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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
62/750,011	10/24/2018		140	Syn2.0/ROAR Prov2		

CONFIRMATION NO. 6333

FILING RECEIPT



0000000103454524

27316
MAYBACK & HOFFMAN, P.A.
5846 S. FLAMINGO ROAD #232
FORT LAUDERDALE, FL 33330

Date Mailed: 10/30/2018

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

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Matthew A. Palmer, Miami, FL;
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Eric Petersen, Homestead, FL;
Tyler Bond, Miami, FL;
Jake Pistiner, Davie, FL;

Applicant(s)

Syntheon 2.0, LLC, Miami, FL;

Power of Attorney: The patent practitioners associated with Customer Number 27316

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 10/30/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/750,011**

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

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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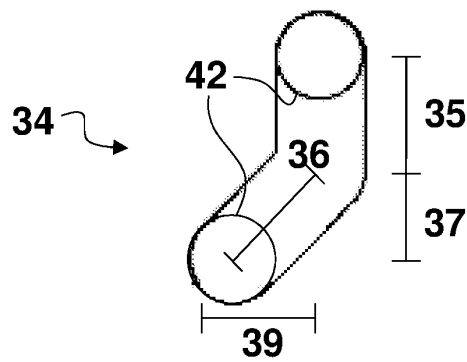
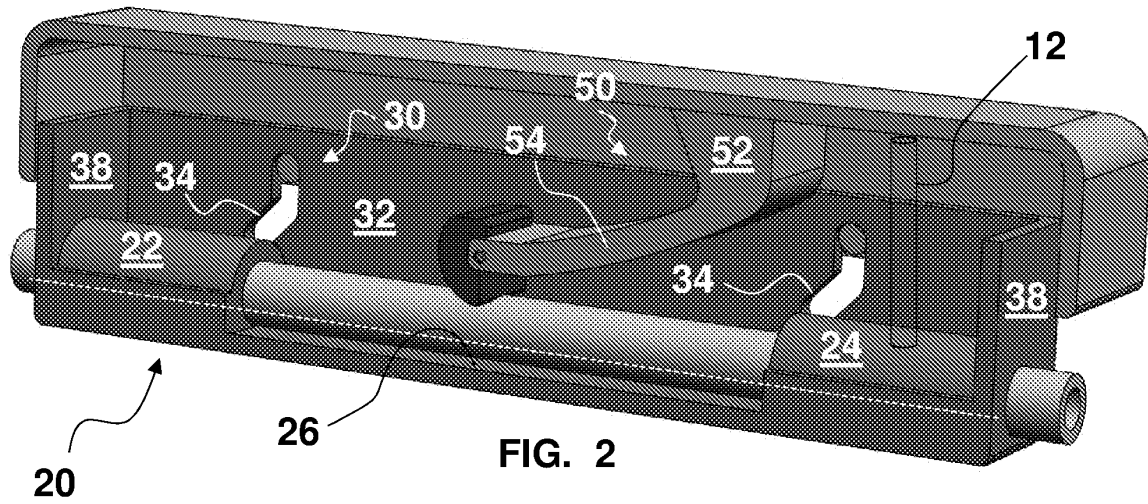
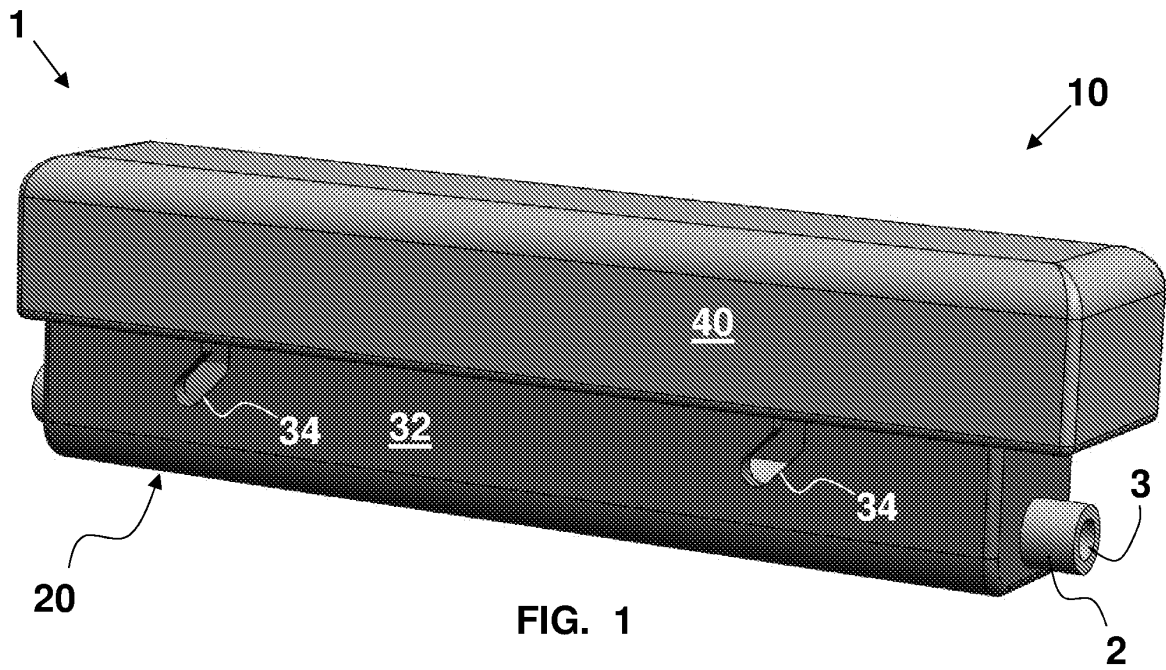
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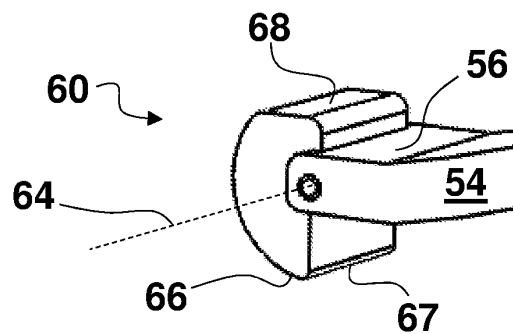
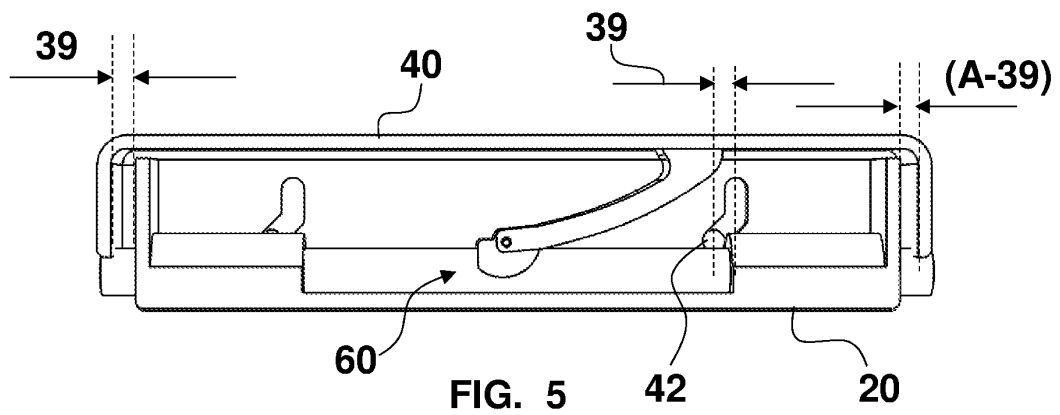
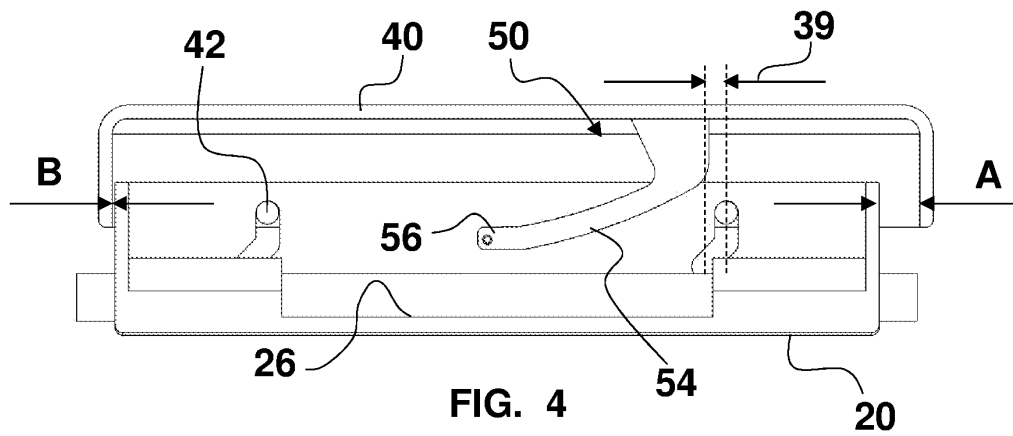
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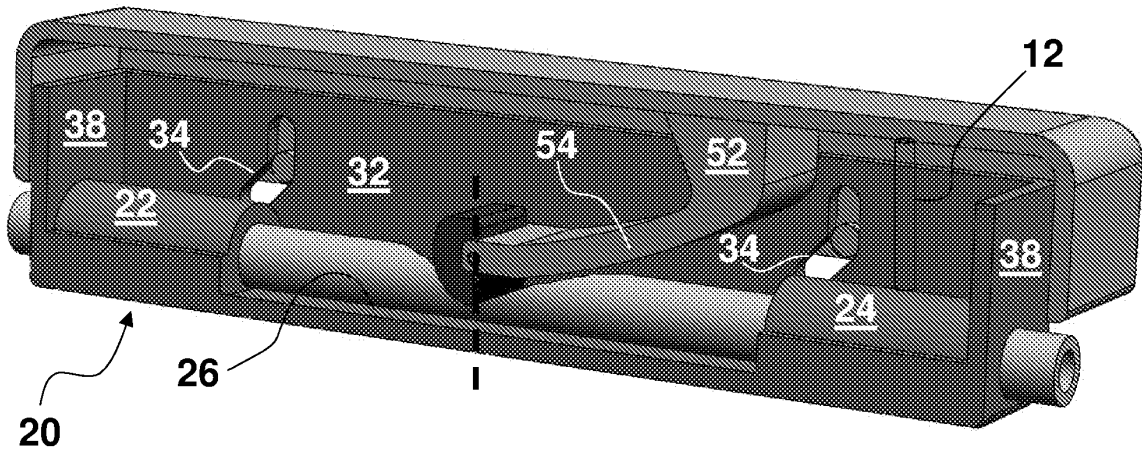
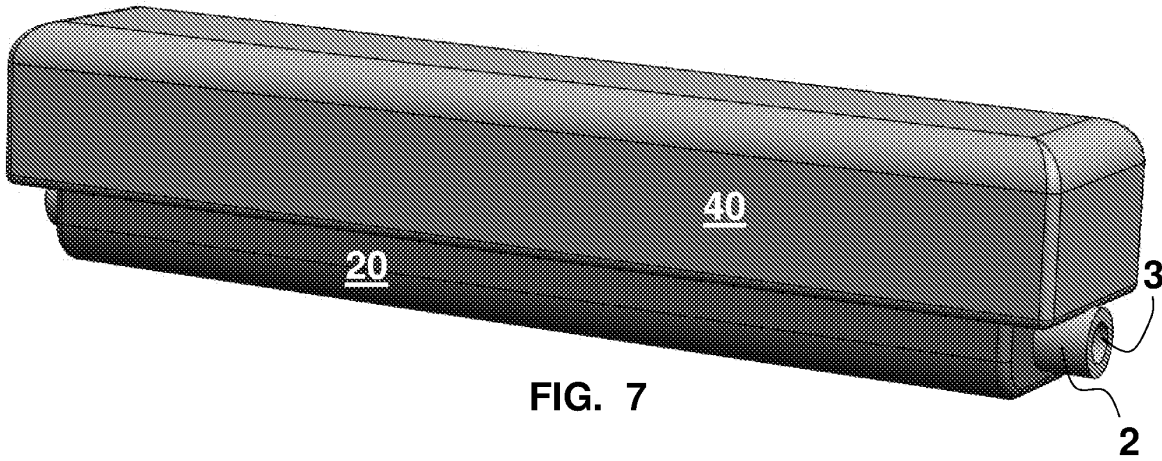
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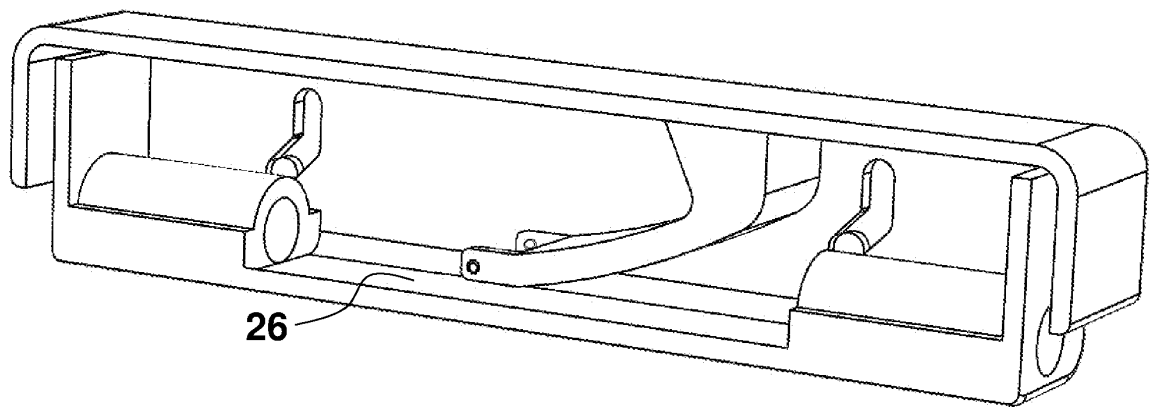
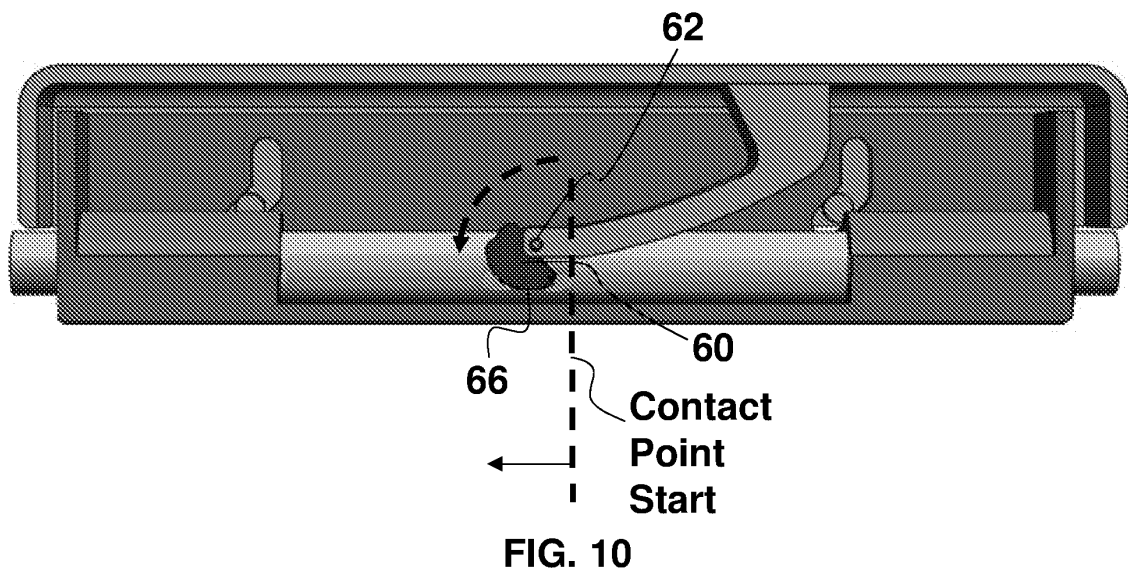
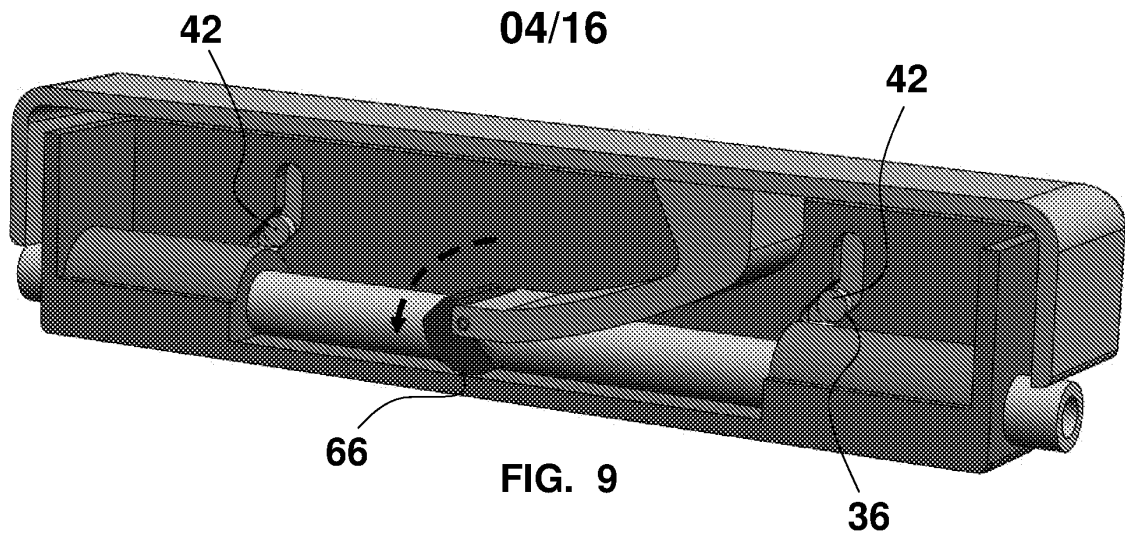
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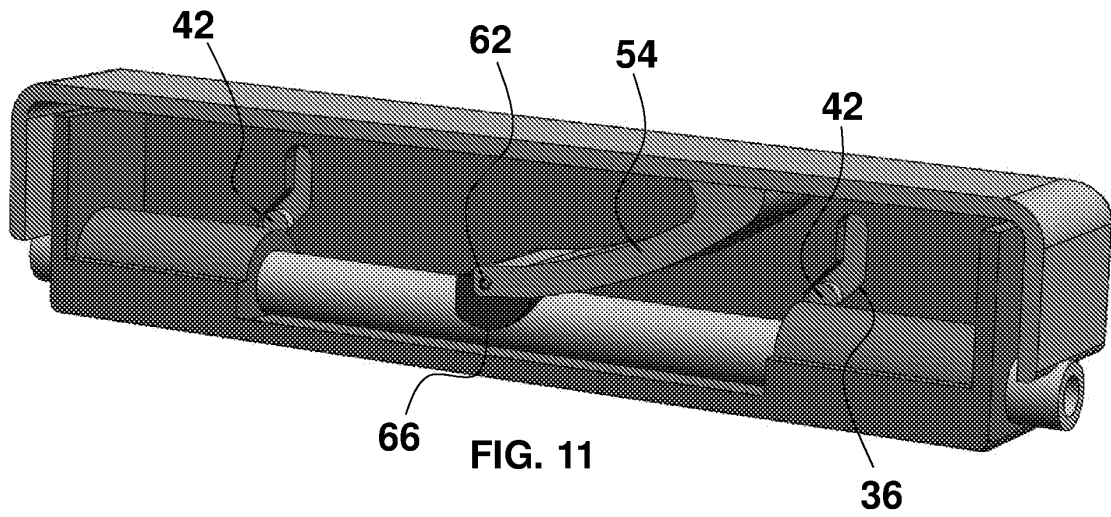


FIG. 11

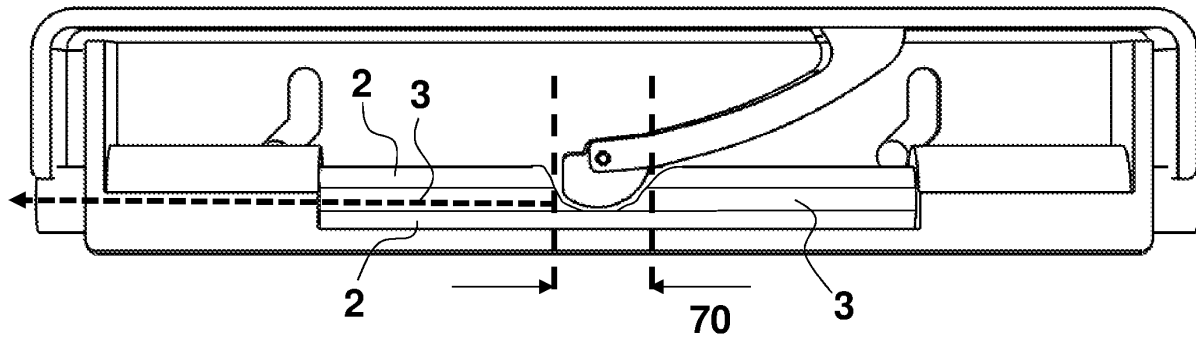


FIG. 12

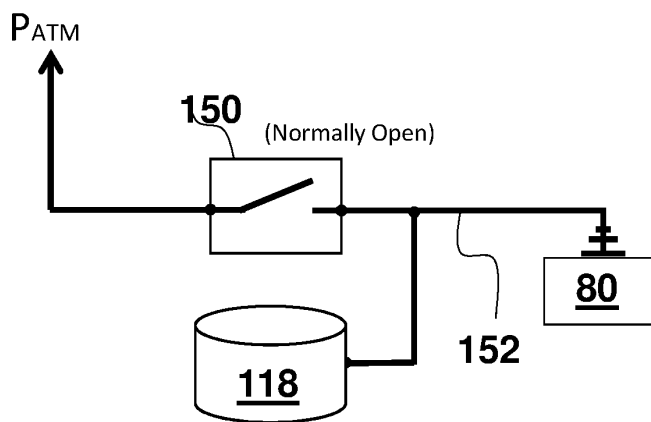


FIG. 23

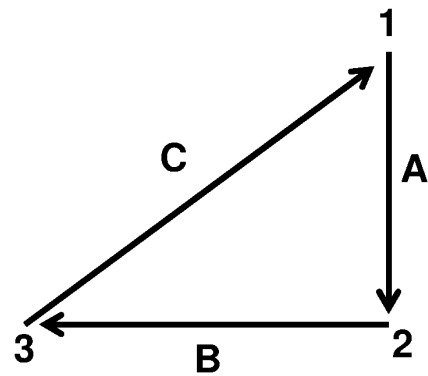


FIG. 24

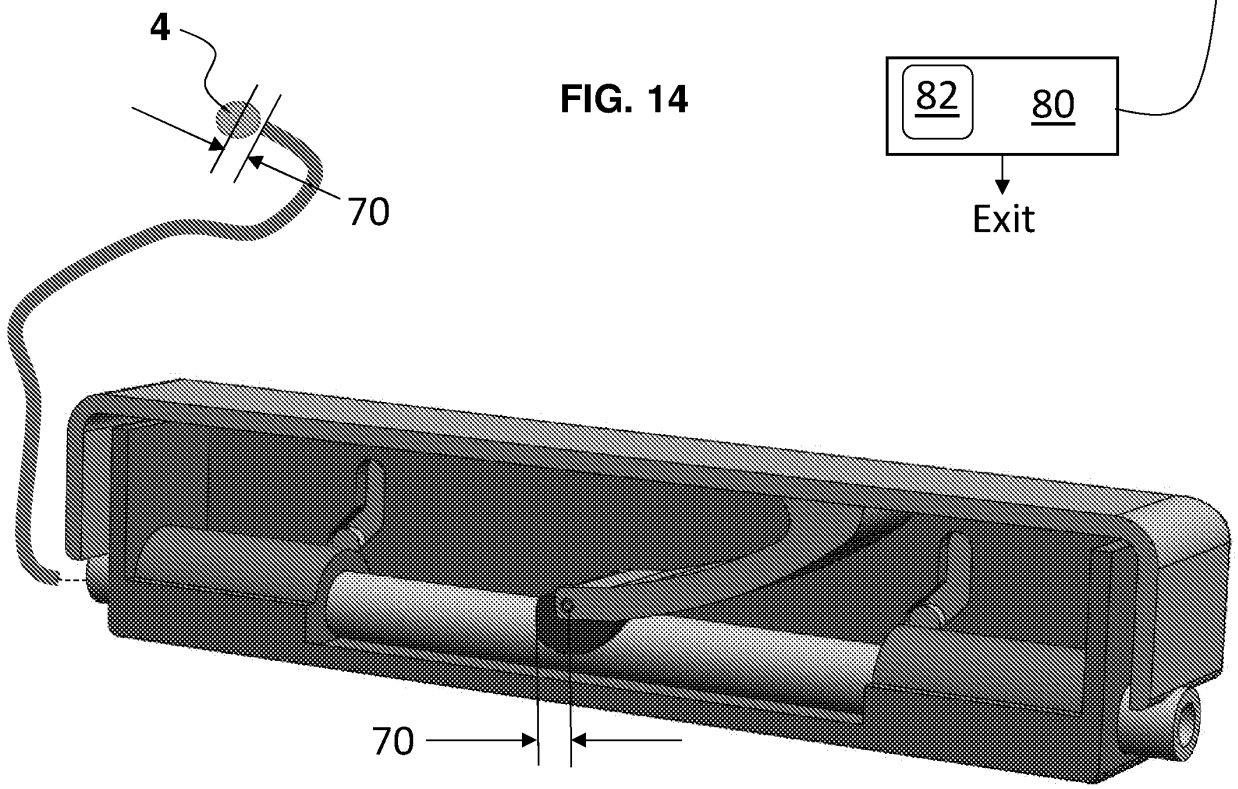
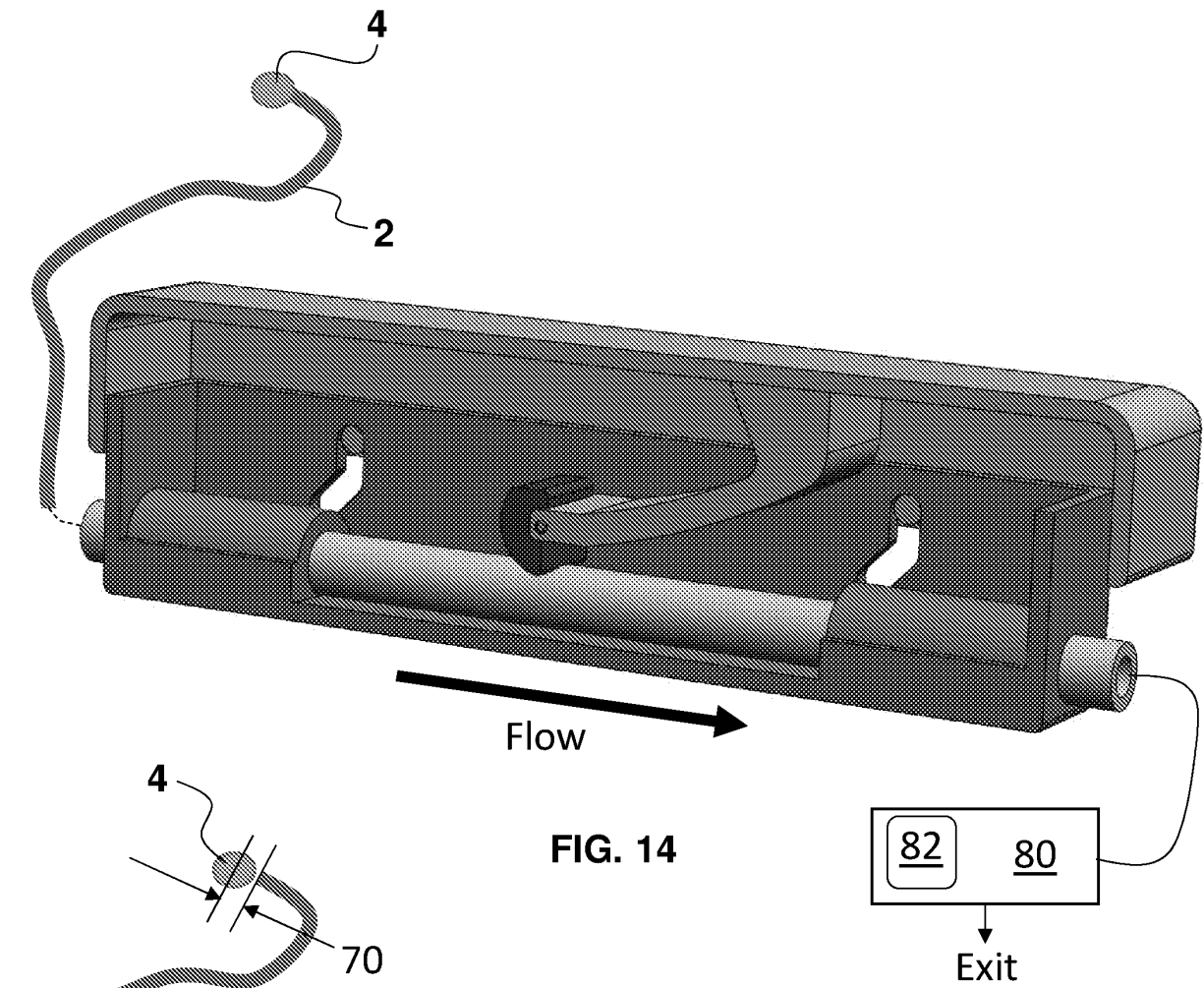


FIG. 15

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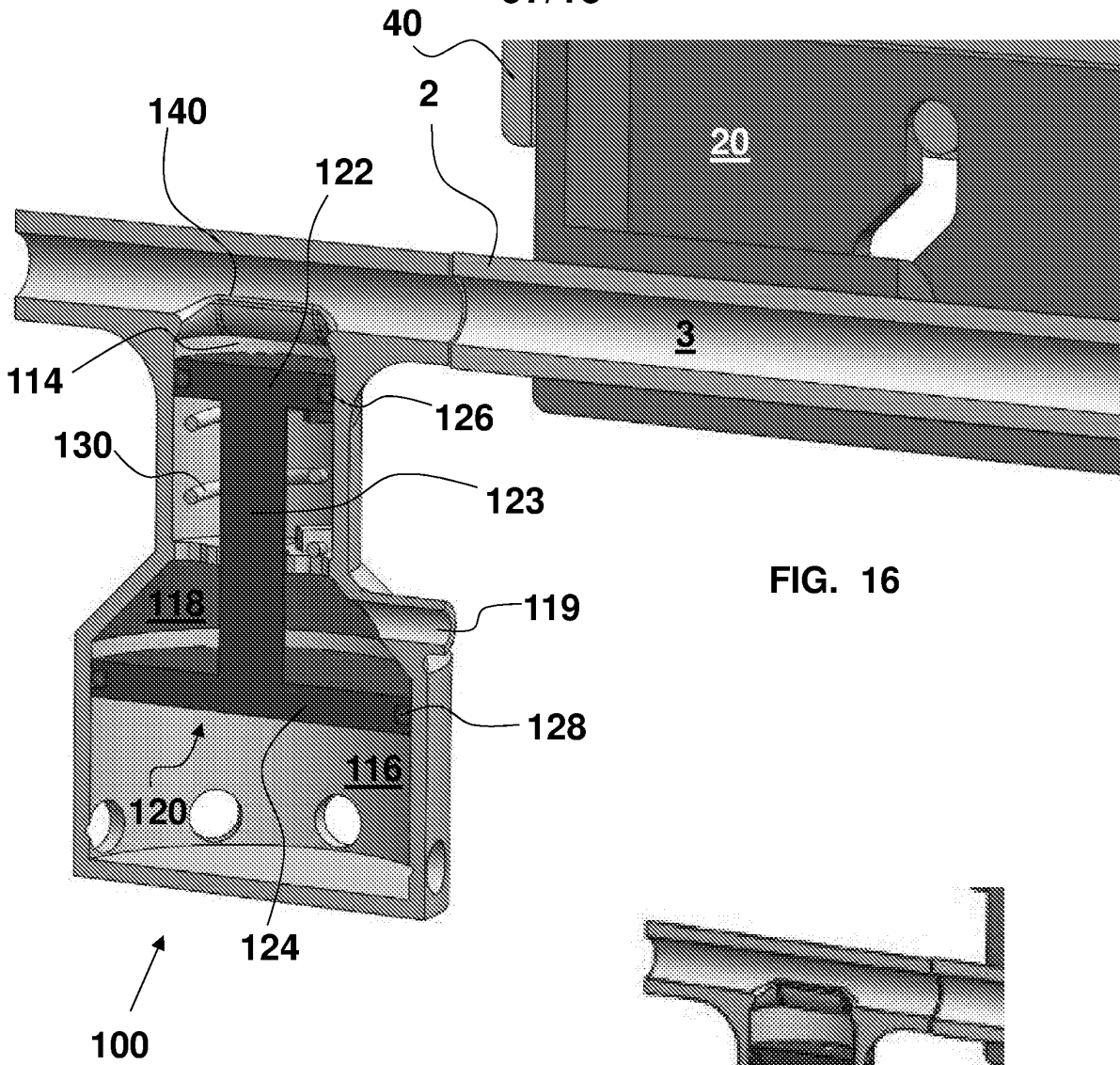


FIG. 16

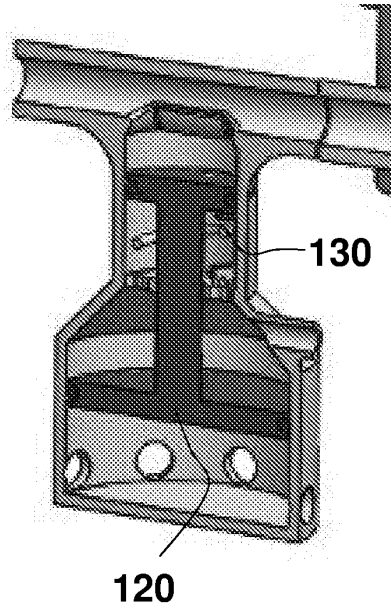


FIG. 17

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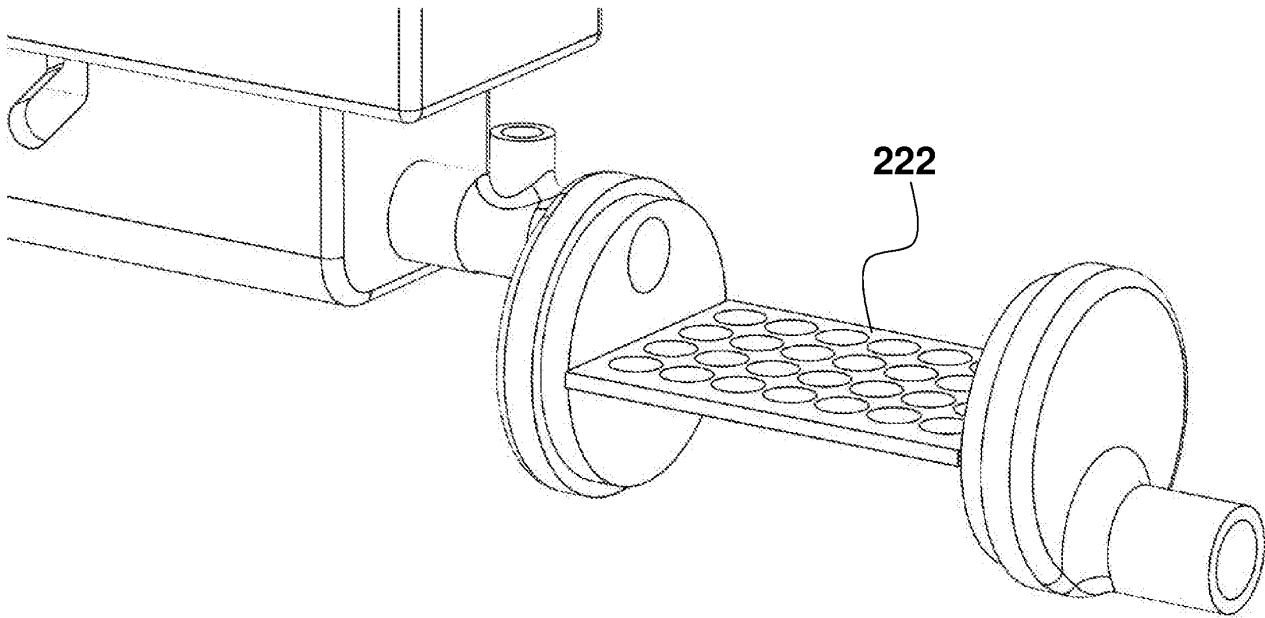
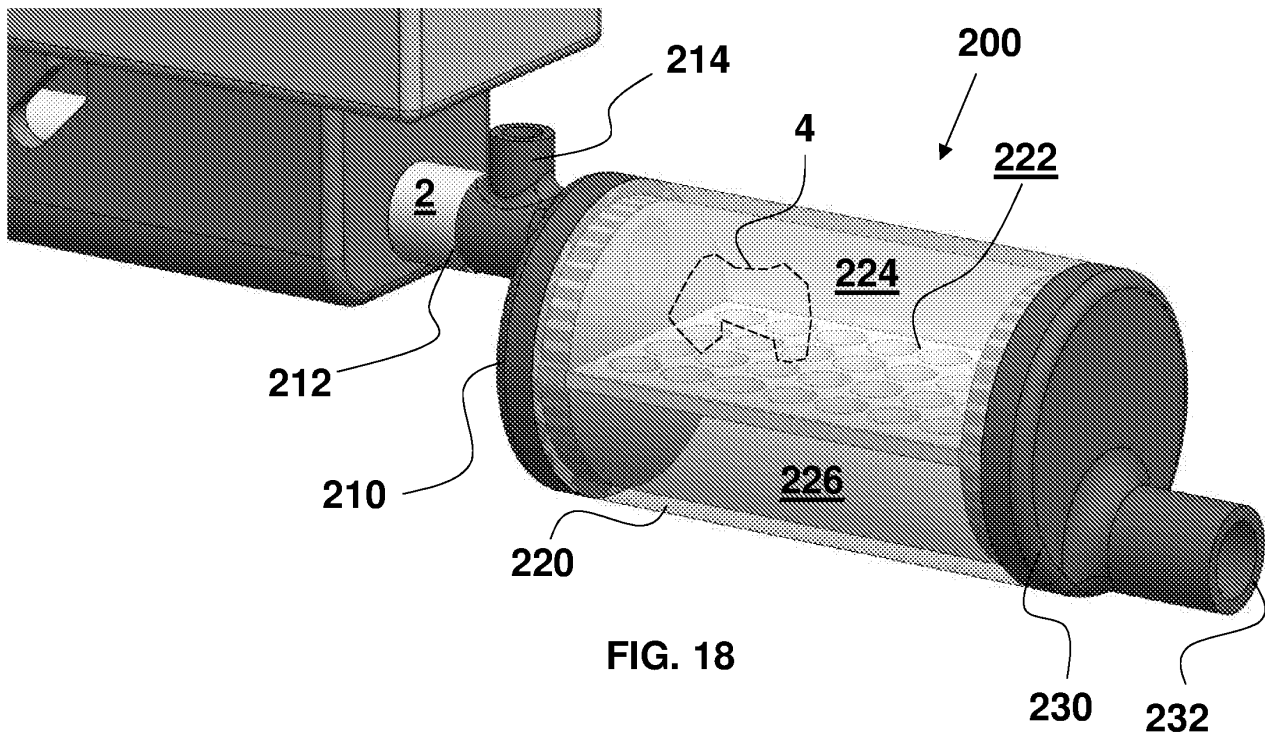


FIG. 20

FIG. 20

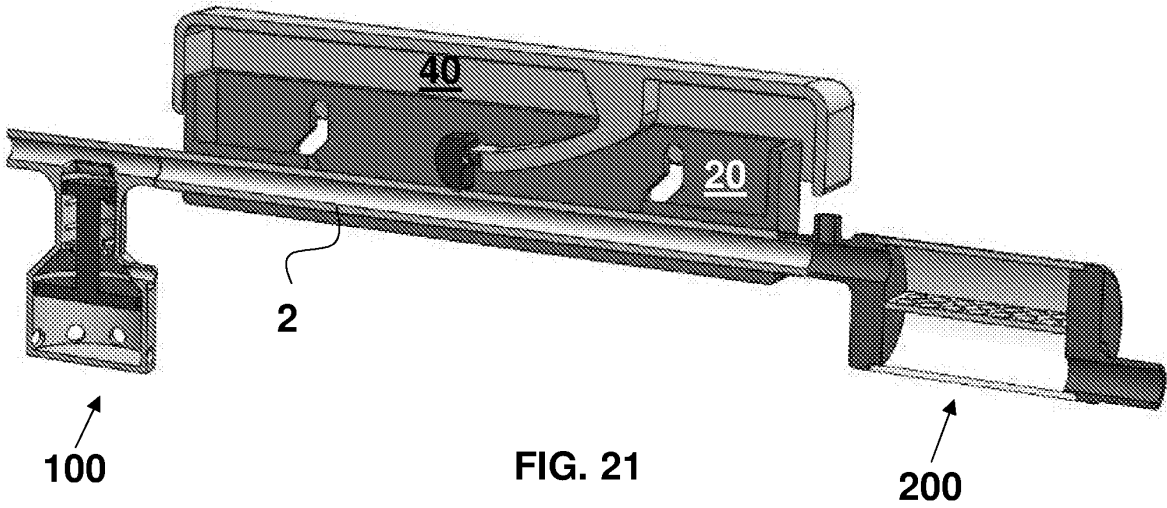


FIG. 21

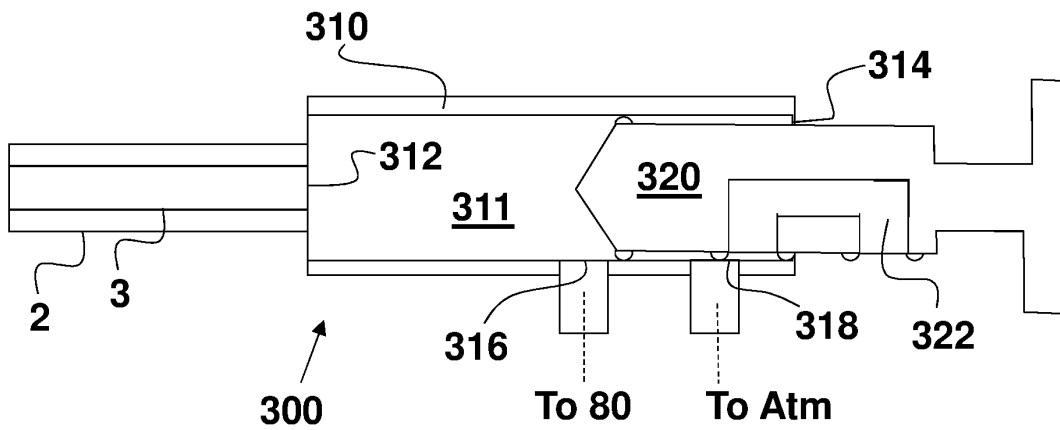
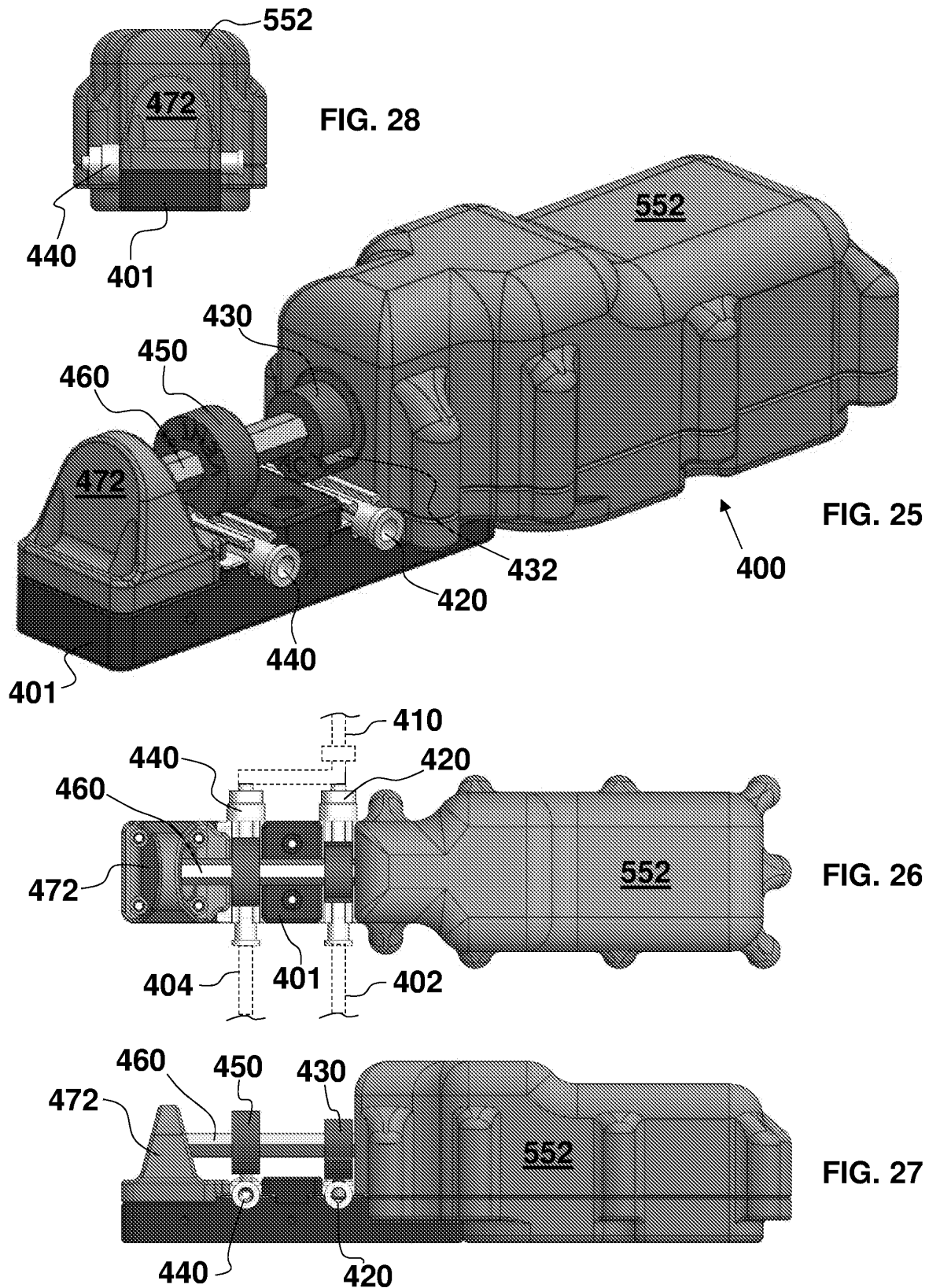
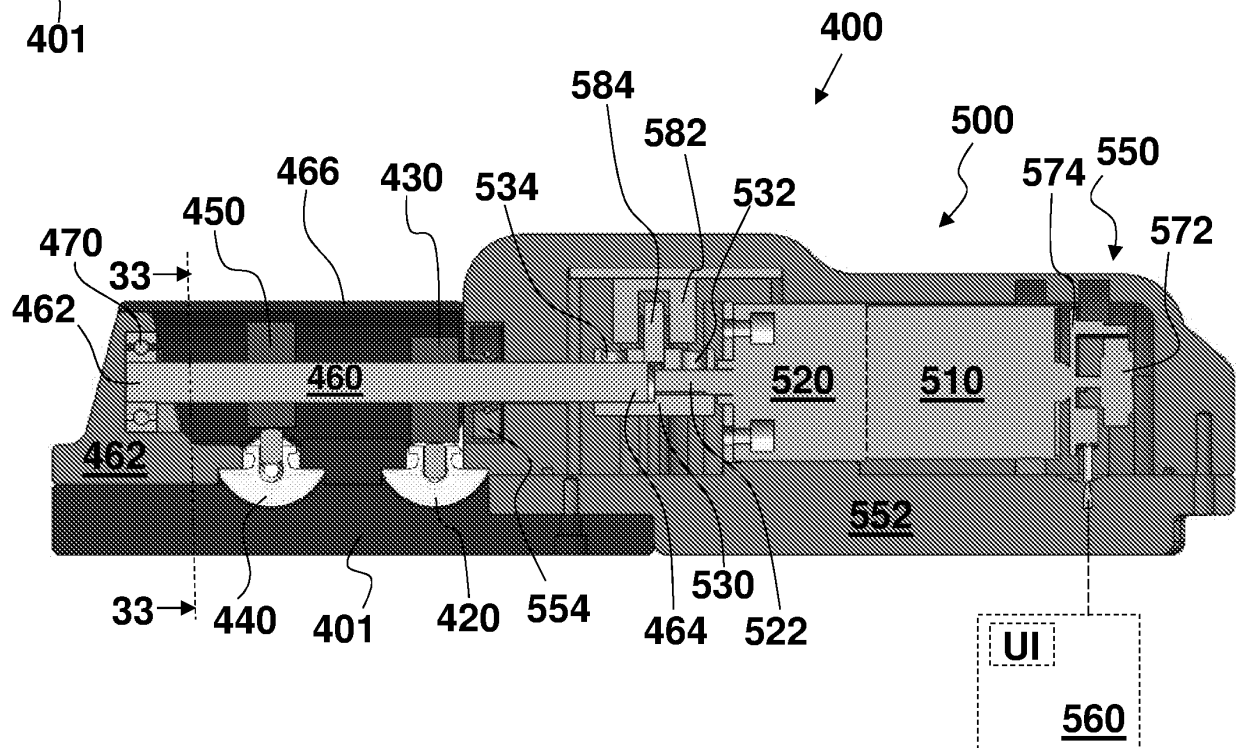
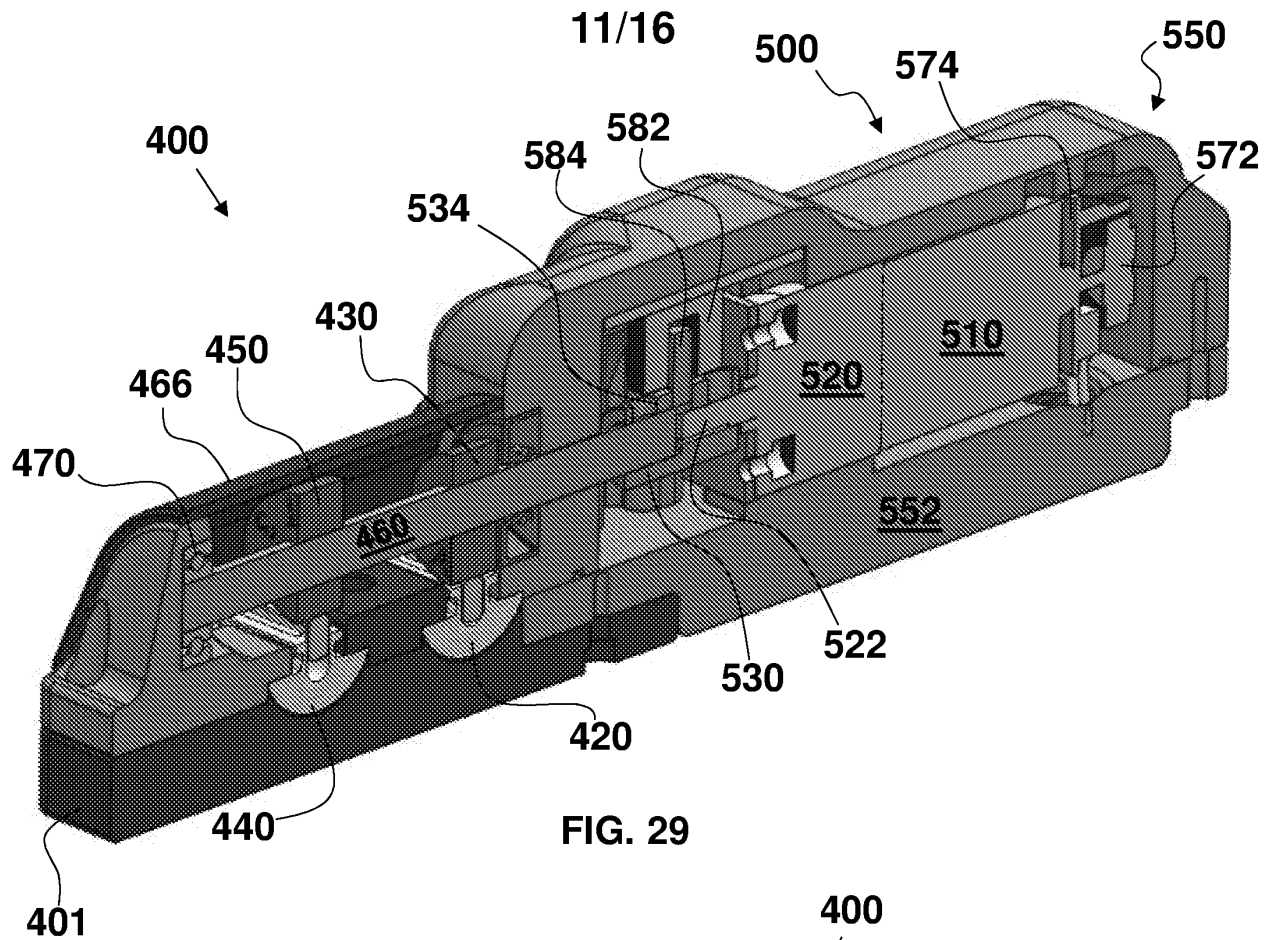
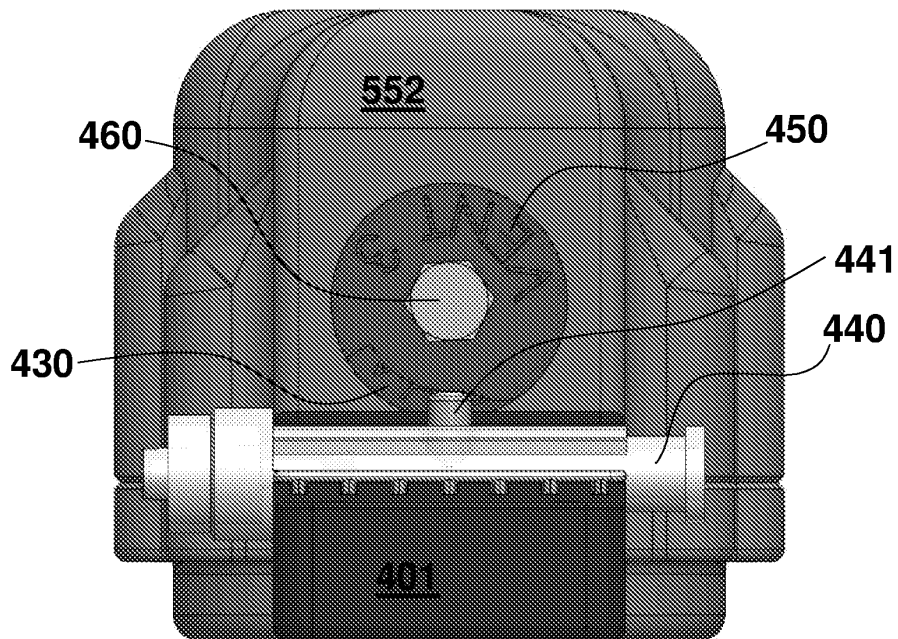
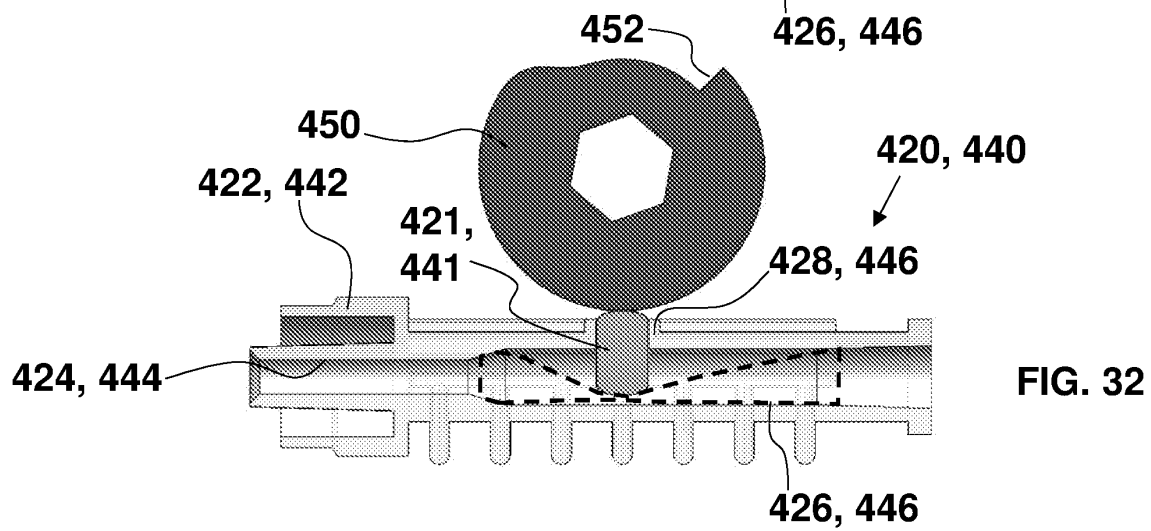
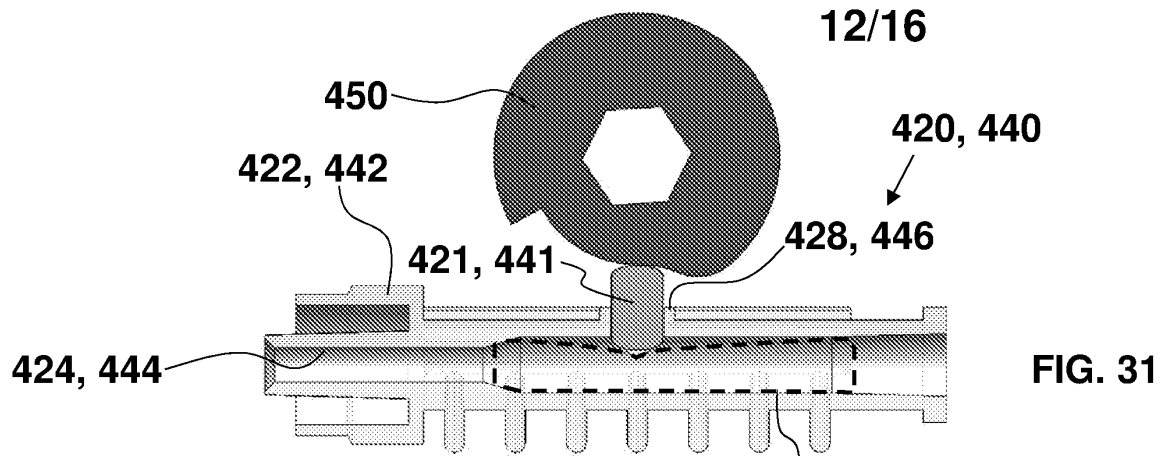
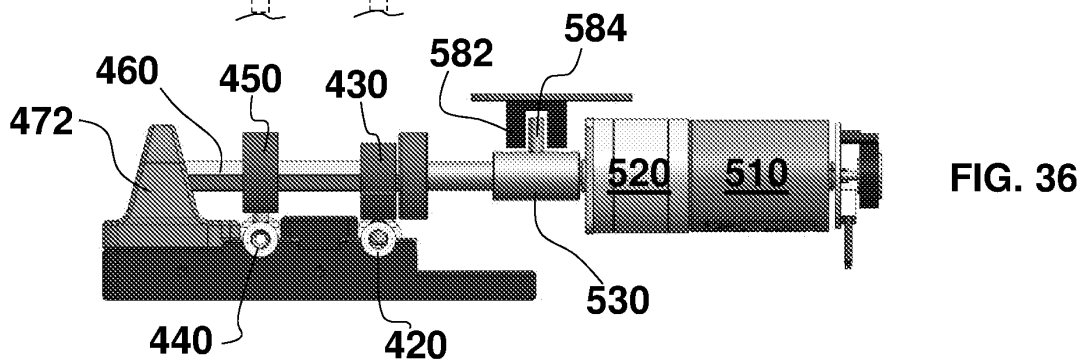
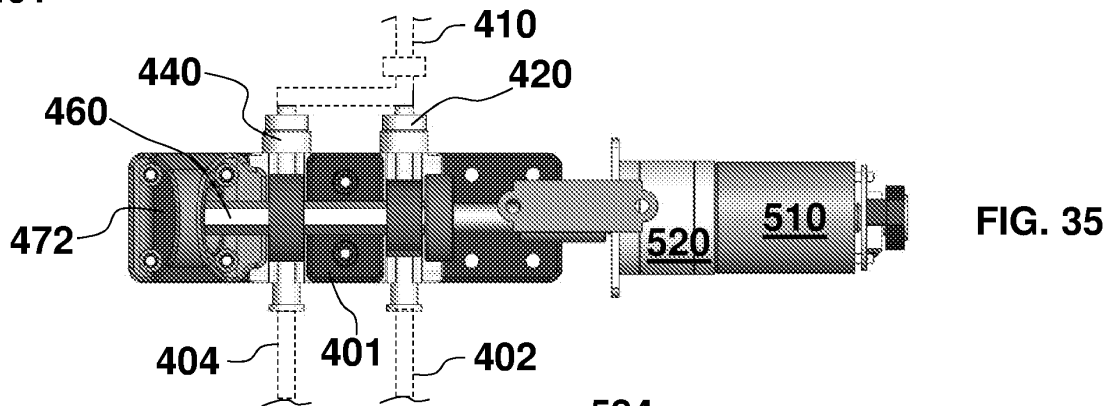
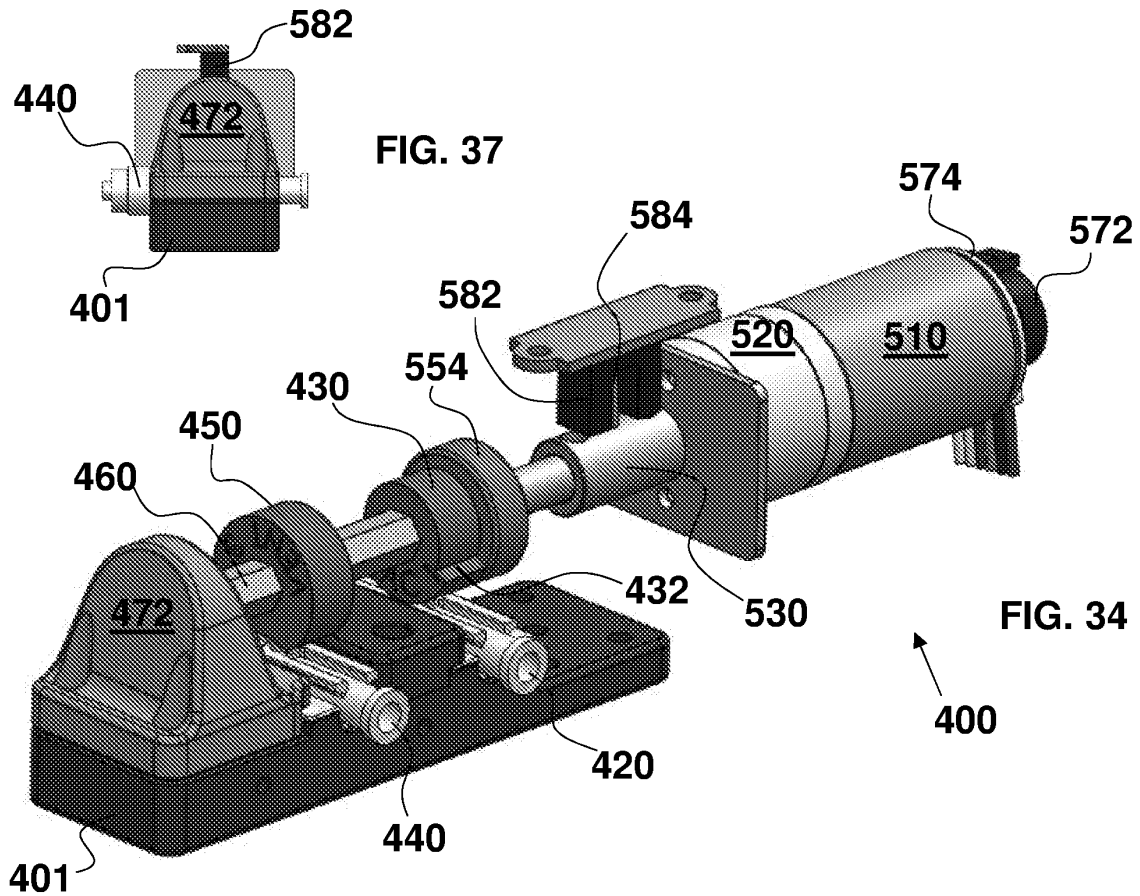


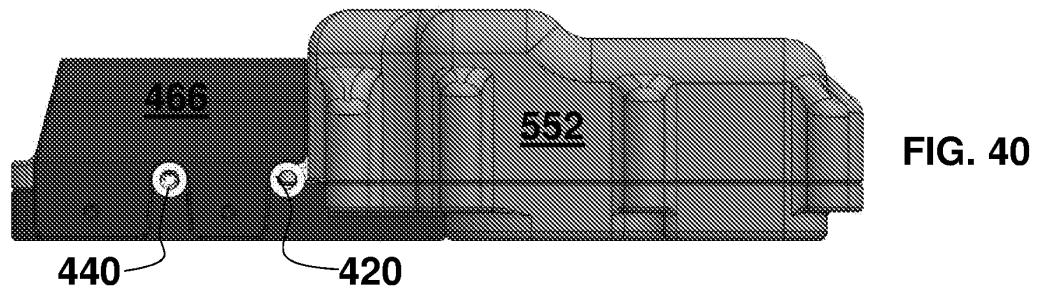
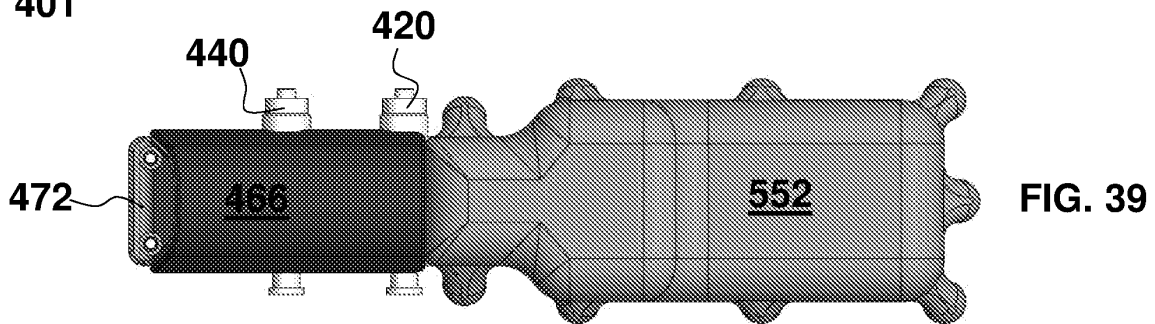
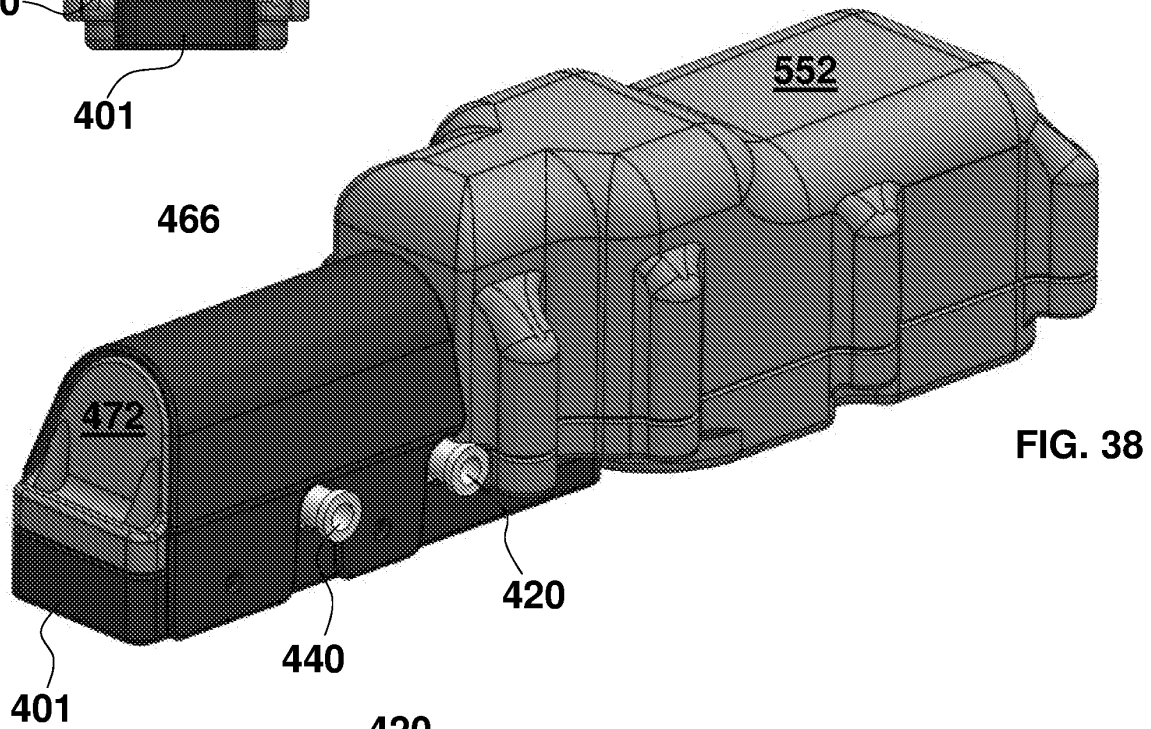
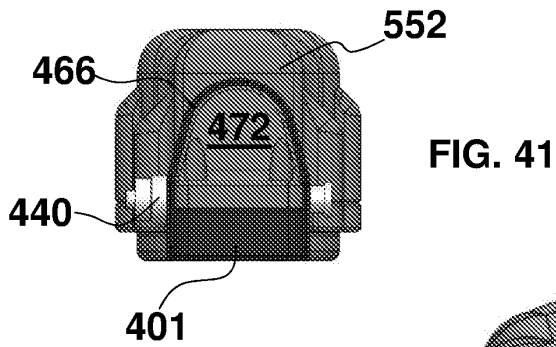
FIG. 22











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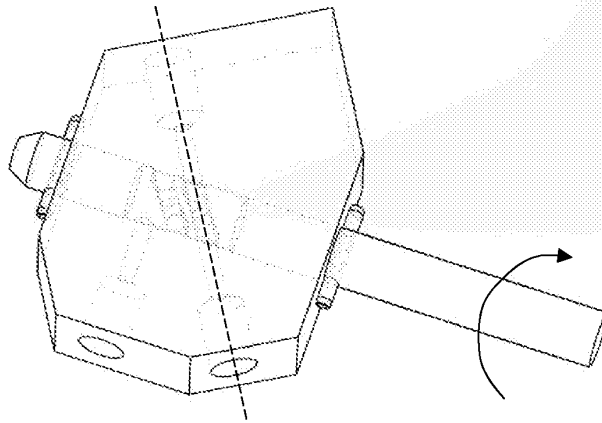


FIG. 42

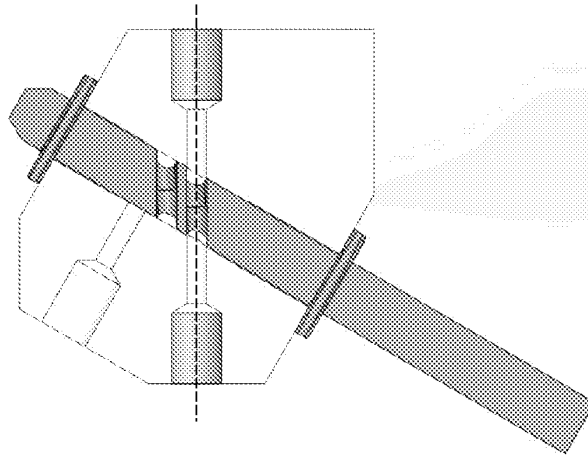


FIG. 43

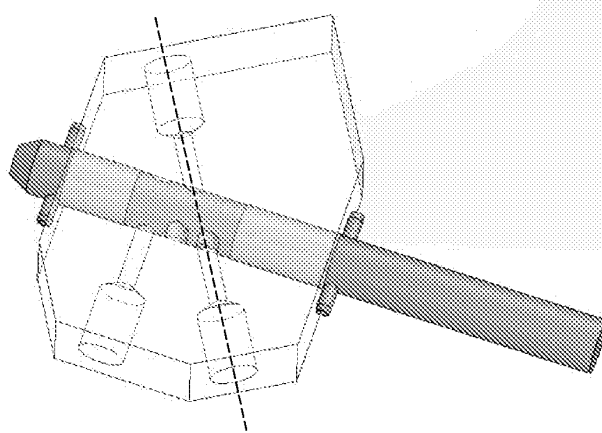


FIG. 44

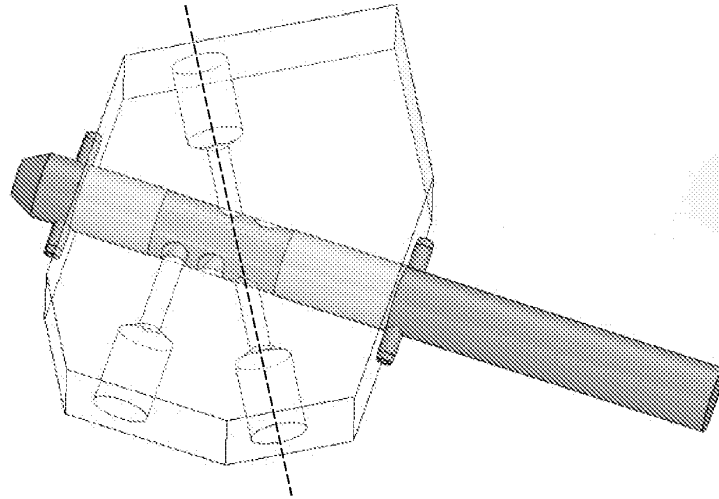


FIG. 45

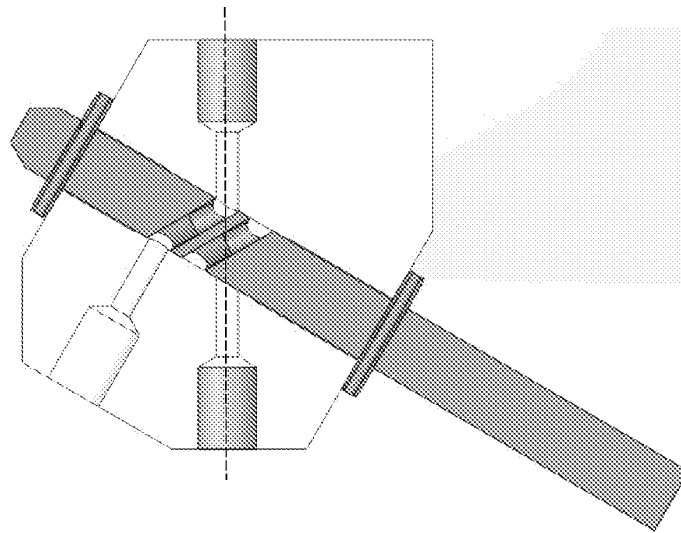


FIG. 46

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor	1				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Derek	Dee	Deville			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Coral Gables	State/Province	FL	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	5500 Oak Lane					
Address 2						
City	Coral Gables	State/Province	FL			
Postal Code	33156	Country	US			
Inventor	2				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Matthew	A.	Palmer			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Miami	State/Province	FL	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	12790 SW 64 Court					
Address 2						
City	Miami	State/Province	FL			
Postal Code	33156	Country	US			
Inventor	3				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	William	T.	Bales			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		Syn2.0/ROAR Prov2	
		Application Number			
Title of Invention		Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter			

City	Miami	State/Province	FL	Country of Residence ⁱ	US
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Mailing Address of Inventor:

Address 1	7630 SW 54 Avenue				
Address 2					
City	Miami	State/Province	FL		
Postal Code	33143	Country ⁱ	US		
Inventor	4				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Eric		Petersen		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Homestead	State/Province	FL	Country of Residence ⁱ	US

Mailing Address of Inventor:

Address 1	27025 S.W. 197 Avenue				
Address 2					
City	Homestead	State/Province	FL		
Postal Code	33031	Country ⁱ	US		
Inventor	5				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Tyler		Bond		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Miami	State/Province	FL	Country of Residence ⁱ	US

Mailing Address of Inventor:

Address 1	2131 S.W. 19 Avenue				
Address 2					
City	Miami	State/Province	FL		
Postal Code	33145	Country ⁱ	US		
Inventor	6				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Jake		Pistiner		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Davie	State/Province	FL	Country of Residence ⁱ	US

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number		Syn2.0/ROAR Prov2	
		Application Number			
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter				
Mailing Address of Inventor:					
Address 1	2751 S.W. 130th Terrace				
Address 2					
City	Davie	State/Province	FL		
Postal Code	33330	Country	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					

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☐ An Address is being provided for the correspondence information of this application.			
Customer Number	27316		
Email Address	patents@mayback.com	Add Email	Remove Email

Application Information:

Title of the Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		
Attorney Docket Number	Syn2.0/ROAR Prov2	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	16	Suggested Figure for Publication (if any)	30

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	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		

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	27316		

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

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. 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)	Remove
			Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		

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	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		

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		Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
		Clear	
☒ Assignee	Legal Representative under 35 U.S.C. 117		Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor:			
If the Applicant is an Organization check here. ☒			
Organization Name	Syntheon 2.0, LLC		
Mailing Address Information For Applicant:			
Address 1	13755 SW 119 Avenue		
Address 2			
City	Miami	State/Province	FL
Country	US	Postal Code	33186
Phone Number	954-704-1599	Fax Number	954-704-1588
Email Address	patents@mayback.com		
Additional Applicant Data may be generated within this form by selecting the Add button.			Add

Assignee Information including Non-Applicant Assignee Information:

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

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	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		

Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
			Remove
If the Assignee or Non-Applicant Assignee is an Organization check here. ☒			
Organization Name	Syntheon 2.0, LLC		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	13755 SW 119 Avenue		
Address 2			
City	Miami	State/Province	FL
Country i	US	Postal Code	33186
Phone Number	954-704-1599	Fax Number	954-704-1588
Email Address	patents@mayback.com		
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			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	/gregory I. mayback/		Date (YYYY-MM-DD)	2018-10-24
First Name	Gregory L.	Last Name	Mayback	Registration Number
Additional Signature may be generated within this form by selecting the Add button.				Add

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	Syn2.0/ROAR Prov2
		Application Number	
Title of Invention	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		

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.**

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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.

Provisional Application for Patent Cover Sheet

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

Inventor(s)

Inventor 1

Given Name	Middle Name	Family Name	City	State	Country i
Derek	Dee	Deville	Coral Gables	FL	US

Inventor 2

Given Name	Middle Name	Family Name	City	State	Country i
Matthew	A.	Palmer	Miami	FL	US

Inventor 3

Given Name	Middle Name	Family Name	City	State	Country i
William	T.	Bales	Miami	FL	US

Inventor 4

Given Name	Middle Name	Family Name	City	State	Country i
Eric		Petersen	Homestead	FL	US

Inventor 5

Given Name	Middle Name	Family Name	City	State	Country i
Tyler		Bond	Miami	FL	US

Inventor 6

Given Name	Middle Name	Family Name	City	State	Country i
Jake		Pistiner	Davie	FL	US

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

Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter

Attorney Docket Number (if applicable)

Syn 2.0/ROAR Prov2

Correspondence Address

Doc Code: **TR.PROV**

Document Description: Provisional Cover Sheet (SB16)

PTO/SB/16 (11-08)

Approved for use through 05/31/2015. OMB 0851-0032

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Direct all correspondence to (select one):	
☒ The address corresponding to Customer Number	☐ Firm or Individual Name
Customer Number	27316

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

Warning

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

Signature

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

Signature	/gregory l. mayback/		Date (YYYY-MM-DD)	2018-10-24
First Name	Gregory L.	Last Name	Mayback	Registration Number (If appropriate)
				40719

This collection of information is required by 37 CFR 1.51. 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 8 hours 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. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

Privacy Act Statement

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

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

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter		
First Named Inventor/Applicant Name:		Derek Dee Deville		
Filer:		Gregory L. Mayback/Serene Keen		
Attorney Docket Number:		Syn2.0/ROAR Prov2		
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	140	140
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 (\$)				140

Electronic Acknowledgement Receipt	
EFS ID:	34106090
Application Number:	62750011
International Application Number:	
Confirmation Number:	6333
Title of Invention:	Aspiration Thrombectomy System and Methods for Thrombosis Removal with Aspiration Catheter
First Named Inventor/Applicant Name:	Derek Dee Deville
Customer Number:	27316
Filer:	Gregory L. Mayback/Serene Keen
Filer Authorized By:	Gregory L. Mayback
Attorney Docket Number:	Syn2.0/ROAR Prov2
Receipt Date:	24-OCT-2018
Filing Date:	
Time Stamp:	17:25:34
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$140
RAM confirmation Number	102518INTEFSW17282900
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Specification	2018-10-24_specification.pdf	241646	no	43
			3a95b2af217f69ccf70d6ad86906fe67104571a2		
Warnings:					
Information:					
2	Drawings-only black and white line drawings	2018-10-24_drawings.pdf	4765215	no	16
			caa0d2b5e73f03974e593406d606d3cae0ce9f1f		
Warnings:					
Information:					
3	Application Data Sheet	2018-10-24_aia14_ADS.pdf	1823303	no	10
			b1867be30f6472273e86c07f8f297f87c9dbca72		
Warnings:					
Information:					
4	Provisional Cover Sheet (SB16)	2018-10-24_ProvisionalSB.pdf	1477345	no	4
			f8eb917e817ca221254f5575258c2c74a5bb9abd		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	29802	no	2
			49b24d8f36b4b71f02d70c98c60d50b81ce121c1		
Warnings:					
Information:					
Total Files Size (in bytes):			8337311		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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APPLICATION
FOR
UNITED STATES LETTERS PATENT

TITLE OF INVENTION

ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR
THROMBOSIS REMOVAL WITH ASPIRATION CATHETER

Inventors:

DEREK DEE DEVILLE
MATTHEW A. PALMER
WILLIAM T. BALES
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Attorney Docket No.: Syn2.0/ROAR Prov2

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0001] Not Applicable

FIELD OF THE INVENTION

[0002] The present systems, apparatuses, and methods lie in the field of thrombosis removal. The present disclosure relates to an aspiration thrombectomy system and methods for thrombosis removal with aspiration catheter.

BACKGROUND OF THE INVENTION

[0003] Ischemic strokes are usually caused by a blood clot that blocks or plugs a blood vessel in the brain. This blockage prevents blood from flowing to the brain. Within minutes, brain cells begin to die, which, if not treated rapidly, causes brain damage or death. The costs associated with removing a clot are significant. Most treatments involve thrombectomy: the removal of the clot by aspiration, mechanical retrieval, or some combination thereof.

[0004] Removal by aspiration is effected by placing a source of vacuum, e.g., an aspiration or vacuum catheter, upstream of the clot and drawing the clot into or against the distal end of the catheter. Conceptually, aspiration is effective but some significant problems occur in practice. The basic configuration for an aspiration catheter includes a length of hollow catheter having a proximal end fluidically connected to a vacuum or suction pump. In this configuration, operation of the suction pump causes fluid and particulates at the distal end of the catheter to enter the distal opening of the hollow lumen and travel to the proximal end of the lumen near or into the suction pump. Conventional aspiration catheters are threaded through a balloon guide catheter. In one exemplary procedure, the balloon of the guide catheter is guided into the internal carotid artery of the brain. The balloon is inflated to occlude the vessel. The aspiration catheter is threaded through the balloon guide catheter and out the distal end of the guide catheter past the balloon. The distal end of the aspiration catheter is advanced to the clot that is occluding the brain vessel. Suction connected to the aspiration catheter is turned on to cause flow reversal. Ideally, this system aspirates the clot entirely out of the neurovasculature and to the proximal end of the aspiration catheter so that extraction and re-establishment of blood flow could be confirmed. In practice, however, this rarely occurs.

[0005] Thrombi are frequently of a larger diameter than the catheter being used to aspirate them. For aspiration to be successful, the thrombus must deform to conform to the inner diameter of the aspiration catheter. During conventional aspirations, it is common for applied vacuum to partially draw a thrombus into the distal opening of the aspiration catheter's lumen, thereby deforming some of the thrombus to the catheter's inner diameter. At this point, the thrombus becomes lodged completely within, partially within, or at the distal opening of the aspiration catheter, a condition that can be referred to as corked or corking. In effect, the distal end becomes a suction cup grasper for the clot. When this situation occurs, a surgeon's only option is to use the aspiration catheter as a fishing line to pull the clot back through the balloon guide and out of body. The other option is not viable, that is, reversing the suction to pressurize the clot and eject it forcibly and uncontrollably out of the distal opening of the aspiration catheter. Such action is dangerous to the patient for many reasons, the primary one being that forcibly and uncontrollably ejecting the clot may cause the clot to move further distally within the vessel in which it was originally lodged. That distal movement would not only cause the clot to be further within the vessel – i.e., in an even smaller diameter of the vessel than when it was originally lodged – but it could permanently lodge the clot into that vessel, making it impossible to remove, or it could burst the vessel. Those of skill in the art know that these situations are to be avoided because of the serious potential risks to the patient.

[0006] Even when the surgeon uses the aspiration catheter to fish out the clot, there is no assurance that the entirety of the clot will be removed. Pieces of the clot can break off during movement, when that occurs, the pieces re-embolize within the same vessel or within different vessels that might be even more difficult to remove.

[0007] When all or most of the clot is drawn out from the patient, it is difficult to confirm that the entire thrombus was removed. A significant disadvantage of current thrombus removal devices is the inability of a surgeon to ascertain thrombus capture/removal without the full withdrawal of a given therapeutic device from a patient's anatomy. Even systems capable of fully aspirating a given thrombus are problematic, because the reservoirs into which aspirated contents are deposited are located outside of the sterile field in an operating room setting. This location, outside the sterile field, makes it difficult or impossible for physicians operating aspiration catheters to easily visualize and appraise aspirated thrombus material.

[0008] To confirm thrombus removal can require the surgeon to attempt aspiration again. The aspiration and balloon guide catheters have to be cleaned out, access to distal anatomy has to be re-established, and, when the aspiration catheter finally is located back at the embolism site, the same issues may be present again with whatever embolus material remains. A disadvantage of these procedures is the significant increase in procedure time, which not only significantly increases the cost (as each minute in an operating room is expensive), it also increases the surgeon's stress, which decreases the success rate of the operation.

[0009] First-pass recanalization rate is a metric used to determine the efficacy of thrombectomy systems. Most current systems offer rates of between 50% and 80%. A system that increases the first-pass recanalization rate is valuable and desirable.

[0010] Thus, a need exists to overcome the problems with the prior art systems, designs, and processes as discussed above.

SUMMARY OF THE INVENTION

[0011] The systems, apparatuses, and methods described provide an aspiration thrombectomy system and methods for thrombosis removal with an aspiration thrombectomy system that overcome the hereinafore-mentioned disadvantages of the heretofore-known devices and methods of this general type and that provide such features with increased first-pass recanalization rate by completely pulling the embolus out and, thereby, reducing the instance of aspiration catheter obstruction/clogging by the embolus.

[0012] The systems, apparatuses, and methods provide an aspiration thrombectomy system that completely vacuums up the clot so that clots are no longer dragged out of vasculature while half hanging out of a catheter tip. The aspiration thrombectomy system moves the vacuumed clot all the way to the proximal end of the vacuum channel and allows the surgeon to confirm recanalization of the vessel in which the clot formerly resided (for example, by injecting contrast through the catheter that remains in place after clot removal) and provides structure to indicate to the surgeon that the thrombus has been removed and that flow has been restored.

[0013] The systems, apparatuses, and methods provide an aspiration thrombectomy system that can be coupled with conventional aspiration catheters to significantly increase the efficacy of such catheter and pump systems.

[0014] Thrombi are frequently of a larger diameter than the catheter being used to aspirate them. In order for aspiration to be successful, the thrombus must deform to conform to the inner diameter of the aspiration catheter. During conventional aspirations, it is common for applied vacuum to partially draw a thrombus into the distal opening of the aspiration catheter's lumen. At this point, the thrombus becomes stuck with some of the thrombus resting within the catheter's inner diameter and some of the thrombus protruding from the distal end.

[0015] The systems, apparatuses, and methods provide an aspiration thrombectomy system with an unclogging structure and technique that temporarily halts vacuum at the distal end of the aspiration catheter, pushes the thrombus distally out of the lumen, and then re-applies vacuum – an occlusion-vacuum-pressure sequence of operation. Upon re-application of the vacuum, the thrombus accelerates back into the catheter and deforms to a diameter allowing it to be completely aspirated. Each halting of the vacuum, thrombus pushing, and reapplication of the vacuum is controlled by the surgeon.

[0016] The systems and methods operate an aspiration/suction catheter with a mechanism to stop the vacuum and then press the distal fluid column in reverse, i.e., a positive displacement without a check valve, referred to herein as a column shift. All functions can be controlled with a single handle, including vacuum shut off and column shift while limiting the amount and the force for the column shift. When the controller is actuated, a positive amount of exit flow is created without possibility of overshooting. The exiting movement of fluid is limited to a specific volume and/or pressure and is automatically and precisely controlled. It is the user who controls when the column shift occurs and when it returns. A trap is disposed at an exit to catch and display the thrombus. A vent can be opened to atmosphere to clear fluid in the trap and show what thrombus remains.

[0017] With the foregoing and other objects in view, there is provided, a vacuum catheter for removing an object from within a human vessel comprising a vacuum tube defining an interior vacuum channel comprising a proximal opening for receiving application of vacuum and a distal capture opening fluidically connected to the proximal opening, the distal capture opening configured to receive therein the object responsive to application of the vacuum, and comprising an intermediate section between the proximal opening and the distal capture opening, and a vacuum interruption controller comprising a body through which a portion of the intermediate section passes and an extrusion compressor movably disposed with respect to the body towards and away from the portion of the intermediate section such that, in a rest state, the extrusion

compressor does not occlude the vacuum channel and, in an actuated state, the extrusion compressor first occludes the vacuum channel and then moves fluid disposed between the portion of the intermediate section and the distal capture opening a given distance distally towards the distal capture opening.

[0018] In accordance with another feature, there is provided a vacuum pump selectively applying vacuum to the proximal opening.

[0019] In accordance with a further feature, the vacuum tube has a proximal portion and which further comprises a catheter body surrounding the vacuum tube and configured to steer at least the proximal portion of the vacuum tube.

[0020] In accordance with an added feature, the vacuum tube has a proximal portion sized to fit within the Circle of Willis in a brain and the object is a blood clot adjacent the Circle of Willis.

[0021] Although the systems, apparatuses, and methods are illustrated and described herein as embodied in an aspiration thrombectomy system and methods for thrombosis removal with aspiration catheter, it is, nevertheless, not intended to be limited to the details shown because various modifications and structural changes may be made therein without departing from the spirit of the invention and within the scope and range of equivalents of the claims. Additionally, well-known elements of exemplary embodiments will not be described in detail or will be omitted so as not to obscure the relevant details of the systems, apparatuses, and methods.

[0022] Additional advantages and other features characteristic of the systems, apparatuses, and methods will be set forth in the detailed description that follows and may be apparent from the detailed description or may be learned by practice of exemplary embodiments. Still other advantages of the systems, apparatuses, and methods may be realized by any of the instrumentalities, methods, or combinations particularly pointed out in the claims.

[0023] Other features that are considered as characteristic for the systems, apparatuses, and methods are set forth in the appended claims. As required, detailed embodiments of the systems, apparatuses, and methods are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the systems, apparatuses, and methods, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one of ordinary skill in the art to variously employ the systems, apparatuses, and methods in virtually any appropriately detailed structure. Further, the terms and phrases used

herein are not intended to be limiting; but rather, to provide an understandable description of the systems, apparatuses, and methods. While the specification concludes with claims defining the systems, apparatuses, and methods of the invention that are regarded as novel, it is believed that the systems, apparatuses, and methods will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views, which are not true to scale, and which, together with the detailed description below, are incorporated in and form part of the specification, serve to illustrate further various embodiments and to explain various principles and advantages all in accordance with the systems, apparatuses, and methods. Advantages of embodiments of the systems, apparatuses, and methods will be apparent from the following detailed description of the exemplary embodiments thereof, which description should be considered in conjunction with the accompanying drawings in which:

[0025] FIG. 1 is a fragmentary, perspective view of an exemplary embodiment of a controller for a thrombectomy aspiration catheter in an unactuated state;

[0026] FIG. 2 is a fragmentary, perspective, longitudinal cross-sectional view of the controller of FIG. 1;

[0027] FIG. 3 is an enlarged, diagrammatic, side elevational view of a compression cam assembly of the controller of FIG. 1;

[0028] FIG. 4 is a fragmentary, longitudinal cross-sectional view of the controller of FIG. 1 with a compression roller removed;

[0029] FIG. 5 is a fragmentary, longitudinal cross-sectional view of the controller of FIG. 1 in an actuated state;

[0030] FIG. 6 is a fragmentary, enlarged, perspective view of a portion of an extrusion compressor of the controller of FIG. 1;

[0031] FIG. 7 is a fragmentary, perspective view of the controller of FIG. 1 in the actuated state;

[0032] FIG. 8 is a fragmentary, perspective and partially longitudinal cross-sectional view of the controller of FIG. 7;

[0033] FIG. 9 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 1 in an intermediate actuated state with the compression roller occluding the aspiration catheter and partially rolled to cause fluid column shift;

[0034] FIG. 10 is a fragmentary, longitudinal cross-sectional view of the controller of FIG.

[0035] FIG. 11 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 1 in the actuated state with the compression roller occluding the aspiration catheter and fully rolled to cause fluid column shift;

[0036] FIG. 12 is a fragmentary, longitudinal cross-sectional view of the controller of FIG. 11;

[0037] FIG. 13 is a longitudinal cross-sectional view of the controller of FIG. 9 with the compression roller and the aspiration catheter removed;

[0038] FIG. 14 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 1 in the unactuated state and diagrammatically connected to a distal portion of the aspiration catheter with a thrombus lodged in a distal opening of a vacuum channel;

[0039] FIG. 15 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 12 in the actuated state with the column shift that distally dislodges the thrombus from the distal opening of the vacuum channel;

[0040] FIG. 16 is a fragmentary, enlarged, perspective and longitudinal cross-sectional view of a distal portion of the controller of FIG. 1 and an exemplary embodiment of a vacuum booster disposed between the controller and a distal extent of the aspiration catheter with the vacuum booster in an energized state;

[0041] FIG. 17 is a fragmentary, enlarged, perspective and longitudinal cross-sectional view of the controller and the vacuum booster of FIG. 16 with the vacuum booster in a relaxed state;

[0042] FIG. 18 is a fragmentary, enlarged, perspective and partially transparent view of a proximal portion of the controller of FIG. 1 and an exemplary embodiment of a thrombus trap;

[0043] FIG. 19 is a fragmentary, enlarged, perspective view of the controller and thrombus trap of FIG. 18 with the intermediate shell of the thrombus trap removed;

[0044] FIG. 20 is a fragmentary, enlarged, perspective view of the controller and thrombus trap of FIG. 18;

[0045] FIG. 21 is a fragmentary, perspective and longitudinal cross-sectional view of the controller of FIG. 16, and the thrombus trap of FIG. 18;

[0046] FIG. 22 is a fragmentary, longitudinal cross-sectional view of an exemplary embodiment of a volume changing controller;

[0047] FIG. 23 is a vacuum circuit diagram of an exemplary embodiment of a vacuum booster and vacuum booster control device;

[0048] FIG. 24 is a cycle flow diagram of the operation of exemplary embodiments of the controller with the vacuum booster and the thrombus trap;

[0049] FIG. 25 is a perspective view of an automatic aspiration thrombectomy system to be connected distally to an aspiration catheter and proximally to vacuum and vent lines and with a cam housing removed;

[0050] FIG. 26 is a fragmentary, top plan view of the aspiration thrombectomy system of FIG. 25 with diagrammatic illustration of the aspiration catheter and the vacuum and vent lines;

[0051] FIG. 27 is an elevational view of a proximal side of the aspiration thrombectomy system of FIG. 25;

[0052] FIG. 28 is an elevational view of a bearing side of the aspiration thrombectomy system of FIG. 25;

[0053] FIG. 29 is a perspective and longitudinally cross-sectional view of the aspiration thrombectomy system of FIG. 25 with a vacuum valve in a closed state, a vent valve in an open state, and a flag of a positional reset assembly in a zero reset state;

[0054] FIG. 30 is a longitudinally cross-sectional view of the aspiration thrombectomy system of FIG. 29;

[0055] FIG. 31 is an enlarged cross-sectional view of a valve and cam set of the aspiration thrombectomy system of FIG. 25 with the cam in a rotational position to set an intermediate closing of the valve;

[0056] FIG. 32 is an enlarged cross-sectional view of the valve and cam set of FIG. 31 with the cam in a rotational position to close the valve;

[0057] FIG. 33 is a cross-sectional view of the aspiration thrombectomy system of FIG. 25 along section line 33-33 in FIG. 30 with the cam housing removed;

[0058] FIG. 34 is a perspective view of the aspiration thrombectomy system of FIG. 25 with the motor assembly housing removed;

[0059] FIG. 35 is a top plan view of the aspiration thrombectomy system of FIG. 26 with the motor assembly housing removed;

[0060] FIG. 36 is an elevational view of the aspiration thrombectomy system of FIG. 27 with the motor assembly housing removed;

[0061] FIG. 37 is an elevational view of the bearing side of the aspiration thrombectomy system of FIG. 28 with the motor assembly housing removed;

[0062] FIG. 38 is a perspective view of the aspiration thrombectomy system of FIG. 25 with the cam housing;

[0063] FIG. 39 is a top plan view of the aspiration thrombectomy system of FIG. 26 with the cam housing;

[0064] FIG. 40 is an elevational view of the aspiration thrombectomy system of FIG. 27 with the cam housing;

[0065] FIG. 41 is an elevational view of the bearing side of the aspiration thrombectomy system of FIG. 28 with the cam housing;

[0066] FIG. 42 is a fragmentary, partially hidden, perspective view of an exemplary embodiment of a rotational pintle valve to be employed with the aspiration thrombectomy system in a first valve state;

[0067] FIG. 43 is a fragmentary, cross-sectional view of the valve of FIG. 42;

[0068] FIG. 44 is a fragmentary, partially hidden, perspective view of the valve of FIG. 42;

[0069] FIG. 45 is a fragmentary, partially hidden, perspective view of the valve of FIG. 42 in a second valve state; and

[0070] FIG. 46 is a fragmentary, cross-sectional view of the valve of FIG. 45.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0071] As required, detailed embodiments of the systems, apparatuses, and methods are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the systems, apparatuses, and methods, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the systems, apparatuses, and methods in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting; but rather, to provide an understandable description of the systems, apparatuses, and methods. While the specification concludes with claims defining the features of the systems, apparatuses, and

methods that are regarded as novel, it is believed that the systems, apparatuses, and methods will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

[0072] In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which are shown by way of illustration embodiments that may be practiced. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope. Therefore, the following detailed description is not to be taken in a limiting sense, and the scope of embodiments is defined by the appended claims and their equivalents.

[0073] Alternate embodiments may be devised without departing from the spirit or the scope of the invention. Additionally, well-known elements of exemplary embodiments of the systems, apparatuses, and methods will not be described in detail or will be omitted so as not to obscure the relevant details of the systems, apparatuses, and methods.

[0074] Before the systems, apparatuses, and methods are disclosed and described, it is to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting. The terms “comprises,” “comprising,” or any other variation thereof are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus that comprises a list of elements does not include only those elements but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. An element preceded by “comprises ... a” does not, without more constraints, preclude the existence of additional identical elements in the process, method, article, or apparatus that comprises the element. The terms “including” and/or “having,” as used herein, are defined as comprising (i.e., open language). The terms “a” or “an,” as used herein, are defined as one or more than one. The term “plurality,” as used herein, is defined as two or more than two. The term “another,” as used herein, is defined as at least a second or more. The description may use the terms “embodiment” or “embodiments,” which may each refer to one or more of the same or different embodiments.

[0075] The terms “coupled” and “connected,” along with their derivatives, may be used. It should be understood that these terms are not intended as synonyms for each other. Rather, in particular embodiments, “connected” may be used to indicate that two or more elements are in direct physical or electrical contact with each other. “Coupled” may mean that two or more

elements are in direct physical or electrical contact (e.g., directly coupled). However, “coupled” may also mean that two or more elements are not in direct contact with each other, but yet still cooperate or interact with each other (e.g., indirectly coupled).

[0076] For the purposes of the description, a phrase in the form “A/B” or in the form “A and/or B” or in the form “at least one of A and B” means (A), (B), or (A and B), where A and B are variables indicating a particular object or attribute. When used, this phrase is intended to and is hereby defined as a choice of A or B or both A and B, which is similar to the phrase “and/or”. Where more than two variables are present in such a phrase, this phrase is hereby defined as including only one of the variables, any one of the variables, any combination of any of the variables, and all of the variables, for example, a phrase in the form “at least one of A, B, and C” means (A), (B), (C), (A and B), (A and C), (B and C), or (A, B and C).

[0077] Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. The description may use perspective-based descriptions such as up/down, back/front, top/bottom, and proximal/distal. Such descriptions are merely used to facilitate the discussion and are not intended to restrict the application of disclosed embodiments. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding embodiments; however, the order of description should not be construed to imply that these operations are order dependent.

[0078] As used herein, the term “about” or “approximately” applies to all numeric values, whether or not explicitly indicated. These terms generally refer to a range of numbers that one of skill in the art would consider equivalent to the recited values (i.e., having the same function or result). In many instances these terms may include numbers that are rounded to the nearest significant figure. As used herein, the terms “substantial” and “substantially” means, when comparing various parts to one another, that the parts being compared are equal to or are so close enough in dimension that one skill in the art would consider the same. Substantial and substantially, as used herein, are not limited to a single dimension and specifically include a range of values for those parts being compared. The range of values, both above and below (e.g., “+/-” or greater/lesser or larger/smaller), includes a variance that one skilled in the art would know to be a reasonable tolerance for the parts mentioned.

[0079] It will be appreciated that embodiments of the systems, apparatuses, and methods described herein may be comprised of one or more conventional processors and unique stored program instructions that control the one or more processors to implement, in conjunction with certain non-processor circuits and other elements, some, most, or all of the functions of the systems, apparatuses, and methods described herein. The non-processor circuits may include, but are not limited to, signal drivers, clock circuits, power source circuits, and user input and output elements. Alternatively, some or all functions could be implemented by a state machine that has no stored program instructions, or in one or more application specific integrated circuits (ASICs) or field-programmable gate arrays (FPGA), in which each function or some combinations of certain of the functions are implemented as custom logic. Of course, a combination of these approaches could also be used. Thus, methods and means for these functions have been described herein.

[0080] The terms “program,” “software,” “software application,” and the like as used herein, are defined as a sequence of instructions designed for execution on a computer system or programmable device. A “program,” “software,” “application,” “computer program,” or “software application” may include a subroutine, a function, a procedure, an object method, an object implementation, an executable application, an applet, a servlet, a source code, an object code, any computer language logic, a shared library/dynamic load library and/or other sequence of instructions designed for execution on a computer system.

[0081] Herein various embodiments of the systems, apparatuses, and methods are described. In many of the different embodiments, features are similar. Therefore, to avoid redundancy, repetitive description of these similar features may not be made in some circumstances. It shall be understood, however, that description of a first-appearing feature applies to the later described similar feature and each respective description, therefore, is to be incorporated therein without such repetition.

[0082] Described now are exemplary embodiments. Referring now to the figures of the drawings in detail and first, particularly to FIGS. 1 to 13, there is shown a first exemplary embodiment of a one-handed controller 10 for an aspiration thrombectomy system 1 utilizing a vacuum tube 2. The controller 10 comprises a first handle part 20 and a second handle part 40. The first handle part 20 is connected to and holds the vacuum tube 2 and, therefore, is also referred

to as a handle base. The second handle part 40 moves with respect to the first handle part 20 and, therefore, the second handle part 40 is also referred to as a compressor-actuator 40.

[0083] In an exemplary embodiment, the first handle part 20 has a distal tube anchor 22 and a proximal tube anchor 24. In this embodiment, the distal and proximal tube anchors 22, 24 are in the form of hollow tubes through which the vacuum tube 2 traverses. The distal and proximal tube anchors 22, 24 hold the vacuum tube 2 therein substantially without compressing the vacuum tube 2 (and thereby does not reduce or close the inner vacuum channel 3). The vacuum tube 2 can be of many materials, including latex, silicone, Pebax®, polyurethane, polyvinyl chloride, or other synthetic rubber. Exemplary sizes for the vacuum tube 2 have an inner diameter (I.D.) of approximately 0.055 to 0.095 inches. One exemplary embodiment for retaining the vacuum tube 2 is an adhesive that bonds the material of the vacuum tube 2 to the interior lumens of the tubular tube anchors 22, 24. In this exemplary embodiment, the vacuum tube 2 is fixed to the first handle part 20. In an alternative embodiment, the first handle part 20 is a clamshell having two first handle part halves (not illustrated) that open to receive the cylindrical vacuum tube 2 and, when closed thereupon, the tube anchors 22, 24 tightly grip the vacuum tube 2 therein substantially without closing or occluding the vacuum channel 3 of the vacuum tube 2. In one exemplary clamshell embodiment, the first handle part 20 is split horizontally at the dashed line in FIG. 2 with a hinge, allowing a portion of the vacuum tube 2 to be inserted into and removed from the distal and proximal tube anchors 22, 24. A lock secures the vacuum tube 2 therein until the user desires removal. The hinge is useful to allow the surgeon to reposition the controller 10 along the vacuum tube 2.

[0084] The exemplary embodiment of the distal and proximal tube anchors 22, 24 are separated from one another over a distance. Between the distal and proximal tube anchors 22, 24 of the first handle part 20 is a compression floor 26. When installed within the first handle part 20, the vacuum tube 2 lays against the compression floor 26 between the distal and proximal tube anchors 22, 24 substantially without closing or occluding the vacuum channel 3. FIG. 13 illustrates the compression floor 26 of first handle part 20 with the vacuum tube 2 removed.

[0085] The first handle part 20 has a hollow interior that defines a set of parallel lateral walls 32 on either side of the vacuum tube 2. The first handle part 20 comprises a compression cam assembly 30 that permits the second handle part 40 to move in two directions with respect to the first handle part 20. More specifically, in the exemplary embodiment, the compression cam

assembly 30 comprises a set of slots 34 formed in the lateral walls 32 of the first handle part 20. As shown in the enlarged view of FIG. 3, these slots 34 have a vertical extent 35 and an angled extent 36. The vertical extent 35 has a vertical length and the angled extent 36 has a vector length that is comprised of a second vertical extent 37 and a horizontal extent 39. Accordingly, as explained below, the slots 34 provide a cam surface for movement of the second handle part 40 in the same shape as the slot 34.

[0086] In the exemplary embodiment, to contact the first and second handle parts 20, 40 together, the second handle part 40 has a hollow interior into which the first handle part 20 is inserted and projects. (In an alternative embodiment, the first handle part 20 has a hollow interior into which the second handle part 40 is inserted and projects.) A width between interior facing lateral surfaces of the hollow compartment of the second handle part 40 is approximately equal to the width of the exterior surfaces of the lateral walls 32 such that the second handle part 40 can move up and down on the first handle part 20 tightly but smoothly with little or substantially no friction. In comparison, the length between interior facing longitudinal surfaces of the hollow compartment of the second handle part 40 is greater than the length of the exterior surfaces of the longitudinal walls 38. The difference in length is sufficiently long enough to allow the second handle part 40 to move along the horizontal extent 39 longitudinally parallel with the vacuum tube 2 throughout the horizontal extent 39.

[0087] Movement of the compressor-actuator 40 with respect to the handle base 20 follows the slots 34 by providing the compressor-actuator 40 with bosses 42 protruding from the interior facing surfaces of the lateral walls 42 of the hollow compartment of the compressor-actuator 40; one circular boss 42 is associated with each of the slots 34. In this way, movement of the compressor-actuator 40 is guided by and restricted by the shape of the slots 34. In an unactuated state of the controller 10, shown in FIGS. 1, 2, and 4, the bosses 42 reside at the end of the vertical extent 35, which in the exemplary embodiment is at the uppermost end of the slot 34. (It is noted that the embodiment shown in FIGS. 1 to 13 provide four slots 34 and four bosses 42. This number is merely exemplary. The cam surface of the slots 34, the extents 35, 36 of the slots 34, and the cam follower of the bosses 42 can take any form or shape that causes the controller to operate as described herein.) As seen most clearly in FIG. 4, a distance A between an interior of the proximal longitudinal wall 38 of the compressor-actuator 40 and an exterior of the proximal wall of the first handle part 20 is longer than the horizontal extent 39 (i.e., $|A| > |39|$). When the compressor-

actuator 40 is fully actuated as shown in FIG. 5, the bosses 42 travel to the opposite (lowermost) end of the slot 34. The compressor-actuator 40, therefore, has traveled a vertical distance equal to the vertical movement of the bosses 42 within the vertical and angled extents 35, 36 and has traveled a horizontal distance equal to the horizontal extent 39. The exemplary embodiments of the first and second handle parts 20, 40 have the interior surface of the distal longitudinal wall of the compressor-actuator 40 touching the exterior surface of the distal longitudinal wall of the handle base 20, this touch being indicated with arrows B in FIG. 4 (i.e., $|B| = 0$). When the compressor-actuator 40 is fully actuated, therefore, these two distal longitudinal walls separate to a distance equal to the horizontal extent 39. Likewise, the distance between an exterior surface of the proximal longitudinal wall of the handle base 20 and an interior surface of the proximal longitudinal wall of the compressor-actuator 40 shortens from A by a length equal to the horizontal extent 39 (i.e., $(A-|39|)$), which is illustrated in FIG. 5. Alternately, a four-bar linkage could be provided to join 20 and 40 to create the same motion as the cam slots and bosses.

[0088] What becomes apparent from movement of the compressor-actuator 40 following the slots 34 is how an extrusion compressor 50 connected to the compressor-actuator 40 operates during this movement. The exemplary embodiment of the extrusion compressor 50 in FIGS. 1, 2 and 4 to 13 has the extrusion compressor 50 project from an interior surface of a ceiling of the hollow compartment of the compressor-actuator 40 downwards towards the handle base 20. In particular, the extrusion compressor 50 projects downwards towards the compression floor 26 of the handle base 20. The extrusion compressor 50 has a base 52 attached to the second handle part 40. A flex arm 54 projects from the base 52 and extends towards the compression floor 26. In the exemplary embodiment, the flex arm 54 is thinner than the base 52. A material from which the base 52 and flex arm 54 are made is not substantially rigid and, therefore, responsive to moving downwards to have a portion of the extrusion compressor 50 touch the compression floor 26 before the entire vertical movement of the compressor-actuator 40 is complete, the flex arm 54 flexes. Example materials for the base 52 and flex arm 54 include ABS, polycarbonate and Nylon®, polypropylene, polyurethane, or other thermoplastic or thermoplastic elastomer and/or fiber filled ABS, polycarbonate and Nylon®. At a distal end of the flex arm 54 is a gear flange 56 shaped to hold thereat a compression roller 60. The gear flange 56 has axle ports in which an axle 62 of the compression roller 60 resides. When installed between the interior sides of the gear flange 56, the compression roller 60 becomes fixed to the gear flange 56 in all directions except for rotational

movement of the compression roller 60 about a rotation axis 64 of the roller 60; in other words, the roller 60 is allowed to rotate about the axis 64.

[0089] It is noted that the extrusion compressor 50 shown is an exemplary embodiment. Different mechanical structures performing the same function can be used. For example, the base 52 and flex arm 54 can be replaced with a single beam that is hinged to the ceiling of the interior hollow of the compressor-actuator 40 and biased with a bias device (e.g., a spring) towards the compression floor 26 such that the point of the compression roller 60 touches the vacuum tube 2 as shown in FIG. 2 enough to grip the vacuum tube 2 but substantially not reduce the cross-sectional area of the vacuum channel 3.

[0090] Rotation of the roller 60 is dependent upon how the roller 60 moves towards the vacuum tube 2 and along the vacuum tube 2. In this regard, the compression roller 60 has an exterior contact surface 66 that contacts the vacuum tube 2 in various ways when the compressor-actuator 40 is moved towards the handle base 20. As shown in FIG. 6, a longitudinal cross-section of the exterior surface 66 is approximately in the shape of a nautilus (alternatively, the shape can be cylindrical). The exterior surface 66 has a contact point 67, which is in contact with the exterior surface of the vacuum tube 2 in the unactuated state of the compressor-actuator 40 as shown in FIG. 2 (the vacuum channel 3 is unoccluded with a substantially patent and open cross-section). As the compressor-actuator 40 is actuated, the compressor-actuator 40 travels along the vertical extent 35. This moves the contact point 67 towards the compression floor 26. When the compressor-actuator 40 has travelled along the entirety of the vertical extent 35, as shown in FIGS. 7 and 8, the contact point 67 has moved against the vacuum tube 2 to occlude the vacuum channel 3 completely. At the stage where the bosses 42 are at this transition point from the vertical extent 35 to the angled extent 36, the contact point 67 is as far towards the compression floor 26 as it can move in that direction – because the thickness of the vacuum tube 2 prevents further movement of the contact point 67 towards the compression floor 26.

[0091] In a procedure where the vacuum tube 2 is used in a thrombectomy, the vacuum channel 3 will be filled with a fluid, i.e., blood. When the vacuum channel 3 is completely occluded, the blood that fills up the vacuum channel 3 from the contact point 67 of the compression roller 60 distally to the distal end of the vacuum channel 3 defines a column of fluid, which fluid is not compressible. The controller 10 is configured to apply the extrusion compressor 50 and the compression roller 60 to move this column of fluid a shift distance 70 in the distal direction. An

exemplary volume of the shift distance is approximately 0.001 ml to approximately 1.0 ml, in particular, approximately 0.1 ml to approximately 0.5 ml. An exemplary length of the shift distance 70 is approximately 0.5 mm to approximately 30 mm, in particular, approximately 0.5 mm to approximately 15 mm. To effect such a movement, the compressor-actuator 40 is moved further in the direction towards the handle base 20, which means that the bosses 42 travel along and through to the end of the angled extent 36. Because the contact point 67 is already as far towards the compression floor 26 as it can move in that direction (i.e., when the bosses 42 are at the transition point from the vertical extent 35 to the angled extent 36), the extrusion compressor 50 has no other way to move than to flex the flex arm 54 and/or to roll the compression roller 60. The contact surface 66 of the compression roller 60 is shaped to roll (counterclockwise in the views of FIGS. 2 and 8 to 12) against an upper surface of the vacuum tube 2. FIGS. 9 and 10 illustrate the rolling start of the compression roller 60 at a point where the bosses 42 are approximately halfway to the distal end of the slot 34 within the angled extent 36. (It is noted that limitation of the computer software that generates FIG. 9 to 12 do not allow for displaying a realistic view of how the vacuum tube 2 compresses as the compression roller 60 rotates. These figures, therefore, illustrate an approximation of the compression roller 60 rolling on and over the shift distance 70 of the vacuum tube 2.) The contact point 67 of the compression roller 60 is offset from the rotation axis 64 towards the contact surface 66. This forms an over center, or toggle, such that the initial rolling motion of the compression roller must first force the contact point 67 over the center of the rotation axis 64. In such a configuration, not only does the compression roller 60 roll once the bosses 42 of the compression-actuator 40 start traveling in the angled extent 37, but there is also a tactile feedback transmitted to the compression-actuator 40 once the axle 62 moves slightly forward. This feedback, when felt by the user, indicates to the user that the contact surface 66 of the compression roller 60 has rolled onto a portion of the vacuum tube 2 and, as it moves along the vacuum tube 2, squeezes that portion to translate the fluid column in the distal direction of the vacuum tube 2. With complete movement of the compression-actuator 40 towards the handle base 20 as shown in FIGS. 11 and 12, the compression roller 60 has completed its defined rotation over the vacuum tube 2 and, in doing so, has squeezed a segment of the vacuum channel 3 from proximal to distal over the length to shift the fluid column distally to a length equal to the shift distance 70.

[0092] To return the controller 10 to the initial, unactuated state shown in FIGS. 1 and 2, for example, a bias device 12 is interposed between any surface of the interior hollow of the compression-actuator 40 and any surface of interior hollow of the handle base 20. In the exemplary embodiment shown in FIGS. 2 and 8, the bias device 12 is disposed between the surface of the ceiling within the interior hollow of the compression-actuator 40 and an upper surface of the proximal tube anchor 24. This configuration for the bias device 12 is merely exemplary and any return spring or similar mechanical device can be placed and used. When the user releases pressure on the compression-actuator 40, the flex arm 54 and/or the bias device 12 causes the compression-actuator 40 to return to the initial, unactuated state. This action rolls the compression roller 60 in the opposite direction (i.e., the progression from FIG. 11 to FIG. 9 to FIG. 8). As the distal end of the vacuum channel 3 experiences positive pressure, the fluid column retreats proximally back into the vacuum channel 3 and, when the compression roller 60 releases from the vacuum tube 2 to cease occluding the vacuum channel 3, vacuum being placed in the vacuum channel 3 from a vacuum pump 80 proximal to the controller 10 automatically reestablishes and draws the fluid column through the segment of the vacuum tube 2 within the controller 10.

[0093] As set forth herein, the vacuum tube 2 is sized to lay against the compression floor 26 on one side and to have the point of the compression roller 60 touch the outer surface of the vacuum tube 2 just slightly enough to grip the vacuum tube 2 but substantially not reduce the cross-sectional area of vacuum channel 3. In an embodiment where the vacuum tube 2 is not fixed within the handle base 20, the compression roller 60 is provided with a non-illustrated bias device that biases the compression roller 60 rotationally into a position shown in FIG. 2. This bias compensates in a situation where the vacuum tube 2 is not touching the compression roller in the unactuated position of the compressor-actuator 40.

[0094] With a configuration as described, the controller 10 is to be used with a vacuum tube 2 that is or is part of a thrombectomy aspiration catheter. Such use is described with regard to FIGS. 14 and 15, in which the vacuum lumen 3 is shown as being an aspiration controller that, distal to the controller 10, is threaded through vasculature and up to a thrombus 4, which in the form of a blood clot, that has corked within or at the distal opening of the vacuum channel 3. On the proximal side of the controller 10, the vacuum channel 3 is fluidically connected to the vacuum pump 80. As indicated above, thrombi typically are trapped at the end of an aspiration catheter and removing the entire catheter from the patient when that occurs is not desirable. The inventors have

discovered that removal of the catheter can be prevented using the controller 10. More particular, when the distal end of the vacuum tube 2 is clogged by a thrombus, the controller 10 is actuated to occlude all flow through the vacuum channel 3. This occurs by the first movement of the compressor-actuator 40 towards the handle base 20. The controller 10 is actuated to cause the fluid column to shift distally to the shift distance 70. This imparts a controlled reversal of flow to the fluid column within the vacuum channel 3 that slightly translates the thrombus to a prescribed shift distance 70 distally relative to the distal opening of the vacuum channel 3. During a third and final phase, the user releases actuation of the controller 10 to reset the fluid column within the vacuum channel 3 and, once again, allows the fluid to flow freely. The inventors have discovered that such movement causes either a repositioning of the thrombus or a deformation of the thrombus or both and that this movement allows the thrombus to pass entirely into and through the vacuum channel 3 where such passage was not possible before.

[0095] Operation of the controller 10 is explained with regard to the system cycle diagram of FIG. 24.

- **State 1:** Normal aspiration is occurring. The vacuum channel 3 is not occluded. The controller 100 is in a rest state where the vacuum pump 80 is connected to the vacuum channel 3.
- **Transition A – Occlusion:** Thrombus 4 occludes distal end of vacuum channel 3. Unclogging controller 10 actuates to occlude vacuum channel 3 and stop vacuum flow distal of the controller 10.
- **State 2:** Flow through the vacuum channel 3 has stopped.
- **Transition B – Unclogging:** Controller 10 continues actuation to cause reverse flow in vacuum channel 3 for a metered volumetric column shift.
- **State 3:** Flow reversal stops.
- **Transition C – Return Column Shift:** Controller 10 is reversed to return column and accelerate thrombus 4 into catheter tip by reconnecting the vacuum pump 80 to the vacuum channel 3.
- **Return to State 1 and Repeat:** Normal aspiration occurs.

[0096] The inventors further discovered that greater accelerations of the thrombus into the catheter provide proportionally quicker aspirations. A magnitude of the thrombus' impact velocity, and therefore its kinetic energy, when it impacts the aspiration catheter's distal tip, affects the amount of the thrombus that is deformed to fit within the diameter of the vacuum channel 3.

When a catheter is extended to a thrombus that is lodged in a vessel, e.g., a vessel within the brain, the controller 10 is not needed until the thrombus 4 is stuck at the distal opening of the vacuum channel 3. Thus, the thrombus does not have any distance to move in order to accelerate towards the opening of the vacuum channel 3. Imparting the shift distance to the thrombus as described maximizes the kinetic energy of the thrombus at the point when it impacts the catheter's tip. The thrombus' acceleration (and therefore its kinetic energy) are generated by a pressure differential between intracranial pressure and the effective aspiration pressure at the catheter's tip. For the thrombus to accelerate, both it and the fluid column within the catheter system must attain a velocity. After catheters are occluded, the fluid velocity within the catheter is substantially zero. In conventional catheter architecture, the pressure that attempts to accelerate this fluid column is provided solely by an external vacuum pump. Significantly, however, this pressure is reduced by head losses in the tubing connecting the vacuum pump to the catheter's proximal end. Accordingly, conventional catheters must be fished out of the vasculature entirely because the thrombus is corked within the distal opening of the vacuum channel.

[0097] This disadvantage is removed by the controller 10. After the distal opening of the vacuum channel 3 is occluded by the thrombus, the fluid velocity within the catheter is substantially zero. The controller 10 is used to unclog the vacuum channel 3 and displace the thrombus 4 distally out from the distal opening. Then, the controller 10 re-applies vacuum. Upon re-application of vacuum, the fluid column accelerates and the thrombus 4 accelerates back into the vacuum channel 3. With such acceleration, the thrombus is deformed to a diameter allowing it to be aspirated. With one or just a few applications to displace the thrombus by the shift distance 70 with the controller 10, the vacuum channel 3 becomes unclogged and the thrombus 4 accelerates sufficiently to be completely aspirated through and out of the vacuum tube 2. With the controller 10, the head losses in the tubing are minimized, thereby allowing the thrombus to accelerate to a much greater extent than in conventional product architectures.

[0098] Realizing that acceleration of the thrombus proximally is a desirable trait, it becomes possible to enhance acceleration in the proximal direction when deactuation of the controller 10 occurs to re-establish vacuum. To maximize the acceleration of the thrombus and the fluid column within the vacuum channel 3 for the purpose of maximizing the thrombus' kinetic energy upon its impact with the distal tip of the vacuum tube 2, a vacuum booster 100, illustrated in FIG. 16, is fluidically connected to the vacuum channel 3 of the vacuum tube 2. In general, the vacuum

booster 100 applies suction to the fluid column in a region of the aspiration catheter's proximal end to maximize acceleration of the catheter's fluid column at a user-selected time. This exemplary embodiment of the vacuum booster 100 comprises a booster body 110 defining a plunger bore 112, a plunger 120 housed within the bore 112, and a bias device 130. The plunger bore 112 is shaped to define a vacuum chamber 114 and an ambient chamber 116. In the exemplary embodiment, the vacuum chamber 114 is cylindrical and has a first inner diameter and the ambient chamber 116 is cylindrical and has a second inner diameter larger than the first inner diameter. The vacuum chamber 114 has a volume that is smaller than a volume of the ambient chamber 116. [0099] The plunger 120 has a vacuum piston 122 and an ambient piston 124, which is connected to the vacuum piston 122 through a rod 123. In the exemplary embodiment, the vacuum piston 122 has a diameter substantially equal to the first inner diameter of the vacuum chamber 114 and is able to move within the vacuum chamber 114. The ambient piston 124 has a diameter substantially equal to the second inner diameter of the ambient chamber 116 and is able to move within the ambient chamber 116. Between the vacuum piston 122 and the ambient piston 124 is a pressure chamber 118 in which is located the rod 123 connecting the two pistons 122, 124 together, for example, in the shape of an asymmetric dumbbell. To seal the pressure chamber 118 off from both the vacuum chamber 114 and the ambient chamber 116, a vacuum seal 126 is disposed between the vacuum piston 112 and the wall of the vacuum chamber 114 and an ambient seal 128 is disposed between the ambient piston 124 and the wall of the ambient chamber 116. The booster body 110 defines the pressure chamber 118 and a pressure port 119 that fluidically connects the pressure chamber 118 to a boost control valve or switch 150. This connection is illustrated diagrammatically in FIG. 23.

[00100] The vacuum chamber 114 operatively communicates with the vacuum channel 3 at a connection 140. The plunger 120 and the bias device 130 are disposed such that, when the bias device 130 is in a relaxed state, the vacuum piston 122 is at a given distance from the connection 140 to the vacuum channel 3; this relaxed state is illustrated in FIG. 17. In the relaxed state, the spring is at a steady state – there is no potential energy stored in the spring. With regard to pressure, in the relaxed state, both the pressure chamber 118 and the ambient chamber 116 are at ambient pressure, i.e., they are substantially equal. When the plunger 120 is moved towards the vacuum channel 3 into an energized state (which is shown in FIG. 16), the bias device 130 (e.g., in the form of a spring that is stretched) thereby stores strain energy that is directed to move the plunger

120 away from the connection 140. Such movement, when it occurs, creates suction within the vacuum chamber 114 and the vacuum channel 3 that communicates with the vacuum chamber 114.

[00101] To actuate the embodiment of the pneumatically actuated vacuum booster 100, the pressure chamber 118 is connected to the vacuum pump 80 (the vacuum source) through a relatively high impedance conduit 152. The pressure chamber 118 is also connected to the boost control valve 150, which is connected to ambient pressure but is normally open to prevent flow from the pressure chamber 118 to the environment (Patm). When the vacuum booster 100 is in a cocked state (FIG. 16), the boost control valve 150 is open (as shown) and, as such, the vacuum pump 80 is able to significantly lower pressure within the pressure chamber 118. When the boost control valve 150 is actuated (i.e., connecting the pressure chamber 118 to the ambient environment), pressure equalization occurs between the pressure chamber 118 and the ambient chamber 116. An impedance of a connection between the pressure chamber 118 and the boost control valve 150 is designed to be substantially less than the impedance between the pressure chamber 118 and the vacuum pump 80 such that, upon actuation of the boost control valve 150 (i.e., closure), rapid pressure equalization is possible.

[00102] Operation of the vacuum booster 100 is explained with regard to the system cycle diagram of FIG. 24.

- **State 1:** Normal aspiration is occurring. The vacuum channel 3 is not occluded. The controller 100 is in a rest state where the vacuum pump 80 is connected to the vacuum channel 3. The vacuum booster 100 is in the cocked state. The thrombus trap 200 is operating without bleed purge.
- **Transition A – Occlusion:** Thrombus 4 occludes distal end of vacuum channel 3. Unclogging controller 10 actuates to occlude vacuum channel 3 and stop vacuum flow distal of the controller 10.
- **State 2:** Flow through the vacuum channel 3 has stopped.
- **Transition B – Unclogging:** Controller 10 continues actuation to cause reverse flow in vacuum channel 3 for a metered volumetric column shift.
- **State 3:** Flow reversal stops.
- **Transition C – Vacuum Boost:** Vacuum booster 100 actuated to re-initiate flow in nominal direction and accelerate thrombus 4 into catheter tip. Shortly before, at the same time, or shortly thereafter, controller 10 opens vacuum channel 3 to reinitiate vacuum of pump 80 for

fluid flow and aspiration of thrombus 4 into thrombus trap 200. Simultaneously or thereafter, controlled purging or automatic purging of thrombus trap 200 occurs allowing inspection of thrombus 4.

- **Return to State 1 and Repeat:** Vacuum booster 100 and self-purging trap 200 are de-actuated. Normal aspiration occurs.

[00103] During the occlusion and column shift phases in the operation of the controller 10, the plunger 120 is held in the energized state, with the plunger 120 raised to place the vacuum piston 122 closer to the connection 140. During or immediately upon the end of the reversal phase, the plunger 120 is released, generating suction within the locally communicating lumen of the vacuum channel 3 and thereby accelerating the fluid column proximally in the vacuum direction. What fluid is begin drawn into or towards the vacuum chamber has an effect on the efficiency of the vacuum booster 100. More specifically, if the fluid arrives only from downstream of the vacuum booster 100 when actuated, then the fluid column will not accelerate proximally as desired. When the controller 10 occludes the vacuum channel 3, fluid into and towards the vacuum chamber 114 will arrive substantially from upstream of the vacuum channel 3, thereby accelerating the fluid column in the desired direction. In an intermediate stage where fluid arrives from both upstream and downstream, the downstream portion can be limited, for example, by placing a non-illustrated check valve between the thrombus trap 200 and the connection 140, in particular, between the connection 140 and the controller 10. The check valve can be external or can use the occlusive function of unclogging handle.

[00104] The following description summarizes the forces in a pneumatic embodiment of the vacuum booster 100. In an un-cocked state of the plunger 120, the pressure chamber 118 and the ambient chamber 116 are at ambient pressure and the bias device 130 is in substantially in the relaxed state, storing little or no strain energy. In a cocked state of the plunger 120, the pressure chamber 118 is caused by the boost control valve 118 to be at a significantly lower pressure than the ambient chamber 116. The geometries of the chambers 114, 116, 118 and the pistons 122, 124, and the characteristics of the bias device 130 are selected such that, in this configuration, a force created by the pressure difference across the ambient (larger) piston is significantly greater than the force required to expand the spring. As such, when the given pressures are held, the piston and spring system translates upwards into a “cocked” position. When the vacuum booster 100 is actuated, the pressure chamber 118 is allowed to rapidly equalize to ambient pressure. With no

net force input from the ambient piston 124 (the larger of the two pistons), any motion of the piston and spring system are now caused by the actions of the bias device 130 and the pressure differential across the smaller, vacuum piston 122. The geometries of the chambers 114, 116, 118 and the pistons 122, 124, and the characteristics of the bias device 130 are selected such that the bias device's restoring force in the cocked configuration is much higher than an opposing force caused by the pressure difference across the smaller vacuum piston 122, which is disposed between ambient pressure and a pressure within the vacuum channel 3. As such, when the vacuum booster 100 is actuated and the pressure chamber 118 is allowed to equalize to ambient pressure, the piston and spring system energetically drives "downwards", generating a negative displacement and a dramatic pressure decrease within the vacuum chamber 114 and thereby the vacuum channel 3 of the aspiration device.

[00105] As indicated herein, current thrombus removal devices are not able to inform the surgeon that the thrombus has been removed without full withdrawal of the device from a patient's anatomy. Surgeons do not have an ability to view the reservoirs into which aspirated contents are deposited, not only because the reservoirs are located outside of the sterile field in an operating room setting, but also because the removed thrombus is present within a significant quantity of blood contained in the reservoir.

[00106] To overcome an inability to visualize the thrombus actually retrieved, a visualization-aiding thrombus trap 200 is provided and shown in FIGS. 18 to 21. The thrombus trap 200 is placed in-line with the aspiration system, in particular, the vacuum channel 3. In the exemplary embodiment, the thrombus trap 200 is within the catheter operator's immediate vicinity between the aspiration catheter and the vacuum source, in particular, between the controller 10 and the vacuum pump 80, so that the surgeon can see the thrombus trap 200 during use of the controller 10. In use, all aspirated material flows through the thrombus trap 200.

[00107] The thrombus trap 200 comprises a container having an inflow section 210 having an input orifice 212 fluidically connected to the vacuum channel 3, a transparent intermediate trap section 220 in which the thrombus is trapped, and an outflow section 230 fluidically connected to the vacuum pump 80. In operation, aspirated material and fluid travel from the vacuum channel 3 past the controller 10 through the inflow section 210 and into the trap section 220. The trap section 220 contains a trap filter 222 that is, in an exemplary embodiment, a screen or a filter through which all aspirated flow must pass. The filter 222 is configured to stop and capture thrombus

material therein but allow the passage of air and fluid with minimal impedance therethrough and, thereby out of the outflow section 230 to the vacuum pump 80 and any associated vacuum pump reservoir 82. In the exemplary embodiment of FIGS. 18 to 22, the filter 222 is in the form of a grating or screen having orifices sufficiently large enough for fluid and air to pass therethrough but sufficiently small enough to substantially prevent the thrombus from passing across the filter 222 from an inflow or trap chamber 224 of the trap section 220 to an outflow chamber 226 of the trap section 220. As used herein, the term “filter” includes any structure that is able to separate fluid from particulate matter by allowing the fluid to pass through the structure while preventing the particular matter from passing through. Other exemplary embodiments of the filter 222 include perforated polymer, textile, or sintered semi-permeable polymer. The outflow section 230 has an output orifice 232 that fluidically connects the outflow chamber 226 to the vacuum pump 80 for directly receiving the vacuum generated.

[00108] The container of the thrombus trap 200 is sealed when closed and in use during a surgical procedure. In an exemplary embodiment, the thrombus trap 200 can be taken apart and opened for removal of the thrombus out of the trap chamber 224 and inspection by the surgeon or pathologist, as well as for sterilization when the thrombus trap 200 is reusable.

[00109] It is noted that when a thrombus 4 is captured in the trap chamber 224, whether or not vacuum is still being applied, the trap chamber 224 is also filled with blood. Thus, the thrombus 4 cannot be visualized even if the entirety of the thrombus trap 200 is transparent for viewing inside by a user. To assist with visualization of the thrombus 4 contained within the trap chamber 224, the thrombus trap 200 is configured to temporarily purge itself of fluids that visually impede inspection of captured thrombus material. In an exemplary embodiment, therefore, the inflow section 212 is formed with an intake bleed valve 214 fluidically connected to the vacuum channel 3 and to the trap chamber 224. The bleed valve 214 is configured to operate in a closed mode, in which any flow of air and/or fluid through the bleed valve 214 and into the trap chamber 224 (or vacuum channel 3) is fully restricted, and a bleed mode, in which the bleed valve 214 intakes a fluid, in particular, ambient air. (Alternatively, if desired, in the bleed mode, the bleed valve 214 can intake a clear liquid such as saline.) During the closed mode operation, the exit of the bleed valve 214 is closed and aspirated materials are unhindered to flow through the thrombus trap 200 from the input orifice 212 and out the output orifice 232 away towards the vacuum source, leaving aspirated thrombus and other solid matter in the trap chamber 224. Accordingly, when the surgeon

has captured a thrombus 4 in the trap chamber 224 during a thrombectomy procedure, the surgeon can immediately visualize that thrombus 4 by setting the bleed valve 214 into the bleed mode, which, due to a relatively larger size of the bleed valve's 214 input opening and to a decreased resistance to the vacuum by opening to ambient air, causes the vacuum pump to draw ambient air rapidly into the trap chamber 224 and thereby evacuate all fluid from the trap chamber 224. During inspection, the bleed valve 214 can be configured to occlude the fluidic connection between the trap chamber 224 and the vacuum channel 3. Actuation of the bleed valve 214 can be separate from the controller 10 or mechanically connected to the controller 10 so that, when the controller 10 is in an unactuated state where aspiration is occurring, a bleed switch on the controller can activate the bleed valve 214. The rapid inflow of air into the trap chamber 224 is directed by the descending pressure gradient between the outside environment and the relatively low pressure existing within the volume existing between the trap chamber 224 and the vacuum pump 80. As such, while the bleed 214 valve is open, airflow displaces fluids from the volume of the thrombus trap 200, leaving the volume mostly full of transparent air, instead of opaque blood. This temporary transparency allows for easier inspection of the material caught by the filter 222. The surgeon then can view the thrombus 4 unobstructed within the trap chamber 224. During this examination, the control of the bleed valve 214 (which can be a mechanical or a processor-based controller) can cause the vacuum pump 80 to reduce vacuum or to shut off completely, at least until the surgeon is ready to continue the thrombectomy procedure if continuation is desired. When the bleed valve 214 is set back to the closed mode and re-connection of the trap chamber 224 to the vacuum channel 3 occurs, normal aspiration resumes.

[00110] Inspection of the thrombus 4 may be enhanced by providing the thrombus trap 200 with optical filters optimized for visual contrast, transparent trap enclosures as described, built-in magnification or visualization systems, lighting, and/or sensor-based thrombus-detection methods.

[00111] In the exemplary configuration, the vacuum booster 100 is disposed upstream of the thrombus trap 200 and is on a side of controller 10 opposite the thrombus trap 200 as shown in FIG. 21. Accordingly, to maintain efficacy of the thrombus trap 200 as a terminus for all aspirated thrombi 4, vacuum booster configurations that might entrap or significantly damage or macerate the thrombus are less desirable. One exemplary embodiment of a gentler vacuum booster 200, instead of the piston design of FIGS. 16 and 17, couples a section of the tubing of the vacuum tube 2 having a deformable interior volume with a mechanical actuation mechanism. This mechanism

is able to collapse and expand the interior cross-section of a length of the vacuum channel 3 to provide an increase or a decrease in pressure along that length. Another mechanical embodiment for the vacuum booster having no pneumatic actuation takes energy for vacuum boost from energy imparted by actuation of the controller 10 or from a separate energy input. For example, as user depresses a lever in the controller 10 that occludes flow and temporarily causes the column shift, the lever's motion also cocks and releases a spring-loaded piston that creates the vacuum boost. Another exemplary embodiment of the vacuum booster places a screen between the vacuum chamber 114 of the vacuum booster 100 and the vacuum channel 3 of the aspiration system. This screen allows fluid communication between the two interior volumes but occludes particulate matter from entering the piston bore defined by the vacuum chamber 114. A further exemplary embodiment that guards against clogging/accidental maceration of the thrombus alters the piston configuration of FIGS. 16 and 17 by having the connection 140 be a flexible diaphragm mechanically disposed between the surface of the vacuum piston 122 and the opening into the vacuum channel 3. The diaphragm can be contained in and cross the actual opening of the vacuum channel 3, for example. Such a membrane transmits volumetric displacement while excluding all flow. The membrane can be separate from the vacuum piston 122, fluidically coupled thereto, or attached. In each of these configurations, the volume through which the fluid column flows is unhindered to prevent entrapping or damaging the thrombus 4 when traveling thereby, whether the vacuum booster 100 is in an energized state or a resting state.

[00112] Both the vacuum booster and the blood-purging clot trap rely on the timely and controlled application of either vacuum or ambient pressures to specific parts of the device, namely the bleed valve 214 of the thrombus trap 200 or the plunger 120 of the vacuum booster 100. The self-unclogging thrombectomy aspiration catheter described and shown herein can be provided with additional features actuated by the same user input as the self-unclogging function, e.g., at or by the controller 10, but which serve to either open or occlude additional conduits for vacuum or atmospheric pressure air that control device features such as the self-purging thrombus trap 200 and/or the vacuum booster 100.

[00113] The vacuum channel 3 of the vacuum tube 2 (and any other tubing within the catheter) can be coated with a hydrophobic coating, such as carnauba wax, for example, to decrease head loss during aspiration.

[00114] With an appropriate sensor, the controller 10 can determine when the vacuum channel 3 is clogged by a thrombus and automatically perform the unclogging procedures described herein. In an exemplary embodiment, a computer connected to the sensor can detect a pressure drop and lack of flow associated with a thrombus clog in or at the vacuum channel 3. When the clog is detected, the sensor triggers the sequence that halts application of vacuum in the vacuum channel 3 and carries out the column shift sequence. With respect to visualization of the thrombus 4 in the device, another exemplary embodiment of a sensor includes an optical sensor that detects the presence of the thrombus in either or both of the distal opening of the vacuum channel 3 and the thrombus trap 200. In the latter configuration, the optical sensor associated with the trap section 220 detects when the thrombus 4 is present and cause purging of fluid by opening the bleed valve 214.

[00115] As set forth herein, the vacuum tube 2 can be made from various materials. Some materials for the vacuum tube 2 have a relatively lower compression strength, such as latex, silicone, and other synthetic rubbers. Other materials for the vacuum tube 2 have a relatively higher compression strength, such as Pebax®, polyurethane, and polyvinyl chloride. Because the vacuum tube 2 within the controller 10 is subject to expansion when positively pressured in the vacuum channel 3 and is subject to contraction when negative pressured, this flexible attribute of the material from which the vacuum tube 2 is made could possibly contribute to a less effective column shift. In order to reduce these effects of pressure (both positive and negative) on the vacuum tube 2, the vacuum tube 2 can be reinforced with a braid or coil or other mechanical structure to support the portion of the vacuum tube 2 within the controller 10 against pressure changes. Where the vacuum tube 2 is made from a material with a relatively lower compression strength, the section of the vacuum tube 2 that resides within the controller 10 is made as short as possible to minimize the expansion/contraction effects.

[00116] An alternative embodiment to the controller 10 of FIG. 1, which indirectly operates on the vacuum channel 3 through the compression roller 60, is shown in FIG. 22. In the exemplary embodiment of FIG. 22, the extrusion compressor is replaced with a volume changing controller 300 that is directly fluidically connected to the vacuum channel 3 of the vacuum tube 3. The volume changing controller 300 has a barrel body 310 with an interior 311 defining an input orifice 312 fluidically connected to the vacuum channel 3. The barrel body 310 also defines a plunger orifice 314, a pump orifice 316, and a purge orifice 318. A plunger 320 sealably connects to the

interior 311 of the barrel body 310 movably towards and away from the input orifice 314. When in the position shown in FIG. 22, vacuum applied by the vacuum pump 80 is connected to the distal opening of the vacuum channel 3 for aspiration of material. When a thrombus becomes clogged at the distal opening, the surgeon presses the plunger 320 inwards. In a first portion of the inwards motion, a surface of the plunger 320 seals off the pump orifice 316 to stop the application of vacuum to the vacuum channel 3. In a second portion of the inwards motion, the plunger 320 moves all fluid contained within the interior 311 and the vacuum channel 3 distally to cause the column shift. Reversal of the plunger reverses the column shift and reapplies vacuum to the vacuum channel 3.

[00117] The plunger 320 can also be used to control purging of the thrombus trap 200. The plunger is provided with a purge conduit 322. When the plunger 320 is placed in a purge position, the plunger 320 closes off the vacuum channel 3 from the vacuum pump 80 and fluidically connects the pump orifice 316 to the purge orifice 318 through the purge conduit 322. In this position, a fluid connected to the purge orifice, e.g., ambient air, is drawn through the purge conduit 322, through the purge orifice 318, and into the thrombus trap 200.

[00118] Operation of the volume changing controller 300 is explained with regard to the system cycle diagram of FIG. 24.

- **State 1:** Normal aspiration is occurring. The vacuum channel 3 is not occluded. The volume changing controller 300 is in a rest state where the vacuum pump 80 is connected to the vacuum channel 3.
- **Transition A – Occlusion:** Thrombus 4 occludes distal end of vacuum channel 3. Controller 300 actuates (plunges) to occlude vacuum channel 3 and stop vacuum flow distal of the controller 300.
- **State 2:** Flow through the vacuum channel 3 has stopped.
- **Transition B – Unclogging:** Controller 300 continues to plunge to cause reverse flow in vacuum channel 3 for a metered volumetric column shift.
- **State 3:** Flow reversal stops.
- **Transition C – Return Column Shift:** Controller 300 is reversed to return column and accelerate thrombus 4 into catheter tip by reconnecting the vacuum pump 80 to the vacuum channel 3.
- **Return to State 1 and Repeat:** Normal aspiration occurs.

[00119] FIGS. 25 to 41 illustrate an exemplary embodiment of an aspiration thrombectomy system 400 operating with an automatic, rapid, and repeated onset of pressure change. An aspiration catheter 410 is diagrammatically indicated in FIG. 26 leading from distal orifices of a pair of valves 420, 440, which in this exemplary embodiment are pinch valves 420, 440. One of these valves is a pinch valve 420 to control vacuum flow and is connected between the aspiration catheter 410 and the aspiration pump (e.g., vacuum pump 80). The other of these valves is a pinch valve 440 to control vent flow and is connected to a supply of vent fluid. In an exemplary embodiment, the vent fluid is sterile saline. The vent fluid can also be any other biocompatible fluid such as contrast media or tissue plasminogen activator (tPa). With such fluids, the catheter 410 can perform different functions. For example, switching the vent fluid to contrast media after it is believed that a clot has been successfully removed allows the surgeon to inject that media into the vessel to confirm removal of the clot. This is significant because the catheter 410 changes from the aspiration function to the contrast injection function without any significant movement within the vasculature. With standard aspiration catheters where a clot becomes lodged in the distal end, the entire catheter needs to be removed from the patient and, if contrast needs to be injected at the site, the catheter needs to be reintroduced through the vasculature just to perform this visualization. The vent fluid can be at atmospheric pressure or at a higher or lower than atmospheric pressure.

[00120] In an exemplary configuration, these valves 420, 440 are mounted to a base 401. Operatively associated with the pinch valves 420, 440 are respective cams, a vacuum cam 430 and a vent cam 450. These cams 430, 450 are connected to a cam shaft 460. A first shaft end 462 of the cam shaft 460 is fixedly connected to a shaft bearing 470 in a freely rotatable manner. The shaft bearing 470 has a bearing body 472 mounted to the base 401. A second shaft end 464 of the cam shaft 460 is connected to a shaft drive assembly 500. The shaft drive assembly 500 comprises a motor 510, a transmission or gear box 520, a shaft coupler 530, and a motor controller assembly 550.

[00121] The transmission 520 has an output shaft 522. To connect the transmission 520 to the cam shaft 460, a first coupler end 532 of the shaft coupler 530 is connected to the output shaft 522 and a second coupler end 534 of the shaft coupler 530 is connected to the second shaft end 464. In this manner, rotation of the motor 510 corresponds to a rotation (at the same or different speed

based upon the gearing of the transmission 520) of the cam shaft 460 with a corresponding rotation of the vacuum and vent cams 430, 450.

[00122] Control of the motor 510 originates from the motor controller assembly 550, which comprises a controller 560, a positional encoder 570 and a positional reset assembly 580. In an exemplary embodiment, the controller 560 is a microcontroller that has a user interface (UI) comprising user inputs that include, for example, control buttons to operate the aspiration thrombectomy system 400 in various states, examples of which are described in further detail below. The controller 560 with the UI is illustrated diagrammatically in FIG. 30. To isolate parts from fluid, in the exemplary embodiment, the motor 510, the transmission 520, the shaft coupler 530, and the motor controller assembly 550, 560, 570, 580 are contained in a motor assembly housing 552. The connection of the motor assembly housing 552 to the cam shaft 460 is sealed fluidically with a shaft seal 554. Similarly, the cams 430, 450, the cam shaft 460, and the shaft bearing 470 are covered with a cam housing 466. The controller 560 is indicated in FIG. 30 as separate from the motor assembly housing 552 (either wired or wireless) but it can also be integrated into or attached to the motor assembly housing 552. In a wireless configuration, the controller 560 can be an app on a computer or smartphone, for example, with all of the UI being available through a touchscreen.

[00123] The vacuum and vent cams 430, 450 are fixed rotationally to the cam shaft 460. These cams 430, 450 have various cam profiles to operate the valves 420, 440. It is desirable to know the exact rotational position of the cams 430, 450 and, therefore, cam shaft 460, so that the controller 560 can set the valves 420, 440 in whatever state that is desired. Because the motor 510 rotates freely and can end its rotation at any rotational position, it is desirable to know the exact rotational position of the cam shaft 560 at all given times. Accordingly, the motor controller assembly 550 includes the positional encoder 570 associated with the motor 510. With this association, the controller is provided with information on the exact rotational state of the cam shaft 460 and, therefore, the cams 430, 450. The positional encoder 570 comprises an encoder disk 572 and an encoder circuit 574. The encoder 570 is able to detect and report out to the controller 560 the current relative rotational position of the motor 510 at any point in time.

[00124] Those of skill in the art know that the motor 510 and/or the positional encoder 570 can drift in use. To account for and correct any drift, the motor controller assembly 550 comprises the positional reset assembly 580. This positional reset assembly 580 assigns a single rotational

position of the cam shaft 460 as a reset point and every time that position crosses a zero-line the positional encoder resets the position of the motor 510 to zero, which in turn allows the system to know the absolute position of the cam shaft 460. In an exemplary embodiment, the positional reset assembly 580 comprises a photodiode 582 and a flag or interrupter 584. As shown in FIG. 30, the flag 584 is fixed to the shaft coupler 530. The photodiode 582 is placed at the path of the flag 584 so that the flag 584 interrupts the photodiode 582 once for each rotation of the cam shaft 460. This exemplary embodiment allows for immediate correction of any skipped steps of the encoder 570.

[00125] The exemplary embodiment of the pinch valves 420, 440 is explained with regard to FIGS. 31 to 33 using the vent pinch valve 440. Each valve 420, 440 comprises a valve body 422, 442 defining a vacuum or vent lumen 424, 444. An elastomeric tube 426, 446 is secured within the lumen 424, 444 at each end of the tube 426, 446. Exemplary embodiments for this connection include but are not limited to fusing, compression sealing, and fixation with an adhesive. Accordingly, the tube 426, 446 spans an extent of the lumen 424, 444 with an intermediate portion of the tube 426, 446 unattached to the lumen 424, 444. A lumen of the tube 426, 446 fluidically connects a distal end of the lumen 424, 444 (to the left of FIGS. 31 and 32) to the proximal end of the lumen 424, 444 (to the right of FIGS. 31 and 32). The intermediate section of the valve body 422, 442 defines a follower connection in which is movably secured a cam follower 421. A first end of the cam follower 421 is biased against the outer surface of the cam 430, 450 with a non-illustrated bias device or is simply trapped in place. The opposing second end of the cam follower 421 rests against the intermediate portion of the tube 426, 446. Accordingly, when moved by the cam 430, 450 towards the tube 426, 446, as shown in FIG. 32, the cam follower 421 fluidically seals off the lumen of the tube 426, 446 and, when allowed to return away from the tube 426, 446, as shown in FIG. 31, the cam follower 421 opens the lumen of the tube 426, 446. In the exemplary embodiment, the cam follower 421 is pill-shaped but it can be formed in any shape to provide the function of closing off the tube 426, 446.

[00126] Both a vacuum line 402 and a vent line 404 are connected through the selectively openable valves 420, 440 to a proximal end of the aspiration catheter 410. In operation, the vacuum cam 430 and the vent cam 450 push down on the respective cam followers 421, which pinch down the short sections of tubing 426, 446, each respectively fluidically connected to the vacuum line 402 and the vent line 404. When the vacuum line 402 is open and the vent line 404 is closed, vacuum is drawn on the aspiration catheter 410. When the distal end of the catheter 410

is clogged with a clot, the closure raises a vacuum level within the catheter 410 to full (the greatest current vacuum generated by the vacuum pump). This closure creates a delta in pressure between the internal lumen of the catheter 410 and the environment external to the catheter 410, which change squeezes down the body of the catheter 410 both radially and longitudinally (e.g., the diameter and length become incrementally smaller). This change also draws out a small volume of liquid from within the lumen of the catheter 410. In an exemplary embodiment, the volume is approximately 0.2 ml. The end effect is the creation of a spring-like force within the catheter 410 that wants to expand the catheter 410 back to its steady state, but when the vacuum line 402 is closed off, that cannot happen. Thus, the vacuum is stored as potential energy until the vent line 404 is opened (as can be seen in FIG. 26, for example, the vacuum and vent lines 402, 404 are connected together distal of the valves 420, 440). When the vent line 404 is opened, there is an in-rush of fluid because of the pressure delta. This rush of fluid balances the radial force of the catheter 410 and draws in fluid to create a distally directed momentum in the column of fluid residing in the catheter 410 distal of the valves 420, 440. The momentum causes a small amount of fluid to move through a distal portion of the catheter 410 and create a small distal movement of the clot that is stuck in the distal opening at the end of the catheter 410. Once the clot is no longer stuck at the distal opening, it is able to be moved proximally into and through the catheter 410 with subsequent vacuum imparted to the catheter 410. Repeated selective actuation of vacuum and venting macerates the clot at the distal opening, thereby reforming it into a state where it can be completely drawn into the lumen of the catheter 410 and out of the vasculature.

[00127] The system 400 can be operated in various modes to remove clots in the vasculature. Rotation of the cams are measured in degrees, a full rotation being 360° of movement. In a first exemplary embodiment, the vacuum cam 430 is configured to establish vacuum in the catheter 410 through approximately 220° of rotation. The vent cam 450 is configured to have venting on through approximately 80° of rotation. The configuration of the cams 430, 450 stop both venting and vacuum between each respective application of vacuum and venting, for example, with a 30° rotation. This configuration, therefore results in operation states according to Table 1 below.

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Table 1

As soon as the vent is opened, there is an in-rush of fluid to balance out the vacuum pressure, then the vent line 404 is closed and the vacuum line 402 is opened, suddenly causing a rapid decrease in pressure that serves to forcefully pull the clot to the catheter. It is desirable, therefore, to close both vacuum and vent lines before resuming vacuum.

[00128] In another exemplary embodiment, the vacuum cam 430 is configured to establish vacuum in the catheter 410 through approximately 220° of rotation. The vent cam 450 is configured to have venting on through approximately 80° of rotation. Thus, there is created, in a desirable second exemplary configuration, a pause between vacuum draw in the catheter and venting of the catheter and another pause between venting of the catheter and resuming vacuum draw in the catheter. In this exemplary configuration, the pause can be through approx. 30° of rotation. To create a purge state, where vacuum and venting occur simultaneously, the vent cam 450 has a small inwards depression in a position of the vent cam 450 that occurs during a long vacuum-on stage (e.g., between +30° to +250°). The extent of the venting is configured to not provide a significant change in pressure or change in the vacuum energy but, instead, is configured to create a single rotation position of the cams 430, 450 where the motor control assembly 550 can stop rotation of the cam shaft 460 in that orientation where both the vacuum line 402 and the vent line 404 are connected to the catheter 410, which allows the user to purge out any air that might be present in the system (e.g., in the vacuum line 402, the vent line 404, and/or the catheter 410). The extent of the depression can be such that it only partially opens the vent to reduce the amount of vent fluid that is drawn in during this purge state. This purging can be a known position of the cam rotation and is placed in that position to ensure that all lines in the system 400 are cleared of air. Such a configuration results in operation states according to Table 2 below.

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +120
Purge	1	1	+120 to +140
Vac	1	0	+140 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Table 2

[00129] A third alternative configuration for operation of the system 400 can include a full-time vacuum with a pulsed venting including the operating states according to Table 3 below.

State	Vacuum	Venting	Cam Angle
Vac	1	0	0 to +120
Purge	1	1	+120 to +150
Vac	1	0	+150 to 0

Table 3

An opposite configuration to the states of Table 3 can including a full-time venting with a vacuum overlap.

[00130] A fourth alternative configuration for operation of the system 400 can include a vacuum during venting, which configuration includes the operating states according to Table 4 below.

State	Vacuum	Venting	Cam Angle
Purge	1	1	0 to +30
Vac	1	0	+30 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Table 4

An opposite configuration to the states of Table 3 can include a full-time venting with a vacuum overlap.

[00131] A fifth alternative configuration for operation of the system 400 can include a venting during vacuum, which configuration includes the operating states according to Table 5 below.

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +250
Purge	1	1	+250 to +280
Vent	0	1	+280 to 0

Table 5

[00132] In further alternative configurations, there can be a variation overlapping of venting and vacuum, which would delete one or more of the OFF states in any of the state tables above.

[00133] The cam-driven valves 420, 440 allow the positional encoder driven motor to create positions for vacuum, venting, off, and purge. The motor controller assembly 550 allows the cams 420, 440 to be controlled by any frequency, e.g., they can be set to move through the various states at any given speed, for example, at 4 Hz. The frequency at which the motor runs may be more appropriate to run at lower frequencies such as 0.5 Hz, 1 Hz, or 2 Hz. Alternatively, it may be more effective to run at higher frequencies such as 8 Hz, 12 Hz, or 16 Hz. The motor control assembly 550 can also dynamically change the rate of cam shaft 460 rotation to sweep the frequency of rotation. In exemplary embodiments, the step in speed is in a range from 1 Hz to

approximately 4 Hz, the change in increment is between approximately 0.25 seconds to approximately 5 seconds, and the range of rotation is between approximately 2 Hz to approximately 12 Hz. One example for the step, increment, and range is 2 Hz and 1 second increments in the following progression 2 Hz/4/6/8/10/12/10/8/6/4/2/... Another example is 4 Hz with 0.5 sec increments in the following progression 4 Hz/8/12/8/4/... In exemplary embodiments, the system uses the higher frequencies in the 8 Hz to 12 Hz range, which has been observed to have less movement of the proximal end of a clot stuck at the distal end of the catheter 410. Alternatively, further increments can be used to sweep the frequency through complex forms, such as sine, sawtooth, stepped, and pulsing variations.

[00134] In an exemplary alternative to the pinch valves 420, 440, the valves can be solenoid-driven pinch valves. In another exemplary alternative, a rotational pintle valve can be used, as shown in FIGS. 42 to 46. The first valve state shown in FIGS. 42 to 44 can, for example, be a vacuum-on/vent-off state and the second valve state shown in FIGS. 45 and 46 can be a vacuum-off/vent-on state.

[00135] It has been determined that the most rapid onset of vacuum and venting is desirable. To create this rapid onset, the cams 430, 450 start vacuum and venting, respectively, with a cliff 452 in the shape of the cam 430, 450. Sudden creation of vacuum creates a rapid decrease of pressure inside the catheter 410, which draws the clot aggressively against the distal end of the catheter 410. Venting, as described above, creates a distal momentum that unsticks the clot and repetition of the vacuum and venting causes mechanical maceration of the clot at the distal opening until the clot completely enters the lumen of the catheter 410 and is removed from the vasculature. Therefore, the instant system 400 can be described as a Rapid Onset Aspiration Repeater or ROAR.

[00136] The control carried out by the motor controller assembly 550 has a selection of user-actuated buttons. In an exemplary embodiment, one button causes both vacuum and venting to be shut off, i.e., off operation. One button causes vacuum to occur in a continuous manner, i.e., manual control. One button causes venting to occur in a continuous manner, i.e., manual control. One button causes the cam shaft 460 to rotate the cams 430, 450 to the position in which the vacuum and vent lines 402, 404 can be purged, i.e., the purge function. One button causes the system to run or pulse repeatedly according to a desired set of states (e.g., according to any of Tables 1 to 5) along with a selection of any number of sets for step, increment, and range. As such, if the surgeon desires to use the system 400 as a simple thrombectomy device, the surgeon

can just use the vacuum button. In this condition, the encoder 570 assists to have the cam shaft 460 to rotate to a position in which vacuum is open. The vacuum pump runs with a fully open vacuum until the surgeon releases the button. If the surgeon wants to purge or inject contrast, for example, then the surgeon can use the vent button to have the encoder 570 assist to rotate the cam shaft 460 to a position in which the vent is open. Likewise, the off button rotates the cam shaft 460 to a position where the cams 430, 450 close both the vacuum and vent lines 402, 404. The purge button causes rotation of the cam shaft 460 to a position where the cams 430, 450 allow simultaneous vacuum and venting.

[00137] In an exemplary embodiment of the run or ROAR mode, rotation of the cam shaft 460 is between approximately 0.5 Hz and approximately 25 Hz, in particular, between approximately 2 Hz and approximately 12 Hz. In this exemplary ROAR cycle, the cam shaft 460 is rotated for between approximately 10 seconds and approximately 30 seconds and, during that time, the motor controller assembly 550 causes the motor 410 to sweep through frequencies between approximately 2 Hz and approximately 12 Hz.

[00138] As set forth above, the elastomeric tube 426, 446 is attached to distal and proximal locations of the valve lumen 424, 444. Compliance in the system 400 distal of the vacuum valve (described above as including reduction of the diameter and/or length of the catheter 410 as well as compliance of the tube 426, 446) when vacuum is applied to the catheter 410 and a clot is stuck at the distal end determines how much fluid is drawn out when the system 400 is under full vacuum and, conversely, how much fluid rushes back into the system 400 when that state is released. In other words, with a greater amount of compliance distal of the valves 420, 440, momentum imparted to the stuck clot by the column of fluid increases. It is desirable to have a minimal amount of momentum transfer from the fluid column to the stuck clot to unstick the clot sufficiently so that the next vacuum cycle macerates the clot against the distal end of the catheter 410 and causes it to enter the lumen of the catheter 410 and be removed from the vessel. To minimize this compliance (which is fixed for a given catheter 410), this tube 426, 446 is made as short as possible to still allow valve operation by the cam follower. Compliance as used herein refers to mechanical compliance of the catheter 410 and the tube 426, 446; it does not refer to any air that might be in the system 400, which air is purged before use as set forth herein. This desire for a reduction in compliance is one reason the valving system is connected directly to the proximal end of the catheter 410. This close connection minimizes overall compliance. In an exemplary embodiment,

the valving system can be located away from the catheter 410 and, in such a case, substantially non-compliant tubing is desired. This configuration may experience lower performance due to the excess compliance.

[00139] To determine the status of a clot at the distal end of the catheter 410, the system 400 is put in the ROAR mode. If there are no sensors associated with the system 400, a surgeon cannot distinguish the situation when a clot is corked during ROAR or not. The surgeon has to turn off ROAR and visualize whether the catheter is corked (in which nothing is being drawn in by the catheter 410) or is not corked (in which blood is being drawn into the catheter 410). With the different situations of aborting pulse based on flow and pulsing until not corked, it is hard to know when a clot is corked.

[00140] The vent line 404 is connected to a vent fluid reservoir (not illustrated), which can contain for example, saline. When a fluid is used to vent the system 400, as described above, all air can be purged out of the system 400. Additionally, knowing that a given amount of vent fluid is used at various stages of clot removal can allow the user to correlate removal of a clot into the catheter after being stuck at the distal end to a rate of vent fluid use. In other words, the amount of vent fluid is different when the clot corked from when it is not corked. Thus, a user or a sensor can look at or measure vent fluid use to determine to turn off the system. If the catheter 410 is aspirating without obstruction (uncorked), then a significant flow of blood will exit the system 400. If the catheter 410 is aspirating while corked, then no blood will appear at the vacuum exit. During a ROAR operation and the catheter 410 is uncorked, the user/sensor will detect some blood at the vacuum exit. Finally, during the ROAR operation when the catheter 410 is corked, the vacuum exit will receive some fluid that is a combination of both blood and vent fluid and, in this state, the flow rate of the vent fluid can indicate if the catheter is corked or uncorked.

[00141] If a surgeon visualizes free flow during vacuum and see a captured clot (for example, in the thrombus trap 200), then the surgeon has the ability to perform a contrast injection with the catheter 410 to confirm revascularization without moving or removing the aspiration catheter 410. This is in contrast to current state-of-the-art aspiration catheters where the catheter removes the clot by holding the clot corked on the end and the surgeon retracts the entire catheter to drag out the corked clot. The increased ability of a smaller diameter catheter to be able to fully ingest or secure a better grip on the clot by drawing a greater amount of it into the catheter is a significant benefit. Many clots are deep enough into the anatomy that it is difficult to get large catheters to

the site of the clot. If a smaller diameter catheter can have increased effectiveness through ROAR than a greater number of clots can be accessed and retrieved.

[00142] It is noted that one desirable goal to achieve with the system 400 is to fully ingest a clot and bring it back a standard aspiration canister (in a typical thrombectomy end reservoir) or into the thrombus trap 200. When using a standard aspiration canister and the thrombus trap 200, the system 400 can use the vent fluid to flush the thrombus trap 200 through the intake bleed valve 214 instead of using air. This allows retention of vacuum pressure in the aspiration canister.

[00143] It is noted that various individual features of the inventive processes and systems may be described only in one exemplary embodiment herein. The particular choice for description herein with regard to a single exemplary embodiment is not to be taken as a limitation that the particular feature is only applicable to the embodiment in which it is described. All features described herein are equally applicable to, additive, or interchangeable with any or all of the other exemplary embodiments described herein and in any combination or grouping or arrangement. In particular, use of a single reference numeral herein to illustrate, define, or describe a particular feature does not mean that the feature cannot be associated or equated to another feature in another drawing figure or description. Further, where two or more reference numerals are used in the figures or in the drawings, this should not be construed as being limited to only those embodiments or features, they are equally applicable to similar features or not a reference numeral is used or another reference numeral is omitted.

[00144] The foregoing description and accompanying drawings illustrate the principles, exemplary embodiments, and modes of operation of the systems, apparatuses, and methods. However, the systems, apparatuses, and methods should not be construed as being limited to the particular embodiments discussed above. Additional variations of the embodiments discussed above will be appreciated by those skilled in the art and the above-described embodiments should be regarded as illustrative rather than restrictive. Accordingly, it should be appreciated that variations to those embodiments can be made by those skilled in the art without departing from the scope of the systems, apparatuses, and methods as defined by the following claims.

CLAIMS

What is claimed is:

1. A vacuum catheter for removing an object from within a human vessel, comprising:

a vacuum tube:

defining an interior vacuum channel comprising:

a proximal opening for receiving application of vacuum; and

a distal capture opening fluidically connected to the proximal opening, the distal capture opening configured to receive therein the object responsive to application of the vacuum; and

comprising an intermediate section between the proximal opening and the distal capture opening; and

a vacuum interruption controller comprising:

a body through which a portion of the intermediate section passes; and

an extrusion compressor movably disposed with respect to the body towards and away from the portion of the intermediate section such that:

in a rest state, the extrusion compressor does not occlude the vacuum channel; and

in an actuated state, the extrusion compressor first occludes the vacuum channel and then moves fluid disposed between the portion of the intermediate section and the distal capture opening a given distance distally towards the distal capture opening.

2. The catheter according to claim 1, which further comprises a vacuum pump selectively applying vacuum to the proximal opening.

3. The catheter according to claim 1, wherein the vacuum tube has a proximal portion and which further comprises a catheter body surrounding the vacuum tube and configured to steer at least the proximal portion of the vacuum tube.

4. The catheter according to claim 1, wherein the vacuum tube has a proximal portion sized to fit within the Circle of Willis in a brain and the object is a blood clot adjacent the Circle of Willis.

**ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBOSIS REMOVAL WITH
ASPIRATION CATHETER**

Abstract of the Disclosure

A thrombectomy vacuum catheter includes a vacuum tube defining a vacuum channel comprising a proximal opening for receiving application of vacuum and a distal capture opening fluidically connected to the proximal opening, the distal capture opening receiving therein the object responsive to application of vacuum, and comprising an intermediate section between the proximal and distal capture openings, and a vacuum interruption controller comprising a body through which a portion of the intermediate section passes and an extrusion compressor movably disposed with respect to the body towards and away from the portion of the intermediate section such that, in a rest state, the extrusion compressor does not occlude the vacuum channel and, in an actuated state, the extrusion compressor first occludes the vacuum channel and then moves fluid disposed between the portion of the intermediate section and the distal capture opening a given distance distally towards the distal capture opening.