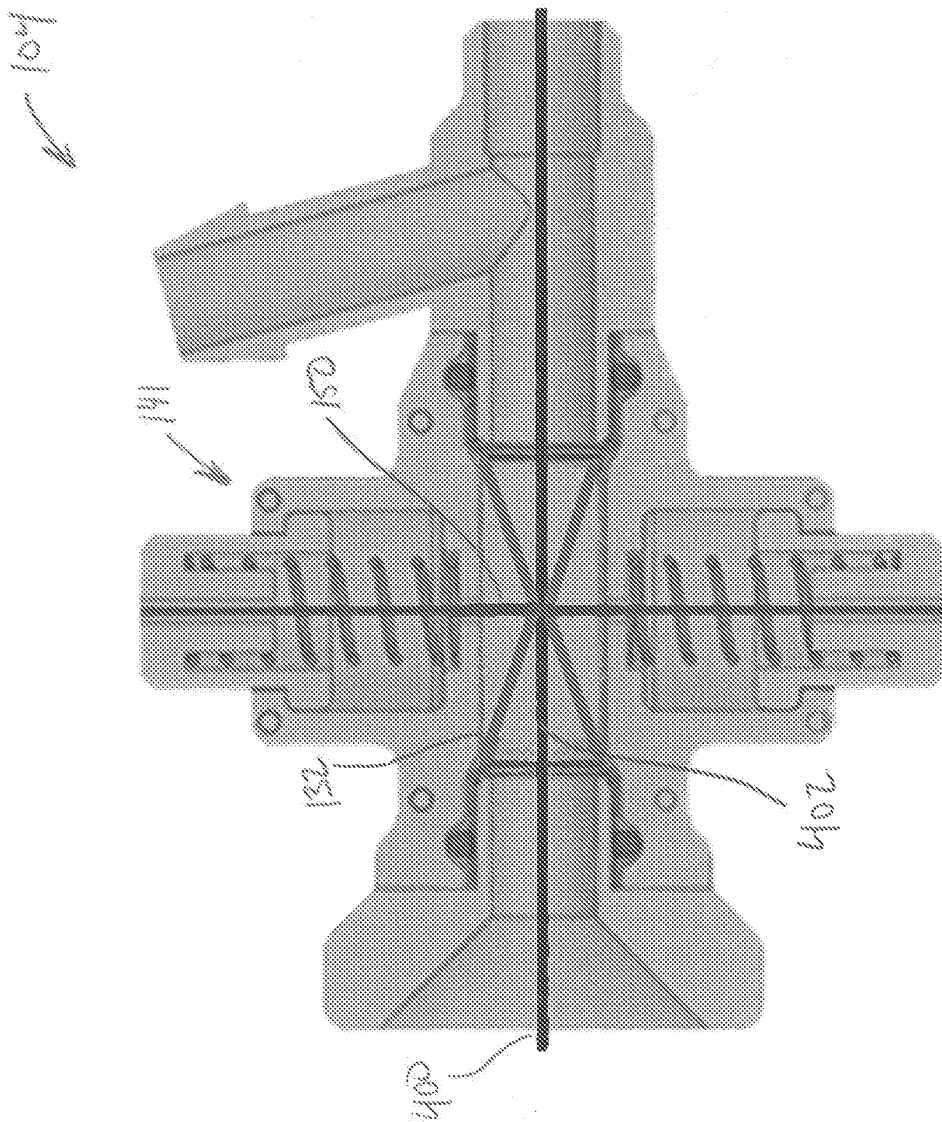


Figure 4

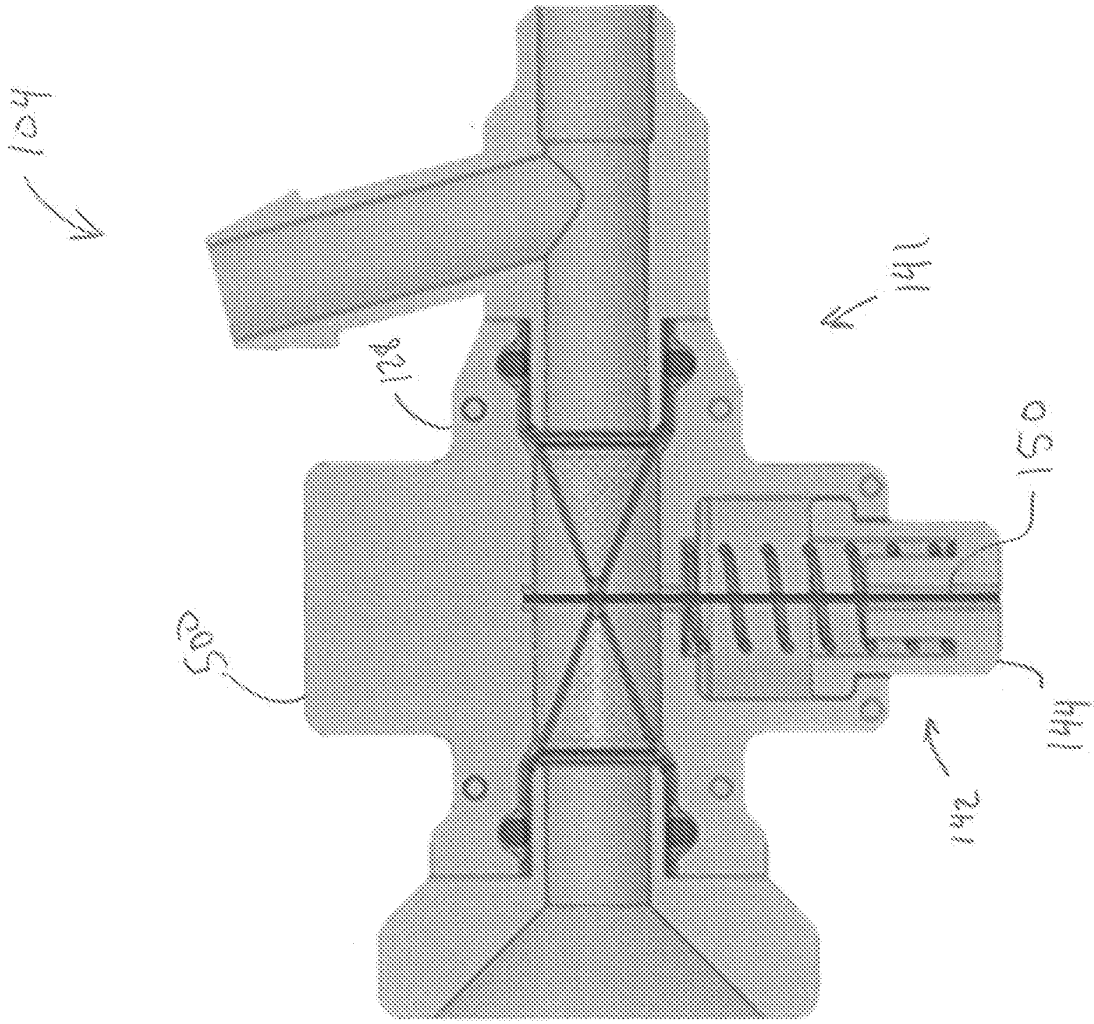


Figure 5



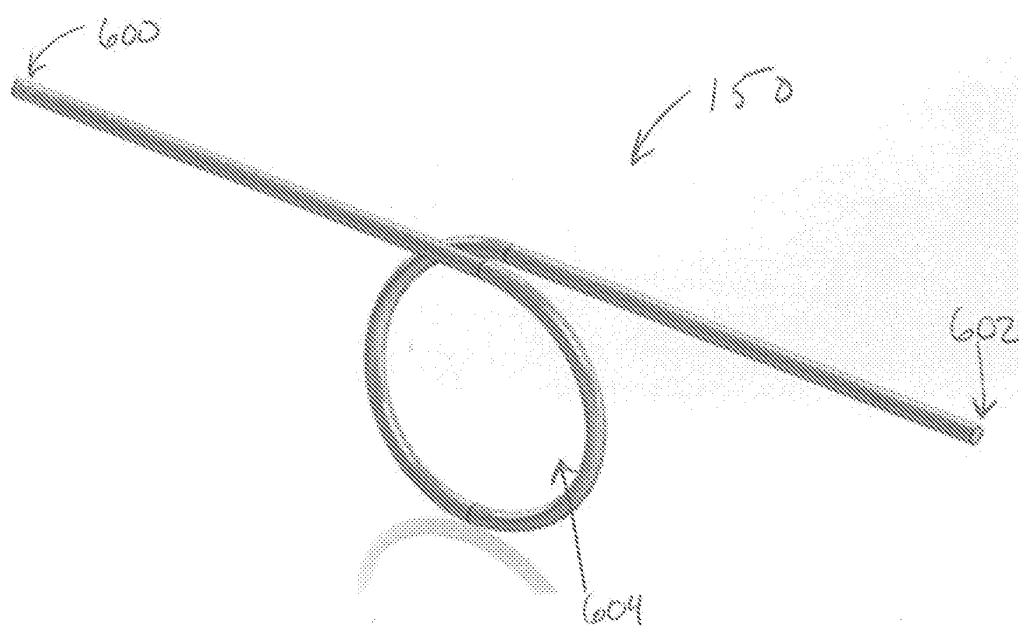


Figure 6

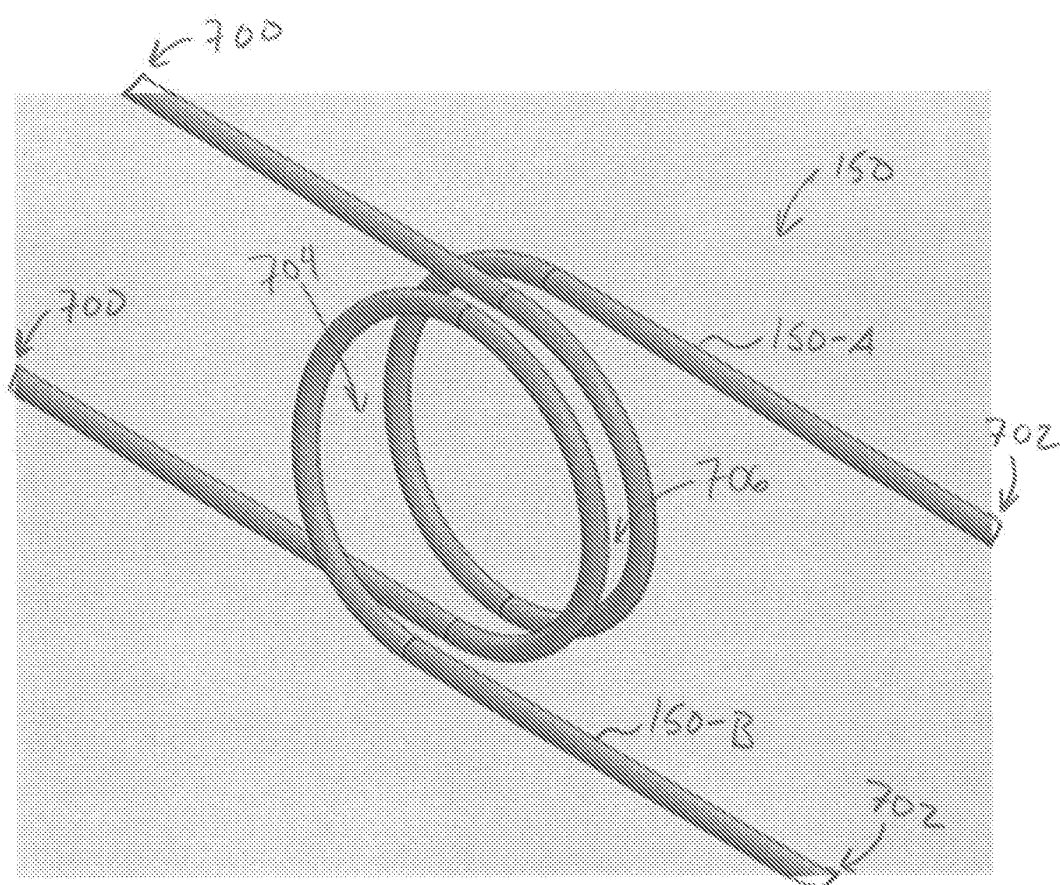


Figure 7

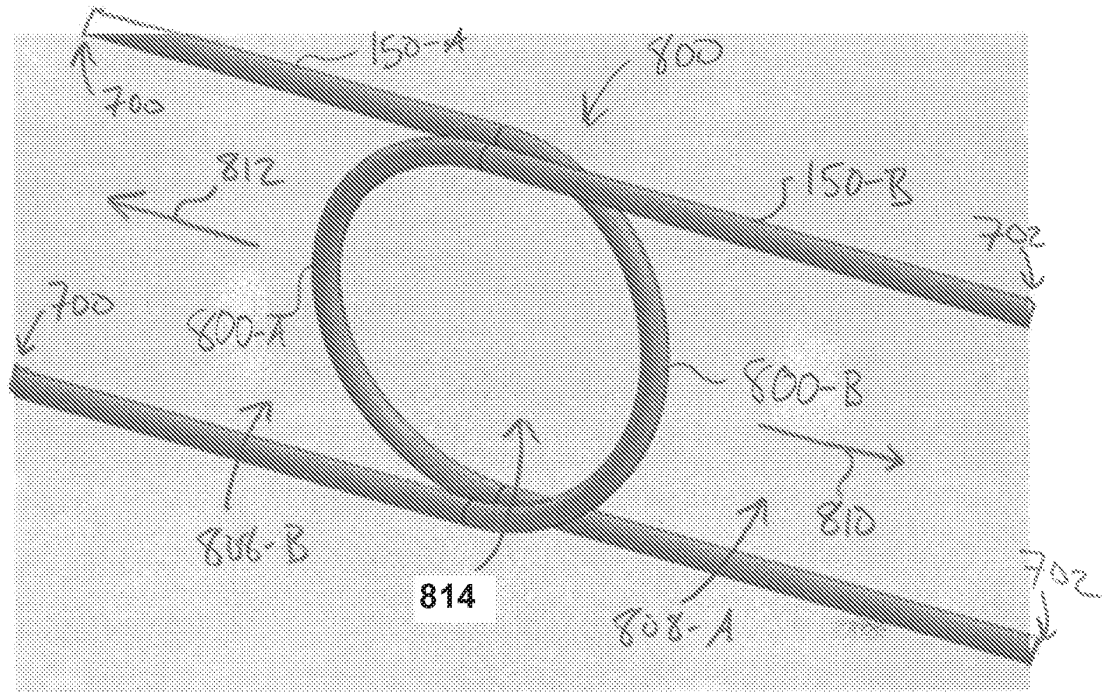


Figure 8

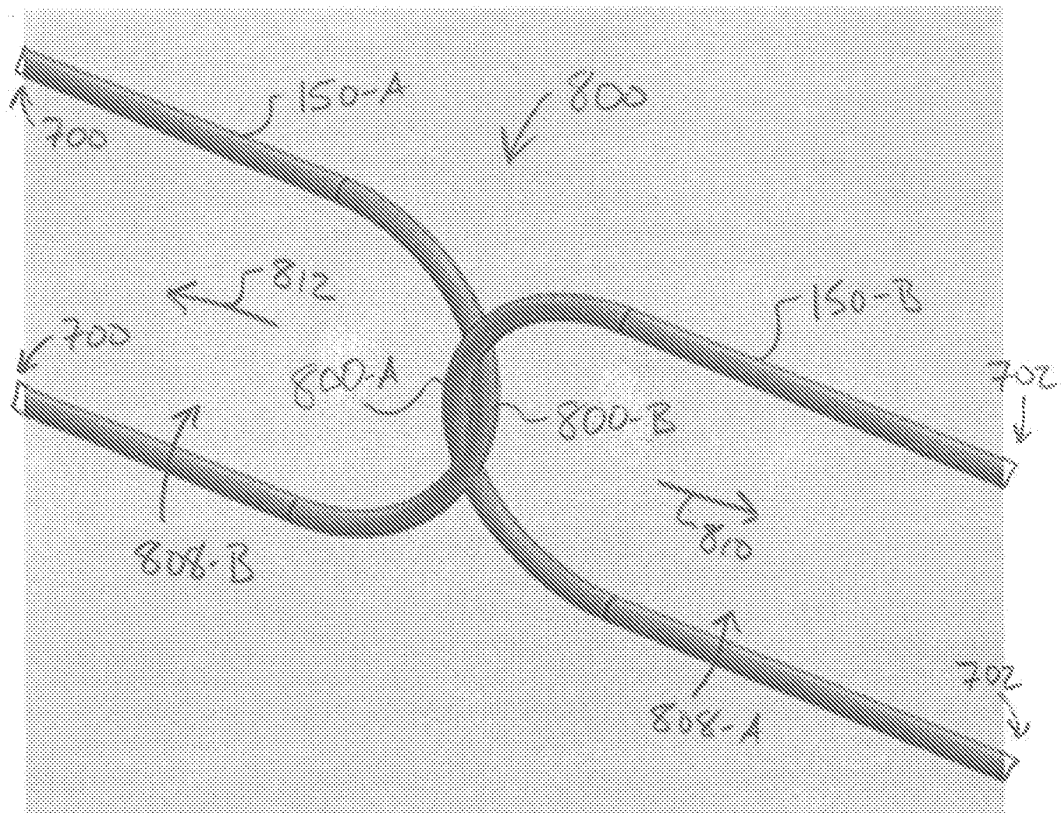


Figure 9

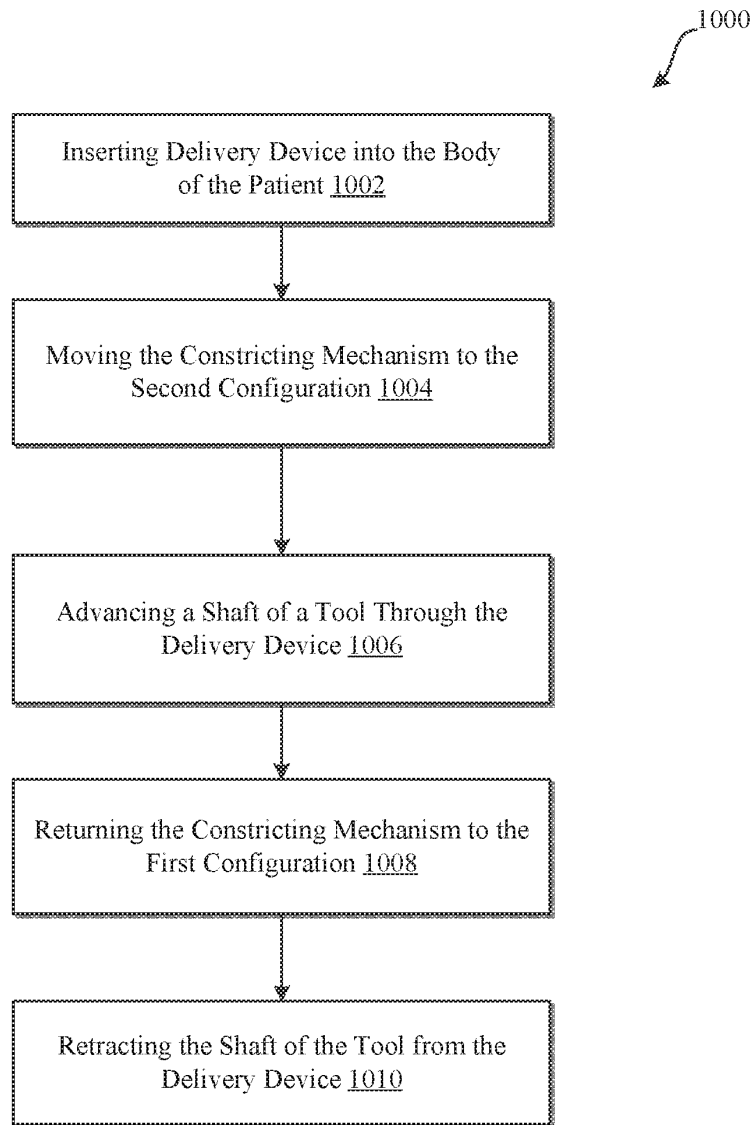


Figure 10

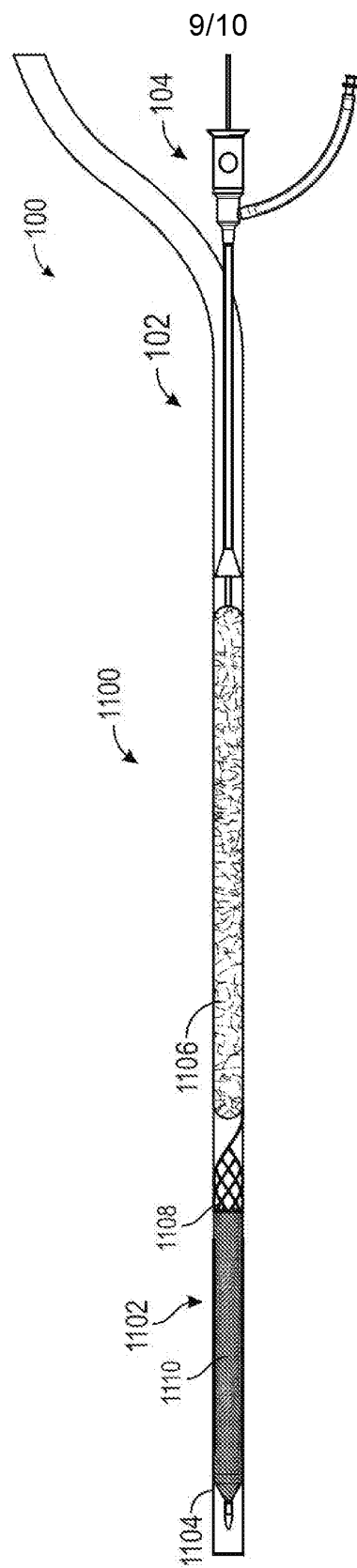


Figure 11

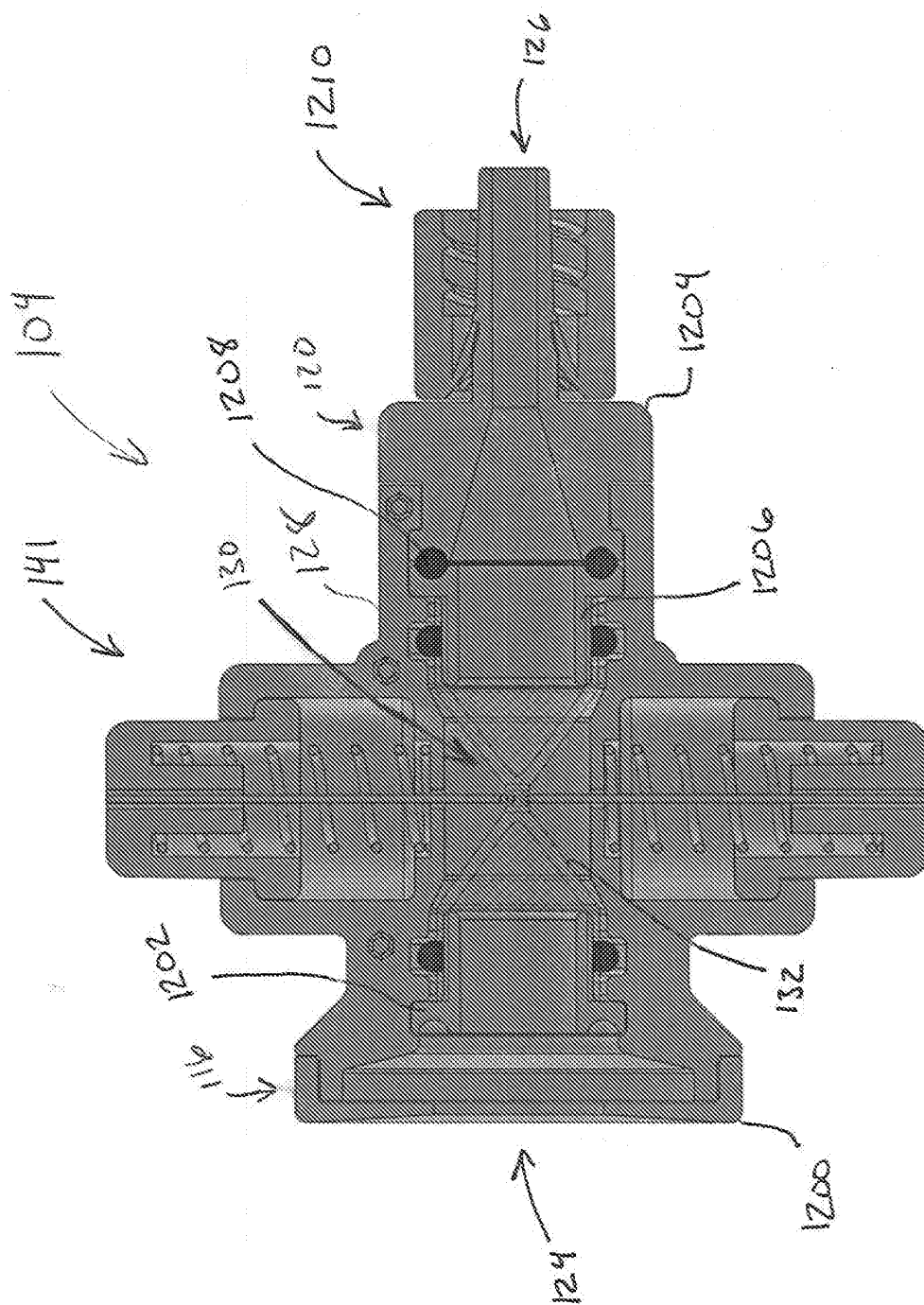


Figure 12

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		HEMOSTASIS VALVES AND METHODS OF USE		
First Named Inventor/Applicant Name:		Benjamin E. Merritt		
Filer:		Richard B. Christiansen/Anh Tuan Nguyen		
Attorney Docket Number:		101594-000300US-1046388		
Filed as Small Entity				
Filing Fees for Provisional				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
PROVISIONAL APPLICATION FILING FEE	2005	1	130	130
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				130

Electronic Acknowledgement Receipt	
EFS ID:	30288829
Application Number:	62554931
International Application Number:	
Confirmation Number:	3223
Title of Invention:	HEMOSTASIS VALVES AND METHODS OF USE
First Named Inventor/Applicant Name:	Benjamin E. Merritt
Customer Number:	20350
Filer:	Richard B. Christiansen/Anh Tuan Nguyen
Filer Authorized By:	Richard B. Christiansen
Attorney Docket Number:	101594-000300US-1046388
Receipt Date:	06-SEP-2017
Filing Date:	
Time Stamp:	18:26:10
Application Type:	Provisional

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Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$130
RAM confirmation Number	090717INTEFSW18283300
Deposit Account	201430
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Provisional Cover Sheet (SB16)	101594-1046388_Provisional_Cover_Sheet.pdf	1477450	no	3
			db94fd2722e6374dddaed678a8416c23a635f1c8		

Warnings:**Information:**

2	Application Data Sheet	101594-1046388_ADS.pdf	1823111	no	9
			ca37eb65ee6369fd1d14ecfcf5c33e1652ebdf1		

Warnings:**Information:**

3		101594-1046388_Application_text.pdf	228929	yes	34
			7222a889794bdb481a64236b9ee5ccbe8bed3144		

Multipart Description/PDF files in .zip description

	Document Description	Start	End
	Transmittal of New Application	1	1
	Specification	2	26
	Claims	27	33
	Abstract	34	34

Warnings:**Information:**

4	Drawings-other than black and white line drawings	101594-1046388_Figures.pdf	1927371	no	10
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Warnings:**Information:**

5	Fee Worksheet (SB06)	fee-info.pdf	30072	no	2
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Warnings:					
Information:					
Total Files Size (in bytes):			5486933		
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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)

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

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Title of Invention

HEMOSTASIS VALVES AND METHODS OF USE

Attorney Docket Number (if applicable)

101594-000300US-1046388

Correspondence Address

Direct all correspondence to (select one):

☒ The address corresponding to Customer Number
 ☐ Firm or Individual Name

Customer Number

20350

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 invention was made by an agency of the United States Government. The U.S. Government agency name is:

Yes, the invention was under a contract with an agency of the United States Government. The name of the U.S. Government agency and Government contract number are:

Entity Status**Applicant asserts small entity status under 37 CFR 1.27 or applicant certifies micro entity status under 37 CFR 1.29**

- ☒ Applicant asserts small entity status under 37 CFR 1.27
- ☐ Applicant certifies micro entity status under 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
- ☐ No

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Signature

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Signature	Richard B. Christiansen/		Date (YYYY-MM-DD)	2017-09-06
First Name	Richard	Last Name	Christiansen	Registration Number (If appropriate)
				69493

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	101594-000300US-1046388
		Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		
<p>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.</p> <p>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.</p>			

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☐ 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						
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Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
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Inventor	2				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	John	C.	Thress			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
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Mailing Address of Inventor:						
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Address 2	9272 Jeronimo Road, Suite 124					
City	Irvine	State/Province	CA			
Postal Code	92618	Country	US			
Inventor	3				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Paul		Lubock			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		101594-000300US-1046388	
		Application Number			
Title of Invention		HEMOSTASIS VALVES AND METHODS OF USE			
City	Monarch Beach	State/Province	CA	Country of Residence	US
Mailing Address of Inventor:					
Address 1		c/o Inari Medical, Inc.			
Address 2		9272 Jeronimo Road, Suite 124			
City	Irvine	State/Province	CA		
Postal Code	92618	Country i	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					<input type="button" value="Add"/>

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Application Information:

Title of the Invention	HEMOSTASIS VALVES AND METHODS OF USE		
Attorney Docket Number	101594-000300US-1046388	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	Suggested Figure for Publication (if any)	

Filing By Reference:

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

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

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

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	101594-000300US-1046388
		Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		

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	20350		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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" field blank.

Prior Application Status	<input type="text"/>	<input type="button" value="Remove"/>	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button. <input type="button" value="Add"/>			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. 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(i)(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).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Additional Foreign Priority Data may be generated within this form by selecting the Add button. <input type="button" value="Add"/>			

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	101594-000300US-1046388
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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

<p>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.</p> <p>☐ 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.</p>
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		Application Number	
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Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is 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 State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	101594-000300US-1046388
		Application Number	
Title of Invention	HEMOSTASIS VALVES AND METHODS OF USE		

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	<input type="button" value="Remove"/>	
<p>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.</p>			
		<input type="button" value="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:			
<div style="border: 1px solid black; height: 20px; width: 100%;"></div>			
Name of the Deceased or Legally Incapacitated Inventor: <div style="border: 1px solid black; width: 400px; height: 20px;"></div>			
If the Applicant is an Organization check here. ☒			
Organization Name	Inari Medical, Inc.		
Mailing Address Information For Applicant:			
Address 1	9272 Jeronimo Road, Suite 124		
Address 2			
City	Irvine	State/Province	CA
Country	US	Postal Code	92618
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button. <input type="button" value="Add"/>			

Assignee Information including Non-Applicant Assignee 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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	101594-000300US-1046388
		Application Number	
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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.				
				<input type="button" value="Remove"/>
If the Assignee or Non-Applicant Assignee is an Organization check here.				☐
Prefix	Given Name	Middle Name	Family Name	Suffix
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Mailing Address Information For Assignee including Non-Applicant Assignee:				
Address 1		<input type="text"/>		
Address 2		<input type="text"/>		
City	<input type="text"/>	State/Province	<input type="text"/>	
Country i	<input type="text"/>	Postal Code	<input type="text"/>	
Phone Number	<input type="text"/>	Fax Number	<input type="text"/>	
Email Address	<input type="text"/>			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Richard B. Christiansen/		Date (YYYY-MM-DD)	2017-09-06
First Name	Richard	Last Name	Christiansen	Registration Number
				69493
Additional Signature may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>

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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 Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.