

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

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

Application Number	Not yet assigned
Filing Date	Filed herewith
First Named Inventor	Curtis J. FRANKLIN
Title	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	688961-25U7

SIGNATURE of Applicant or Patent Practitioner

Signature	/Ragi A.I. Elias/	Date (Optional)	
Name	Ragi A.I. Elias	Registration Number	67,772
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			
<p>NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.</p>			
☐ *Total of _____ forms are submitted.			

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

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

Applicant: Prytime Medical Devices, Inc.

GENERAL POWER OF ATTORNEY BY PATENT APPLICANT (USPTO)

I hereby revoke all previous powers of attorney given in the patent application identified in the attached Transmittal Letter or other paper.

I hereby appoint the Practitioners associated with Customer No. 000570 as my/our attorneys/agents to transact all business in the U.S. Patent and Trademark Office in connection therewith.

I am the Applicant:

- ☐ Inventor or Joint Inventor
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is currently being filed in this document)

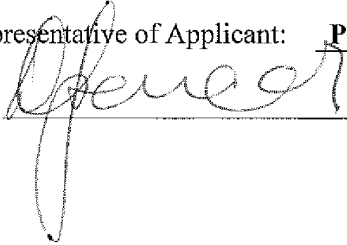
The undersigned Representative of Applicant states that he/she is authorized and empowered to sign this document on behalf of Applicant.

Please address all correspondence to Customer No. 000570, namely, **PANITCH SCHWARZE BELISARIO & NADEL LLP**, One Commerce Square, 2005 Market Street, Suite 2200, Philadelphia, PA 19103, e-mail address: usptomail@panitchlaw.com. Please direct all communications and telephone calls to the attorney/agent identified in the attached Transmittal Letter.

Applicant: **Prytime Medical Devices, Inc.**

Name of Representative of Applicant: **David A. Spencer**

Title of Representative of Applicant: **President & CEO**

Signature:  Date: 3 May 16

Attorney Docket No: 688961-25U4

**INVENTOR'S COMBINED
DECLARATION (37 CFR 1.63) AND ASSIGNMENT
(Utility Patent Application)**

As a below-named inventor/assignor of a certain new and useful invention for which I have executed an application for Letters Patent entitled:

SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

DECLARATION

I hereby declare that:

This Declaration is directed to the patent application attached hereto or the United States application number 15/551,504 filed on August 16, 2017.

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

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

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

Note to Inventor: 37 C.F.R. § 1.63(c) states: "A person may not execute an oath or declaration for an application unless that person has reviewed and understands the contents of the application, including the claims, and is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56."

ASSIGNMENT

WHEREAS, I ("ASSIGNOR") desire/am obligated to assign to the below-named ASSIGNEE the invention identified above;

WHEREAS, ("ASSIGNEE"):

**Prytime Medical Devices, Inc.
(a Delaware Corporation)
229 North Main Street
Boerne, TX 78006**

is desirous of acquiring the entire right, title and interest in and to the invention throughout the United States and the world, and all right, title and interest in, to and under any and all Letters Patent of the United States resulting from the invention or design and all countries throughout the world;

FOR GOOD and VALUABLE CONSIDERATION, the full receipt and sufficiency of which are hereby acknowledged, ASSIGNOR(S), intending to be legally bound, do hereby:

AUTHORIZE said ASSIGNEE, or its representatives to insert above the filing date and application number of the application when these are known;

SELL, ASSIGN, TRANSFER and CONVEY to ASSIGNEE the whole and entire right, title and interest for the United States and its possessions and territories and all foreign countries in and to the invention which is disclosed in the above-identified patent application, and, in and to any and all patent applications related thereto including, but not limited to, all provisionals, non-provisionals, divisionals, continuations, continuations-in-part, substitutes, reexaminations, reissues and all other applications for patent which have been or shall be filed in the United States and all foreign countries on the invention; all original, reissued and reexamined patents and extensions thereof which have been or shall be issued in the United States and all foreign countries on the invention to the full end of the term or terms for which the patent(s) may be granted, as fully and entirely as the same would have been held by the undersigned ASSIGNOR(S) had this Assignment not been made; and specifically including all rights of priority created by the above patent application under any treaty, convention or law relating thereto;

AUTHORIZE and REQUEST the issuing authority to issue any and all United States and foreign patents granted on the invention to ASSIGNEE;

WARRANT and REPRESENT that no assignment, grant, mortgage, license or other agreement affecting the rights and property herein conveyed has been or will be made to others by ASSIGNOR(S), and that the full right to convey the same as herein expressed is possessed by ASSIGNOR(S);

AGREE and UNDERTAKE, when requested and at the expense of ASSIGNEE, to carry out in good faith the intent and purpose of this Assignment, ASSIGNOR(S) will execute all non-provisionals, divisionals, continuations, continuations-in-part, substitutes, reexaminations, reissues, and all other patent applications on the invention; execute all lawful oaths, declarations, assignments, powers of attorney and other papers; communicate to ASSIGNEE all facts known to ASSIGNOR(S) relating to the invention and the history thereof; and generally do everything possible which ASSIGNEE shall consider desirable for vesting title to the invention in ASSIGNEE, and for securing, maintaining and enforcing proper patent protection for the invention; all without further compensation to ASSIGNOR(S);

TO BE BINDING on the heirs, assigns, representatives and successors of ASSIGNOR(S) and extending to the successors, assigns, and nominees of ASSIGNEE.

First Inventor/Assignor:

Date: 24 AUG 2017 Signature: Curtis J. Franklin
Typed Legal Name: Curtis J. Franklin

Second Inventor/Assignor:

Date:

8 Sep 17

Signature:



Typed Legal Name:

David Spencer

Third Inventor/Assignor:

Date:

8-24-2017

Signature:



Typed Legal Name:

Todd J. Krummenacher

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		SYSTEM FOR LOW-PROFILE OCCLUSION BALLOON CATHETER		
First Named Inventor/Applicant Name:		Curtis J. FRANKLIN		
Filer:		Ragi A.I. Elias/Angela Kryszczak		
Attorney Docket Number:		688961-25U7		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				830

Electronic Acknowledgement Receipt	
EFS ID:	44624205
Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	00570
Filer:	Ragi A.I. Elias/Angela Kryszczak
Filer Authorized By:	Ragi A.I. Elias
Attorney Docket Number:	688961-25U7
Receipt Date:	28-DEC-2021
Filing Date:	
Time Stamp:	16:00:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$830
RAM confirmation Number	E2021BRG00460534
Deposit Account	501017
Authorized User	Angela Kryszczak
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>37 CFR 1.16 (National application filing, search, and examination fees)</p> <p>37 CFR 1.17 (Patent application and reexamination processing fees)</p>	

37 CFR 1.19 (Document supply fees)
37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	Application_Data_Sheet_Fillable_PDF.pdf	1256442	no	10
			2b1cd44a3f043c480c9caf3655b7e1210aa45976		
Warnings:					
Information:					
2		Specification_25U7.PDF	464785	yes	95
			c7b56dc3e5fa8a88fc562841f306242cc85401d		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	92	
	Claims		93	94	
	Abstract		95	95	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	Drawings.PDF	1119084	no	33
			c8a1497d66a5702f658e930a39ba7b26d3a11a89		
Warnings:					
Information:					
4	Power of Attorney	POA_TRANSMITTAL.PDF	164565	no	1
			d4a3c1de2e64bc67eb6af2e9782d4b6aa8c45454		
Warnings:					
Information:					
5	Power of Attorney	GENERAL_POA.PDF	55030	no	1
			16345be92406d7cc1953b7895ae25f95b418b021		

Warnings:					
Information:					
6	Oath or Declaration filed	DEC_ASSIGN.PDF	147158	no	3
			0973a71cb0d601eb0e1f7495eb66686d86b5d4fd		
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	44368	no	2
			3476cb6eafb5f70a8d513aab25d33e184dbe78a5		
Warnings:					
Information:					
Total Files Size (in bytes):			3251432		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

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	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor	1				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
Mr. ▾	Curtis	J.	FRANKLIN	▾		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service						
City	Lakewood	State/Province	CO	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	575 Union Boulevard					
Address 2	Suite 107					
City	Lakewood	State/Province	CO			
Postal Code	80228	Country i	US			
Inventor	2				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
Mr. ▾	David		SPENCER	▾		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service						
City	Boerne	State/Province	TX	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	229 North Main Street					
Address 2						
City	Boerne	State/Province	TX			
Postal Code	78006	Country i	US			
Inventor	3				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
Mr. ▾	Todd	J.	KRUMMENACHER	▾		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service						

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		688961-25U7	
		Application Number			
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER				
City	Lakewood	State/Province	CO	Country of Residence	US
Mailing Address of Inventor:					
Address 1	575 Union Boulevard				
Address 2	Suite 107				
City	Lakewood	State/Province	CO		
Postal Code	80228	Country	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	00570		
Email Address	usptomail@panitchlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER		
Attorney Docket Number	688961-25U7	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	33	Suggested Figure for Publication (if any)	1

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	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON 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	00570		

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		Pending		Remove	
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
	Continuation of		16/133193	2018-09-17	
Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/133193	Continuation of	15/551504	2017-08-16	10149962	2018-12-11
Prior Application Status				Remove	
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
15/551504	a 371 of international		PCT/US16/23223	2016-03-18	
Prior Application Status		Expired		Remove	
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
PCT/US16/23223	Claims benefit of provisional		62/204804	2015-08-13	
Prior Application Status		Expired		Remove	
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
PCT/US16/23223	Claims benefit of provisional		62/136571	2015-03-22	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER		

Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136123	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136152	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136180	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136230	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136326	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136370	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/136390	2015-03-20
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/135552	2015-03-19
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/135528	2015-03-19

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	688961-25U7	
		Application Number		
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER			

Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/135576	2015-03-19
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/135603	2015-03-19
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US16/23223	Claims benefit of provisional	62/135609	2015-03-19

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](#)

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	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON 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	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON 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		<input type="button" value="Remove"/>
<p>If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.</p>			
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☐ Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor	
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If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
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Name of the Deceased or Legally Incapacitated Inventor: <div style="border: 1px solid black; width: 400px; height: 20px;"></div>			
If the Applicant is an Organization check here. ☒			
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Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON 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.				
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Signature	/Ragi A.I. Elias/		Date (YYYY-MM-DD)	2021-12-28
First Name	Ragi	Last Name	Elias	Registration Number
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	688961-25U7
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER		

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TITLE OF THE INVENTION

System and Method for Low-Profile Occlusion Balloon Catheter

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 16/133,193, filed September 17, 2018 and titled, "System and Method for Low-Profile Occlusion Balloon Catheter," which is a continuation of U.S. Patent Application No. 15/551,504, filed August 16, 2017 and titled, "System and Method for Low-Profile Occlusion Balloon Catheter," and issued as U.S. Patent No. 10,149,962 on December 11, 2018, which is a Section 371 of International Patent Application No. PCT/US2016/023223, filed March 18, 2016, which was published in English on September 22, 2016 as International Publication No. WO 2016/149653 and claims the benefit of U.S. Provisional Patent Application Nos. 62/135,552, filed March 19, 2015 and titled, "Anti-Hypertensive Vascular Occlusion Catheter and Method," 62/135,528, filed on March 19, 2015 and titled, "Anti-Hypertensive Vascular Occlusion Catheter with Electromechanical Actuation and Method," 62/135,576, filed March 19, 2015 and titled, "Anti-Hypertensive Vascular Occlusion Catheter and Method," 62/135,603, filed March 19, 2015 and titled, "Anti-Hypotensive Vascular Occlusion Catheter with Electromechanical Actuation Method," 62/135,609, filed March 19, 2015 and titled, "Control Processing System for Regulating Vascular Occlusion and Method," 62/136,123, filed March 20, 2015 and titled, "System and Apparatus for Vascular Pre-Conditioning and Method," 62/136,152, filed March 20, 2015 and titled, "Vascular Pre-Conditioning Occlusion Catheter and Method," 62/136,180, filed March 20, 2015 and titled, "Vascular Occlusion Catheter with Infusion Capability and Method," 62/136,230, filed March 20, 2015 and titled, "Vascular Occlusion-Perfusion Catheter and Method," 62/136,326, filed March 20, 2015 and titled, "Vascular Occlusion Catheter with Variable Perfusion Flow and Method," 62/136,370, filed March 20, 2015 and titled, "Vascular Occlusion-Perfusion Catheter with Plural Occlusion Members and Method," 62/136,390, filed March 20, 2015 and titled, "Vascular Occlusion-Perfusion Catheter with Mechanically Actuated Variable Occlusion-Perfusion Properties and Method," 62/136,571, filed March 22, 2015 and titled, "Low Profile Sensing Vascular Occlusion Catheter and Method of Vascular Occlusion," and 62/204,804, filed August 13, 2015 and titled, "System and Method for Low-Profile Occlusion Balloon Catheter," the entire contents of each of which are incorporated by reference

herein in their entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made with government support under Contract No. W911QY-15-C-0099 and grant title “Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Research”, awarded by U.S. Army Medical Materiel Agency. The government has certain rights in the invention.

BACKGROUND OF THE INVENTION

[0003] The present invention pertains generally to vascular occlusion catheters and methods of vascular pre-conditioning while controlling occlusion and perfusion during an occlusion procedure. Pre-conditioning is employed to mitigate ischemia before, during and/or after a vascular occlusion procedure, as well as used to reduce or ameliorate the onset of hypertension during or reduce or ameliorate the onset of hypotension after a vascular occlusion procedure. Vascular occlusions may be indicated in either the venous system and/or the arterial system. Endoarterial occlusion is a procedure in which a blood vessel is at least partially occluded in order to restrict blood flow upstream or downstream the occlusion site for purposes of a vascular procedure or repair. It is known that transient hypertension is a risk factor in arterial occlusion, particularly aortic occlusion. Transient hypertension occurs when the blood pressure upstream the occlusion site rises to a potentially unsafe level during the time duration of the occlusion. Upon completion of a procedure requiring arterial occlusion, particularly aortic occlusion, care must be taken during the process of reestablishing blood flow to reduce or ameliorate the onset of hypotension. Thus, arterial occlusion carries with it two twin risks, hypertension during the occlusion and hypotension as the occlusion is withdrawn and blood flow restored, that must be managed.

[0004] Temporary aortic occlusion as an operative method to increase proximal or central perfusion to the heart and brain in the setting of shock due to major trauma is generally known. Despite potential advantages over thoracotomy with aortic clamping, resuscitative endovascular balloon occlusion of the aorta (“REBOA”) for trauma has not been widely adopted.

[0005] Many attempts have been made at developing technologies to control non-compressible abdominal hemorrhage. For example, non-occlusive, abdominal tamponade

procedures have been developed to address the problem of non-compressible hemorrhage, such as providing introducing an expandable biocompatible foam into the abdominal cavity to apply pressure to the abdominal organs and vasculature. Pharmacological efforts have also been developed to address the problem of non-compressible hemorrhage. Conventional REBOA procedures are typically performed in an operating room and with the aid of fluoroscopy or other imaging.

[0006] Devices that automate inflation and deflation of a balloon are known. Intra-aortic balloon counterpulsation catheters for blood pressure augmentation coordinated with electrocardiography signals are also known. Over inflation safety devices are also known, such as a pressure-relief valve coupled to an inflation lumen that opens when pressure within the inflation lumen exceeds a threshold pressure, but is still that relative pressure within the balloon necessary to maintain occlusion of the blood vessel.

[0007] It would be desirable to design, develop and implement a system that intermittently and automatically releases an occlusion by releasing apposition of an occlusive member against the vascular wall and allowing perfusion past the occlusion member in response to a physiological parameter, then re-establishing occlusion in response to potential changes in the physiological parameter, either during a vascular repair procedure to control hypertension or post-repair procedure to control hypotension.

BRIEF SUMMARY OF THE INVENTION

[0008] In accordance with a preferred embodiment of the present invention, there is provided an arterial occlusion catheter system including an occluding member carried at a distal aspect of a catheter, an atraumatic guiding tip forming a distal end of the catheter and a pressure accumulator communicating with the occluding member. The atraumatic guiding tip alleviates the need for a guide wire, and, therefore for initial guide wire placement, allowing the preferred arterial occlusion catheter to be used in field operations and without the necessity of fluoroscopy or other imaging modality.

[0009] In accordance with another preferred embodiment of the present invention, there is provided an arterial occlusion catheter system including an occluding member carried at a distal aspect of a catheter, an atraumatic guiding tip forming a distal end of the catheter, a pressure valve communicating with the occluding member that release expansive force applied to the occluding member to allow perfusion past the occluding member when hypertension is present,

and a means for re-applying the expansive force to re-establish occlusion when the arterial pressure is normalized.

[0010] In accordance with still another preferred embodiment of the present invention, there is provided an arterial occlusion catheter system having a computer hardware and software control over the physiological parameter set points at which automatic computer controlled occlusion or release of occlusion occur, including, without limitation, set points for systolic and/or diastolic arterial blood pressure, heart rate, heart rhythm (including, without limitation, the P, Q, R, S, T and U peaks, their size, timing and duration), blood oxygenation, tissue oxygenation or the presence or absence of metabolic blood products.

[0011] In accordance with yet still another preferred embodiment of the present invention, there is provided an arterial occlusion catheter system having computer hardware and software control monitoring physiological parameter set points for systolic and/or diastolic arterial blood pressure, heart rate, heart rhythm (including, without limitation, the P, Q, R, S, T and U peaks, their size, timing and duration), blood oxygenation, tissue oxygenation or the presence or absence of metabolic blood products and which provides visual, auditory or tactile feedback to a medical practitioner as signals for the medical practitioner to take certain recommended actions based upon the monitored physiological parameter set points.

[0012] In accordance with still yet another preferred embodiment of the present invention, there is provided an arterial occlusion system and method in which fluids, such as blood, plasma, saline, blood products or blood substitutes, are infused proximal and/or distal the occlusion site.

[0013] In accordance with another preferred embodiment of the present invention, there is provided an arterial occlusion system and method in which the occlusion member has a geometric conformation such that at different degrees of deployment it assumes different transverse geometric profiles that yield different degrees of arterial occlusion and permit perfusion past the occlusion member. The occlusion member may have a torroidal shape when fully deployed and a fluted or corrugated shape with longitudinally oriented flutes or corrugations and valleys between adjacent flutes or corrugations when in its partially deployed state. Alternatively, the occlusion member may have a helical shape when either fully or partially deployed, such that fluid flow around the occlusion member is maintained while at least partially occluding the artery. Further, the occlusion member may have a torroidal shape with vanes, the vanes being either longitudinally oriented or helically oriented, the vanes being

sufficiently pliant so that they deflect and fold against the occlusion member when the occlusion member is in full apposition with the vascular luminal wall surface, but pliantly recover to project from the occlusion member and define fluid flow pathways between adjacent vanes and past the occlusion member.

[0014] In accordance with yet another preferred embodiment of the present invention, there is provided an arterial occlusion system and method having a catheter with at least one occlusion member at a distal end thereof, a plurality of fluid flow ports communicating with a common fluid flow lumen within the catheter and an luminal occluding member that is movable within the common fluid flow lumen to open or close one or more of the plurality of fluid flow ports, thereby controlling the volume and rate of perfusion fluid flow past the at least one occlusion member.

[0015] While in all preferred embodiments of the present invention, the occluding member is preferably a balloon, the occluding member may also consist of a woven or non-woven shape memory metal membrane, a superelastic metal membrane, an elastic metal membrane, a woven or non-woven polymer material or a shape memory polymer and that the occluding member may or may not be supported by an expansive or reinforcing frame.

[0016] As noted above, arterial hypertension is a frequent result of arterial occlusion for any clinically significant period of time, particularly, in aortic occlusion situations. A need has been recognized to provide a catheter system in which clinically significant hypertension is alleviated automatically and without medical practitioner intervention or control, concurrently with the arterial pressure exceeding a pre-determined level upstream in the blood flow from the occlusion member.

[0017] The preferred present invention generally relates to endovascular arterial occlusion catheters that are particularly well suited to emergency or trauma use for REBOA procedures to occlude non-compressible hemorrhage either in the field, on the battlefield or in emergency room environments where guidance imaging is typically not available. More particularly, the preferred present invention pertains to an arterial occlusion catheter that has an atraumatic guiding tip made of a generally flexible material, elastic material, shape memory material or superelastic material. The atraumatic guiding tip may be formed at least in part of elastomeric polymer that permits guide wire and fluoroscopy free guidance of the arterial occlusion catheter to the site requiring occlusion. Still more particular, the present invention relates to a low profile aortic

occlusion catheter having an atraumatic guiding tip formed of polymer, metal or polymer reinforced with an elastic, shape memory or superelastic material and having a lumen for introducing or withdrawing fluids from a body into which the catheter is placed and/or for introducing sensors, adjunctive medical devices or other diagnostic or therapeutic modalities, to determine and evaluate a condition within the body, such as arterial pressure or flow rate, to diagnose a condition in the body and/or to treat a condition in the body.

[0018] Balloon catheters generally comprise an elongated catheter shaft with a deflated balloon on the distal end of the shaft, and are used in a number of different medical procedures, including, for example, angioplasty, stent placement, occlusion, drug delivery, etc. The catheter is introduced through a percutaneous sheath and maneuvered into the patient's blood vessels until the balloon is properly positioned across the stenotic area to be dilated. Once properly in position, the balloon is inflated with liquid one or more times to a predetermined size and pressure to widen the coronary passageway and increase blood flow.

[0019] It is desirable for balloon catheters to attain very low profiles in order to facilitate passage of the balloon across severe and remote vascular obstructions. High strength materials are commonly required in the design of balloon catheter components to prevent shaft buckling when the balloon is inflated. Additionally, high strength materials are required so that torque applied to the proximal end of the catheter results in rotation of the distal tip of the catheter. High flexibility materials are also commonly required in the design of balloon catheter components to maintain a low-profile and avoid trauma or perforation of the blood vessels while the catheter is maneuvered through the patient's tortuous vasculature.

[0020] However, conventional balloon catheters, particularly those designed for aortic occlusion, generally do not properly balance the need for proximal segment stiffness with the need for a low profile, flexible distal segment and trackability through the tortuous vascular pathway without entry into collateral vessels. A low profile balloon catheter with a high strength and relatively stiff proximal segment and a flexible distal segment with an atraumatic tip having a design that restricts tracking and entry into collateral vessels, which is employed by preferred embodiments of the present invention.

[0021] In one preferred embodiment, the devices comprise an elongate catheter having a proximal and a distal region. The catheter may also have a lumen extending between the proximal and distal regions. An expandable occlusion member, e.g., a balloon, a membrane with

or without an expandable frame or an expandable section of the catheter itself, is carried at the distal region of the catheter. The catheter in certain preferred embodiments may include plural expandable occlusion members, i.e., second, third, fourth, etc. expandable occlusion members, at the distal region of the catheter, proximal and/or distal the first expandable occlusion member.

[0022] In certain preferred embodiments, the catheter will also include means for measuring physiological parameters distal and/or proximal one or more of the expandable occlusion members, including, for example blood pressure sensors, heart rate sensors, flow sensors, chemical sensors, temperature sensors, oxygenation sensors, ischemia sensors, biological sensors, imaging sensors or the like.

[0023] In use, the catheter having one expandable device is located in the descending aorta so that the expandable device is suprarenal or infrarenal. The expandable device is then expanded to partially or completely obstruct the descending aorta. Cerebral blood flow and cerebral blood pressure rises and is maintained at an increased level, as desired. Cephalic blood pressure and/or cerebral blood flow may be monitored, and the expandable device adjusted as needed. Therapeutic instruments may be deployed through the lumen (when present) of the occlusion catheter systems.

[0024] In another preferred embodiment, the occlusion member, when expanded, has a maximum periphery that conforms to the inner wall of the vessel, thereby providing a sealed contact between it and the vessel wall. The occlusion catheter system may have a blood flow or other fluid flow conduit allowing blood flow from a location upstream to a location downstream. The preferred devices further include a variable flow mechanism in operative association with the blood conduit, thereby allowing blood flow through the conduit to be adjusted and controlled. The preferred devices can optionally include a manometer and/or pressure limiter to provide feedback to the variable flow mechanism for precise control of the upstream and downstream blood pressure.

[0025] In certain preferred embodiments of the invention, the arterial occlusion catheter system includes an additional access lumen that allows access and passage of other medical devices or adjunctive therapies. Devices, such as flow wires, imaging catheters or devices, infusion, atherectomy, angioplasty, hypothermia catheters or devices, or electrophysiologic study (EPS) catheters, can be introduced through the additional access lumen to access a position in the blood vessel to provide diagnostic or therapeutic interventions. Hypothermia is one example of

an adjunctive therapy that may be delivered using the additional access lumen of the preferred arterial occlusion catheter. Where cerebral cooling is desired the additional access lumen may be used to introduce cooled blood or other cooled fluids, a cooling wire, or other type of heat exchanger, such as a cooling catheter.

[0026] In still another preferred embodiment, the occlusion member comprises a first balloon mounted to a distal end of the catheter, and a second balloon mounted on the distal end of the catheter and proximal the first balloon, with a region of the catheter being intermediate the first and the second balloons. The first balloon has a first balloon inflation chamber and the second balloon has a second balloon inflation chamber, the first balloon inflation chamber and the second balloon inflation chamber may communicate with a common inflation lumen or, alternatively, may communicate with separate inflation lumens, termed herein, first inflation lumen and second inflation lumen, such that the first and second balloons are either concurrently or separately inflatable. A perfusion lumen may also be provided in the catheter and communicates with perfusion openings passing through the wall of the catheter to permit fluids, including blood and blood products to be introduced through the catheter. The perfusion openings are preferably located distal the first balloon (first perfusion openings), proximal the first balloon and intermediate the first balloon and the second balloon (second perfusion openings), and/or proximal the second balloon (third perfusion openings), or in any combination thereof, such that fluid flow may be established either concurrently or selectively through all of or only some of the perfusion openings. Selective fluid flow through the perfusion openings may be accomplished in a number of alternative manners. For example, a plurality of perfusion lumens may be provided in the catheter. A first perfusion lumen communicating with the perfusion openings distal the first balloon, a second perfusion lumen communicating with the perfusion openings proximal the first balloon and intermediate the second balloon and the first balloon, and a third perfusion lumen communicating with the perfusion openings proximal the proximal balloon. Alternatively, a single common perfusion lumen may communicate with all of the perfusion openings, and a selector member is disposed within the perfusion lumen and movable within the perfusion lumen to selectively expose only those perfusion lumens in the catheter regions through which perfusion is desired. A non-limiting example of a selector member comprises a tubular hypotube having non-fenestrated wall surfaces that is longitudinally movable within the perfusion lumen to select either the first perfusion openings, the second

perfusion openings or the third perfusion openings, or portions thereof. The hypotube may, itself, have fenestrations or openings passing through its wall surfaces, wherein rotational movement of the fenestrated hypotube within the perfusion lumen will align the hypotube fenestrations with one or more of the perfusion openings to permit fluid flow from the lumen of the hypotube and through the aligned fenestrations and perfusion openings and into the vascular structure.

[0027] It will be understood that there are many advantages in using the partial aortic occlusion devices and methods disclosed herein. For example, the devices can be used (1) to provide variable partial occlusion of a vessel; (2) to augment and maintain cerebral perfusion in patients suffering from global or focal ischemia; (3) to condition the brain or spinal cord to secrete neuroprotective agents prior to a major surgery which will necessitate reduced cerebral or spinal perfusion; (4) to prolong the therapeutic window in global or focal ischemia; (5) to accommodate other medical devices, such as an atherectomy catheter; (6) prophylactically by an interventional radiologist, neuroradiologist, or cardiologist in an angiogram or fluoroscopy suite; (7) for prevention of cerebral ischemia in patients undergoing procedures, such as coronary catheterization or surgery, where cardiac output might fall as a result of arrhythmia, myocardial infarction or failure; (8) to treat shock, thereby eliminating or reducing the use of systemic vasoconstrictors; (9) to prevent hypotensive neurologic damage during carotid stenting, and (10) to rescue vasospasm induced by hemorrhage or interventional procedures.

[0028] Provided herein are systems, methods and compositions for an occlusion balloon catheter system comprising: a first catheter member having a first lumen extending longitudinally through the first catheter member and open at a distal end of the first catheter member; a second catheter member having a second lumen extending longitudinally through the second catheter member and open at a distal end of the second catheter member, the second catheter member is positioned over and in spaced apart relationship relative to a proximal section of the first catheter member forming an annular space between the second catheter member and the first catheter member, the proximal section of the first catheter member resides within the second lumen of the second catheter member and the first catheter member extends beyond the distal end of the second catheter member, a third catheter member that may comprised a proximal shaft of an atraumatic tip having a third lumen extending longitudinally and partially through the third catheter member; the third catheter member is positioned over a distal section

of the first catheter member, the third catheter member having a distal section that extends distally from a distal end of the first catheter member such that the first lumen and the third lumen are in fluid flow communication, whereby the second and third catheter are spaced apart from each other along a longitudinal axis of the first catheter member with the first catheter member extending therebetween; an atraumatic tip member having a proximal section co-axially coupled to a distal end of the third catheter member; and a balloon coupled at its proximal end to the second catheter member and at its distal end to the third catheter member and in fluid flow communication with the second catheter member; the balloon being positioned such that the space between the second catheter member and the third catheter member is within the balloon.

[0029] REBOA is preferably performed, as follows:

STEP 1: ARTERIAL ACCESS AND POSITIONING OF INITIAL SHEATH

[0030] Access to the arterial circulation for REBOA for trauma is obtained through the femoral artery. After femoral artery access is obtained, a ten to fifteen centimeter (10- 15 cm) long sheath is positioned in the femoral and external iliac artery. Access to the femoral artery can be obtained using several techniques, including: percutaneous, open exposure (i.e., cut down), or exchange over a guide wire from an existing femoral arterial line. Percutaneous access is commonly accomplished under ultrasound guidance. Ultrasound or direct surgical identification of the femoral artery lateral to the vein is preferred in the hypotensive patient without a palpable pulse. Once identified, the artery should be entered at a forty-five degree (45°) angle with a hollow eighteen gauge (18-gauge) needle through which a thirty-five thousandths inch (0.035") wire or similarly sized wire can be passed. After the wire has been passed into the artery, the needle is removed and a small incision made at the interface of the wire and the skin. Next the sheath is placed over the wire into the artery. Any time a sheath is passed over a wire into the arterial system, the sheath's internal dilator is preferably firmly in place to allow a smooth reverse taper from the wire to the diameter of the sheath. Once the dilator and sheath have been advanced over the wire through the skin into the artery, the dilator is removed leaving the sheath as a working port through which other maneuvers can be accomplished.

STEP 2: SELECTION AND POSITIONING OF THE BALLOON

[0031] Selection of a Balloon: A balloon inflated inside the aorta to occlude flow should be compliant and of large diameter. Stiff or noncompliant balloons pose a risk of arterial damage.

[0032] Positioning of the Balloon (Zones of the Aorta): Balloon selection should be made in view of the aortic zone to be occluded. Aortic zones can be considered I, II, and III spanning from cranial or proximal to caudal or distal. Zone I is preferably considered the descending thoracic aorta between the origin of the left subclavian and celiac arteries. Zone II preferably represents the para-visceral aorta between the celiac and the lowest renal artery and zone III preferably represents the infrarenal abdominal aorta between the lowest renal artery and the aortic bifurcation, depending on patient anatomy. In most instances of shock and pending cardiovascular collapse, the aim is to position the occlusive balloon to occlude zone I. In this case, a larger diameter balloon and a longer sheath are advanced into the thoracic aorta. REBOA in zone I typically requires a longer sheath, such as a sheath having a forty-five to sixty centimeter (45–60 cm) length, to be positioned in the descending thoracic aorta to support or hold the balloon against aortic pulsation once it is inflated. Inflation of a compliant balloon in aortic zone III may provide specific utility in cases of pelvic or junctional femoral hemorrhage. In this instance, a relatively smaller diameter balloon may be sufficient. Because the aortic bifurcation will support or hold the inflated balloon against pulsation, this maneuver can potentially be accomplished using a large diameter but shorter sheath, such as ten to fifteen centimeters (10–15 cm).

[0033] Wire Control and Positioning of the Large Sheath and Balloon: Positioning of the balloon in the aorta preferably takes place over a thirty-five thousandths inch (0.035”) wire, but is not so limited, and through an appropriately sized sheath that takes the place of the initial sheath previously described. Re-sheathing may be accomplished by inserting a two hundred sixty centimeter (260 cm) long, thirty-five thousandths inch (0.035”) stiff wire (e.g., Amplatz Stiff Wire Guide; Cook Medical) through the initial sheath in the femoral artery. The stiff wire is preferably advanced under fluoroscopic guidance or visualization such that the floppy tip is in the distal aortic arch. The extent of the wire outside of the sheath at this point should be noted and marked so that the wire is not advanced or withdrawn significantly, such as by more than five centimeters (>5 cm). Failure to maintain control of the wire’s insertion depth during this and subsequent maneuvers may result in inadvertent injury to coronary or cerebral vessels if it is advanced too far or an inability to advance the balloon to the occlusion zone if it is withdrawn.

[0034] The initial sheath may be removed and backed off of the wire with pressure held proximally over the femoral artery for hemostasis. The larger sheath is then advanced over the wire, preferably lead by its internal dilator, through the skin opening and into the femoral and iliac artery. In this manner, the wire acts as a rail over which the large sheath or balloon catheter can be advanced or withdrawn as the operator focuses on the fluoroscopic image.

[0035] To occlude zone I, the larger, longer sheath is preferably advanced over the stiff wire under fluoroscopic guidance into the thoracic aorta to the desired location of occlusion. Fluoroscopically, zone I can be estimated to exist above the twelfth (12th) rib and below the medial head of the clavicle. Next, the internal dilator is preferably removed from the sheath and the back end of the extended wire. The balloon is next preferably loaded on and advanced over the stationary wire into and through the sheath. Under fluoroscopic visualization, after the balloon advances from the end of the sheath, it is ready to be inflated. To occlude zone III typically requires a large diameter but shorter sheath, such as ten to twenty-five centimeters (10–25 cm), to allow passage of the balloon into the terminal aorta under fluoroscopic visualization. The concept in this scenario is that once the balloon is inflated, any aortic pulsation will push the balloon to the terminal aorta and its bifurcation.

STEP 3: INFLATION OF THE BALLOON AND SECURING OF THE APPARATUS

[0036] Balloon Inflation: Similar to step 2, inflation of the balloon is preferably accomplished under fluoroscopic guidance. A large-volume syringe, usually thirty to sixty milliliters (30–60 mL) is filled with a half and half solution of sterile saline and iodinated contrast. This mixture allows visualization of the balloon inflation as well as more rapid inflation and deflation times by reducing viscosity. Preferably with fluoroscopy, the balloon is inflated until the outer edges of the balloon change from convex to parallel as the balloon takes on the contour of the aortic wall. One may notice that during systole, the balloon changes shape and creates a “mushroom cap” as it is pulsed inferiorly. In zone I occlusion, the previously positioned long sheath can then support the balloon and maintain its position within the aorta. When inflation appears adequate to gain aortic wall apposition and augment central blood pressure, the three-way stopcock on shaft of the balloon should be turned off toward the balloon to maintain inflation and occlusion while other maneuvers are undertaken.

[0037] Securing the Inflated Balloon, Sheath, and Wire Apparatus: It is next preferred to

hold the balloon, sheath, and wire securely so that none generally change position as the central aortic pressure returns pushing the balloon caudal. Although the balloon, sheath, and wire can be secured with sutures or an occlusive dressing that pin the apparatus to the patient, these are preferably observed continuously to limit downward or caudal migration.

STEP 4: DEFLATION OF THE BALLOON

[0038] Once a decision to attempt deflation is made, care is preferably taken to deflate the balloon slowly as this step can be anticipated to result in a decrease in afterload and hypotension. After prolonged balloon inflation or in situations where incomplete resuscitation has occurred, deflation of the balloon can potentially result in reperfusion, washout of metabolic byproducts, and acidosis. As such, intermittent balloon inflation and deflation is preferred until some hemodynamic stability is restored.

STEP 5: REMOVAL OF THE BALLOON AND SHEATH

[0039] After REBOA is no longer required, the deflated balloon and wire are preferably removed from the large sheath which is preferably flushed with heparinized saline, such as one hundred milliliters (100 mL) of saline or one thousand (1,000) units of heparin. The relatively large diameter sheaths used to deploy currently available compliant balloons are best removed with open surgical exposure of the femoral artery. This can be accomplished using a longitudinal or transverse groin incision with dissection through the soft tissues overlying the femoral sheath. The femoral artery proximal and distal to the sheath entry site should be exposed to allow control. Proximally, this often requires dissection for two to three centimeters (2-3 cm) underneath the inguinal ligament as an assistant uses a narrow handheld retractor (e.g., short Wylie renal vein retractor) to lift the inguinal ligament off of the femoral sheath. During this maneuver, the surgeon preferably considers the circumflex iliac veins, which course over the top of the distal external iliac and proximal common femoral artery. Exposure distal to the sheath entry site preferably includes identification and control of both the superficial and profunda femoris arteries.

[0040] Once proximal and distal exposure and control have been accomplished, the sheath may be removed. The resulting arteriotomy should be closely examined and closed. Restoration of flow through the arterial segment is preferably confirmed using manual palpation for pulses

and use of continuous wave Doppler of both the artery and more distal extremity. Closure of the femoral artery exposure is preferably accomplished in layers using absorbable suture in the soft tissues and skin.

[0041] REBOA can be considered in the following five steps, each with specific procedural considerations: 1. Arterial access, 2. Balloon selection and positioning, 3. Balloon inflation, 4. Balloon deflation, and 5. Sheath removal. REBOA procedures may be conducted under fluoroscopy or other suitable imaging modality.

[0042] There is a need for a device that permits medical practitioners to conduct REBOA procedures without the conventional necessity of using fluoroscopy or other imaging modality together with the suitability of using the device and techniques for field applications outside the hospital or in hospital emergency room settings. In trauma situations where a patient is undergoing severe central torso hemorrhaging, particularly when not in a hospital setting, such as on a battlefield or on a public street or highway, imaging capability is simply not available to emergency responders or field medical practitioners. In such situations, it is preferred to temporarily occlude a central torso hemorrhage so that the patient may be stabilized in the field and transported to a hospital or other facility in which repair of the traumatic injury may be conducted.

[0043] Injuries in modern warfare are often caused by explosion and related high-velocity penetrating shrapnel leading to non-compressible bleeding. Non-compressible bleeding accounts for approximately eighty-five percent (85%) of preventable deaths on the battlefield, eighty percent (80%) of which include acute hemorrhage within the abdomen/torso. Abdominal hemorrhage involves injury to the spleen, liver, or retroperitoneal vasculature, and is typically non-compressible, meaning that it cannot be treated by external compression or the application of tourniquets or topical dressings.

[0044] Emergency surgical intervention is currently the only available method for treating non-compressible abdominal hemorrhage. Battlefield or other major trauma generally occurs in an austere, resource constrained environment, often with extended evacuation time due to persisting tactical threats or environmental constraints. Transport time to reach a hospital where surgery can take place varies, but is estimated to average one hour (1 hr). The majority of preventable deaths due to abdominal hemorrhage is nearly fifty percent (50%) and can be attributed to delays in hemorrhage control during transportation, highlighting the need for rapid,

far-forward hemorrhage treatments.

[0045] Systems, methods and compositions for an occlusion balloon catheter system comprising: a first catheter member having a first and second lumens extending along a longitudinal axis thereof that forms a proximal section of the catheter system, a second catheter member having a third lumen forming a distal section of the catheter system and coupled to a distal end of the first catheter member, an inflatable balloon coupled at its proximal end to a distal end of the first catheter member and at its distal end to a proximal end of the second catheter member, a first lumen of the first catheter member terminating within the inflatable balloon to communicate an inflation fluid to an area within the inflatable balloon and a second lumen of the first catheter member being in fluid flow communication with the third lumen of the second catheter member; an atraumatic guiding tip coupled to a distal end of the third lumen of the second catheter member; and a third catheter member having at least one lumen passing longitudinally therethrough, the third catheter member being disposed within each of the second lumen of the first catheter member and the third lumen of the second catheter member and passing therethrough.

[0046] Preferred embodiments of the present invention have been actively conceptualized, modeled, iterated and working prototypes produced of multiple REBOA related devices. The concepts are responses to the following lists of clinical needs, including (1) Pushing back the ischemic injury envelope, (2) Reperfusion mitigation/prevention, (3) Ischemia mitigation/prevention, (4) Hypertension mitigation/prevention, (5) Traumatic brain injury (“TBI”) mitigation/prevention, (6) Pre-hospital use, (7) Rapid deployment, (8) Field specific packaging, (9) Easier to use, and (10) Lower profile

[0047] Preferred embodiments of the present invention may also include:

Infusion Catheter

[0048] The infusion catheter or occlusion catheter system is a preferably multi-purpose, low profile, such as approximately five French (5 Fr) catheter, although the preferred system is not limited to catheters having this size. The preferred systems may be used independently or in conjunction with a REBOA catheter from the contralateral leg to administer fluids (i.e. reperfusion mitigation/ischemia prevention) or gas/fluid angiography below the REBOA occlusion balloon. The combination of the P-tip and hybrid shaft design preferably allow for

proper placement in large vessels without needing to be inserted over a guidewire. The infusion catheter of the preferred embodiments may be compatible with power injection.

Smart REBOA

[0049] Smart REBOA is a REBOA accessory that can preferably be connected to and used with any REBOA catheter. Smart REBOA preferably controls the occlusion balloon inflation volume and inflation/deflation rate, using the patient's own vital signs as feedback. A validated algorithm is capable of using feedback from a variety of vital signs (i.e. heart rate, respiration rate, pulse oxygenation, blood pressure, etc.) to modulate the inflation volume of the balloon for an optimized REBOA procedure.

Decision Support REBOA (DS REBOA)

[0050] DS REBOA builds upon the preferred Smart REBOA concept. DS REBOA preferably combines the real time monitoring and feedback of the Smart REBOA device with a historical and constantly updated database of known REBOA cases and outcomes to provide forward looking possible diagnoses and other decision support information (collectively called 'prognostics') through sophisticated statistical means. The DS REBOA also preferably provides a patient specific, real time step through clinical practice guide and other decision support mechanisms to assist the clinician.

Power Injection Capable REBOA (PIC REBOA)

[0051] PIC REBOA is preferably a REBOA Catheter that is approximately seven French (7 Fr) compatible and offers the same or similar features as the ER-REBOA Catheter (balloon occlusion, built-in arterial line, guidewire and fluoroscopy-free), but preferably adds the ability to perform power injections. The PIC REBOA is not limited to being seven French (7 Fr) compatible.

REBOA with Above & Below Balloon Lumens (ABBL REBOA)

[0052] ABBL REBOA is a REBOA Catheter that preferably offers the same or similar features as the ER-REBOA Catheter, but contains an additional lumen below the balloon for fluid/gas injections/sampling. ABBL REBOA is preferably compatible with power injectors for either above or below the balloon angiography.

REBOA with a Partial Occlusion Balloon (POB REBOA)

[0053] POB REBOA is a REBOA Catheter that preferably provides the clinician the ability to selectively control the degree of occlusion. Balloon design preferably permits minimal occlusion, such as ten percent (10%), up to total or near total occlusion, such as one hundred percent (100%).

REBOA with Large Bore Lumen for High Flow Rate Infusions (LBL REBOA)

[0054] LBL REBOA is a REBOA Catheter that preferably includes the same or similar features as the ER-REBOA Catheter (balloon occlusion, built-in arterial line, guidewire and fluoroscopy-free), but has a larger diameter central lumen that provides the ability to perform high flow rate infusions (i.e. selective aortic arch perfusion (SAAP)).

ECMO/Cryogenic/CRRT Adjuncts

[0055] Extra Corporeal Membrane Oxygenation (“ECMO”) continues to become more clinically widespread. ECMO is preferably used in cases where the patient’s lungs have been damaged or temporarily compromised, by bypassing the patient’s lungs through the use of catheters to shunt the blood away from the damaged organs and through an ECMO device instead. Recent advances have reduced the size, weight and cost of ECMO, while improving its efficacy. Combining the REBOA technology with various ECMO catheters to provide a “one stop” solution for patients with lung or other major organ compromise in the setting of hemorrhage may become a clinically preferred method. Similar combinations with existing and proposed cryogenic devices and Continuous Renal Replacement Therapy (CRRT) systems also are contemplated.

REBOA with Anti-Hypertension Feature (A-HYPER REBOA)

[0056] A-HYPER REBOA is a REBOA accessory that uses the patient’s own supra-occlusion blood pressure to control the inflation/deflation of the REBOA balloon is contemplated. Should the patient’s *supra* occlusion blood pressure rise dangerously high, potentially increasing the risk of hemorrhagic stroke, the system preferably automatically and temporarily deflates the REBOA balloon until the blood pressure drops to a safer level.

REBOA with Anti-Hypotension Feature (A-HYPO REBOA)

[0057] A-HYPO REBOA is a REBOA accessory that uses the patient's own blood pressure to control balloon deflation during the removal of the REBOA balloon is contemplated. If the patient's blood pressure should drop dangerously low during the deflation of the REBOA balloon, the system may automatically re-inflate the balloon to restore adequate pressure to the vital organs. The system will then preferably begin a pre-programmed cycle of deflation/repeat inflations until the patient can be weaned completely off occlusion.

Inflation Safety Device (ISD)

[0058] The ISD is a REBOA accessory that can preferably be used with the ER-REBOA Catheter to decrease the risk of over-inflating the balloon during fluoroscopy-free balloon inflation (i.e. field use). The ISD is preferably connected in line between the ER-REBOA Catheter and the inflation syringe. The user advances the syringe plunger, pausing occasionally to read the pressure gauge. When the pressure gauge needle comes to rest in the 'blue zone' or a preferred marked zone of the pressure gauge, proper occlusion has generally been achieved.

Infection Control Sleeve (ICS)

[0059] The infection control sleeve ("ICS") is a REBOA accessory that is preferably pre-loaded on the ER-REBOA Catheter to minimize the risk of infection when the device is deployed in austere environments. The ER-REBOA Catheter with the ICS preferably remains compatible with seven French 7 Fr components and has the same or similar features (balloon occlusion, built-in arterial line, guidewire and fluoroscopy-free) to other preferred REBOA systems and catheters.

Ruggedized, Low Volume (cube) Packaging (REBOA w/ LV PKG)

[0060] REBOA w/ LV PKG is a modified ER-REBOA Catheter and redesigned, ruggedized, low volume package (approximately twenty-five percent (25%) of the current ER-REBOA package volume) specific configured for field use. The ER-REBOA Catheter preferably remains compatible with seven French (7 Fr) components and has the same or similar features (balloon occlusion, built-in arterial line, guidewire and fluoroscopy-free) to other preferred REBOA systems.

Zone 3 REBOA (Z3 REBOA)

[0061] The Z3 REBOA is a REBOA Catheter preferably designed for Zone 3 placement relative to the aorta. The Z3 REBOA is preferably six French (6 Fr) compatible that has a shorter shaft length and an optimized balloon for generally less cumbersome Zone 3 placements.

Ultra-Low Profile REBOA (ULP REBOA)

[0062] The ULP REBOA is a preferred REBOA system that is compatible with six French or less (≤ 6 Fr) components. The ULP REBOA is preferably designed and configured for faster placement and improved ease-of-use. The balloon is filled with carbon dioxide (CO₂), preferably using a pressure regulated system, that preferably inflates the balloon to a set pressure, regardless of the diameter of the aorta. The use of the carbon dioxide (CO₂) also enables the catheter shaft to be ultra-low profile, such as less than or equal to six French (≤ 6 Fr) compatible. An electronic, catheter-based pressure sensor typically requires no priming/flushing, so arterial line measurements can preferably be taken as soon as the device is inserted.

REBOA Gas Balloon Inflator (GBI)

[0063] The GBI is a REBOA accessory that is preferably used with the ER-REBOA Catheter to provide rapid balloon inflation/deflation. The GBI preferably fills the balloon with carbon dioxide (CO₂) gas to a set pressure, regardless of the vessel diameter, preferably making pre-hospital balloon inflation less technique dependent.

Guidewire Compatible REBOA (GWC REBOA)

[0064] The GWC REBOA is a preferred REBOA Catheter that can be used with a guidewire but doesn't require one and is preferably compatible with seven French (7 Fr) components. The preferred GWC REBOA allows the user to leave behind a guidewire when finished with REBOA for additional procedures. The GWC REBOA Catheter preferably, but not necessarily, remains seven French (7 Fr) compatible and has the same or similar features (balloon occlusion, built-in arterial line, guidewire and fluoroscopy-free) to other preferred REBOA systems.

[0065] When a fluid is used as the pressure source to activate the occlusion member, such as to fill an occlusion balloon, that fluid may be a liquid, including water, saline, contrast medium or any combination thereof, or may be a gas, including carbon dioxide, helium, air or oxygen.

[0066] It would be desirable to develop a system that intermittently and automatically releases an occlusion by releasing apposition of an occlusive member against the vascular wall and allowing perfusion past the occlusion member in response to a physiological parameter, then reestablishing occlusion in response to the same physiological parameter.

[0067] The methods, systems, and apparatus are set forth in part in the description which follows or can be learned by practice of the methods, apparatus, and systems. The advantages of the methods, apparatus, and systems will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims and the below description. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the methods, apparatus, and systems, as claimed or described.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0068] The foregoing summary, as well as the following detailed description of the invention, will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings embodiments which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown. In the drawings:

[0069] Fig. 1 is a top perspective view of a first preferred embodiment of an occlusion catheter system in accordance with the present invention;

[0070] Fig. 2 is an enlarged perspective view of the occlusion catheter system of Fig. 1 taken from within circle 2 of Fig. 1 with a transparent occlusion balloon;

[0071] Fig. 3 is a cross-sectional view the occlusion catheter system of Fig. 1, taken along line 2-2 of Fig. 2.

[0072] Fig. 4 is an enlarged perspective view of the occlusion catheter system of Fig. 1, taken from within circle 4 of Fig. 1 with a transparent occlusion balloon;

[0073] Fig. 5 is a cross-sectional view the occlusion catheter system of Fig. 1, taken along line 5-5 of Fig. 2 directly into the page of Fig. 2;

[0074] Fig. 6 is a cross-sectional view of the occlusion catheter system of Fig. 1, taken along line 6-6 of Fig. 1;

[0075] Fig. 7 is a combination partial cross-sectional view of the occlusion catheter system

taken along line 7-7 of Fig. 1 and a magnified top perspective view of the occlusion catheter system near a proximal end of the occlusion balloon of the occlusion catheter system of Fig. 1;

[0076] Fig. 8 is a cross-sectional view of the occlusion catheter system of Fig. 1, taken along line 8-8 of Fig 1;

[0077] Fig. 9 is a magnified top perspective view of a portion of a second preferred embodiment of the occlusion catheter system proximate a occlusion balloon of the second preferred occlusion catheter system of the present invention;

[0078] Fig. 9A is a cross-sectional view of the occlusion catheter system of Fig. 9, taken along line 9A-9A of Fig. 9.

[0079] Fig. 9B a combination partial cross-sectional view of the occlusion catheter system taken along line 9B-9B of Fig. 9 and a magnified top perspective view of the occlusion catheter system near a proximal end of the occlusion balloon of the occlusion catheter system of Fig. 9;

[0080] Fig. 9C is a cross-sectional view of the occlusion catheter system of Fig. 9, taken along line 9C-9C of Fig. 9;

[0081] Fig. 9D is a cross-sectional view of the occlusion catheter system of Fig. 9, taken along line 9D-9D of Fig. 9, wherein the lumens and catheters are sized differently than the embodiment of Fig. 9C;

[0082] Fig. 10 is a magnified top perspective view of an alternative embodiment of a distal portion of the occlusion catheter system of Fig. 9;

[0083] Fig 11 is a magnified top perspective view an atraumatic tip of the occlusion catheter system of Fig. 10, taken from within shape 11 of Fig. 10;

[0084] Fig. 12 is a top perspective view of a third preferred embodiment of an occlusion catheter system of the preferred present invention;

[0085] Fig. 13 is an enlarged top perspective view of the occlusion catheter system of Fig. 12, taken from within shape 13 of Fig. 12;

[0086] Fig. 14 is a cross-sectional view of the occlusion catheter system of Fig. 13, taken along line 14-14 of Fig. 13;

[0087] Fig. 15 is a top perspective view of the occlusion catheter system of Fig. 12, taken from within shape 15 of Fig. 1;

[0088] Fig. 16 is a cross-sectional view of the occlusion catheter of Fig 12, taken along line 16-16 of Fig. 12;

[0089] Fig. 17 is a cross-sectional view of the occlusion catheter system of Fig. 12, taken along line 17-17 of Fig. 12;

[0090] Fig. 18 is a cross-sectional view of the occlusion catheter system of Fig. 12, taken along line 18-18 of Fig. 12;

[0091] Fig. 19 is a diagrammatic rendering of a first preferred pressure regulation system for automatically releasing occlusion by any of the occlusion catheter systems of the first, second and third preferred embodiments of Figs. 1-18;

[0092] Fig. 20 is a diagrammatic rendering of a second preferred pressure regulation system for controlling the occlusion balloon of any of the occlusion catheter system of the first, second and third preferred embodiments of Figs. 1-18;

[0100] Fig 21 is a diagrammatic rendering of a third preferred pressure regulation system for controlling the occlusion balloon of any of the occlusion catheter system of the first, second and third preferred embodiments of Figs. 1-18;

[0101] Fig. 22 is a diagrammatic rendering of a fourth preferred pressure regulation for controlling the occlusion balloon of any of the occlusion catheter system of the first, second and third preferred embodiments of Figs. 1-18;

[0102] Fig. 23 is a top perspective view of a first preferred embodiment of an alternative occlusion perfusion balloon system that may be utilized with any of the occlusion catheter systems of the first, second and third preferred embodiments of the occlusion catheter system of Figs. 1-18, wherein the occlusion perfusion balloon is in a minimal inflation configuration;

[0103] Fig. 24 is a rear elevational view of the occlusion perfusion balloon system of Fig. 23;

[0104] Fig. 25 is a top plan view of the occlusion perfusion balloon system of Fig. 23;

[0105] Fig. 26 is a top perspective view of the occlusion perfusion balloon system of Fig. 23, wherein the occlusion perfusion balloon is in a low inflation volume configuration;

[0106] Fig 27 is a top perspective view occlusion perfusion balloon system of Fig. 23, wherein the occlusion perfusion balloon is in a medium inflation configuration;

[0107] Fig. 28 is a top perspective view of the occlusion perfusion balloon system of Fig. 23, wherein the occlusion perfusion balloon is in a full inflation configuration;

[0108] Fig. 28A is a cross-sectional view of the occlusion perfusion balloon system of Fig. 23, taken along line 28A-28A of Fig. 28;

[0109] Fig. 29A is side perspective view of a second preferred embodiment of an alternative occlusion perfusion balloon system that may be utilized with any of the occlusion catheter systems of the preferred embodiments described herein, wherein the occlusion perfusion balloon is in an inflated configuration;

[0110] Fig. 29B is a cross-sectional view taken along line 29B-29B of Fig. 29A;

[0111] Fig. 30A is a side perspective view of a third preferred embodiment of an alternative occlusion perfusion balloon system that may be utilized with any of the occlusion catheter systems of the preferred embodiments of the occlusion catheter system described herein, wherein the occlusion perfusion balloon is in an inflated configuration;

[0112] Fig. 30B is a cross-sectional view taken along line 30B-30B of Fig. 30A;

[0113] Fig. 31 is a side elevational view of fourth and fifth preferred embodiments of an alternative occlusion perfusion balloon system that may be utilized with any of the occlusion catheter systems of the preferred embodiments of the occlusion catheter systems described herein, wherein the occlusion perfusion balloon is in an inflated configuration;

[0114] Fig. 31A is a cross-sectional view of the occlusion perfusion balloon system of Fig. 31, taken along line 31A-31A of Fig. 31 in accordance with the fourth preferred embodiment;

[0115] Fig. 31B is a cross-sectional view of the occlusion perfusion balloon system of Fig. 31, taken along line 31A-31A of Fig. 31, wherein a restraining filament is incorporated into the occlusion perfusion balloon in accordance with the fifth preferred embodiment;

[0116] Fig. 32 is a top perspective view of a sixth preferred embodiment of an occlusion perfusion balloon system comprised of an occlusion perfusion balloon assembly that may be utilized with any of the preferred occlusion catheter systems described herein, wherein the occlusion perfusion balloon assembly is in an inflated configuration;

[0117] Fig. 32A is a cross-sectional view of the occlusion perfusion balloon system of Fig. 32, taken along line 32A-32A of Fig. 32;

[0118] Fig. 33 is a top perspective view of a seventh preferred embodiment of an occlusion perfusion balloon system that may be utilized with any of the preferred occlusion catheter systems described herein, wherein the occlusion perfusion balloon is in an inflated configuration;

[0119] Fig. 34 is a top perspective view of a eighth preferred embodiment of an occlusion perfusion balloon system that may be utilized with any of the preferred occlusion catheter

systems of described herein, wherein the occlusion perfusion balloon is in an inflated configuration;

[0120] Fig. 35A is a side perspective view of a ninth preferred embodiment of an occlusion/perfusion balloon system that may be utilized with any of the occlusion catheter systems described herein, wherein the occlusion/perfusion balloon is in a partially inflated configuration within a vessel;

[0121] Fig. 35B is a side elevational view of the occlusion/perfusion balloon system of Fig. 35A, wherein the balloon is in the partially inflated configuration;

[0122] Fig. 35C is a side elevational view of the occlusion/perfusion balloon system of Fig. 35A, wherein the balloon is in a fully inflated configuration;

[0123] Fig. 35D is a side perspective view of an occlusion/perfusion balloon system in accordance with a tenth preferred embodiment that may be utilized with any of the occlusion catheter systems described herein;

[0124] Fig. 36 is a top perspective view of an occlusion catheter system in accordance with a fourth preferred embodiment of the present invention;

[0125] Fig. 36A is a cross-sectional view of the occlusion catheter system of Fig. 36, taken along line 36A-36A of Fig. 36;

[0126] Fig. 36B is a cross-sectional view of the occlusion catheter system of Fig. 36, taken along line 36B-36B of Fig. 36;

[0127] Fig. 36C is a cross-sectional view of the occlusion catheter system of Fig. 36, taken along line 36C-36C of Fig. 36;

[0128] Fig 37 is a top perspective view of an occlusion catheter system in accordance with a fifth preferred embodiment of the present invention;

[0129] Fig. 37A is a cross-sectional view of the occlusion catheter system of Fig. 37, taken along line 37A-37A of Fig. 37;

[0130] Fig. 37B is a cross-sectional view of the occlusion catheter system of Fig. 37, taken along line 37B-37B of Fig. 37;

[0131] Fig. 37C is a cross-sectional view of the occlusion catheter system of Fig. 37, taken along line 37C-37C of Fig. 37;

[0132] Fig. 38 is a top perspective view of a catheter system in accordance with a sixth preferred embodiment of the present invention, wherein the system is particularly adaptable for use as a hemorrhage exclusion system;

[0133] Fig. 39 is a top perspective view of a catheter system in accordance with a seventh preferred embodiment of the present invention, wherein the system is also particularly adaptable for use as a hemorrhage exclusion system;

[0134] Fig. 39A is a cross-sectional view of the catheter system of Fig. 39, taken along line 39A-39A of Fig. 39;

[0135] Fig. 39B is a magnified top perspective view of the catheter system of Fig. 38, taken from within shape 39B of Fig. 39;

[0136] Fig. 40 is a top perspective view of a first preferred inflation control system that may be utilized with any of the occlusion catheter systems of the first, second and third preferred embodiments of the occlusion catheter system of Figs. 1-18;

[0137] Fig. 41 is a top perspective view of a second preferred inflation control system that may be utilized with any of the occlusion catheter systems of the first, second and third preferred embodiments of the occlusion catheter system of Figs. 1-18;

[0138] Fig. 41A is a cross-sectional view of a third preferred inflation control system that may be utilized with any of the occlusion catheter systems of the first, second and third preferred embodiments of the occlusion catheter system of Figs. 1-18;

[0139] Fig. 42A is a side perspective view of a first preferred infection/contamination control system that may be utilized with any of the occlusion catheter systems of the first, second and third preferred embodiments of the occlusion catheter system of Figs. 1-18;

[0140] Fig. 42B is a magnified top perspective view of the infection/contamination control system of Fig. 42A, taken from within shape 42B of Fig. 42A;

[0141] Fig. 43 is side perspective view of a catheter system in accordance with a eighth preferred embodiment of the present invention, wherein the system is adaptable for use with a guidewire;

[0142] Fig. 43A is cross-sectional view of the catheter system of Fig. 43, taken along line 43A-43A of Fig. 43;

[0143] Fig. 43B is a side perspective view of an alternative preferred catheter system in accordance with the eighty preferred embodiment of the present invention;

[0144] Fig. 43C is a cross-sectional view of the alternative preferred catheter system of Fig. 43B, taken along line 43C-43C of Fig. 43B;

[0145] Fig. 44 is bottom perspective view of an occlusion catheter system in accordance with a ninth preferred embodiment of the present invention, wherein the system is adaptable for use as a power injection compatible vascular occlusion balloon catheter; and

[0146] Fig. 45 is side elevational view of an occlusion catheter system in accordance with a tenth preferred embodiment of the present invention, wherein the system is also adaptable for use as an infusion catheter.

DETAILED DESCRIPTION OF THE INVENTION

[0147] The foregoing and other features and advantages of the invention will become more apparent from the following detailed description of exemplary embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

[0148] Certain terminology is used in the following description for convenience only and is not limiting. Unless specifically set forth herein, the terms “a”, “an” and “the” are not limited to one element but instead should be read as meaning “at least one”. The words "right", "left", "lower" and "upper" designate directions in the drawings to which reference is made. The words "inwardly" or “distally” and "outwardly" or “proximally” refer to directions toward and away from, respectively, the patient’s body, or the geometric center of the preferred occlusion balloon catheter and related parts thereof. The words, “anterior”, “posterior”, “superior,” “inferior”, “lateral” and related words and/or phrases designate preferred positions, directions and/or orientations in the human body to which reference is made and are not meant to be limiting. The terminology includes the above-listed words, derivatives thereof and words of similar import.

[0149] It should also be understood that the terms “about,” “approximately,” “generally,” “substantially” and like terms, used herein when referring to a dimension or characteristic of a component of the invention, indicate that the described dimension/characteristic is not a strict boundary or parameter and does not exclude minor variations therefrom that are functionally the same or similar, as would be understood by one having ordinary skill in the art. At a minimum, such references that include a numerical parameter would include variations that, using

mathematical and industrial principles accepted in the art (e.g., rounding, measurement or other systematic errors, manufacturing tolerances, etc.), would not vary the least significant digit.

[0150] While the invention has been described in connection with various embodiments, it will be understood that the invention is capable of further modifications. This application is intended to cover any variations, uses or adaptations of the invention following, in general, the principles of the invention, and including such departures from the present disclosure as, within the known and customary practice within the art to which the invention pertains.

[0151] Certain terminology is used in the following description for convenience only and is not limiting. The words “lower,” “bottom,” “upper” and “top” designate directions in the drawings to which reference is made. The words “inwardly,” “outwardly,” “upwardly” and “downwardly” refer to directions toward and away from, respectively, the geometric center of the vascular occlusion catheter system, and designated parts thereof, in accordance with the present disclosure. Unless specifically set forth herein, the terms “a,” “an” and “the” are not limited to one element, but instead should be read as meaning “at least one.” The terminology includes the words noted above, derivatives thereof and words of similar import.

[0152] It should also be understood that the terms “about,” “approximately,” “generally,” “substantially” and like terms, used herein when referring to a dimension or characteristic of a component of the invention, indicate that the described dimension/characteristic is not a strict boundary or parameter and does not exclude minor variations therefrom that are functionally similar. At a minimum, such references that include a numerical parameter would include variations that, using mathematical and industrial principles accepted in the art (e.g., rounding, measurement or other systematic errors, manufacturing tolerances, etc.), would not vary the least significant digit.

Vascular Occlusion Systems

[0153] Furthermore, while the invention is described as a balloon catheter occlusion system, it will be understood that the described variants of the preferred balloon catheter system may be used clinically for a variety of different therapeutic or diagnostic indications involving vascular interventions, including, for example and without limitation, arterial occlusion, angioplasty, stent delivery, atherectomy, drug delivery, imaging or the like. In accordance with an exemplary and preferred embodiment, the preferred balloon catheter system is well suited for use as an arterial

occlusion balloon catheter, and in particular an aortic occlusion balloon catheter. Applications making advantageous use of embodiments of the invention may use any suitable access site for vascular intervention. For example, applications of the catheter system may involve access at the femoral artery, the brachial artery, the subclavian artery, or any other blood vessel suitable for use as an access site for catheterization, including venous vessels.

[0154] Moreover, it will be understood that while a balloon is referred to herein as an example of occlusion member, other types of occlusion members are contemplated as being expressly within the scope of the present invention. In addition to balloons, the occlusion members may include stents, coils, grafts, sheaths, cages, plugs, supported or unsupported membranes, or the like. The occlusion member, including the occlusion balloons, may be fabricated of biocompatible polymer or biocompatible metal, or combinations thereof, and may be woven or non-woven in structure. Biocompatible metals include, but are not limited to, stainless steel, titanium, nitinol, cobalt, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, such as cobalt-chromium-molybdenum or zirconium-titanium-tantalum alloys. The metals and/or the polymers may be elastic, shape memory or superelastic. More recent advanced materials may also be used, including carbon fibers, carbon nanotubes or carbon composites, such as carbon/polyetheretherketone (PEEK). In the present application, when the term “balloon” is used it is intended to mean a fluid fillable member capable of expanding from a first smaller diameter to a second larger diameter under the influence of fluid introduced into the balloon. Unless otherwise stated, a balloon is not limited in size, shape, geometry, material or construction. When used in this application, the term “occlusion member” is intended to be inclusive of balloons and other structures, including stents, coils, grafts, sheaths, cages, plugs or supported or unsupported membranes.

[0155] In one aspect of the invention, a pressure relief apparatus for a balloon catheter is provided. The balloon catheter includes a shaft having a balloon attached to the distal end of the shaft, an inflation/deflation lumen for inflating and deflating the balloon and a pressure relief port. The pressure relief port may alternatively be formed through the wall of the inflation/deflation lumen, through the wall of the proximal hub, or may be part of the fluid pathway that couples to the proximal hub. A pressure relief member is secured either across or within the pressure relief port to form a fluid tight seal. The fluid tight seal is configured to open

or fail (e.g. open, burst, rupture, tear or leak) at a predetermined pressure to release pressure from the inflation/deflation lumen through the pressure relief port. The predetermined pressure may be less than or equal to the rated burst pressure of the balloon.

[0156] In one variation, the pressure relief port comprises a first outwardly opening passage and a second passage in fluid communication with the first passage. The second passage extends inwardly from the first passage and opens into the inflation/deflation lumen. In this variation, the cross-sectional area of the first passage may be larger than the cross-sectional area of the second passage.

[0157] In one embodiment, a wall extends radially between an inside end of the first passage of the pressure relief port and an outside end of the second passage of the pressure relief port. The pressure relief member may be disposed adjacent the wall and across the outside end of the second passage of the pressure relief port to block the pressure relief port and form a fluid tight seal. The pressure relief member may be a plastic film, a thin metallic film, a pop-off valve or other similar biased valve. The bias of the pressure relief member is less than or equal to a predetermined pressure known to protect the device from overpressure and burst and to protect the patent from injury.

[0158] In another aspect, a pressure relief apparatus for a balloon catheter having a balloon with a rated burst pressure includes a proximal hub adapted for connection to a proximal end portion of a balloon catheter shaft wherein a pressure relief port is formed in the proximal hub. In one embodiment, the proximal hub may comprise a plastic body that defines an inflation/deflation lumen and a may or may not include guide wire lumen or a working lumen.

[0159] The proximal hub may be formed from a substantially rigid material and includes a wall defining the inflation/deflation lumen for directing a fluid into and from an inflation/deflation lumen of the catheter shaft. In this alternative embodiment, the proximal hub includes a pressure relief port formed through the wall of the hub and a pressure relief member disposed across or in the pressure relief port, forming a fluid tight seal across the pressure relief port. The pressure relief member is configured to open or fail, (e.g. open, rupture, tear, burst or leak), at a predetermined pressure to release pressure from the inflation/deflation lumen through the pressure relief port.

[0160] In the case of an occlusion balloon, it is preferable that the balloon be of a compliant or partially compliant balloon material and typically formed relatively distensible plastic or

polymer material. The balloons may also be constructed of substantially compliant or partially compliant polymeric, biocompatible materials, such as PBAX or other related polymers. The balloon may alternatively be constructed of a non-compliant material, which will typically expand less than about ten percent (10%), and more typically less than about five percent (5%), when pressurized from their rated operating pressure to the balloon's rated burst pressure.

[0161] Where an occlusion balloon is the occlusion member, the proximal and distal ends of the balloon may be attached to the catheter shaft using techniques known in the art, for example, with an adhesive such as a medical grade epoxy adhesive or may be reflowed to become an integral part of the catheter shaft wall.

[0162] In the following description, when reference is made to the terms “proximal” or “proximally” it is intended to mean a portion or component of the preferred vascular occlusion catheter system that is oriented away from the body into which the system is or is intended to be placed. Conversely, when reference is made to the terms “distal” or “distally” it is intended to mean a portion or component of the preferred balloon catheter system that is oriented toward the body into which the system is or is intended to be placed. Thus, for example, the guiding atraumatic tip described hereinafter is located at a distal end of the balloon catheter system, while the proximal hub is located at a proximal end of the balloon catheter system.

[0163] As shown in the accompanying figures, the vascular occlusion catheter system 100 generally includes a catheter assembly having a first catheter member 130 having a first lumen 230, a second catheter member 110 having a second lumen 210, a third catheter member 120 having a third lumen 220, an occlusion member 140, a proximal hub 190 and a guiding atraumatic tip 150. The first lumen 230 of the first catheter member 130 extends longitudinally through the first catheter member and is coupled at its proximal end to the proximal hub 190 and at its distal end to a proximal section of the third catheter member 120 and in communication with the third lumen 220 of the third catheter member. The second lumen 210 of the second catheter member 110 also extends longitudinally through the second catheter member 110, and terminates in a first port 160 distal to a proximal end of and within a space 142 at least partially bounded by the occlusion member 140, best seen in Figs. 9 and 9A. Where the occlusion member 140 is a balloon, the second lumen 210 is in communication with the space 142 bounded by the balloon 140 and conveys inflation fluid to and from the balloon 140 from a source external to the balloon catheter system 100. The third catheter member 120 is coupled at a

proximal end thereof to a distal end of the first catheter member 130 such that the third lumen 220 of the third catheter member 120 is in communication with the first lumen 230 of the first catheter member 130. As best seen in Fig. 1, the second catheter member 110 and the third catheter member 120 are positioned in longitudinal co-axial spaced apart relationship from one and other along a longitudinal axis 131 of the first catheter member 130 thereby defining an intermediate region 115 of the first catheter member 130 within the space 142 that is not covered by either the second catheter member 110 or the third catheter member 120.

[0164] When a balloon is the occlusion member 140, balloon 140 is attached, at its proximal end 144 to a distal end of the second catheter member 110 and at its distal end 146 to a proximal end of the third catheter member 120. Referring to Figs. 2-5, a proximal radio opaque marker 158 may be affixed to the first catheter member 130 at or near the first port 160, which is near the attachment position of the inflatable balloon at the proximal end 144 of the balloon 140. A distal radio opaque marker 159 may be affixed to the first catheter member 130 near the attachment position on the distal end 146 of the balloon 140. The proximal and distal radio opaque markers 158, 159 may be implemented as bands made of a radio opaque material. In one example, the radio opaque material is a metal that is radio opaque such as stainless steel, or an alloy, such as a platinum iridium alloy. In another example, the proximal and distal radio opaque markers 158, 159 may be sections of the catheters that have been impregnated with radio opaque material such as for example stainless steel or a suitable alloy. In another example, the proximal and distal radio opaque markers 158, 159 may be implemented as bands or sections of plastic or a polymer such as PEBAX that has been mixed with barium sulfate. The implementation of the proximal and distal radio opaque markers 158, 159 on the catheter system would aid in visualization of the balloon position within the vasculature using fluoroscopy or x-ray.

[0165] When a balloon is used as the occlusion member 140, in operation, balloon 140 is inflated by introducing an inflation fluid, such as saline, from an external source, such as a syringe, coupled to the proximal hub 190, into and through the second lumen 210, out of the first port 160 and into the space 142 within the balloon 140. As is known in the art, the inflation fluid is introduced until the balloon 140 is inflated to a desired diameter or a desired fluid pressure of the inflation fluid is achieved, or both. Deflation of the balloon 140 is simply the reverse process of withdrawing the inflation fluid from the space 142 of the inflation balloon 140. In its deflated or collapsed state, the inflation balloon 140 will be positioned either within or adjacent to the

intermediate region 115 of the first catheter member 130, thereby providing a lower profile to the entire balloon catheter system 100.

[0166] When a fluid is used as the pressure source to activate the occlusion member, such as to fill an occlusion balloon, that fluid may be a liquid, including water, saline, contrast medium or any combination thereof, or may be a gas, including carbon dioxide, helium, air or oxygen. Catheter balloons may be inflated with gas, rather than liquid, because the balloon can be inflated and deflated more quickly than a comparable volume of saline or other liquid inflation media. Although air is relatively easy to load into an inflation device, air is not an ideal inflation medium, because air does not rapidly dissolve in blood. In the event that the balloon bursts or leaks, bubbles could be formed in the arterial blood, impeding blood flow. In addition, as nitrogen is a chief component of air, nitrogen has thrombogenic properties that may present clinical risks in the event the balloon bursts. Accordingly, it is desirable to use a gas other than air and to prevent air contamination of the gas used. A preferable gas used for balloon inflation is either carbon dioxide or helium.

[0167] As will be described in more detail hereinafter, with exemplary reference to Figs. 19-22, the present invention also includes alternative embodiments of occlusion control systems that regulate the position of the occlusion member 140 and the apposition of the occlusion member 140 against a vascular wall surface. It is understood that when the occlusion member 140 is at least partially in non-apposition with the vascular wall surface, that fluid flow or perfusion past the occlusion member may or will occur. This fluid flow or perfusion may be of circulatory blood, or may be of fluids introduced through the preferred vascular occlusion catheter system, or through another fluid introduction system, such as a catheter.

[0168] The third catheter member 120 is depicted more particularly in Figs. 4-5. The third catheter member 120 is coupled at its proximal end concentrically about a distal end of the first catheter member 130. A plurality of side ports 170 pass through a side wall of the third catheter member 120 and provides fluid communication between the third lumen 220 and external environments proximate the external surface of the third catheter member 130, such as the inside of the patient's major vessel when inserted into the patient. The distal end of the first catheter member 130 is preferably positioned within the third lumen 220 and does not occlude the plurality of side ports 170, but terminates proximal to the plurality of side ports 170 such that fluid may be freely communicated between the first lumen 230, the third lumen 220 and the

plurality of side ports 170 to either introduce fluid or withdraw fluid through the plurality of side ports 170. The plurality of side ports 170 may also be utilized for power injection of a contrast medium into the major vessel of the patient distally relative to the occlusion member 140, as will be described in further detail herein. It will also be understood by those skilled in the art that maintaining fluid communication between the first lumen 230, the second lumen 220 and the plurality of side ports 170 also permits introduction of tethered sensors, such as flow sensing wires, pressure sensing wires, ischemia sensors or the like to the distal end of the balloon catheter system 100.

[0169] Finally, a guiding atraumatic tip 150 is coupled to a distal end section of the third catheter member 120. The guiding atraumatic tip 150 may be made of an elastic, shape memory and/or superelastic material, such as a metal or polymer. A reinforcing member 152 (depicted in phantom) may optionally be included either within the guiding atraumatic tip 150 or wound about an external surface of the guiding atraumatic tip 150 to offer additional reinforcement to the tip 150. A proximal end of the guiding atraumatic tip 150 is coupled to a distal end of the third lumen 220 of the third catheter member 120 and a distal end of the guiding atraumatic tip 150 projects distally from the third catheter member 120 and preferably has a generally circular profile when viewed from the side in a relaxed configuration. The atraumatic tip 150 preferably curves proximally from the longitudinal axis 131 upwardly and then back toward the central longitudinal axis 131 of the balloon catheter system 100, but leaves an unconnected end 161 of the distal end of the guiding atraumatic tip 150 as it returns to a position proximate the longitudinal axis 131. The atraumatic tip 150 is designed and configured to permit the tip 150 to assume a linear or delivery configuration co-axial with the central longitudinal axis 131 of the balloon catheter system 100 for delivery and introduction into the patient's vessel through a catheter. Once the atraumatic tip 150 is introduced into the vessel and emerges from the introduction catheter, the atraumatic tip 150 preferably returns to the relaxed configuration to inhibit introduction of the catheter system 100 into smaller vessels as it moves into the patient.

[0170] In the first embodiment of the preferred balloon catheter system 100 illustrated in Figs. 1-8, the balloon catheter system 100, when the inflatable balloon 140 is in an uninflated condition, is of sufficiently small cross-segmental dimension to pass through a 6 to 8 French (2-2.67 mm)-percutaneous sheath, such as, for example 7 French (2.33 mm). Thus, the balloon catheter system 100 has a greatest outer diameter, when the inflatable balloon 140 is uninflated,

of less than 2-2.67 mm. It will be understood by those skilled in the art that the balloon catheter system 100 is not limited to a dimension sufficient to pass through a 2-2.67 mm (6 to 8 French) percutaneous sheath, but that such lower profile or smaller is generally considered desirable to enable passage of a balloon catheter system 100 through tortuous vasculature and to a desired position within the body for purposes of arterial occlusion. The balloon catheter system 100 is, therefore, not intended to be limited to this dimensional size, but may be made of smaller or larger dimension as desired or needed.

[0171] In one embodiment of the invention, the first catheter member 130 is formed of stainless steel metal and is radio opaque, in accordance with another embodiment of the invention, it is constructed of nitinol and in accordance with still another embodiment of the invention it is formed of biocompatible polymers. The first catheter member 130 lends columnar strength to the balloon catheter system 100 and provides a functional backbone for carrying the second catheter member 110, the third catheter member 120 and the inflatable balloon.

[0172] The outer diameter of the first catheter member 130 is smaller than the inner diameter of the second lumen 210 of the second catheter member 110, thereby forming an annular space 212 between the outer surface of the first catheter member 130 and the inner surface of the second catheter member 110, as best shown in Fig. 7.

[0173] In one embodiment of the invention, the distal end of the second catheter member 110 may have a tapering or narrowing diameter of the outside surface and/or the second lumen 210 diameter. Preferably, there is a minimal amount of narrowing on the second catheter member 110 and the proximal lumen 210 to allow the annular space 212 to remain sufficiently large down the length of the second catheter member 110 to permit adequate flow of the inflation fluid through the annular space 212.

[0174] Turning now to Figs. 4-5, the distal portion of the balloon catheter system 100 is illustrated. The first lumen 230 of the first catheter member 130 may be used as a pressure monitoring line, such as by using a fluid column therein to sense pressures through the plurality of side ports 170. The first lumen 230 may alternatively be used to introduce or withdraw fluids, such as drugs, contrast media or blood through the plurality of side ports 170. Referring to Fig. 5, the outer surface of the first catheter member 130 is coupled to at least a portion of the inner surface of the distal lumen 220, such that there is no annular space between the outer surface of the first catheter member 130 and the inner surface of the second lumen 220. In one

embodiment, the portion of the inner surface of the distal lumen 220 may be the length of the second lumen 220. Referring now to Fig. 4, the third catheter member 120 or the proximal shaft of the atraumatic tip 150 may include a plurality of segments of distally decreasing durometer polymer to provide a step-down transition to the guiding atraumatic tip 150. The number of step down durometer segments may be between one (1) and six (6) and may step down in decreasing fashion by regular or irregular increments, such, for example 75D, 63D, 55D, 40D, etc. Alternatively, the third catheter member 120 may be made of a single durometer polymer, but having distally tapering wall thicknesses to impart a flexibility gradient to the third catheter member 120. The plurality of segments of decreasing durometer plastic may be abutted and be bonded together or may be manufactured from a single extrusion including decreasing durometer hardness.

[0175] Referring now to Fig. 5, the guiding atraumatic tip 150 is shown in its unstrained and undeformed state as it would assume when in the body. The guiding atraumatic tip 150 is used to minimize trauma to or perforation of the vasculature as the balloon catheter system 100 is advanced through the patient's tortuous anatomy, and to prevent departure from an intended vessel path, such as diversion into an undesired branch vessel. The size, shape and material of the distal section of the tip 150 are such that it will not pass into collateral vessels during delivery. The guiding atraumatic tip 150 has a constrained state when passing through an introducer sheath in which the distal section of the tip 150 is substantially linear and co-axial with the longitudinal axis 131 of the balloon catheter system 100, and a relaxed state, as depicted, which is assumed upon exiting the introducer sheath and entering a blood vessel. In one embodiment, the guiding atraumatic tip 150 may be formed of an elastomeric, shape memory or superelastic material, including metals and polymer. In another embodiment, the guiding atraumatic tip 150 may have a reinforcing elastic, shape memory or superelastic core 152 which aids in transition between the unstressed state and the stressed state of the guiding atraumatic tip 150. In accordance with an exemplary embodiment of the tip 150, the outer diameter of the guiding atraumatic tip 150 (in the relaxed state) may be between 1-7 mm, preferably between 2-6 mm and most preferably between 4-6 mm.

[0176] Turning now to Fig. 6, the proximal portion of the balloon catheter system 100 is illustrated. The second catheter member 110 is coupled to the proximal hub 190 and the distal end of the first catheter member 130 may be operably coupled to the proximal hub 190 at a

proximal bonding site using an adhesive 180 to bond an inner wall surface of the proximal hub 190 to an outer wall surface of the first catheter member 130. As illustrated, the proximal hub 190 has two fluid pathways 192 and 194. A first fluid pathway 192 communicates with the first lumen 230 of the first catheter member and a second fluid pathway 194 communicates with the second lumen 210 of the second catheter member 120. It will be understood that the proximal hub 190 may be configured to have more than two fluid pathways, with each fluid pathway communicating with a different lumen in the balloon catheter system 100. The first fluid pathway 192 of the proximal hub 190 may be connected to an external pressure sensor, which would transduce pressure from a fluid column within the first lumen 230 and through the plurality of side port 170 (Fig. 5).

[0177] Referring to Figs. 1-5, in the first preferred embodiment, the balloon catheter system or occlusion catheter system 100 also includes the plurality of side ports 170 positioned between the occlusion member 140 and the atraumatic tip 150 in the third catheter member 120, the proximal shaft of the atraumatic tip 150 and/or the first catheter member 130. The plurality of side ports 170 preferably facilitates power injection of a contrast medium into the patient's major vessel distally relative to the occlusion member 140 during use. Such power injection may be utilized for procedures such as angiography or arteriography. In the first preferred embodiment, the plurality of side ports 170 include a first side port 170a, a second side port 170b, a third side port 170c, a fourth side port 170d, a fifth side port 170e and a sixth side port 170f. The plurality of side ports 170 is not limited to including six (6) side ports 170a, 170b, 170c, 170d, 170e, 170f and the occlusion catheter system 100 may include more or less side ports 170a, 170b, 170c, 170d, 170e, 170f and the plurality of side ports 170 may be sized and configured in nearly any manner desired by the designer and/or medical technician for pressure sensing, power injection or other related procedures utilizing the plurality of side ports 170.

[0178] Turning now to Figs. 9 and 9A-9D, an alternative or second preferred embodiment of the balloon catheter system 300 is illustrated. The balloon catheter system 300 includes generally a catheter assembly including a first catheter member 310 having at least two lumens 210, 330 passing longitudinally through the first catheter member 310, a second catheter member 320 having a single lumen 230 passing longitudinally through the second catheter member 320 and an inflatable balloon 140. The first catheter member 310 is coupled at its proximal end to a proximal hub 190 (not shown) and at a distal end thereof to a proximal end of the inflatable

balloon 140. The second catheter member 320 is coupled at its distal end to a proximal end of the first catheter member 310 such that one of the first lumen 210 or the second lumen 330 is in fluid flow communication with the second catheter member 320. The other of the first lumen 210 or the second lumen 330 terminates at the distal end of the first catheter member 310. For purposes of illustration only and for clarity in the following description, it will be assumed that second lumen 330 terminates at the distal end of the first catheter member 310 and has a distal port opening 160, it will also be assumed that the first lumen 210 is in fluid flow communication with the second catheter member 320. As with the first embodiment of the balloon catheter system 100 described above, the second embodiment of the balloon catheter system 300, when the inflation balloon 140 is in an uninflated condition, is of a sufficiently small cross-sectional diameter to pass through a 6-8 French (2-2.67 mm)-percutaneous sheath, such as, for example, 7 French (2.33 mm). Thus, the balloon catheter system 300 has a greatest outer diameter, when the inflatable balloon 140 is uninflated, that is less than 2-2.67 mm. It will be understood by those skilled in the art that the balloon catheter system 100 is not limited to a dimension sufficient to pass through a 2-2.67 mm (6 to 8 French) percutaneous sheath, but that such lower profile or smaller is generally considered desirable to enable passage of a balloon catheter system 300 through tortuous vasculature and to a desired position within the body for purposes of arterial occlusion. The balloon catheter system 300 is, therefore, not intended to be limited to this dimensional size, but may be made of smaller or larger dimension as desired or needed.

[0179] Referring now to Fig. 9A, the first catheter member 310 includes first lumen 330 and a second lumen 210. The second catheter member 320 includes a first lumen 220. The first catheter member 310 terminates at its distal end within the space defined under the balloon 140, where it is both coupled to the second catheter member 320 and terminates with an open port 160 in fluid communication with lumen 330, permitting fluid to be delivered to and from the balloon 140 for inflation and/or deflation. In accordance with an alternative embodiment, the distal end of the first catheter member 310 may, optionally, be tapered, such as by narrowing the wall thickness of the catheter member 310 or by crimping the first catheter member 310 to a smaller diameter, thereby compressing and reducing the open area of the first lumen 330 and the second lumen 210. If the first catheter member 310 is crimped to a tapered diameter, it is preferable that the extent of the crimping does not compress the open area of the first lumen 330 and the second lumen 210 in a manner that significantly reduces fluid flow there through of fluid flow pressures

therein, particularly with the second lumen 330 when it is used for the inflation fluid for the inflation balloon 140.

[0180] The third catheter member 130 is positioned within one of the first lumen 210 or the second lumen 330 of the first catheter member 310. As depicted in the figures, this arrangement is illustrated with the third catheter member 130 being positioned within the first lumen 210 of the first catheter member 310 and also within the first lumen 220 of the second catheter member 320. The outer diameter of the third catheter member 130 is less than the inner diameter of the first lumen 210 of the first catheter member 310 as well as smaller than the inner diameter of the first lumen 210 of the second catheter member 320, such that an annular space 212 is formed therebetween as depicted in Figure 9C. In the more distal region of the first catheter member 310, within the region of the distal taper discussed above, the annular space 212 is compressed and either closes or is substantially closed to fluid flow, thereby effectively sealing the distal end of the first lumen 210 near the transition to the proximal attachment point of the inflatable balloon 140, as depicted in Fig. 9A.

[0181] The third catheter member 130 passes longitudinally into the first lumen 230 of the second catheter member 320 and has a first lumen 230 passing longitudinally through the third catheter member 130. As with the first catheter member 130 of the first alternative embodiment described above, the first lumen 230 of the third catheter member 130 permits monitoring of conditions within the body, such as arterial pressure monitoring by hydrostatic pressure within a fluid column within the first lumen 230, or allows for the introduction of tethered sensors, such as flow sensing wires, pressure sensing wires or the like to the distal end of the balloon catheter system 300. First lumen 230 may also be used to deliver drugs, contrast media, or permit the introduction or withdrawal of fluids to and from the body.

[0182] As with the alternative embodiment discussed above with reference to Figs. 1-8, the embodiment depicted in Figs. 9 – 9D may, optionally, include the second catheter member 320 being constructed of plural segments having distally increasing flexibility, such as by making the segments of distally decreasing durometer polymer or fashioning the second catheter member 320 to have a distally tapering wall thickness. The second catheter member 320 may be formed of discrete segments abutted and coupled together to form an elongated second catheter member 320 with either distally decreasing durometer or distally tapering wall thicknesses. Alternatively,

the second catheter member 320 may be made by extrusion or molding polymers of distally decreasing durometer or distally tapering wall thicknesses.

[0183] As with the alternative embodiment of the balloon catheter system 100, the second catheter member 320 includes an open port 170 that is in fluid flow communication with the first lumen 230 of the third catheter member. Similarly, as with the balloon catheter system 100, the balloon catheter system 300 of the second preferred embodiment includes a guiding atraumatic tip (not shown in Figs. 9-9D) as described above with reference to guiding atraumatic tip 150 of the first preferred embodiment, which is coupled to a distal end of the second catheter member 320.

[0184] With reference to Figs. 10 and 11, there is depicted an alternative embodiment of the guiding atraumatic tip 450. It will be understood that guiding atraumatic tip 450 may be employed with any of the foregoing embodiments of the preferred balloon catheter system 100 or of the second preferred balloon catheter system 300. The guiding atraumatic tip 450 is comprised generally of a polymeric cylindrical or tubular member 452 that has a distal section 454 that has been formed into a generally flattened cylinder having two generally planar opposing surfaces 455, 457 and two generally curved opposing surfaces 458, 459. The two generally planar opposing surfaces 455, 457 include an inner planar surface 455 and an outer planar surface 457. The distal section 454 has a distally extending section 453 that projects distally and a curved section 456 continuous with the distally extending section that curves away from the central longitudinal axis 131 of the balloon catheter system 100, 300 then proximally toward the occlusion balloon 140 and subtends a generally circular arc toward the central longitudinal axis 131 of the balloon catheter system 100, 300. The angle of the curve may be between about one hundred eighty degrees (180°) and three hundred fifty-five degrees (355°), more preferably between about two hundred seventy degrees (270°) and three hundred fifty degrees (350°) and even more preferably between about three hundred degrees (300°) and three hundred fifty degrees (350°) such that a gap is provided between the terminal end of the generally cylindrical flattened distal section 454 and the more proximal surface of the distal section 454. It will also be understood that the distally extending section 453 and curved section 456 may be formed as a generally in-plane circular shape or may be formed as an out-of-plane generally helical shape, where a terminal end of the curved section 456 is laterally displaced from the central longitudinal axis 131 of the balloon catheter system 100 or balloon catheter

system 300. In this manner, the generally flattened distal section 454 is characterized by a generally circular profile. The atraumatic tip 550 preferably operates in a manner similar to the guiding atraumatic tips 150, 350 of the previously described preferred embodiments, but is made of a polymer material without the need for a reinforcing member 152, as described above.

[0185] In the preferred embodiment, a tip thickness T_t is defined between the inner planar surface 455 and the outer planar surface 457 and tip width W_t is defined between the opposing curved lateral surfaces 458, 459. The tip width W_t is preferably greater than the tip thickness T_t such that the atraumatic tip 450 is readily flexible about a central tip axis 450a. The atraumatic tip 450 is preferably flexible about the central tip axis 450a from the substantially circular profile in the relaxed configuration to the introduction configuration, wherein the atraumatic tip 450 is relatively straight or positioned on the longitudinal central axis 431. In the preferred embodiment, the tip thickness T_t is less than the tip width W_t . The relatively smaller tip thickness T_t in comparison to the tip width W_t facilitates the flexing of the atraumatic tip 450 from the relaxed configuration with the substantially circular profile to the introduction configuration, wherein the atraumatic tip 450 is substantially straight and is positioned on the longitudinal central axis 431 and renders bending of the atraumatic tip 450 laterally more difficult.

[0186] A tapered transition section 451 may, optionally, be provided between the polymeric cylindrical or tubular member 452 and the generally flattened cylindrical distal section 454. Guiding atraumatic tip 450 may be integral with the third catheter member 120 of balloon catheter system 100 or the second catheter member 320 of balloon catheter system 300. Alternatively, guiding atraumatic tip 450 may be fabricated as a discrete member and joined to the third catheter member 120 of balloon catheter system 100 or the second catheter member 320 of balloon catheter system 300.

[0187] The guiding atraumatic tip 450, which may be made of polyether block amide (PBAX, Arkema, Paris France) having a durometer of forty (40D), or a similar polymer, such as polyurethane or polyethylene, that is compatible with the catheter shaft and balloon to make bonding easier and more secure. As discussed above, the guiding atraumatic tip 450 may be either cylindrical or tubular, or have a solid cylindrical section and a tubular section. The curve of the guiding atraumatic tip 450 may be made by any of a wide number of processes, including, for example, injection molding, round extrusion, flattening and post-processing into the curved

distal section 456, a flat extrusion bonded to a round extrusion, or an extrusion that is pressed into a hot die having a shape of the desired curved distal section 450.

[0188] The atraumatic tip 450 may include a radio opaque tip marker 460. The radio opaque tip marker 460 may be implemented as a band surrounding the tip 450 or as a two-dimensional planar material on one or both of the planar opposing surfaces 455. Alternatively, the radio opaque tip marker 460 may be located at the most distal point of the atraumatic tip 450 indicated at 460' in Fig. 11. The band or the planar material may be composed of any suitable radio opaque material, such as for example, stainless steel or a suitable alloy such as platinum iridium. In another example embodiment, the tip 450 may be made of a plastic or polymer, such as for example, PEBAX that is impregnated with a radio opaque material. In another example embodiment, the plastic or polymer composition forming the tip 450 may be mixed with a radio opaque compound such as for example barium sulfate sufficient to permit visualization of the tip 450 using x-ray or fluoroscopy.

[0189] In an alternative embodiment described herein with reference to Figs. 12-18, a balloon catheter system 500 generally includes a catheter assembly having a stiffener member 530, which is preferably comprised of a solid wire, an inflation catheter member 510 having an inflation lumen 610, a distal catheter member 520, an inflatable balloon 540, a proximal hub 590 and a guiding atraumatic tip 550. The stiffener member 530 is secured to the proximal hub 590 and extends longitudinally through the inflation catheter member 510 along the longitudinal axis 531 of the stiffener member 530, which substantially comprises the longitudinal axis 531 of the catheter system 500. The stiffener member 530 includes a proximal end 530b, a distal end 530c and defines the longitudinal axis 531. The stiffener member 530 is coupled at the proximal end 530b to the proximal hub 590 and at the distal end 530c to a proximal section of the distal catheter member 520. The proximal hub 590 includes an inflation connection port 590a with an inflation fluid pathway 594 therein. The inflation lumen 610 of the inflation catheter member 510 is in fluid communication with the inflation fluid pathway 594 and extends longitudinally through the inflation catheter member 510. The inflation lumen 610 preferably terminates at a first port 560 distal to a proximal balloon end 544 of and within a space 542 defined by the inflatable balloon 540, such that the inflation lumen 610 is in fluid flow communication with the space 542 within the inflatable balloon 540 to convey an inflation fluid to and from the inflatable balloon 540 from a source external the balloon catheter system 500 that is preferably connected

to the inflation connection port 590a. The distal catheter member 520 is coupled at a proximal end thereof to a distal end of the stiffener member 530. The inflation catheter member 510 and the distal catheter member 520 are positioned in longitudinal co-axial spaced apart relationship from one and other along a longitudinal axis 531 of the stiffener member 530, thereby defining an intermediate region 530a of the stiffener member 530 within the space 542 within the inflatable balloon 540 that is not covered by either the inflation catheter member 510 or the distal catheter member 520.

[0190] In this preferred embodiment of the balloon catheter system 500, when the occlusion balloon 540 is in an uninflated condition, the catheter system 500 is of sufficiently small cross-segmental dimension to pass through a five to six (5-6) French (1.67-2 mm) percutaneous sheath, such as, for example six (6) French (2 mm) introduction sheath. Thus, the balloon catheter system 500 has a greatest outer diameter, when the occlusion balloon 540 is uninflated, of less than 1.67-2 mm. The balloon catheter system 500 of the preferred embodiment of Figs. 12-18 preferably has a smaller greatest outer diameter when the occlusion balloon 540 is uninflated than the above-described preferred catheter system 100 because of the solid stiffener member 530, which replaces the first catheter 130 with the first lumen 230 therein. It will be understood by those skilled in the art that the balloon catheter system 500 is not limited to a dimension sufficient to pass through a five to six (5-6) French percutaneous sheath, but that such lower profile or smaller maximum diameter when the occlusion balloon 540 is uninflated is generally considered desirable to enable passage of a balloon catheter system 500 through tortuous vasculature and to a desired position within the body for purposes of arterial occlusion. In addition, the reduced maximum diameter limits the size of the percutaneous introduction puncture in the patient's skin and may limit the clinical requirements for the medical professionals performing the procedure. The balloon catheter system 500 is, therefore, not intended to be limited to this dimensional size, but may be made of smaller or larger dimension as desired or needed.

[0191] In general, the alternative embodiment described herein with reference to Figs. 12-18 includes the stiffener member 530, preferably the solid wire, instead of a tube with a lumen. The solid stiffener member 530 may be implemented as a solid flexible wire made of any suitable material that may be formed into a wire-like component. Examples of materials that may be used include polymeric materials, biocompatible metals, nitinol and stainless steel. The stiffener

member 530 of this preferred embodiment may be constructed of a solid nitinol hypotube. The nitinol hypotube stiffener member 530 provides flexibility and sufficient stiffness along the longitudinal axis 531 and is generally a small diameter tube or wire. The stiffener member 530 implementation without a lumen removes the fluid communication with a third lumen. The stiffener member 530 does, however, allow for the implementation of a catheter system having a lower profile than the first embodiment of the catheter system 100.

[0192] In the alternative embodiment of Figs. 12-18, the catheter system 500 preferably includes a pressure sensor 533 mounted distally of the occlusion balloon 540 or on a surface of the occlusion balloon 540 proximate its distal balloon end 546. The pressure sensor 533 preferably communicates with a processor 501 that may be wired to the pressure sensor 533 or may receive pressure readings from the pressure sensor 533 through wireless communication techniques. In the preferred embodiment, the pressure sensor 533 is wired to and in communication with the processor 501 by an electrical wire 533a that carries pressure signals from the pressure sensor 533 to the processor 501. The electrical wire 533a of the preferred embodiment extends at least partially through the inflation lumen 610 and is in electrical contact with the pressure sensor 533 and the processor 501. The preferred pressure sensor 533 is mounted to an external surface of the distal catheter member 520 to sample and detect pressures at the distal side of the inflatable balloon 540. For example, the pressure sensor 533 may sample pressure near the distal balloon end 546 of the inflatable balloon 540 during use and transmit the pressure readings to the processor 501 for review by an operator, medical technician or physician. The pressure sensor 533 may also be utilized to provide pressure measurements at predetermined intervals to the processor 501. The processor 501 may adjust the inflation of the occlusion balloon 540 to permit limited flow through the vessel to the distal balloon end 546 of the occlusion balloon 540. The processor 501 may be controlled to maintain a range of pressures at the distal balloon end 546 or a minimum pressure based on inflation and deflation of the occlusion balloon 540.

[0193] Referring to Figs. 12-18, the inflatable balloon 540 is attached at its proximal balloon end 544 to a distal end of the inflation catheter member 510 and at its distal balloon end 546 to a proximal end of the distal catheter member 520. In operation, the inflatable balloon 540 is inflated by introducing an inflation fluid, such as saline, from an external source, such as a syringe, coupled to the proximal hub 590, into and through the inflation lumen 610, out of the

first port 560 and into the space 542 within the inflatable balloon 540. Inflation and deflation of the inflatable balloon 540 in Figs. 1-8 is performed as described above with reference to Figs. 1-8.

[0194] Referring to Figs. 15 and 16, the distal catheter member 520 is fixedly coupled at its proximal end concentrically about a distal end of the stiffener member or solid wire 530. In the preferred example shown in Fig. 16, the distal catheter member 520 has a lumen 620 extending longitudinally through the distal catheter member 520 and coupled concentrically about a proximal end of the atraumatic tip 550. The distal catheter member 520 is not limited to including the lumen 620 and may be configured as substantially solid between its proximal and distal end or integrally formed with or fixed to the atraumatic tip 550. The guiding atraumatic tip 550 may be constructed of an elastic, shape memory and/or superelastic material, such as a metal or polymer. A reinforcing member 552 (depicted in phantom) may optionally be included either within the guiding atraumatic tip 550 or wound about an external surface of the guiding atraumatic tip 550 to offer additional reinforcement to the tip 550. The guiding atraumatic tip 550 projects distally from the distal catheter member 520 and preferably has a generally flattened configuration, curving proximally and then toward the central longitudinal axis 531 of the balloon catheter system 500, but leaving a disconnected end 561 at the distal end of the guiding atraumatic tip 550. The atraumatic tip 550 is preferably designed and configured such that the atraumatic tip 550 is able to unfold from a relaxed configuration (Fig. 16) and assume a linear configuration co-axial with the central longitudinal axis 531 of the balloon catheter system 500 for delivery. During introduction, the atraumatic tip 550 is preferably straightened along the longitudinal axis 531 in an introduction configuration such that the atraumatic tip may be positioned within a catheter for introduction and returns to the substantially circular-shape in the relaxed configuration when the atraumatic tip 550 emerges from the catheter in the patient's vessel. Specifically, the atraumatic tip 550 preferably has sufficient flexibility such that the substantially circular curve of the atraumatic tip 550, in the relaxed configuration, may be straightened coaxially with the longitudinal axis 531 for introduction of the catheter system 500 into the patient's vessel through an introduction catheter.

[0195] The atraumatic tip 550 of the preferred embodiment has a smaller thickness between the inner and outer planar surfaces 555, 557 than the lateral outer opposing surfaces 558, 559 of the atraumatic tip 550. This flattened shape of the atraumatic tip 550 facilitates the folding or

flexing of the atraumatic tip along the longitudinal axis 531. The shape and configuration of the preferred atraumatic tip 550 preferably limits bending and folding of the atraumatic tip 550 laterally relative to the longitudinal axis 531. In addition, the relatively flattened atraumatic tip 550 provides manufacturing advantages when the atraumatic tip is constructed of a polymeric material compared to the substantially cylindrical atraumatic tip 150 shown in the first preferred embodiment. In the preferred embodiment, the lateral outer surfaces 558, 559 are substantially arcuate, but are not so limited and may be relatively planar or otherwise configured.

[0196] In the preferred embodiment, a tip thickness T_t is defined between the inner planar surface 555 and the outer planar surface 557 and tip width W_t is defined between the opposing curved lateral surfaces 558, 559. The tip width W_t is preferably greater than the tip thickness T_t such that the atraumatic tip 550 is readily flexible about a central tip axis 550a. The atraumatic tip 550 is preferably flexible about the central tip axis 550a from the substantially circular profile in the relaxed configuration to the introduction configuration, wherein the atraumatic tip 550 is relatively straight or positioned on the longitudinal central axis 531. In the preferred embodiment, the tip thickness T_t is less than the tip width W_t . The relatively smaller tip thickness T_t in comparison to the tip width W_t facilitates the flexing of the atraumatic tip 550 from the relaxed configuration with the substantially circular profile to the introduction configuration, wherein the atraumatic tip 550 is substantially straight and is positioned on the longitudinal central axis 431 and renders bending of the atraumatic tip 550 laterally more difficult.

[0197] The atraumatic tip 550 of the alternative preferred embodiment of the catheter system 500 is preferably configured and functions similar to the above-described atraumatic tip 450 of the preferred embodiment of Figs. 10 and 11. The atraumatic tip 550 is preferably formed into the generally flattened frusta-cylinder having the two generally planar opposing inner and outer surfaces 555, 557 and two generally curved opposing lateral surfaces 558, 559. The atraumatic tip 550 has a distally extending section 553 that projects distally and a curved section 556 continuous with the distally extending section 553 that curves away from the central longitudinal axis 531 of the balloon catheter system 500 then proximally toward the occlusion balloon 540 and subtends a generally circular arc toward the central longitudinal axis 531 of the balloon catheter system 500. In the relaxed configuration, the atraumatic tip 550 preferably has a substantially circular profile when viewed from the side, but is not so limited and may have

nearly any sized and shaped profile that limits introduction of the atraumatic tip 550 into an alternative or smaller vessel path than desired by the physician or medical professional. The angle of the curvature may be between about one hundred eighty degrees (180°) and three hundred fifty-five degrees (355°), more preferably between about two hundred seventy degrees (270°) and three hundred fifty degrees (350°) and even more preferably between about three hundred degrees (300°) and three hundred fifty degrees (350°) such that a gap 561a is provided between the unconnected end 561 of the generally cylindrical flattened distal section 554 and the more proximal surface of the distal section 554. The generally flattened section 554 provides manufacturing and functional advantage when compared to a cylindrical atraumatic tip, such as the atraumatic tip 150 described in Figs. 4 and 5. The flattened atraumatic tip 550 of this alternative preferred embodiment permits flexibility of the atraumatic tip 550 about a plane or axis extending substantially laterally through the atraumatic tip 550, generally perpendicular to the longitudinal axis 531 to accommodate straightening of the atraumatic tip 550 coaxially with the longitudinal axis 531 for introduction. In addition, the greater lateral thickness of the atraumatic tip 550 laterally relative to the longitudinal axis 531 provides stiffness to the atraumatic tip 550 such that the tip 550 is more difficult to bend or flex out of its preferred shape laterally relative to the longitudinal axis 531 during placement of the balloon 540 and movement of the catheter system 550 through the major vessels of the patient.

[0198] A tapered transition section 551 is preferably provided between a substantially cylindrical portion of the distal catheter member 520 and the generally flattened distal section 554. The preferred guiding atraumatic tip 550 is integral with the distal catheter member 520 of balloon catheter system 500. Alternatively, the guiding atraumatic tip 550 may be fabricated as a discrete member and joined to the distal catheter member 520 of balloon catheter system 500.

[0199] The guiding atraumatic tip 550 is preferably constructed of a polyether block amide (PBAX, Arkema, Paris France) having a durometer of forty (40D), or a similar polymer, such as polyurethane or polyethylene, that is compatible with the distal catheter member 520 and the balloon 540 to make bonding easier and more secure. As discussed above, the guiding atraumatic tip 550 may be generally flattened, cylindrical or tubular, or have a solid cylindrical section and a tubular section. The curve of the guiding atraumatic tip 550 may be made by any of a wide number of processes, including, for example, injection molding, round extrusion, flattening and post-processing into the curved distal section 556, a flat extrusion bonded to a

round extrusion, or an extrusion that is pressed into a hot die having a shape of the desired curved distal section 550.

[0200] The atraumatic tip 550 may include a radio opaque tip marker 560a at the unconnected end 561. The radio opaque tip marker 560a may be implemented as a band surrounding the tip or unconnected end 561 or as a two-dimensional planar material on one or both of the planar opposing surfaces 555, 557. The radio opaque marker 560a may be constructed of any suitable radio opaque material, such as for example, stainless steel or a suitable alloy such as platinum iridium. In another example embodiment, the tip 550 may be constructed of a plastic or polymer, such as for example, PEBAX that is impregnated with a radio opaque material to define the radio opaque tip marker 560a. In another example embodiment, the plastic or polymer composition forming the atraumatic tip 550 may be mixed with a radio opaque compound such as for example barium sulfate sufficient to permit visualization of the tip 550 using x-ray or fluoroscopy to define the radio opaque tip marker 560a.

[0201] As noted above in the description of the first preferred embodiment of the balloon catheter system 100 illustrated in Figs. 1-8, the balloon catheter system 100, when the inflatable balloon 140 is in an uninflated condition, is of sufficiently small cross-segmental dimension to pass through a 6 to 8 French (2-2.67 mm) percutaneous sheath, such as, for example, 7 French (2.33 mm). Thus, the balloon catheter system 100 has a greatest outer diameter, when the inflatable balloon 140 is uninflated, of less than 2-2.67 mm. It will be understood by those skilled in the art that example implementations of the alternative embodiment of the balloon catheter system 500 described herein with reference to Figs. 12-18 may have an even smaller cross-sectional dimension due to the use of the stiffener member or solid wire 530 instead of a catheter with a lumen. The diameter of the stiffener member 530 is smaller than the inner diameter of the inflation lumen 610 of the inflation catheter member 510, thereby forming an annular space 612 between the outer surface of the solid stiffener member 530 and the inner surface of the inflation catheter member 510. The dimensions of the inner diameter of the inflation lumen 610 and the diameter of the stiffener member 530 may be specified in example implementations to provide optimal inflation fluid flow as well as a reduced profile that may further ease deployment.

[0202] Turning now to Figs. 14-16, the distal portion of the balloon catheter system 500 is illustrated. As shown in Fig. 16, the outer surface of the stiffener member 530 is coupled to at least a portion of the inner surface of the second lumen 620, such that there is no annular space between the outer surface of the stiffener member 530 and the inner surface of the second lumen 620. Referring now to Fig. 15, the distal catheter member 520 may include a plurality of segments of distally decreasing durometer polymer to provide a step-down transition to the guiding atraumatic tip 150. The number of step down durometer segments may be between one (1) and six (6) and may step down in decreasing fashion by regular or irregular increments, such, for example 75D, 63D, 55D, 40D, etc. Alternatively, the distal catheter member 520 may be made of a single durometer polymer, but having distally tapering wall thicknesses to impart a flexibility gradient to the third catheter member 520. The plurality of segments of decreasing durometer plastic may be abutted and be bonded together or may be manufactured from a single extrusion including decreasing durometer hardness.

[0203] In an alternative embodiment, the stiffener member 530 may extend completely into the space shown for the second lumen 620 such that the distal catheter member 520 completely covers the distal end of the stiffener member 530. The atraumatic tip 550 may be formed as an extension of the second catheter body 520.

[0204] Turning now to Fig. 17, the proximal portion of the balloon catheter system 500 is illustrated. The inflation catheter member 510 is coupled to the proximal hub 590 and the proximal end of the stiffener member or solid wire 530 is fixedly coupled to the proximal hub 590 at a proximal bonding site, preferably using an adhesive 580, to bond an inner wall surface of the proximal hub 590 to an outer wall surface of the solid stiffener member 530. The amount of adhesive 580 used is preferably sufficient to fixedly couple the solid stiffener member 530 to the proximal hub 590. As shown in Fig. 17, the adhesive 580 may fill the entire portion 592 of the proximal hub 590 that holds the stiffener member 530. The proximal end of the stiffener member 530 is not limited to being adhesively bonded to the proximal hub 590 and may be otherwise fastened, secured or fixed to the proximal hub 590, as long as the stiffener member 530 is substantially secured to the proximal hub 590 such that the stiffener member 530 provides stiffness for the balloon catheter system 500, the stiffener member 530 is substantially secured relative to the inflation catheter member 510 and the occlusion balloon 540, the assembly is able to withstand the normal operating conditions of the catheter system 500 and securement results

in a structure able to perform the preferred functions of the catheter system 500, as is described herein. Since the solid stiffener member 530 has no lumen, no fluid pathway is needed in the portion 592 that holds the stiffener member 530 and the stiffener member 530 can have a relatively small diameter, thereby reducing the overall diameter of the catheter system 500. As illustrated, the proximal hub 590 has an inflation fluid pathway 594. The inflation fluid pathway 594 communicates with the inflation lumen 610 of the inflation catheter member 520. In this alternative preferred embodiment, the inflation lumen 610 is defined between the outer surface of the stiffener member 530 and an inner surface of the inflation catheter member 510. It will be understood that the proximal hub 590 may be configured to have more than the inflation fluid pathway 594, with each fluid pathway communicating with a different one of any additional lumens in the balloon catheter system 500.

[0205] It will be understood that when reference is made to coupling two or more component sections, members or pieces of the balloon catheter system, that conventional catheter material bonding modalities are intended to be encompassed and employed. For example, a wide variety of biocompatible adhesives useful in catheter manufacture are known, similarly, thermobonding techniques used in catheter manufacture are also known. Thus, for example, where it is described that the guiding atraumatic tip is coupled to the third catheter member or to the distal catheter member, it is contemplated that such coupling may be made using thermobonding, biocompatible adhesives or other methods of fixedly bonding two components in medical devices.

[0206] It will also be understood by those skilled in the art that it is well known to manufacture catheters of a variety of medical grade, biocompatible polymers, such as, for example and without limitation, silicone, nylon, polyurethane, PETE, latex, thermoplastic elastomers, polyether block amides (PBAX, Arkema, Paris, France). Alternatively, it is known to manufacture catheters of metals, such as nitinol or stainless steel. Similarly, it is known to manufacture catheters of metal-reinforced polymer, such as, for example and without limitation, stainless steel braiding over polyurethane, stainless steel helical windings over silicone or nitinol reinforced polymer. Thus, any or all of the first catheter member, the second catheter member, the inflation catheter member, the distal catheter member, or the third catheter member in any of the foregoing embodiments may be fabricated of biocompatible polymers, biocompatible metals or metal-reinforced polymers, as is known in the art.

[0207] It will also be understood by those skilled in the art that while the implementation of radio opaque markers are described in the context of embodiments described with reference to Figs. 1-8, it may be desirable to include radio opaque marker bands positioned at the proximal and distal ends of the balloon in implementations of embodiments described above with reference to Figs. 9-11, and embodiments described above with reference to Figs. 12-18. It is also desirable to include length markers on the outer catheter shaft to indicate to the physician the insertion depth of the balloon catheter system 100, the balloon catheter system 300, or the balloon catheter system 500. The length markers may be printed or laser etched onto the outside of the catheter shaft.

[0208] In each of the foregoing described embodiments of the vascular occlusion systems depicted in Figs. 1-18, the catheter may also include sensors, transmitters, receivers, interrogators or other means for measuring physical and/or physiological parameters distal and/or proximal one or more of the expandable occlusion members, including, for example blood pressure sensors, heart rate sensors, flow sensors, chemical sensors, temperature sensors, oxygenation sensors, biological sensors, imaging sensors or the like.

[0209] The preferred catheters, sheaths, guide wires, balloons or other occlusion members, or other components that are introduced into the vasculature may be coated with a variety of coatings, including without limitation, antibacterial, antimicrobial, lubricants, anticoagulant and/or antifouling coatings. Thus, any or all components of any of the preferred systems described herein may further include one or more biocompatible coatings.

Occlusion Control System

[0210] Control over the apposition of the occlusion member against the vessel walls is preferably accomplished by controlling the inflation of the preferred balloons, selection of the size of the occlusion member, placement of the occlusion member or other methods and techniques that provide control to users of the preferred systems. Aortic occlusion may result in arterial hypertension upstream of an occlusion site as pressure builds against the occlusion member. If the arterial pressure reaches a deleterious hypertensive state, vascular rupture, stroke or other undesirable events may occur that could potentially injure the patient. Conversely, after the vascular occlusion is complete and blood flow is restored, there is a potential for concomitant

drop in arterial blood pressure potentially leading to a hypotensive event that could result in a dangerously low blood pressure and, in extreme cases, cardiac arrest.

[0211] The preferred control systems are not limited to their utility with the preferred vascular occlusion catheter systems 100, 300, 500 of the present invention, but may be used virtually with any type of vascular occlusion system. Thus, in Fig. 19, there is shown a generic type of vascular occlusion system 700, while in Figs. 20-22, the vascular occlusion catheter system is generically shown schematically and is designated by box 710, to denote a non-specific vascular occlusion catheter system, including, for all of Figs. 19-22, without limitation, the first, second and third preferred vascular occlusion catheter systems 100, 300, 500 described above. Other vascular occlusion catheter systems that rely upon a pressure being applied to an occlusion member to urge the occlusion member into apposition with a vascular wall, thereby at least partially occluding the blood vessel are expressly included within the scope of occlusion control system of the present invention, such as the additional occlusion/perfusion systems described herein.

[0212] In each of the preferred embodiments of the occlusion control systems, the pressure sources are denominated schematically by a generic box or oval to denote that a wide variety of pressure sources are intended to be included within the preferred embodiments of the invention. The pressure source may be a syringe or syringe-like inflation device, an endoflator device, a pump or other similar means of applying a pressure to the occlusion member in the vascular occlusion catheter 710. As noted above, when a fluid is used as the pressure medium to activate the occlusion member, such as to fill an occlusion balloon, that fluid may be a liquid, including water, saline, contrast medium or any combination thereof, or may be a gas, including carbon dioxide, helium, air or oxygen. The fluid source may, in the instance of a liquid, be a liquid reservoir, a pre-measured volume of liquid in a vessel that is removably engageable with the pressure source or other similar container for holding and dispensing liquid from the fluid source to the pressure source. In the instance of a gas, the fluid source may be a gas reservoir or a pre-measured volume of pressurized gas in a canister that is removably engagement with the pressure source to deliver the pre-measured volume of gas to the pressure source. A canister with a pre-measured gas volume at a known pressure is also contemplated, for example, a carbon dioxide cartridges that are commercially available in a wide variety of mass of pressurized gas, including without limitation eight, twelve, sixteen, twenty-five or thirty-three grams (8g, 12g, 16g, 25g,

33g). Converting mass to volume of a gas at standard temperature and pressure (STP) typically entails resolving the gas constant equation, as follows: $V = nRT/P$ wherein V is volume, n is mass, R is the molar volume of the gas, T is temperature (Kelvin) and P is pressure (atm). The volume of gas needed to inflate a specific occlusion member to a given inflation volume and inflation pressure may be calculated utilizing this preferred formula.

[0213] Referring to Fig. 19, a first embodiment of the occlusion control system 700 includes a vascular occlusion catheter 711 has a proximal hub 790 that includes at least one pressure line port 794. The pressure line port 794 communicates with a pressure conduit or lumen 712 in the vascular occlusion catheter 711. The pressure conduit 712 may be a lumen within the vascular occlusion catheter 711 or may be a tubular conduit placed within a lumen in the vascular occlusion catheter 711. A pressure accumulator or reservoir 730 communicates with the pressure line port 794 via pressure line 732 that is, in turn, coupled to a connecting conduit 720 associated with pressure line port 794. An actuator 744, such as a fluid pump, is coupled to the pressure accumulator 730 and to a fluid source (“FS”) 742. The actuator 744 is also operably coupled to a controller or central processing unit (“CPU”) 750. The controller 750 operates as a computer control and may have an interface, not shown, that permits programming of computer control software that monitors and controls activation of the actuator 744 to regulate pressure in the occlusion member 740 and to collect data from sensors associated with the occlusion control system 700.

[0214] In accordance the preferred embodiment of occlusion control system 700, the occlusion member 740 has a first pressure P_{max} , which is below the failure pressure of the occlusion member 740. The pressure accumulator 730 is preferably pressurized, such as with a fluid, to an accumulator pressure P_a , where the accumulator pressure $P_a < P_{max}$, and where the accumulator pressure P_a is less than a predetermined maximum safe blood pressure P_{bp} within the vascular system being occluded, such that $P_a < P_{bp} < P_{max}$. When the occlusion member 740 is in apposition with the vascular wall and the vessel is substantially occluded, the pressure exerted at the occlusion member 740 may be considered the apposition pressure P_{app} , wherein the apposition pressure P_{app} is substantially equal to the pressure in the accumulator 730 or the accumulator pressure P_a . In this preferred embodiment, when during occlusion the blood pressure P_{bp} against the occlusion member 740 exceeds the apposition pressure P_{app} , the accumulator pressure P_a in the accumulator 730 and in the occlusion member 740 is exceeded

and the occlusion member 740 may yield to the blood pressure P_{bp} and release apposition against the vascular wall surface and allow fluid flow past the occlusion site. Since the apposition pressure P_{app} within the occlusion member 740 and the accumulator pressure P_a within the accumulator 730 is preferably a closed system, the pressure in the accumulator 730, such as the accumulator pressure P_a , will rise and when blood pressure reduces to be less than the accumulator pressure P_a in the accumulator 730 and the apposition pressure P_{app} within the occlusion member 740, the occlusion member 740 will preferably reestablish occlusion.

[0215] This effect of automatically adjusting apposition pressure P_{app} in response to an elevation in blood pressure P_{bp} , causing a release of apposition against the vascular wall and, therefore, releasing the occlusion and permitting fluid flow past the occlusion site, in turn lowers the blood pressure head against the occlusion member 740. When the blood pressure P_{bp} upstream of the occlusion member 740 has downwardly adjusted to below the accumulator pressure P_a and the apposition pressure P_{app} , the occlusion member 740, under the influence of the elevated pressure in the accumulator 740, reestablishes apposition and, therefore, occlusion is reestablished. This cycle may be likened to “burping” as a pressure release.

[0216] One further aspect of the occlusion control system 700 illustrated in Fig. 19, is that the preferred computer controller 750 preferably monitors the accumulator pressure P_a , the blood pressure P_{bp} and the apposition pressure P_{app} and, when required, either automatically or after providing audible or visual notification to a medical practitioner and input from the medical practitioner, actuates the actuator 744 to draw fluid from fluid source 742 and communicates the drawn fluid to the occlusion member 740 to increase the apposition pressure P_{app} . Conversely, where apposition pressure P_{app} is determined by the computer controller 750 or by the medical practitioner to be too high, the actuator 744 may be controlled to withdraw fluid from the occlusion member 740, lowering apposition pressure P_{app} and moving fluid from the occlusion member 740 to the fluid source 742.

[0217] The occlusion control system 700 is preferably a bidirectional system capable of increasing the occlusion pressure or apposition pressure P_{app} or decreasing the occlusion pressure or apposition pressure P_{app} under either manual control or under control of the computer processor 750. Moreover, the preferred occlusion control system 700 is operable to automatically release the apposition when the blood pressure P_{bp} impinging on the occlusion member 740 is above a pre-determined level (typically that regarded as safe for the patient).

Accordingly, the occlusion control system 700 preferably includes a pressure sensor that is able to sense blood pressure on the proximal or distal side of the balloon 740 to measure the blood pressure P_{bp} impinging on the occlusion member 740 and to adjust inflation pressure or apposition pressure P_{app} of the occlusion member 740 to at least partially control the blood pressure P_{bp} in the vessel.

[0218] An alternative or second preferred embodiment of occlusion control system 751 is depicted in Fig. 20. In alternative or second preferred embodiment of the occlusion control system 751, the occlusion catheter 710 is under control of a pressure source (“I”) 752, which in the case of a fluid is coupled to a fluid source (“FS”) 751. Similar to the first preferred occlusion control system 700, the pressure source 752 may be under manual control, under automatic control of a computer processor 753, or under manual control interfacing with the computer processor 753. A pressure conduit 754 preferably bifurcates into a free line 756 and a regulated line 758. A check valve 760 is preferably positioned in-line in the regulated line 758. An actuable valve 762 is preferably interposed in both the free line 756 and the regulated line 758, and is operable to select the free line 756, the regulated line 758 or both the free line 756 and the regulated line 758. A fluid conduit 766 leads from the actuable valve 762 to the occlusion catheter 710. A pressure sensor 764 may be interposed within fluid conduit 766 to monitor pressure during operation of the second preferred occlusion control system 751 and may alternatively be positioned in the occlusion control system 751 to detect pressure at various locations relative to the system 751, such as within an occlusion balloon or at proximal and/or distal ends of the occlusion balloon. The pressure sensor 764 may be a pressure gauge, electronic pressure sensor or pressure sensor that provides visual signal to the medical practitioner directly or may feed a pressure signal to the computer processor 753 that controls the occlusion control system 751, in turn, upon the pressure signal and/or displays pressure data to the medical practitioner.

[0219] Referring to Fig. 21, there is shown yet another alternative or third preferred embodiment of an occlusion control system 800. Unlike the occlusion control system 751 of the second preferred embodiment, the preferred occlusion control system 800 preferably has a single pressure conduit communicating between the occlusion catheter 710, which is utilized herein as a generic occlusion catheter 710, and a pressure source (“I”) 752, which, in the case of a fluid, is coupled to a fluid source (“FS”) 801. Similar to the occlusion control system 700 of the first

preferred embodiment, the pressure source (“P”) 802 of the third preferred embodiment may be under manual control, under automatic control of a computer processor 803, or under manual control interfacing with the computer processor (“CPU”) 803. A pressure conduit 804 preferably provides fluid communication between the pressure source 802 and the occlusion catheter 710. A check valve 806 is preferably in-line with the pressure conduit 804. The check valve 806 may be any type of manual or automatically actuatable valves that operate both to prevent back-flow of an inflation fluid and as a pressure relief if there is an overpressure in the occlusion catheter 710. A fluid conduit 866 leads from the check valve 806 to the occlusion catheter 710. A pressure sensor 808 may be interposed within the fluid conduit 804, 866 to monitor pressure during operation of the occlusion control system 800. The pressure sensor 808 may be a pressure gauge that provides visual signal to the medical practitioner directly or may output a pressure signal to computer control 803 that controls the occlusion control system 800, in turn, upon the pressure signal and/or displays pressure data to the medical practitioner. An additional feature of the occlusion control system 800 may be the addition of a timer 810. The timer 810 is preferably incorporated into the computer processor 803 or may be positioned in-line with the fluid conduit 804, 866. The timer 810 preferably communicates a time signal to the check valve 806, to the computer control 803 and/or to the pressure source 802, as indicated by dashed lines in Fig. 21. The time signal may be a regular, consistent signal representative of the timer status, or may be a single time elapse signal that activates the check valve 806, the pressure source 802 and/or the CPU 803 to withdraw pressure communicated to the occlusion catheter 710. Similarly, the timer 810 may issue a series of time signals according to a pre-programmed routine stored in the CPU 803 or in the timer 810 itself, to control cycling of the pressure source 802 and/or opening and closing cycles of the check valve 806.

[0220] In a fourth preferred embodiment of the occlusion control system 820, the pressure source 802 is again in communication with the occlusion catheter 710 via a pressure conduit 826. An actuatable valve 828 is preferably in-line in the pressure conduit 826 and operates under the influence of a controller 822. The controller 822 is preferably operably coupled, such as by electrical, mechanical or electromechanical coupling, to both the actuatable valve 828 and to the pressure source 802. The controller 822 may also communicate with a computer control or CPU 803. In this preferred embodiment, the actuatable valve 828 is operable under the control of the controller 822 to open or close to allow pressure from the pressure source 802 to be applied to

the occlusion catheter 710 or to withdraw pressure from the occlusion catheter 710, depending upon the pressure state at the occlusion member 740 of the preferred occlusion catheter 710. Again, similar to the above-described embodiments the pressure source 802 is operable to increase pressure or decrease pressure applied to the occlusion catheter 710, such as by drawing fluid from fluid source 801 and supplying the fluid to the occlusion catheter 710 to inflate the occlusion balloon 740. In the reverse, the pressure source 802 is operable to decrease pressure by drawing fluid from the occlusion balloon 740, thereby deflating the occlusion balloon 740, releasing apposition and occlusion at the vascular wall and permitting perfusion past the occlusion member 740 when the occlusion member 740 is positioned in the vessel.

[0221] Pressure sensors 764, 808 may be positioned external the occlusion catheter 710, as shown in the second and third preferred embodiments of Figs. 20 and 21, or may be incorporated in the occlusion catheter 710 itself and be positioned distal the occlusion member 740 with either an electrical connection at the proximal hub 790, may be wireless or may be comprised of pressure sensors positioned both distal and proximate relative to the occlusion member 740 and external relative to the occlusion catheter 710 to sense pressure both distal relative to the occlusion member 740, proximal the occlusion member 740, within the occlusion member 740 and within the pressure line 804, 866, 826, 766 proximal the occlusion member 740.

[0222] In each of the foregoing described preferred embodiments of the occlusion control systems 700, 751, 800, 820 depicted and described with reference to Figs. 19-22, the systems may also include sensors, transmitters, receivers, interrogators or other means for measuring physical and/or physiological parameters distal and/or proximal one or more of the expandable occlusion members, including, for example blood pressure sensors, heart rate sensors, flow sensors, chemical sensors, temperature sensors, oxygenation sensors, ischemia sensors, biological sensors, imaging sensors or the like.

Occlusion/Perfusion Systems

[0223] The preferred occlusion control systems 700, 751, 800, 820 described above function to control the apposition of the occlusion member 140, 540, 740 against the vascular wall of the patient's vessel by regulating the pressure applied to the occlusion member 140, 540, 740. These preferred systems 700, 751, 800, 820 regulate and mitigate both hypertension and hypotension, by controlling the relative degree of occlusion and perfusion, such as during and after a vascular

repair procedure. The occlusion catheter system 100, 300, 500, 700, itself, can also be configured to regulate the degree of occlusion and perfusion. Referring to Figs. 23-34, there are provided alternative preferred occlusion balloon geometries that at least partially occlude the vascular lumen of the patient's vessel, thereby permitting at least a partial perfusion flow of blood past the occlusion site, if desired by the physician or medical technician performing a procedure with the preferred systems.

[0224] A first preferred embodiment of the occlusion/perfusion balloon system 1200 is depicted in Figs 23-28A, a second preferred embodiment of the occlusion/perfusion balloon 1220 is depicted in Figs. 29A and 29B, a third preferred embodiment of the occlusion/perfusion balloon 1230 is depicted in Figs. 30A and 30B, a fourth and fifth preferred embodiment of the occlusion/perfusion balloon system 1240 is depicted in Figs. 31-31B, a sixth preferred embodiment of an occlusion/perfusion balloon system 1260 is depicted in Figs. 32 and 32A, a seventh preferred embodiment of the occlusion/perfusion balloon system 1270 is depicted in Fig. 33, an eighth preferred embodiment of the occlusion/perfusion balloon system 1280 is depicted in Fig. 34, a ninth preferred embodiment of the occlusion/perfusion balloon system 2000 is depicted in Figs. 35A and 35B and a tenth preferred embodiment of the occlusion/perfusion balloon system 2100 is depicted in Fig. 35D.

[0225] Referring to Figs. 23-28A, a balloon 1201 of the occlusion/perfusion balloon system 1200 of the first preferred embodiment is fabricated of a substantially compliant biocompatible material, which may be a polymer, metal or composite material. The balloon 1201 of the occlusion/perfusion balloon system 1200 may alternatively be constructed of a substantially compliant material such that the balloon has a substantially defined shape in a fully inflated configuration that facilitates at least partial flow of fluid through channels 1206a. The term "substantially non-compliant" is intended to mean a compliance range of about zero to fifteen percent (0-15%) of its expanded diameter when inflated to its rated pressure. The balloon 1201 of the occlusion/perfusion balloon 1200 is preferably constructed of polymeric balloon materials, including, but not limited to, polyethylene terephthalate ("PET"), nylon, polyethylene, polyether block amides, such as PEBAX, polyurethane and polyvinyl chloride. Highly compliant polymer materials may be made substantially non-compliant by incorporation of composite materials, such as carbon fibers or other substantially non-elastic materials, into or on the polymer material

of the preferred balloon 1201. Similarly, a compliant balloon material may be constrained by a substantially non-compliant material, including polymer, metal or composite.

[0226] While the first preferred balloon 1201 is depicted in the accompanying figures in an elliptical-shape, it may have a different geometric shape than elliptical, including, without limitation, spherical, elliptical, conical, square, rectangular, dog-boned, tapered, stepped, or combinations thereof, such as, for example, conical/square or conical/spherical.

[0227] The first preferred occlusion/perfusion balloon system 1200 has a plurality of radially projecting members 1204 on the balloon 1201 when the occlusion/perfusion balloon system 1200 is in a partially-inflated to nearly fully-inflated configuration. The projecting members 1204 preferably project outwardly relative to a central longitudinal axis 1200a of the balloon 1201. Landing areas 1206 and channels 1206a are preferably defined between adjacent pairs of the projecting members 1204 when the balloon 1201 is partially-inflated to nearly fully-inflated. The balloon 1201 has a proximal end 1208 and a distal end 1212 that engage with and are joined to a proximal catheter member 1200b and a distal catheter member 1200c. The proximal catheter member 1200b includes an inflation lumen 1210 therein that facilitates inflation of the balloon. The balloon 1201 may be utilized with any of the preferred occlusion catheter systems 100, 300, 500, 700, 800, 1300, 1350 described herein by mounting the proximal and distal ends 1208, 1212 to the associated catheters. The first preferred balloon 1201 defines an open envelope within the balloon 1201, which receives an inflation fluid or gas to expand the balloon 1201 from a collapsed configuration (not shown), wherein the balloon 1201 is folded to have substantially the same diameter as the proximal and/or distal catheters 1200b, 1200c for introduction into a patient's vessel, to its fully expanded state or inflated configuration (Figs. 28 and 28A). In the inflated configuration, the projecting members 1204 and landing areas 1206 are nearly, visually imperceptible from each other, as the balloon 1201 has a substantially smooth, continuous outer surface shape in the inflated configuration. In contrast, in partially inflated configurations (Figs. 23-27), the projecting members 1204 and the landing areas 1206 or channels 1206a are visually identifiable with the projecting members 1204 typically positioned further from the central longitudinal axis 1200a than the associated landing areas 1206, with the channels 1206a defined in the spaces between the projecting members 1204.

[0228] In this first preferred embodiment of the occlusion/perfusion balloon system 1200, the channels 1206a of the balloon 1201 permit flow of fluid and blood past the balloon 1201,

substantially parallel or along the longitudinal axis 1200a when the system 1200 is inserted into a patient's vessel. The balloon 1201 of the first preferred occlusion/perfusion system 1200 may take on numerous shapes, each with channels 1206a depending on the level of inflation. For example, in a minimal inflation configuration (Figs. 23-25), the balloon 1201 has relatively deep and large channels 1206a to accommodate relatively significant blood and fluid flow, in a low inflation configuration (Fig. 26), the balloon 1201 has comparatively smaller channels 1206a, in a medium inflation configuration (Fig. 27), the balloon 1201 has again comparatively smaller channels 1206a and, in a full inflation configuration (Fig. 28), the balloon 1201 does not include perceptible channels, such that the vessel may be completely occluded when the balloon 1201 is inflated to the fully inflated configuration.

[0229] The plurality of radially projecting members 1204 and landing areas 1206 preferably extend along or substantially parallel to the central longitudinal axis 1200a of the balloon 1201. The radially projecting members 1204 may be oriented substantially parallel to the longitudinal axis 1200a of the balloon 1201 or may extend at an angle relative to the longitudinal axis 1200a of the balloon system 1201. For example, the projecting members 1204 may spiral in a curved manner along an outside surface 1200d of the balloon 1201, such that the channels 1206a extend in a substantially spiral or arcuate orientation relative to the longitudinal axis 1200a. The angular orientation of the projecting members 1204 and landing areas 1206 are preferably sufficient to channel blood or fluid flow along the length of the balloon 1201 within the vessel and to generally not impede flow or contribute substantially to highly disrupted blood flow that may result in thromboses. A preferred angular offset of the projecting members 1204 and landing areas 1206 may be between zero and forty-five degrees (0 - 45°) relative to the longitudinal axis 1200a of the balloon 1201. The radially projecting members 1204 may have either a generally linearly extending orientation, as is shown in the first preferred embodiment, a curvilinear orientation or nearly any other orientation that permits formation of the landing areas 1206 between the projecting members 1204 such that blood and fluid may flow through the landing areas 1206 when the balloon 1201 is inserted in the vessel and is at least partially inflated.

[0230] In the first preferred embodiment, the occlusion/perfusion balloon system 1200 includes four (4) regularly arrayed radially projecting members 1204 on or incorporated into the balloon 1201. The balloon 1201 is not limited to including four (4) regularly arrayed radially projecting members 1204 and associated landing areas 1206 and the number of radially

projecting members 1204 may be any number greater than two (2) that permit blood and fluid to flow through the landing areas 1206 when the balloon 1201 is in one of its partially inflated configuration. In the first preferred embodiment, there is sufficient surface area on the radially projecting members 1204 to seat in apposition with a vascular wall surface of the patient's vessel and that there is sufficient surface area in the landing areas 1206 to channel fluid or blood flow along a length of the balloon 1201 when the balloon 1201 is in one of its partially inflated configurations, such as the partially inflated configurations of Figs. 23-27.

[0231] In the first preferred embodiment of the occlusion/perfusion balloon system 1200, each of the plurality of radially projecting members 1204 has a generally circular or arcuate transverse profile, as depicted in Fig. 27, on an upper aspect 1205 thereof, and a stem portion 1207 that extends from the landing area 1206. The stem portion 1207 connects with the upper aspect 1205 of each radially projecting member 1204 such that the stem portions 1207 have a smaller stem width than an upper aspect width (See Fig. 24). In the first preferred embodiment, the projecting members 1204 each have an apex 1218 that is preferably located intermediate a length of each radially projecting member 1204 or centrally between the proximal end 1208 and distal end 1212 of the preferred balloon 1201. The projecting members 1204 of the first preferred embodiment also preferably include a proximal, generally flattened or planar area 1214 and a distal, generally flattened or planar area 1216 on an outermost surface of each radially projecting member 1204 relative to the central longitudinal axis 1200a. The proximal and distal generally flattened or planar areas 1214, 1216 preferably extend proximally and distally, respectively, from the apexes 1218. As will be seen from the series of Figs. 23-28, representing a sequence of the balloon 1201 of the first preferred occlusion/perfusion balloon system 1200 with increasing degrees of inflation, the apex 1218 forms the outermost equatorial circumference at the longitudinal midpoint of the balloon 1201 along the longitudinal axis 1200a. The proximal and distal generally flattened or planar areas 1214, 1216 facilitate diametric expansion and transition to the preferred fully elliptical-like shape of the fully expanded balloon 1201 in its full inflation configuration (See Fig. 28).

[0232] The first preferred embodiment of the occlusion/perfusion balloon system 1200 may be constructed by forming the balloon 1201 of two or more materials having differing hardness or moduli of elasticity. In the first preferred embodiment, as depicted in Fig. 28A, the balloon 1201 may be formed such that the plurality of projecting members 1204 are made of a higher

durometer material, while the landing areas 1206 are made of a relatively lower durometer material. These materials may be co-extruded or molded to define the preferred balloon 1201. In addition, the occlusion/perfusion balloon 1201 may be alternatively designed and configured with different materials that are able to take on the general size and shape of the occlusion/perfusion balloon 1201, particularly the minimal inflation, low inflation, medium inflation and full inflation configurations and related inflation configurations between these configurations shown in the drawings, and withstand the normal operating conditions of the occlusion/perfusion balloon 1201.

[0233] The size, shape and configuration of the plurality of projecting members 1204 of the first preferred balloon 1201 is but one exemplary embodiment and may take on other various sizes, shapes and configurations. As described above, the plurality of projecting members 1204 are preferably an integral part of the balloon 1201 itself, and form the wall surfaces of the balloon 1201. Alternatively, the projecting members 1204 may be elongate filaments, tubes, cylinders or other members that are either joined to or integrally formed with an outer wall surface of the occlusion/perfusion balloon 1201. For example, the projecting members 1204 may be constructed of a high durometer polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), polyether block amide (PBAX) or other similar biocompatible material, formed in solid or tubular members having a circular, elliptical, quadrilateral, polygonal or other suitable transverse cross-sectional shape. These alternative projecting members 1204 may also be separately connected to the balloon 1201 and separately inflatable and deflatable to control the inflation configuration of the occlusion/perfusion balloon 1201. The preferred projecting members 1204 may be configured in nearly any shape, size and configuration such that the occlusion/perfusion balloon 1201 is able to selectively permit flow of fluid and blood past the projecting members 1204, at least in certain inflation configurations, along the longitudinal axis 1200a. In addition, the occlusion/perfusion balloon 1201 may be configured such that the channels 1206 are comprised of flow channels or holes (not shown) that are surrounded by the material of the occlusion/perfusion balloon 1201 to permit flow of blood and fluid through or around the occlusion/perfusion balloon 1201 generally parallel or along the longitudinal axis 1200a.

[0234] Referring to Figs. 29A and 29B, an occlusion balloon system 1220 in accordance with a second preferred embodiment includes a balloon 1222 with a plurality of projecting

members 1224 projecting from an outer wall surface 1223 of the balloon 1222. The balloon 1222 is connected to a proximal catheter member 1220b and a distal catheter member 1220c, which may be incorporated into any of the preferred occlusion catheter systems 100, 300, 500, 700, 1700, 1800, described herein. The proximal catheter member 1220b includes an inflation lumen therein that facilitates inflation of the balloon 1222. The projecting members 1224 preferably extend substantially radially away from the outer surface 1223 of the balloon 1222 and extend along the outer surface 1223 substantially longitudinally relative to the longitudinal axis 1220a. The preferred projecting members 1224 preferably extend along an entire length of a substantially tubular section 1223a of the balloon 1222, which tapers to the proximal and distal catheters 1220b, 1220c in a substantially funnel-shape at its ends. The outer surface 1223 of the balloon 1222 preferably has a constant diameter in the tubular section 1223a. The projecting members 1224 are not limited to extending substantially longitudinally along the entire length of the tubular section 1223a and the tubular section 1223a is not limited to having a substantially constant diameter and the balloon 1222 may be otherwise designed and configured such that the balloon 1222 is able to partially and fully occlude a vessel and withstand the normal operating conditions of the preferred occlusion balloon system 1220.

[0235] The projecting members 1224 preferably define channels 1224a between the projecting members 1224 or adjacent the projecting members 1224 that permit flow of blood and fluid substantially parallel to the longitudinal axis 1220a when the occlusion balloon system 1220 is positioned within a vessel. The balloon of the system 1220 may be inflated to various levels to enhance or reduce the channels 1224a, depending on the preferred procedure, preferences of the medical technician or conditions encountered or detected within the vessel.

[0236] Referring to Figs. 30A and 30B, an occlusion/perfusion balloon system 1230 in accordance with a third preferred embodiment includes a balloon 1232 and a plurality of vanes 1234 that project from an outer wall surface 1233 of the balloon 1232. In this third preferred embodiment of the occlusion/perfusion balloon system 1230, the vanes 1234 are preferably resilient in nature and are capable of deforming or folding over against an outer wall surface 1233 of the balloon 1232, as depicted by phantom lines 1238 (Fig. 30B), when the balloon 1232 is in apposition against a vascular wall surface and occluding the vessel or partially occluding the vessel. The vanes 1234 of the third preferred embodiment also preferably extend substantially radially away from the outer surface 1233 and extend along the outer surface 1233 substantially

longitudinally relative to the longitudinal axis 1230a. The vanes 1234 preferably extend along an entire length of a substantially tubular section 1233a, which tapers to the proximal and distal catheters 1230b, 1230c. The proximal catheter 1230b includes an inflation lumen therein that facilitates inflation and deflation of the balloon 1232. The outer surface 1233 preferably has a constant diameter in the tubular section 1233a. The vanes 1234 preferably extend to tips 1234a that are spaced at a greater distance from the outer surface 1233 when compared to the similar projecting members 1224 of the second preferred embodiment. The outer surface 1233 of the balloon 1232 preferably has a constant diameter in the tubular section 1233a. The projecting members 1234 are not limited to extending substantially longitudinally along the entire length of the tubular section 1233a and the tubular section 1233a is not limited to having a substantially constant diameter and the balloon 1232 may be otherwise designed and configured such that the balloon 1232 is able to partially and fully occlude a vessel and withstand the normal operating conditions of the preferred occlusion balloon system 1220.

[0237] In this third preferred embodiment of the system 1230, the vanes 1234 preferably define channels 1234b therebetween and with the walls of the vessel that permit flow of blood and fluid through the vessel along or substantially parallel to the longitudinal axis 1230a. The channels 1234b may be manipulated or controlled by the user or designer by the inflation of the balloon 1232, the stiffness of the vanes 1234, the height of the vanes 1234, the separation of the vanes 1234 and related other factors that may increase or decrease the size of the channels 1234b that facilitate flow of fluid through the vessel when the balloon 1232 is inflated.

[0238] Referring to Figs. 31-31B, fourth and fifth preferred embodiments of the occlusion/perfusion system 1240 includes a compliant occlusion balloon 1242 and at least one restraining filament 1250 connected to proximal and distal catheters 1240b, 1240c with the restraining filament 1250 positioned on an outside of an outer surface 1243 of the balloon 1242. The proximal catheter 1240b includes an inflation lumen therein that carries fluid or gas to and from the balloon 1242 to facilitate inflation and deflation of the balloon 1242, respectively. The restraining filament 1250 deforms at least one section of the occlusion balloon 1242 radially inward toward a longitudinal axis 1240a of the balloon 1242 and away from the vascular wall or allows an adjacent portion of the balloon 1242 to extend further away from the longitudinal axis 1240a than the portion proximate the filament 1240. The inclusion of the restraining filament 1250 preferably creates a reverse curvature in the balloon 1242 and permits fluid to flow past the

balloon 1242, substantially parallel to the longitudinal axis 1240a when the balloon 1242 is positioned within the vessel. When a desired time elapses, a desired arterial blood pressure is achieved, or when other indicators suggest, the tension on the restraining filament 1250 may be released, the reverse curvature will expand and the balloon 1242 and the balloon 1242 will return to its occlusion position in apposition with the vessel wall.

[0239] In the occlusion/perfusion system 1240 of the fourth preferred embodiment, the catheters 1240b, 1240c preferably accommodate the at least one restraining filament 1250 within the catheter 1240b, 1240c, such that the filament 1250 exits the catheter 1240b, 1240c proximate the balloon 1242, overlay the balloon 1250 along a portion of the length of the balloon 1250 and is configured to provide tension against the outer surface 1243 of the balloon 1250 to define channels or flow paths along the balloon 1250, preferably substantially parallel to or along the direction of the longitudinal axis 1240a. In order to accommodate this arrangement, the catheter 1240b, 1240c of the fourth preferred embodiment is provided with a distal port 1246 passing through the outer wall of the distal catheter 1240c and a proximal port 1248 also passing through the outer wall of the proximal catheter 1240b. The restraining filament 1250 is preferably lead from the proximal end of the proximal catheter 1240b, where it is accessible to the medical practitioner for tensioning, is passed through a lumen in the proximal catheter 1240b (not shown), exits the proximal port 1248, passes over the balloon 1242 and adjacent the outer surface 1243 of the balloon 1242, and anchor or is attached at the distal port 1246 to the distal catheter 1240c. In this manner, tensioning the at least one filament 1250 at the proximal end of the proximal catheter 1240b preferably causes the filament 1250 to tension against the balloon 1242 or block expansion of the balloon 1242 proximate the filament 1250. When the balloon 1242 is inflated, the portions of the balloon 1242 spaced from the filament 1250 expand away from the longitudinal axis 1240a, while the portions of the balloon 1242 adjacent and beneath the filament 1250 are blocked from expansion by the filament 1250. Accordingly, the outer surface 1243 of the balloon 1242 forms or defines channels 1254 extending substantially parallel to the longitudinal axis 1240a or along the length of the filament 1250 between the expanded portions of the balloon 1242 between the filament 1250 that permit fluid flow in the channels 1254 created between the vessel wall 1252 (shown in phantom in Fig. 31A) and the reverse curve of the outer surface 1243 of the balloon 1242.

[0240] Referring specifically to Fig. 31B, the fifth preferred occlusion/perfusion balloon system 1240 entails running the at least one restraining filament 1250 within the interior space or within the material defined by the balloon 1242 and joining the at least one filament 1250 to the inner wall surface of the balloon 1242. This joining between the at least one restraining filament 1250 and the inner wall surface of the balloon 1242 may be accomplished by adhesives, thermobonding or reflowing. Alternatively, one or more lumens may be co-extruded with the inner wall surface of the balloon 1242 or tubular members joined to the inner wall surface of the balloon 1242, and the at least restraining filament 1250 run within this at least one lumen or tubular member and anchored therein. The balloon 1242 may alternatively be formed from different materials, with the filament 1250 being constructed of a stiffer material than the remainder of the balloon 1242, such that the portion of the balloon 1242 with the filament 1240 therein does not expand at the same rate or to the same extent as the remainder of the balloon 1242. In this fifth preferred embodiment, occlusion/perfusion balloon system 1240 does not necessarily include the proximal port 1248 and the distal port 1246, as the filament 1250 may be positioned within the catheters 1240b, 1240c or within a lumen of the catheters 1240b, 1240c. The filament 1250 would, therefore, typically not be exposed to the blood vessel or blood flow in such a configuration, as the filament 1250 would be encased within the balloon 1242 and the catheters 1240b, 1240c, where the filament 1250 would not typically be exposed to fluid and blood flow during use.

[0241] Referring to Figs. 32 and 32A, a sixth preferred embodiment of an occlusion/perfusion balloon system 1260 includes a plurality of balloons 1264 carried commonly on a catheter 1262. The plurality of balloons 1264 may be incorporated with any of the preferred occlusion catheter systems 100, 300, 500, 700, 1700, 1800, described herein. The plurality of balloons 1264 are preferably independently expandable through inflation lumens or an inflation lumen 1265 in the catheter 1262. The inflation lumen 1265 preferably communicates independently with each one of the plurality of balloons 1264. The catheter 1262 preferably includes a seal member 1266 movably mounted therein and a plurality of openings 1268 that pass through the outer wall of catheter 1262 and communicate with the fluid flow lumen 1265. The seal member 1266 is reciprocally movable within the fluid lumen 1265 and selectively occludes or opens one or more of the plurality of openings 1268 in the outer wall of the catheter 1262, thereby permitting fluid flow through the fluid flow lumen 1265 and independently or

concurrently into each of the plurality of balloons 1264. In this manner, the volume and rate of fluid flow into the plurality of occluding balloons 1264 may be adjusted by the relative position of the seal member 1266 within the fluid flow lumen 1265.

[0242] Referring to Figs. 33 and 34, a seventh preferred embodiment of an occlusion/perfusion balloon system 1270 preferably does not rely upon an occlusion balloon or upon a fluid pressure to activate an occlusion balloon. Rather, in this seventh preferred embodiment, the occlusion member consists of a supporting cage structure 1272 formed of a plurality of structural members, which may be longitudinally oriented struts 1276 that taper distally, connect to a distal catheter member 1274 and taper proximally where the struts 1276 connect to a proximal catheter member 1275. An occluding membrane 1278 is preferably coupled to the supporting cage structure and may consist of a partial covering on the supporting cage structure 1272 or may be comprised of a full covering (on the supporting cage structure 1272, as illustrated in Fig. 34 with reference to occlusion/perfusion system 1280 of the eighth preferred embodiment.

[0243] The struts of the supporting cage structure 1272 are preferably, fixedly coupled at their distal ends to the distal catheter member 1274 and at their proximal end are preferably, fixedly coupled to the proximal catheter sleeve member 1275. The proximal catheter sleeve member 1275 is reciprocally movable relative to the distal catheter 1274. The relative movement of the proximal catheter sleeve member 1275 relative to the distal catheter 1274 preferably causes deformation of the supporting cage structure 1272 and allows the cage structure 1272 to diametrically expand or diametrically contract under the influence of such relative movement. Such diametric expansion preferably brings the supporting cage structure 1272 and the occluding membrane 1278 into an occlusive position within the lumen of a blood vessel, while diametric contraction preferably reduces the diametric profile of the supporting cage structure 1272 and the occluding membrane 1278, thereby allowing for fluid and blood flow past the occlusion site or past the cage structure 1272.

[0244] The supporting cage structure 1272 of the seventh and eighth preferred embodiments, like a balloon, may assume a wide variety of geometries, including, without limitation, spherical, elliptical, conical, square, rectangular, dog boned, tapered, stepped, or combinations thereof, such as, for example, conical/square or conical/spherical. The supporting cage structure 1272 and its struts 1276 may be made of any suitable biocompatible material, including polymers,

metals and/or composites or combinations thereof. The biocompatible material may be an elastic, superelastic, shape memory material and is preferably able to take on the general size and shape of the cage structure 1272, perform the functions of the preferred cage structure 1272 and withstand the normal operating conditions of the cage structure 1272.

[0245] The occluding membrane 1278 preferably covers at least a portion of the supporting cage structure 1272 in order to at least partially occlude the blood vessel into which the occlusion/perfusion systems 1270, 1280 are placed. The occluding membrane 1278 may cover a proximal portion of the supporting cage 1272, a distal portion of the supporting cage 1272, the entire cage 1272, such as is shown in the eighth preferred embodiment (Fig. 34), or it may cover only portions of the cage 1272 to permit partial or partially occluded flow through the vessel. The supporting cage 1272 may facilitate pre-conditioning systems that infuse fluid into the vessel to pre-emptively and prophylactically mitigate possible ischemia during occlusion. The catheters 1272, 1275, 1284, 1285 may include infusion holes 1284a therein that facilitate infusion of fluid into the vessel and the infusion holes 1284 may extend along all or a portion of the longitudinal length of the catheters 1272, 1275, 1284, 1285. Furthermore, the occluding membrane 1278 may have an opening 1279 in a proximal end to allow fluid flow therethrough to facilitate partial occlusion and perfusion.

[0246] The occluding membrane 1278 is preferably constructed of a woven or non-woven biocompatible material, such as polymers, metals, composites and combinations thereof, and may be elastic, superelastic or shape memory. The occluding membrane 1278 may cover the outer surface of the supporting cage 1272, the inner surface of the supporting cage 1272, or both. The occluding membrane 1278 may be joined to the supporting cage 1278 by sutures, biocompatible adhesive, by reflow, by thermal welding, or by joining to another layer of occluding membrane 1278 on the opposing surface of the supporting cage 1272 such that the struts of the supporting cage 1278 are at least partially encapsulated by the occluding membrane 1278. Methods and materials for joining the occluding membrane 1278 to supporting cage 1272 may include adhesive bonding, fastening, clamping, co-molding and other related engagement techniques.

[0247] Referring to Figs. 35A-35C, in a ninth preferred embodiment, an occlusion balloon system 2000 includes a balloon or inflatable occlusion member 2001 with a plurality of projecting members 2002 projecting from an outer wall surface 2003 of the balloon 2001. The

balloon 2001 is connected to a proximal catheter member 2004 and a distal catheter member 2005, which may be incorporated into any of the preferred occlusion catheter systems 100, 300, 500, 700, 1700, 1800, described herein. The proximal catheter member 2004 includes an inflation lumen therein that facilitates inflation of the balloon 2001. The projecting members 2002 preferably extend substantially radially away from a central longitudinal axis 2006 of the balloon 2001 and extend along the outer surface 2003 substantially laterally or circumferentially around the longitudinal axis 2006. The preferred projecting members 2002 preferably extend around an entire circumference of the balloon 2001, but are not so limited and may extend partially around the outer surface 2003, may extend at angles relative to the longitudinal axis 2006, may be comprised of various pockets on the surface 2003 or may be otherwise configured to create spacing between a vessel 2008 and the outer surface 2003, at least when the balloon 2001 is partially inflated. The balloon 2001 of the ninth preferred embodiment includes four projecting members 2002 longitudinally spaced along the length of the balloon 2001. The end projecting members 2002 taper in an arcuate shape to connections with the proximal and distal catheters 2004, 2005. The outer surface 2003 of the balloon 1222 preferably has a constant diameter at the peaks of the projecting members 2002, but is not so limited and may have tapered or variable spacing relative to the longitudinal axis 2006. Lateral channels 2007 are preferably defined between the projecting members 2002 when the balloon 2001 is at least partially inflated and are comprised of circumferentially extending voids wherein the vessel 2008 is out of contact with the outer surface 2003 in the channels 2007. In contrast, when the balloon 2001 is fully inflated or is in an inflated configuration, the balloon 2001 expands such that the outer surface 2003 is substantially consistent and channels 2007 are not formed. In this fully inflated configuration or at least close to the fully inflated configuration, the outer surface 2003 is in direct contact with the vessel 2008 and fluid and blood flow are substantially occluded in the vessel 2008. The projecting members 2001 defined in at least the partially inflated configuration are not limited to extending substantially laterally or circumferentially around the longitudinal axis 2006 and the projecting members 2002 are not limited to having a substantially constant diameter. The balloon 2001 may be otherwise designed and configured such that the balloon 2001 is able to partially and fully occlude the vessel 2008 and withstand the normal operating conditions of the preferred occlusion balloon system 2000.

[0248] The projecting members 2002 in the partially inflated configuration of the balloon 2001 preferably permit at least partial flow of blood and fluid substantially parallel to the longitudinal axis 2006 when the occlusion balloon system 2000 is positioned within the vessel 2008. The balloon 2001 of the system 2000 may be inflated to various levels to enhance or reduce the channels 2007 and the position of the projecting members 2002 relative to the inner wall of the vessel 2008, depending on the preferred procedure, preferences of the medical technician or conditions encountered or detected within the vessel. Generally, as the pressure is increased within the balloon 2001, the projecting members 2002 come into closer positioning relative to the inner surface of the vessel 2008 and, therefore, limit flow of fluid and blood through the vessel 2008.

[0249] Referring to Fig. 35D, in a tenth preferred embodiment, an occlusion/perfusion balloon system 2100 includes a balloon or inflatable occlusion member 2101 with a spiral-shape projecting from a longitudinal axis 2106 of the tenth preferred occlusion/perfusion balloon system 2100. The inflatable occlusion/perfusion balloon 2101 includes channels 2107 defined between projecting portions 2102 of the spiral-shaped balloon 2101 that permit flow of blood past the balloon 2101 when inserted into the vessel and at least partially inflated. Similar to the ninth preferred occlusion balloon system 2000, the tenth preferred occlusion/perfusion balloon system 2100 may be fully inflated within the vessel and substantially or completely occlude the vessel. The tenth preferred occlusion/perfusion system 2100 also includes a proximal catheter 2104 and a distal catheter 2105 connected to proximal and distal balloon ends of the balloon 2101, which may be incorporated into any of the preferred occlusion catheter systems and other preferred systems having inflatable balloons or occlusion members described herein.

[0250] In each of the foregoing described embodiments of the occlusion/perfusion balloon systems depicted and described with reference to Figs. 23-35C, the systems may also include sensors, transmitters, receivers, interrogators or other means for measuring physical and/or physiological parameters distal and/or proximal one or more of the expandable occlusion members, including, for example blood pressure sensors, heart rate sensors, flow sensors, chemical sensors, temperature sensors, oxygenation sensors, ischemia sensors, biological sensors, imaging sensors or the like. Data collection of the readings from the sensors may be utilized with a controller or processor to control inflation of the balloons or occlusion members

of the preferred systems to facilitate partial flow of fluid and blood through the vessel 2008 when desired or to fully occlude the vessel 2008, as desired by the medical technician.

Pre-Conditioning Systems

[0251] Referring to Figs. 36-37C, pharmacologically active agents, such as pressors, anticoagulants, anti-inflammatory agents, anti-hypertensive agents, anti-hypotensive agents, anti-arrhythmic agents, or any other indicated agent may be delivered using a fourth preferred embodiment of and occlusion catheter system 1300 or a pre-conditioning system 1300. Larger volume infusions are also deliverable using the pre-conditioning system or the fourth preferred embodiment of the occlusion catheter system 1300, including blood, blood products, extracorporeal membrane oxygenation adjuncts, hypothermia adjuncts, saline, contrast or other therapeutic or diagnostic agents.

[0252] A four preferred occlusion catheter system or pre-conditioning system 1300 generally comprises a balloon catheter that has a plurality of proximal side ports 1308 positioned proximal an occlusion member or balloon 1304 and a plurality of distal side ports 1310 positioned distally relative to the occlusion member or balloon 1304. The plurality of proximal side ports 1308 and the plurality of distal ports 1310 are operable independently of each other to deliver fluids from the forth preferred occlusion catheter system 1300 to the blood vessel into which the forth preferred system 130 is introduced. The pre-conditioning system 1300, synonymously termed “infusion system,” includes a second catheter member 1302 that is connected to a proximal hub 1301 attached to a proximal end of the second catheter member 1302. The occlusion member 1304 is coupled toward a distal end of the second catheter member 1302. The occlusion member 1304, while depicted in Fig. 43 as a balloon, may be any type of member capable of vascular occlusion, such as those other embodiments of occlusion members disclosed herein or as are known in the art.

[0253] The second catheter member 1302 has a second lumen 1303 passing along a substantial longitudinal length of the second catheter member 1302. The second catheter member 1302 also has at least one, but preferably the plurality of proximal side ports 1308 passing through an outer wall of the second catheter member 1302. The plurality of proximal side ports 1308 is preferably in fluid flow communication with the second lumen 1303. The plurality proximal side ports 1308 may be in a regular or irregular pattern and may be positioned about the circumference of the second catheter member 1302 or may have only a single orientation relative to the central longitudinal axis 1331 of the infusion catheter system 1300.

[0254] A third catheter member 1320 of the fourth preferred occlusion catheter system 1300 extends distally relative to the occlusion member 1304 and terminates in an atraumatic tip 1306 or forms a proximal shaft or portion of the atraumatic tip 1306. The third catheter member 1320 has a third lumen 1322 passing along a substantial longitudinal length of the third catheter member 1302, preferably along and coaxially with the longitudinal axis 1331 near the distal end of the infusion catheter system 1300. The atraumatic tip 1306 is described above in greater detail with reference to the embodiments of the occlusion catheter 100, 300, 500, and serves to guide the catheter system 1300 as it traverses the vasculature and prevents the fourth preferred catheter system 1300 from tracking into collateral vessels, while preferably eliminating the need for a guide wire for placement of the occlusion catheter system 1300. The occlusion catheter system 1300 may also incorporate the atraumatic tip 450, 550 of the second the third preferred embodiments of the occlusion catheter system 300, 500, as is described herein.

[0255] At least one of and preferably all of the plurality of distal side ports 1310 pass through the outer wall of the third catheter member 1320 and communicate with the third lumen 1322 to communicate fluid distally relative to the occlusion member 1304. The plurality of distal side ports 1310 may be in a regular or irregular pattern and may be positioned about the circumference of the third catheter member 1320 or may have only a single orientation relative to the central longitudinal axis 1331 of the infusion catheter system 1300.

[0256] In the fourth preferred embodiment of occlusion catheter system 1300 where the occlusion member 1304 is a balloon, three lumens are preferred to service inflation of the occlusion member 1304 and fluid delivery to or sample collection from both of the plurality of proximal side ports 1308 and the plurality of distal side ports 1308. At least one hypotube or second catheter member 1312 is disposed within the second lumen 1303. Where the second catheter member or hypotube 1312 is employed, the second catheter member 1312 preferably has at least a first hypotube lumen 1314 and a second hypotube lumen 1316, with the first hypotube lumen 1314 configured to communicate an inflation fluid to the occlusion balloon 1304 and the second hypotube lumen 1316 configured to communicate fluid to the third catheter member 1320 and the plurality of distal side ports 1310 through the third lumen 1322, such that the third lumen 1322 is in fluid communication with the second hypotube lumen 1316. The second lumen 1303, between the second catheter member 1312 and the first catheter member 1302, preferably communicates fluid from the proximal hub 1301 to the plurality of proximal side ports 1308.

[0257] The at least one hypotube or second catheter member 1312 is preferably constructed of a material having different material properties than the first catheter member 1302 or the third catheter member 1320, such that the first lumen 1312 increases the column strength, pushability and pullability of the occlusion/infusion catheter system 1300 within the vasculature. In accordance with the fourth preferred embodiment of the occlusion catheter system 1300, the second catheter member 1312 is constructed of a relatively strong metal, preferably stainless steel or nitinol. The second catheter member 1312 may alternatively be constructed of a polymer, preferably a polymer having a higher hardness than that of either the first catheter member 1302 or the third catheter member 1320, but is not so limited. The first catheter member 1302, second catheter member 1312 and third catheter member 1320 may also be combined in construction and configuration to have a transitioning stiffness, to include a separate stiffening member, such as a nitinol wire or braided shaft, to have sufficient pushability to have the appropriate amount of column strength.

[0258] Referring to Figs. 37-37C, a fifth preferred embodiment of the occlusion/infusion system 1350 is generally similar to the infusion system or occlusion catheter system 1300 of the fourth preferred embodiment. The occlusion/infusion system or occlusion catheter system 1350 of the fifth preferred embodiment employs a first hypotube 1362 and a second hypotube 1364 within a second lumen 1353 of a second catheter member 1352. The second hypotube 1364 extends from the proximal end of the second catheter member 1352 and terminates in communication with the occlusion balloon 1354. Inflation fluid is communicated through a second hypotube lumen 1365 of the second hypotube 1364, through an inflation port 1357 in the second catheter member 1352 that is positioned within a space 1355 defined within the balloon 1354 and fills the space 1355 to inflate the balloon 1354. A seal 1349 is positioned within the second catheter member 1352 distal to the inflation port 1357 to seal the second lumen 1353 distally of the seal 1349 and permit the inflation fluid to flow through the inflation port 1357 and into the balloon 1354, but not distally of a distal end of the balloon 1354 in the second lumen 1353. The first hypotube 1362 extends within the second lumen 1353 of the second catheter member 1352, extends beyond the seal 1349 and terminates within the third lumen 1368 in the distal portion of the second catheter member 1352 or a proximal portion of the atraumatic tip (not shown) to communicate with a plurality of distal side ports 1360. In this manner, fluid introduced into the first hypotube 1362 is communicated through the first hypotube lumen 1363

to the plurality of distal side ports 1360 for release through the plurality of distal side ports 1360 distal to the occlusion balloon 1354.

[0259] It will be appreciated, therefore, that fluids may be infused through either the plurality of proximal side ports 1358 or the plurality of distal side ports 1360, independently, or through both, concurrently. The same or different infusion fluids may be infused through the plurality of proximal side ports 1358 and the plurality of distal side ports 1360, as well. The size, shape and position of the plurality of proximal side ports 1358 and that of the plurality of distal side ports 1360 may be configured to be the same or different and may be configured depending upon the type of fluid being infused. Furthermore, the plurality of proximal side ports 1358, the plurality of distal side ports 1360, the first hypotube 1362 and the second hypotube 1364 may be constructed of materials and tolerances suitable for powered injection at higher pressures and flow rates.

[0260] Alternatively, an adjunctive or secondary infusion catheter, such as those that are known in the art, that comprises a low-profile catheter shaft, a fluid connector at a proximal end of the catheter shaft and a plurality of fluid openings at a distal end of the catheter shaft, may be engaged to pass within the second lumen 1353, down the length of the second catheter member 1352 and out of a port distal to the occlusion member 1354. In this manner, the fourth and fifth preferred occlusion catheter systems 1300, 1350 may or may not have the plurality of proximal and distal side ports 1308, 1310, 1358, 1360, but may simply employ a secondary infusion catheter that is inserted into the second lumen 1303, 1353 of the second catheter member 1302, 1352, or, where the preferred occlusion catheter systems 1300, 1350 include the plurality of proximal and distal side ports 1308, 1310, 1358, 1360, the secondary infusion catheter may be inserted into a lumen, for instance the second hypotube lumen 1316, such that it will be able to extend a substantial longitudinal length of second catheter member 1302, 1352 and deliver fluid through the plurality of distal side ports 1310, 1360.

[0261] Finally, it will be understood by those in the art, that the terminus of the third lumens 1322, 1368 may be configured to laterally guide a guiding tip of a guide wire or catheter out of either the plurality of distal side ports 1310, 1360 or out of a dedicated skive (not shown) formed in the distal wall surface of third catheter member 1320, 1370.

[0262] An alternative configuration of the fourth and fifth preferred occlusion catheter systems 1300, 1350 may employ a secondary or adjunctive infusion catheter that is utilized for

the primary occlusion, then as infusion is required, to endoluminally delivery the secondary infusion catheter laterally to the already placed occlusion catheter, diametrically collapse the occlusion member to permit luminal space for the infusion catheter to pass the occlusion member, then reestablish occlusion when the infusion catheter is positioned distal to the occlusion member, thereby forming occlusion around the infusion catheter.

[0263] In each of the foregoing described embodiments of the pre-conditioning systems or the fourth and fifth preferred embodiments of the occlusion catheter systems 1300, 1350 depicted and described with reference to Figs. 35-36C, the systems 1300, 1350 may also include sensors, transmitters, receivers, interrogators or other means for measuring physical and/or physiological parameters distal and/or proximal one or more of the expandable occlusion members 1304, 1354, including, for example blood pressure sensors, heart rate sensors, flow sensors, chemical sensors, temperature sensors, oxygenation sensors, ischemia sensors, biological sensors, imaging sensors or the like.

Hemorrhage Exclusion and Flow Restoration Systems

[0264] The foregoing described embodiments of the vascular occlusion catheter system operate by creating a luminal obstruction to blood flow to the hemorrhage site to at least partially stem the outflow of blood and permit vascular repair of the hemorrhage site while preserving blood flow to the patient's brain and other vital organs. Alternative embodiments of the present invention operate to create an obstruction and occlude the hemorrhage site within the vascular wall. Moreover, rather than create luminal obstruction to blood flow, typically superior to the hemorrhage site, these alternative embodiments, restore patency of the blood vessel at the hemorrhage site and permit blood flow past the hemorrhage site while obstructing and occluding the trauma or injury to the vessel wall itself.

[0265] Fig. 38 illustrates a first preferred embodiment a hemorrhage exclusion system 1400 in accordance with the present invention. The preferred hemorrhage exclusion system 1400 is conceptually similar to occlusion/perfusion system 1270 depicted in Fig. 33. In the first preferred hemorrhage exclusion system 1400, an elongate support structure 1412 is formed of a plurality of structural support members- and is connected to a longitudinally extending catheter or catheter sleeve 1406. The structural support members, which may be longitudinally oriented struts, form a distal cage section 1408 and a proximal cage section 1402. The distal cage section

1408 is preferably, immovably coupled to a distal end of the catheter 1406 and, when an atraumatic guiding tip 1404 is provided, proximal to the atraumatic guiding tip 1404. The proximal cage section 1410 is coupled to the catheter sleeve member 1406. An intermediate cage section 1416 extends between the proximal cage section 1410 and the distal cage section 1408. The hemorrhage exclusion system 1400 also includes an elongate support structure in the intermediate cage section 1416 that is preferably comprised of a continuation of the structural support members of the proximal and distal cage sections 1410, 1408 with a large open volume within the support structure. The open volume between the structural support members of the proximal cage section 1410 and distal cage section 1408 facilitates blood flow longitudinally through the elongate support structure along the outside of the catheter sleeve 1406. The elongate support structure –may be constructed of any appropriate biocompatible material, including polymers, metals, composite materials or combinations thereof, as discussed above with reference to the occlusion members.

[0266] An exclusion member 1414 is carried on the intermediate cage section 1416 by the structural support members. The exclusion member 1414 extends along at least a substantial extent of the intermediate cage section 1416. The exclusion member 1414 may be fabricated of any appropriate woven or non-woven biocompatible material, including polymers, metals, composite materials or combinations thereof, as discussed above in reference to the occlusion members. The exclusion member 1414 may be plastically deformable, elastically deformable, or have shape memory or superelastic properties. The exclusion member 1414 is preferably, generally tubular and may be porous, non-porous or bio-absorbable. The exclusion member 1414 may be coupled to either the outer or inner surface of the elongate support structure 1412, or both. Coupling between the exclusion member 1414 may be in accordance with any methods and materials for joining biomaterials to support structures, including, without limitation, sutures, biocompatible adhesive, by reflow, by thermal welding, or by joining to another layer of exclusion member 1414 on the opposing surface of the support structure 1412 such that the struts of the support structure 1412 are at least partially encapsulated by the joined layers of the exclusion member 1414.

[0267] The catheter sleeve or catheter 1406 is preferably comprised of proximal and distal sections that are movably coupled to each other such that relative movement of the proximal and distal catheter sleeve members 1406 translates to diametric expansion or contraction of the

elongate support structure 1412 and the exclusion member 1414. The proximal and distal portions of the catheter sleeve member 1406 are preferably comprised of a tubular structure with a lumen through which an opposing catheter passes. The catheter sleeve 1406 is not so limited and may be constructed of nearly any assembly or construction that permits collapse and expansion of the elongate support structure 1412, wherein the elongate support structure 1412 has a similar diameter to the catheter sleeve 1406 in the collapsed configuration and has an expanded (Fig. 38) diameter that allows blood flow through the intermediate cage section 1416 in the expanded configuration.

[0268] The elongate support structure 1412, may assume a wide variety of geometries, provided that the exclusion member 1414 supported on the elongate support structure defines a fluid flow pathway to restore patency to the vessel and allow blood to flow past the hemorrhage site.

[0269] In use, the hemorrhage exclusion system 1400 is advanced to a hemorrhage site. Contrast may be injected through the catheter 1406 and out of a port 1403 near the distal end of the catheter 1406 to image the hemorrhage, determine its position in the vessel wall and preferably estimate its relative size. The exclusion member 1414 is preferably positioned in such a manner as to span the hemorrhage site and extend both proximal and distal relative to the hemorrhage site. The support structure 1412 and the exclusion member 1414 are diametrically expanded into apposition with the vascular luminal wall surface, by relative movement of the proximal and distal portions of the catheter sleeve 1406. The exclusion member 1414 preferably blocks flow of blood out of the hemorrhage site and allows blood to continue to flow through the vessel and, preferably, preventing flow of blood out of the hemorrhage. Further imaging using injected contrast may be employed to verify successful positioning of the exclusion member 1414 and coverage of the hemorrhage site to stem the outflow of blood from the vessel trauma or injury. Alternatively or additionally blood pressure and/or blood flow data may be obtained by pressure and/or flow sensors operably associated with the hemorrhage exclusion system 1400, to also verify successful placement of the exclusion member 1414 and restoration of vascular patency and blood flow through the lumen of the exclusion member 1414, through the elongate support structure 1412 and through the vessel. The exclusion member 1414 is preferably maintained in place blocking the hemorrhage site at least until the medical practitioner is able to develop a plan to repair the hemorrhage.

[0270] An alternative preferred embodiment of the occlusion catheter system, which is similar to the foregoing hemorrhage exclusion system 1400 of the first preferred embodiment, involves eliminating the central catheter sleeve member 1406 and affixing the proximal cage section 1402 to a more proximal section of the catheter 1406. A constraining sheath (not shown) is then placed over the catheter 1406, the elongate structural support 1412 and the exclusion member 1414, constraining the structural support 1412 and exclusion member 1414 in a reduced diametric state until the constraining sheath is withdrawn. This configuration is particularly well suited where the elongate structural support 1412 is made of an elastic, shape memory or super elastic material. This alternate preferred embodiment is conceptually similar to the manner in which self-expanding or shape memory stents are endovascularly delivered and placed.

[0271] Referring to Figs. 39-39B, another or second preferred embodiment of the occlusion catheter system or hemorrhage exclusion system 1450 does not employ an elongate support structure 1414, as is utilized in the first preferred embodiment of the hemorrhage exclusion system 1400. The second preferred system 1450 includes a catheter 1452 having a relatively larger diametric profile which carries within a lumen in the catheter 1452 a furled or rolled sheet of an exclusion material 1456. An elongate spindle member 1453 carrying a rolled sheet of exclusion material 1456 is preferably positioned within a lumen of the catheter 1452. The catheter 1452 has an elongated slot 1455 passing through a wall surface of the catheter 1452. The exclusion material 1456 preferably has a leading edge that projects out of an elongate slot 1455 and, when the elongate spindle member 1453 is rotationally moved within the lumen of catheter 1452, the exclusion material 1456 unfurls or unrolls out of the elongated slot 1455. As the exclusion material 1456 fully unrolls from within the catheter lumen, the exclusion material 1456 preferably forms a diametrically enlarged generally tubular structure with at least one region of overlap of the exclusion material 1456, such that a first winding of the exclusion material 1456 forms an outer layer 1459 of the tubular structure and a second winding of the exclusion material 1456 forms an inner layer of the tubular structure. The tubular structure so formed defines a central lumen 1460 that allow blood flow through the tubular structure while the exclusion member 1456 is deployed in its diametrically expanded state.

[0272] In use, the hemorrhage exclusion system 1450 of the second preferred embodiment is endoluminally delivered to a hemorrhage site. Similar to the hemorrhage exclusion system 1400 of the first preferred embodiment, the hemorrhage site may be imaged by contrast injection to

position the exclusion system 1450 relative to the hemorrhage site. Once properly positioned, the elongate spindle 1453 is rotatably actuated to unfurl or unroll the exclusion member 1456 through the elongate slot 1455 until it assumes its enlarged tubular shape and defines the blood flow central lumen 1460 and is preferably in apposition with the vascular wall surface and excludes or bypasses the hemorrhage site. Exclusion or bypass of the hemorrhage may be verified by contrast imaging or by blood pressure and/or blood flow data obtained from the patient or from blood pressure and/or blood flow sensors operably associated with, preferably attached to the exclusion system 1450.

[0273] In each of the foregoing preferred embodiments of the hemorrhage exclusion systems 1400, 1450 depicted and described with reference to Figs. 38-39B, the systems 1400, 1450 may also include sensors, transmitters, receivers, interrogators or other means for measuring physical and/or physiological parameters distal and/or proximal one or more of the expandable occlusion members, including, for example blood pressure sensors, heart rate sensors, flow sensors, chemical sensors, temperature sensors, oxygenation sensors, ischemia sensors, biological sensors, imaging sensors or the like. The sensors may communicate with a controller, which may control various aspects of the operation of the systems 140, 1450, such as unfurling the exclusion member 1456 or collapsing the exclusion member 1456.

Inflation Control Systems

[0274] Referring to Fig. 40, a first preferred of an inflation control system 1500 may be utilized with any of the preferred occlusion catheter systems and other preferred systems having inflatable balloons or occlusion members described herein. In the first preferred embodiment, the inflation control system 1500 is preferably connected in-line between an inflation device (i.e. pressure source) and the balloon catheter, such as the first preferred occlusion catheter system 100. The inflation control system 1500 preferably helps to prevent the user from overinflating the balloon, such as the occlusion member 140 and damaging the blood vessel into which the occlusion member or balloon 140 is inserted. The inflation control system 1500 preferably includes a pressure source 1502, such as a syringe, which may be manually actuated or may be coupled to any of a large number of known automated injectors or pressure systems. The pressure source 1502 has a fluid source contained within the syringe, and is coupled to a bifurcated pressure conduit 1506, that in turn communicates with a free line and a regulated line.

A one-way check valve 1508 is interposed in the regulated line to prevent both backpressure and backflow to the syringe 1502. A selectable flow valve 1504 is interposed in the free line and communicates with the regulated line. The selectable flow valve 1504 is operable to select the free line, the regulated line or both the free line and the regulated line. A fluid conduit leads from the selectable flow valve 1504 to a pressure sensor 1510. A coupling 1512, preferably a luer lock fitting, is provided to couple the occlusion catheter (not shown) to the pressure sensor 1510. While an analog pressure gauge is shown in Fig. 55, the analog pressure gauge is not limiting and a wide variety of analog or digital pressure sensors 1510 are capable of being used to provide the medical practitioner with information concerning the pressure in the inflation control system 1500.

[0275] In use, the inflation control system 1500 allows the practitioner to apply fluid pressure to the occlusion catheter, e.g., by advancing the syringe plunger, to inflate the occlusion balloon, while simultaneously preventing both backpressure and backflow. When the selector valve 1504 is positioned to open the regulated line and close the free line, fluid is free to flow through the check valve 1506 to the occlusion catheter and ultimately to the balloon. Pausing during inflation will not result in deflation of the balloon because when force is no longer applied to the syringe plunger, the fluid no longer advances through the check valve 1508 and the backpressure from the elastic balloon causes the fluid to try to exit the balloon/catheter, thereby causing the check valve 1508 to close.

[0276] The pressure sensor 1510 preferably senses the applied pressure at the pressure source 1502, but not necessarily at the occlusion balloon. Namely, because of the length of the occlusion catheter and the high resistance of the fluid passing through the narrow annular space of the catheter shaft, the pressure at the pressure gauge 1510 may be higher than the actual pressure in the balloon, but allowances and compensation may be calculated to predict or measure the pressure within the balloon with the gauge 1510. A dwell time typically exists between the time pressure is applied at the pressure source 1502 and when the pressure equilibrates at the occlusion balloon, but the pressure in the system between the check valve 1508 and the balloon quickly equalizes and the pressure sensor 1510 accurately reads the true pressure in the balloon. Excluding backpressure and backflow via the check valve 1508 creates a closed system in which the pressure can be allowed to equilibrate, as represented by a constant

pressure readout on the pressure sensor 1510, which will then represent the pressure at the occlusion balloon. Additional fluid pressure may then be applied at the pressure source 1502.

[0277] As should be understood, the pressure sensor 1510 may have a “target occlusion pressure” identified thereon (i.e. such as a blue zone of the gauge 1510) that the practitioner knows to keep inflating until the needle comes a rest in the blue zone. This would indicate occlusion but not over inflation. Therefore, since this system is based on pressure and not volume, it is not necessary to know the vessel diameter before inflating the balloon. Rather, the practitioner need only fill the balloon until the needle of the pressure gauge 1510 comes to a rest in the “blue zone”.

[0278] Pressure may be withdrawn from the occlusion balloon by means of the selector flow valve 1504 being switched to open the free line, by-passing the check valve 1508, and releasing pressure back to the pressure source 1502 from the occlusion balloon. The syringe plunger is preferably retracted and the fluid is drained from the balloon back into the syringe 1502.

[0279] Referring to Fig. 41, a preferred second embodiment of an inflation control system 1550 is useful in the preferred inflation method of the present invention. A conventional balloon inflation device 1562 is illustrated in Fig. 41 (such as a QL Inflation Device, Atrion Medical, Arab, Alabama). The inflation device 1562 has a fluid chamber and a plunger 1564. The plunger 1564 is preferably threaded to allow for rotation of the plunger 1564 relative to the fluid chamber and controlled depression of the plunger 1564 within the fluid chamber. A fluid conduit 1563 communicates with an outlet 1561 in the inflation device 1562 to communicate the inflation fluid to the occlusion catheter (not shown), such as the occlusion catheter system 100 of the first preferred embodiment or any of the other preferred occlusion systems described herein, that is coupled to the inflation device 1550 via a coupling 1561. A pressure sensor 1560 is preferably provided in the outlet line of the inflation device 1550. A lock 1566 is preferably provided that engages the threaded plunger 1564 during pressurization and disengages from the threaded plunger 1564 during depressurization. The lock 1566 acts, essentially, to isolate the pressure within the occlusion balloon, catheter and fluid conduit 1563 and resists transmitting backpressure or fluid backflow to the plunger 1564. Essentially, the lock 1566 functions in a manner similar to the check valve 1508 in the preceding first preferred embodiment of the inflation control system 1500.

[0280] The method of inflating the occlusion balloon (not shown) using the inflation device 1562 entails the practitioner filling the fluid chamber with an inflation fluid by withdrawing the plunger 1564 to fill the fluid conduit 1563 and the fluid chamber. Expelling any air present in the fluid chamber and fluid conduit and connecting the inflation device 1550 to the occlusion catheter (not shown). To inflate the occlusion balloon, the plunger 1564 is actuated either by linear force or by rotating the plunger 1564 to engage the threads for a controlled pressurization. The lock 1566 should be engaged with the plunger 1564 to resist backpressure as the balloon occlusion member inflates. The pressure sensor 1560 will sense the applied pressure at the inflation device 1550, but not necessarily at the occlusion balloon. Because of the length of the occlusion catheter, a dwell time exists between the time pressure is applied at the inflation device 1550 and when the pressure equilibrates at the occlusion balloon. By excluding backpressure and backflow, the lock 1566 serves to create a closed system in which the pressure can be allowed to equilibrate, as represented by a constant pressure readout on the pressure sensor 1560. When the pressure indicated on the pressure sensor 1560 is stable, this will then represent the pressure at the occlusion balloon. Additional fluid pressure may then be applied or pressure may be withdrawn from the occlusion balloon by either reversing the rotation of the plunger, essentially unthreading the plunger 1564, and depressurizing the balloon, or by means of releasing the lock 1566 and withdrawing the plunger 1564.

[0281] The second preferred inflation device 1550 is not limited to the specific arrangement described and shown herein and further mechanisms may be employed to prevent the user/practitioner from overinflating the balloon and damaging the blood vessel or the balloon. For example, as shown in Fig. 41A, any of the preferred vascular occlusion catheter systems, such as the first, second or third preferred occlusion catheter systems 100, 300, 500, may include a spring biased valve 1501 positioned within the catheter, proximal the atraumatic guiding tip 150, 450, 550, including a plunger 1501a sealingly engaging the catheter lumen and occluding a port 1503 located distally therefrom. The spring 1501b biases the piston 1501a into the position occluding the port 1503 and may define a spring constant configured to be overcome by a counteracting force corresponding to a pressure equal to or less than the cracking pressure of the vessel. Therefore, prior to overinflating the balloon and damaging the vessel, the pressure within the catheter overcomes the spring 1501b bias and pushes the plunger 1501a distally to expose the

port 1503 and permit pressure release therethrough. The spring 1501b will push the plunger 1501a back into the position occluding port 1503 once sufficient pressure is released.

Infection/Contamination Control System

[0282] Rapid endovascular occlusion or exclusion of a traumatic hemorrhagic injury while on the battlefield or on the street involves not only a non-sterile environment, but an environment that is may be highly contaminated and prone to a wide variety of sources of bacterial or viral infections. It is desirable to design, construct and deploy a device that facilitates vascular access and endovascular delivery of a vascular occlusion catheter while minimizing infections resulting from contamination when used in austere environments, i.e., on the battlefield or on the street, rather than in a hospital or other sterile or controlled environment.

[0283] Referring to Figs. 42A and 42B, a first preferred infection control catheter sleeve system 1600 provides a substantially sterile field for the occlusion catheter 1602 and the occlusion balloon 1608 during access and endovascular delivery and through the vascular occlusion procedure. The occlusion catheter preferably includes an inflation catheter 1602a positioned proximate the balloon 1608 and a distal catheter member 1602b positioned distally relative to the balloon 1608. The inflation catheter member 1602a preferably has an inflation lumen similar to the inflation lumens described herein with respect to the preferred occlusion catheter members that has a port opening into an inner area of the occlusion balloon 1608 to permit inflation and deflation of the occlusion balloon 1608. The catheter sleeve system 1600 generally comprises a sleeve 1610 that is preferably comprised of an elongate tubular structure fabricated of a highly resilient material capable of being sterilized. The catheter sleeve 1610 is preferably a thin walled, elastic in inelastic polymer material that is capable of being longitudinally collapsed in an accordion-like fashion to ease insertion of the catheter 1602 into the sterile lumen of the elongate tubular structure 1610 and thereafter elongated in an accordion-like fashion as needed to cover substantially the entire shaft of the catheter 1602 in a covered configuration. The catheter sleeve 1610 preferably has hub members 1604, 1606 at respective proximal sleeve and distal sleeve ends 1610a, 1610b of the catheter sleeve tubular structure 1610 that permit the catheter 1602 to extend into and through the catheter sleeve 1600 while generally maintaining hemostasis and a sterile field within the catheter sleeve 1600. The preferred system 1600 includes proximal and distal hub members 1604, 1606 that may be constructed and

configured as any type of hemostatic valve that permits the catheter 1602 to pass through the valve, such as, for example, without limitation, a Tuohy Borst valve.

[0284] The distal hub member 1606 may also include surfaces, such as flanges, wings, or other projections from the distal hub member 1606 that facilitate close approximation with the patient's skin and application of a shield dressing or other adhesive dressing to retain the distal hub member 1606, catheter sleeve 1600 and catheter 1602 positioned on the patient after the occlusion catheter has been delivered.

[0285] In use, as the distal tip of the catheter 1602 is inserted into an introducer sheath or the patient's body with the atraumatic tip 1605 substantially straightened along the longitudinal axis 1601 and the distal hub member 1606 of the catheter sleeve 1600 preferably remains mated to the introducer sheath during insertion of the catheter 1602. The preferred thin polymer of the catheter sleeve 1610 collapses in an accordion-like manner as the catheter 1602 is advanced into the body. Therefore, if something non-sterile comes into contact with the outside of the catheter sleeve 1610, it generally does not contaminate the catheter shaft 1602 that is inserted into the body. In addition, as the catheter 1602 is withdrawn from the patient, the sleeve 1610 is able to expand from its working configuration to the covered configuration such that materials, such as blood, from the vessel of the patient is substantially maintained within the sleeve 1610 or is swiped from the catheter 1602 by the distal hub 1606.

Guide Wire Compatibility

[0286] As indicated above, the vascular occlusion catheter systems, such as, for example, without limitation, the first, second and third preferred vascular occlusion catheter systems or occlusion catheter systems 100, 300, 500, are preferably capable of use without the need for a guide wire 1700. Guide wires 1700 are typically designed to navigate vessels to reach a desired vessel segment. Once the guide wire 1700 arrives at the destination in the vessel, the guide wire 1700 acts as a guide that facilitates delivery of the catheter system to the destination vessel segment. The atraumatic tip described above in detail with reference to the preferred embodiments of the occlusion catheter system 100, 300, 500, serves to guide the catheter as it traverses the vasculature and typically prevents the catheter from tracking into collateral vessels, while preferably eliminating the need for a guide wire for catheter placement.

[0287] Practitioners, may desire for the preferred vascular occlusion catheter systems described herein to include guide wire capability for familiarity purposes. Accordingly, as shown in Figs. 43 and 43A, an eighth preferred vascular occlusion catheter system 1701 is provided with guide wire capability, while not requiring the guide wire 1700 for use. In this preferred embodiment, the spiral or substantially circular shape of the atraumatic tip 1706, which is preferably configured in the same manner as the atraumatic tips 450, 550 of the second and third preferred embodiments, is positioned proximate an exit port 1702 of the catheter system 1701. The atraumatic tip 1706 may alternatively be removed and replaced with a distal end defining a substantially straight, compliant end and having the exit port 1702. The exit port 1702 is in communication with a guide lumen 1703 defined in a tip shaft 1705 of the atraumatic tip 1706. The guide lumen 1703 is preferably positioned coaxially or substantially parallel and proximate a longitudinal axis 1707 of the catheter system 1701. The catheter system 1701 preferably includes multiple lumens therein for inflation of an occlusion balloon 1708 and sliding receipt of the guide wire 1700.

[0288] In the preferred embodiment, the guide wire 1700 may be comprised of an eighteen thousandths of an inch (0.018") to an approximately twenty-five thousandths of an inch (0.025") or thirty-five thousandths (0.035") diameter guide wire 1700. The guide lumen 1703 and other lumens in the catheter system 1701 are designed and configured to accept sliding acceptance of the guide wire 1700. The guide wire 1700 may be slidably inserted and extend through the catheter system 1701, preferably coaxially or proximate and substantially parallel to the longitudinal axis 1707, and extend out of the distal end of the system 1701 through the exit port 1702. Accordingly, after the guide wire 1700 is inserted into a patient's body, the catheter system 1701 is capable of advancing over the guide wire 1700 to reach the desired vascular destination and the guide wire 1700 may subsequently be removed from the patient while retaining the system 1701, particularly the occlusion balloon 1708 therein.

[0289] The preferred catheter system 1701 includes a proximal hub (not show) that is the same or similar to the proximal hub of the herein described preferred embodiments. The proximal hub is connected to an inflation catheter member 1709 that is positioned at a proximal end of the occlusion member or occlusion balloon 1708. The inflation catheter member 1709 has an inflation lumen 1709a therein that opens into an internal space of the occlusion balloon 1708 at a first port 1709b. The inflation lumen 1790a and inflation catheter member 1709 are

preferably position on or along the longitudinal axis 1707. The occlusion balloon 1708 preferably has a proximal end 1708a and a distal end 1708b, wherein the proximal end is connected to the inflation catheter member 1709. A distal catheter member 1705, which may be comprised of the tip shaft 1705 or may be a separate catheter member is positioned substantially on the longitudinal axis 1707 and is connected to the distal end 1708b of the balloon 1708.

[0290] The atraumatic tip 1706 is connected to or formed integrally with the distal catheter member or tip shaft 1705. The guide lumen 1703 is formed within the distal catheter member or tip shaft 1705 for slidable receipt of the guide wire 1700, preferably substantially along the longitudinal axis 1707.

[0291] In the preferred embodiment, the catheter system 1701 may maintain the generally spiral or substantially circular shaped atraumatic tip 1706 during insertion and the guide wire 1700 exits the catheter system 1701 through the exit port 1702 below the atraumatic tip 1706 such that the guide wire 1700 may be initially inserted into the patient and the system 1701 is guided into position along the guide wire 1700. The lumens of the preferred system 1701, including the guide lumen 1703 are in communication with the exit port 1702 and are appropriately dimensioned to accommodate the desired diameter guide wire 1700. In the preferred embodiment, the exit port 1702 is positioned on a lower side of the atraumatic tip 1706, opposite the circular profile, such that the circular profile is preferably oriented in its relaxed configuration after insertion into the patient's vessel and during the guiding movement into the appropriate location for the procedure in the vessel.

[0292] The catheter system 1701 of the eighth preferred embodiment may also be configured such that the exit port 1702 is located on an opposite side of the atraumatic tip 1706 in the tip shaft 1705. Referring to Figs. 43B and 43C, the alternative eighth preferred embodiment of the catheter system 1701' has similar features when compared to the preferred catheter system 1701 and like reference numerals are utilized to identify and describe like features with a prime symbol (') utilized to distinguish the eighth preferred embodiment from the alternative preferred embodiment. In the alternative preferred embodiment, the exit port 1702' is positioned proximate an inner tip surface 1709' of the atraumatic tip 1706' such that the guide wire 1700 would extend out of the alternative preferred system 1701' into the inner surface 1709' of the atraumatic tip 1706'. The guide wire 1700 is preferably sufficiently flexible to deflect out of the way of the atraumatic tip 1706' as it extends out of the exit port 1702' to guide the catheter

system 1701' to the appropriate location in the vessel and position the occlusion member (not shown) in the appropriate zone, such as zone I, II or III, as is described above in the Summary of the Invention section. The alternative eighth preferred embodiment otherwise operates substantially the same as the eighth preferred embodiment of the system 1701 with the guide wire 1700.

Power Injection Capability

[0293] Injecting contrast media into a patient's vasculature enables increased visualization using fluoroscopy. Contrast delivery is most effective and efficient using a medical device called a "power injector" that can be programmed to deliver specific amounts of contrast agent at specific flow rates.

[0294] Referring to Figs. 44, in a ninth preferred embodiment, an occlusion catheter system 1800 includes multiple or a plurality of side ports 1809 to distribute contrast medium in the vasculature rapidly and evenly, preferably distally relative to an occlusion member 1808. At least one side port 1809 (multiple side ports in the illustrated embodiment) is in fluid communication with a lumen, e.g., the first, second and/or third lumen as described above with respect to the preferred catheter systems 100, 300, 500, 1300, 1350, accessible from the proximal hub (not shown), such as, for example, without limitation, the proximal hubs 190, 590, 790. Accordingly, contrast medium pumped into the catheter 1800 from the proximal hub is dispensed from the plurality of side ports 1809 and into the surrounding vasculature.

[0295] The catheter 1800 is preferably configured in a similar manner to the occlusion catheter system 100 with the first catheter member 130 having the first lumen 230, the second catheter member 110 having the second lumen 210 and the atraumatic tip 150 with a proximal portion comprised of the third catheter member 120 with the third lumen 220. The multiple side ports 1809 are preferably formed in the proximal portion of the atraumatic tip 150, the third catheter member 120 or the first catheter member 130 and may also be formed in each of these components of the catheter 1800. The plurality of side ports 1809 are in fluid communication with the first lumen 230 through the first catheter member 130, which is preferably in fluid communication with a power injection mechanism (not shown) through the first fluid pathway 192 in the proximal hub 190. The space within the occlusion member 1808 is preferably in fluid communication with an injection mechanism, such as the inflation control system 1500 through

the second fluid pathway 194 and the second lumen 210, which introduces pressurized fluid or gas into the occlusion member 1808 through the distal port opening 160.

[0296] In the illustrated embodiment, the side ports 1809 are located distally from the occlusion member 1808. The side ports 1809, however, may be located proximally and/or distally of the occlusion member 1808 and the number of side ports 1809 may be determined according to the desired dispensing rate. The plurality of side ports 1809 may also be located in a single plane or in a circumferential manner around the catheter shaft. The plurality of side ports 1809 may also be utilized to withdraw fluids from the patient's vasculature, such as, for example, for blood sampling.

[0297] The lumen in fluid communication with the side ports 1809 may be a hypotube constructed of a metal (e.g., nitinol), a polymer, a reinforced polymer (e.g., braided), or a composite material in order to withstand power injection pressures. The catheter hub, extension lines, and connectors are also constructed of the appropriate polymer/composite material in order to withstand power injection pressures. For example, extension lines may be braid reinforced or otherwise reinforced to withstand the power injection pressures. The catheter 1800 is, therefore, capable of being used safely with a power injector for contrast injections. The catheter 1800 may also be used for visualization of hemorrhage using fluoroscopy by injecting visualization agent into the patient and visualizing flow and, particularly hemorrhage.

Infusion Catheter

[0298] Referring to Fig. 45, an infusion catheter or occlusion catheter system 1900 in accordance with a tenth preferred embodiment (not including an occlusion member) can be utilized to infuse and withdraw fluids from a patient's vascular system. Similarly to the occlusion catheter 100, 300, 500, the infusion catheter 1900 includes a distal, curled/spiral, polymeric atraumatic tip 1906 to assist the catheter 1900 to track up a blood vessel and remain in the central lumen of the vasculature. The catheter shaft 1910 is configured to have an appropriate stiffness to be pushable without kinking, while also being sufficiently flexible to not damage blood vessels. The catheter shaft 1910 may be constructed of a polymeric material, a metallic material, or a combination of plastic, metal, and composite materials (e.g., fiberglass, carbon fiber, nylon, etc.) to achieve the appropriate stiffness. The catheter shaft 1910 may be approximately five French (5 Fr) or five and twenty-four hundredths millimeters (5.24 mm), but

may alternatively be constructed in other sizes as necessary. Similarly, the diameter of the generally circular profile of the atraumatic tip 1906 (discussed below) may also be sized appropriately according to the destination vessel size. The atraumatic tip 1906 is preferably designed and configured similar to the atraumatic tips 450, 550 of the second and third preferred embodiments of the occlusion catheter system 300, 500, as is described above.

[0299] Similarly to the occlusion catheter systems 100, 300, 500 of the first, second and third preferred embodiments, the infusion catheter 1900 of the tenth preferred embodiment is intended to be used without a guide wire for rapid insertion. The combination of the atraumatic tip 1906 and catheter shaft 1910 substantially negates the need for a separate guide wire, as is typically utilized in procedures introducing catheters, stents, screws or other devices into the patient. The infusion catheter 1900 preferably has a single lumen 1912 connected to a hub (not shown), e.g., with a standard luer lock fitting (not shown) at the proximal end of the occlusion catheter system 1900. The occlusion catheter system 1900 may alternatively be connected with a hub via any of numerous different connectors/fittings, that are currently known or that later become known.

[0300] The catheter shaft 1910 of the tenth preferred embodiment includes a plurality of side ports 1909 (a plurality of ports 1909 in the illustrated embodiment) proximal relative to the atraumatic tip 1906. The plurality of side ports 1909 is in fluid communication with the lumen 1912. A fluid may be injected at the catheter hub and exit into the vasculature at the plurality of side ports 1909. The plurality of side ports 1909 preferably assist in distributing the fluid evenly to prevent the fluid stream from causing damage to the blood vessel. The plurality of side ports 1909 maybe be positioned in a single plane or spiral around the catheter shaft 1910 or may otherwise be arranged and configured to facilitate injection in a manner desired by the medical professional or designer.

[0301] As explained above, the catheter shaft 1910 is preferably constructed of a material capable of withstanding the pressures and flow rates of power injection for contrast visualization. The catheter shaft 1910 could be braided or non-braided. The catheter 1900 may also be used for blood pressure monitoring via an external pressure sensor or to withdraw fluids (i.e. blood sampling, blood filtration/oxygenation (extracorporeal membrane oxygenation (“ECMO”), etc.).

[0302] The infusion catheter 1900 may be used in combination with an occlusion catheter system, but is not so limited. For example, an occlusion catheter system could be placed in the

right femoral artery and advanced to the aorta and the occlusion member inflated to occlude the vessel. The infusion catheter 1900 could be inserted via the left femoral artery and used to infuse fluids (i.e. blood products, hyperoxygenated perfusate, crystalloids, etc.). The infusion catheter 1900 could also be used with a power/hand injector to inject radiopaque contrast (CO₂, Isovue, etc.) to visualize the hemorrhage.

[0303] The infusion catheter 1900 may be packaged with a pre-installed “peel-away sheath” that is used to straighten the atraumatic tip 1906 for insertion into the valve of the introducer sheath or directly into the blood vessel. The peel-away sheath is advanced distally to capture and straighten the atraumatic tip 1906 and then can be retracted proximally toward the catheter hub and peeled off the catheter shaft 1910 if necessary.

Decision Support Systems

[0304] Intelligent systems are becoming widely accepted and are finding their way into acceptance in medical diagnostics and in the performance and predictive analysis of medical device clinical trials. Articles and presentations have been given related to this subject matter.

[0305] An approach based on Bayesian statistics is an approach for learning from evidence as it accumulates. In clinical trials, traditional statistical methods may use information from previous studies only at the design stage. Then, at the data analysis stage, the information from these studies is considered as a complement to, but not part of, the formal analysis. In contrast, the Bayesian approach uses Bayes’ Theorem to formally combine prior information with current information on a quantity of interest. The Bayesian idea is to consider the prior information and the trial results as part of a continual data stream, in which inferences are being updated each time new data become available.

[0306] The Bayes theorem may be used to calculate the probability of coronary artery disease based upon clinical data and non-invasive test results. Pre-test probabilities of disease are assigned based on clinical data and the equation is used to calculate post-test probabilities after multiple sequential tests. When good prior information on clinical use of a device exists, the Bayesian approach enables this information to be incorporated into the statistical analysis of a given decisional matrix.

[0307] Good prior information is often available for medical devices because of their mechanism of action and evolutionary development. The mechanism of action of medical

devices is typically physical. As a result, device effects are typically local, not systemic. Local effects can sometimes be predictable from prior information on the previous generations of a device when modifications to the device are minor. Good prior information can also be available from studies of the device overseas.

[0308] Bayesian methods are usually less controversial when the prior information is based on empirical evidence such as data from clinical trials. Bayesian methods can, however, be controversial when the prior information is based mainly on personal opinion.

[0309] Bayesian analyses are often computationally intense. Recent breakthroughs in computational algorithms and computing speed have, however, made it possible to carry out calculations for very complex and realistic Bayesian models. These advances have resulted in an increase in the popularity of Bayesian methods. A basic computational tool is a method called Markov Chain Monte Carlo (“MCMC”) sampling, which is a method for simulating from the distributions of random quantities.

[0310] As the Bayesian predictive modeling scheme has become well known, it is useful in conjunction with the various control systems of the present invention, as described above, as predictive analysis profiling during a vascular occlusion procedure.

[0311] In connection with the present invention, the various preferred embodiments of the occlusion catheter systems and related components and devices described herein, and the occlusion or the occlusion/perfusion control over the vascular occlusion devices, is well suited to oversight and control using intelligent systems, such as those in which Bayesian probability analysis is applied. In each of the above-described embodiments, including without limitation, the vascular occlusion devices, the occlusion catheter systems, the control systems for controlling apposition of the occlusion member against the vessel wall or for excluding the hemorrhage site, the pre-conditioning systems or the occlusion/perfusion systems, both physical and/or physiological data is either acquired or is capable of being acquired. Acquisition of real-time physical and/or physiological data during an occlusion procedure or during a vascular repair involving a vascular occlusion includes, without limitation, blood pressure, heart rate, flow, chemistry, temperature, oxygenation, imaging or the like. In combination with prior data obtained from clinical practice guides, standard of care protocols, process flowcharts, and other data acquired during prior procedures, intelligent predictive analysis may be applied in software or firmware resident at the computer controllers, e.g., controllers 750, 753, 803, to either

automatically control the preferred systems described herein or to output intelligently processed information to the medical practitioner to aid in decision making during the occlusion procedure.

[0312] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. For example, nearly any of the individual components of the various embodiments may be incorporated with other preferred embodiments without departing from the spirit and scope of the preferred inventions. The plurality of proximal and distal side ports may be incorporated in nearly any of the preferred occlusion catheter systems, the atraumatic tips may be mixed and matched with the various embodiments of the occlusion catheter systems, nearly any of the preferred occlusion members, such as the first preferred occlusion balloon system 1200 with the projecting members 1204 may be incorporated with any of the preferred occlusion catheter systems and other similar arrangement of the disclosed features of the preferred systems may be employed without departing from the spirit and scope of the disclosed preferred inventions. It is understood, therefore, that the invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention, as defined by the appended claims.

CLAIMS

We claim:

1. An occlusion catheter system comprising:
 - a proximal hub having a flow valve;
 - a proximal catheter section in fluid communication with the proximal hub;
 - a distal catheter section distally terminating with an atraumatic tip;
 - an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being constructed of a compliant biocompatible material;
 - at least one length marking on an exterior of the proximal catheter shaft to indicate an insertion depth of the occlusion catheter system;
 - a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon; and
 - a solid wire extending within the proximal catheter section, the occlusion balloon and the distal catheter section,
- the occlusion balloon, the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.
2. The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.
3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.
4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.
5. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.
6. The occlusion catheter system of claim 1, wherein the solid wire is secured to the proximal hub.

7. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.

8. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.

9. The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon;

10. An inflation control system kit comprising:
the occlusion catheter system of claim 1; and
a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.

ABSTRACT OF THE DISCLOSURE

An occlusion catheter system includes a proximal hub having an inflation connection port and an inflation pathway. An inflation catheter member is connected to the proximal hub and has an inflation lumen. A stiffener member defines a longitudinal axis. The proximal end of the stiffener member is connected to the proximal hub. The stiffener member extends through a portion of the inflation lumen. An occlusion balloon has a proximal balloon end and a distal balloon end. A distal catheter member is positioned substantially on the longitudinal axis and is connected to the distal end of the stiffener member. An atraumatic tip is positioned on a distal end of the distal catheter member. The atraumatic tip has a substantially circular profile in a relaxed configuration. A pressure sensor is connected to the occlusion catheter system distally relative to the occlusion balloon and is connected to a processor by electrical wiring.

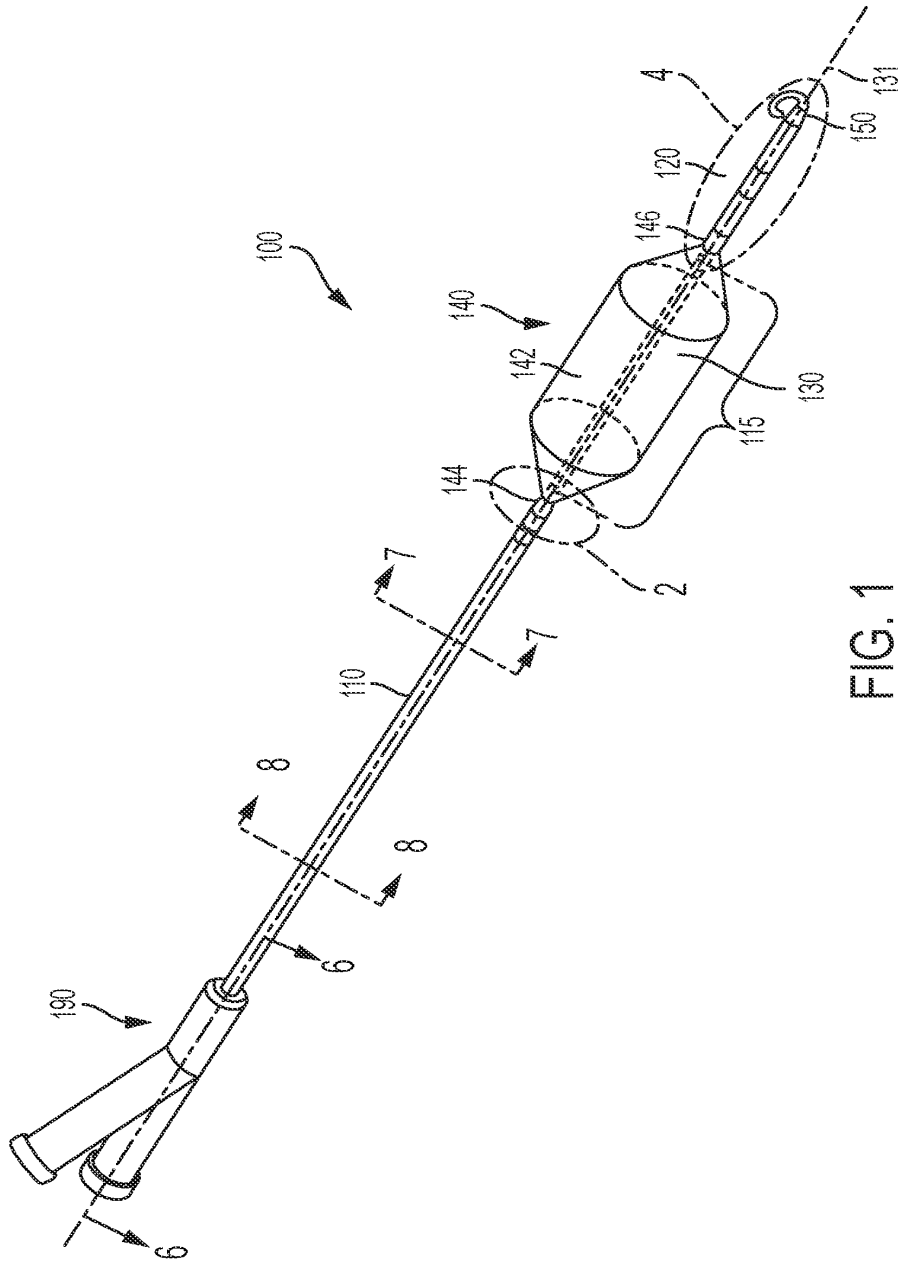


FIG. 1

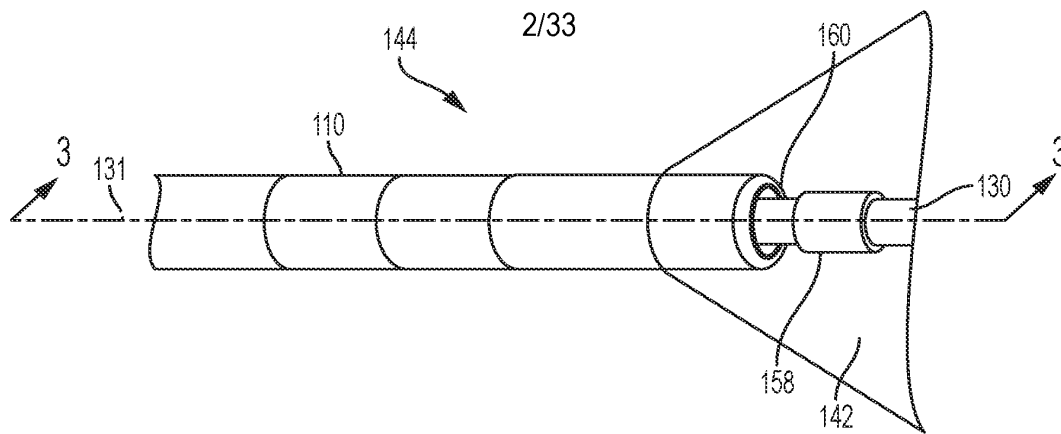


FIG. 2

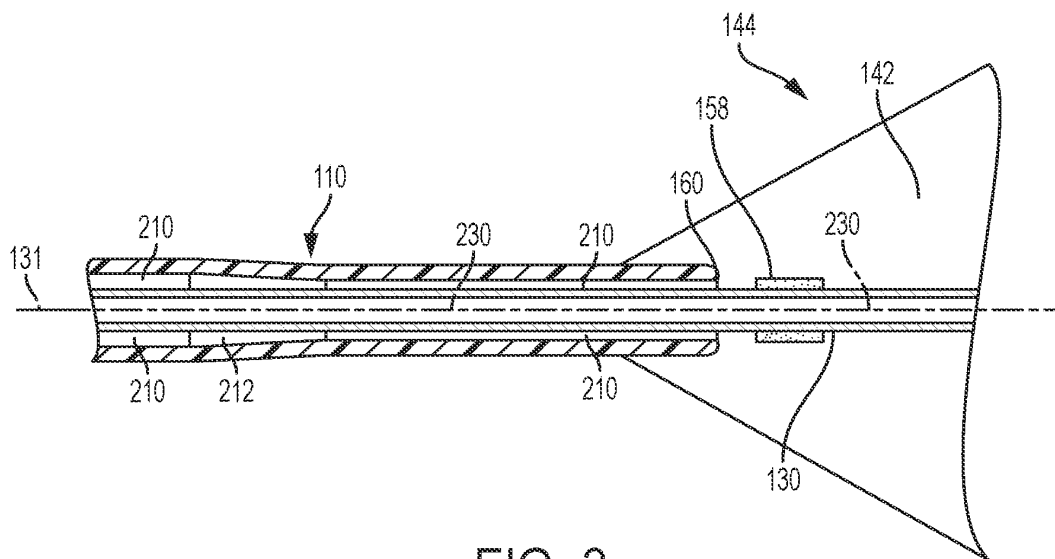


FIG. 3

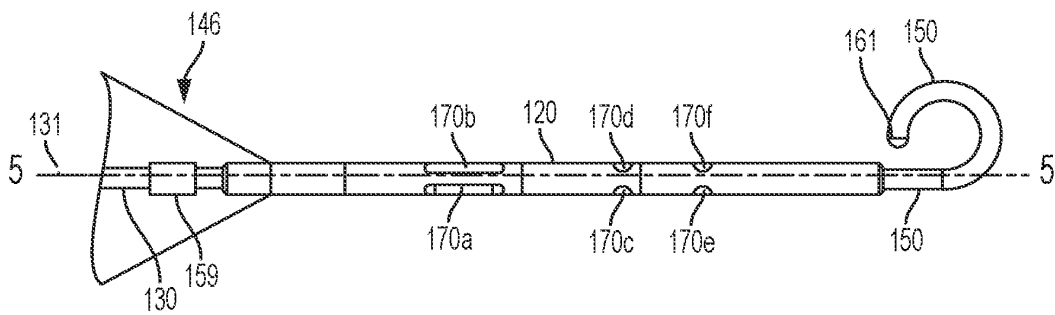


FIG. 4

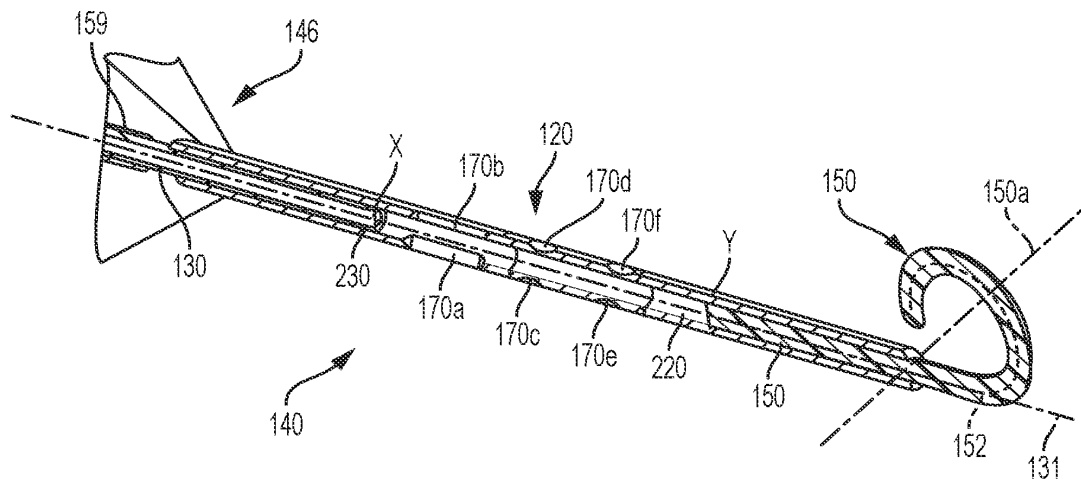


FIG. 5

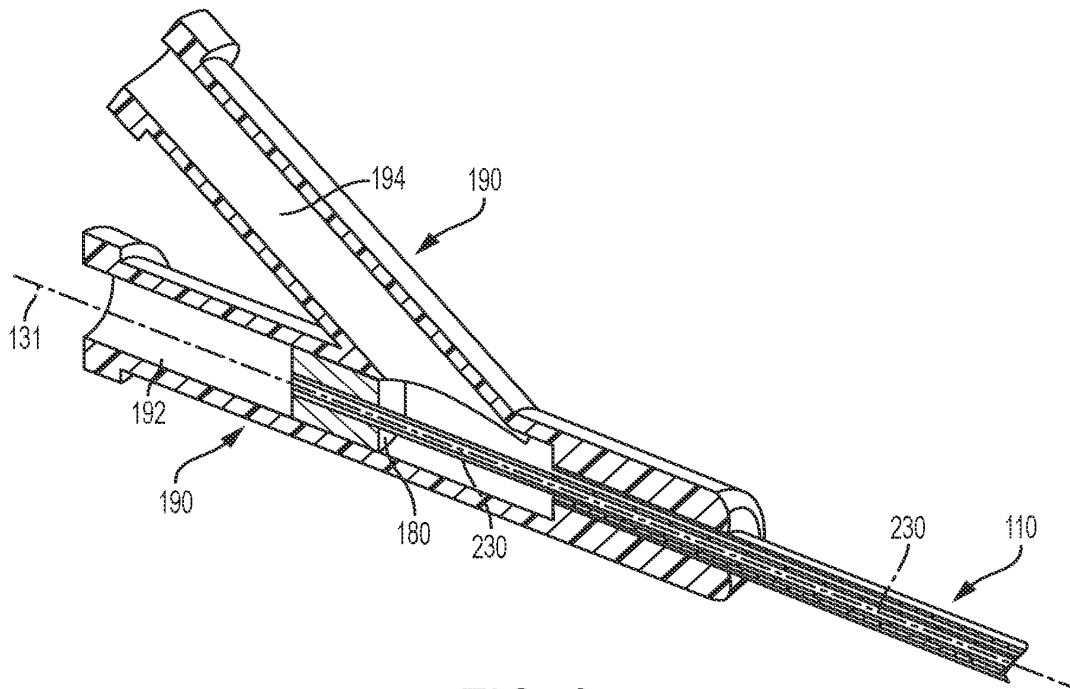


FIG. 6

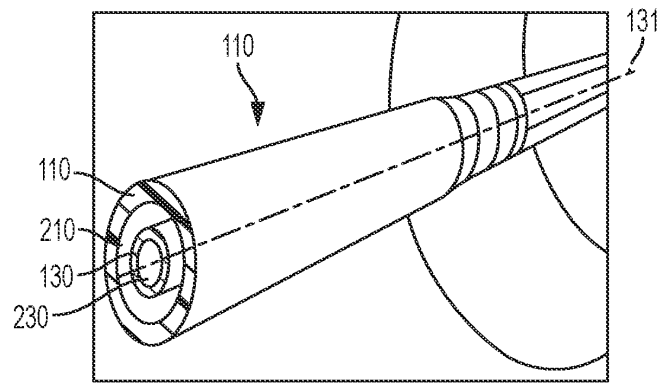


FIG. 7

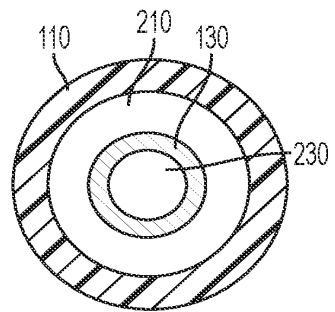


FIG. 8

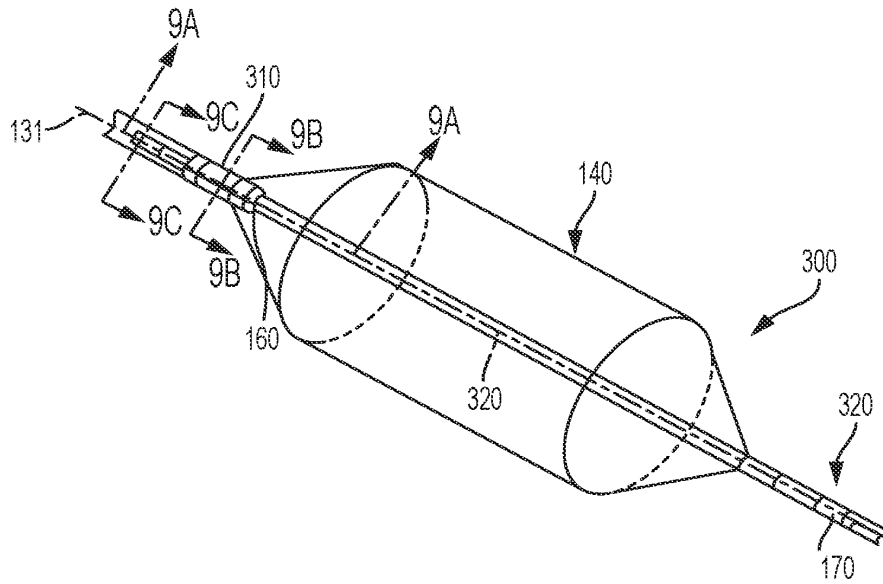


FIG. 9

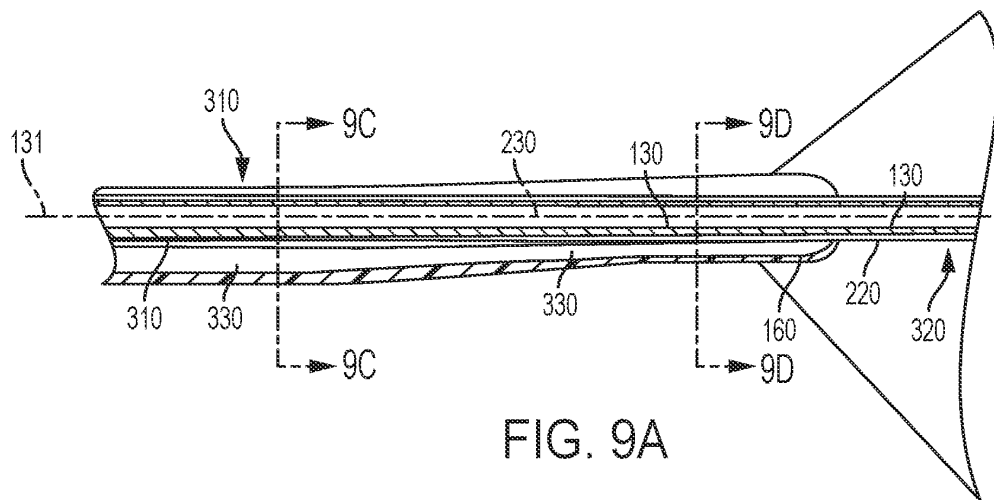


FIG. 9A

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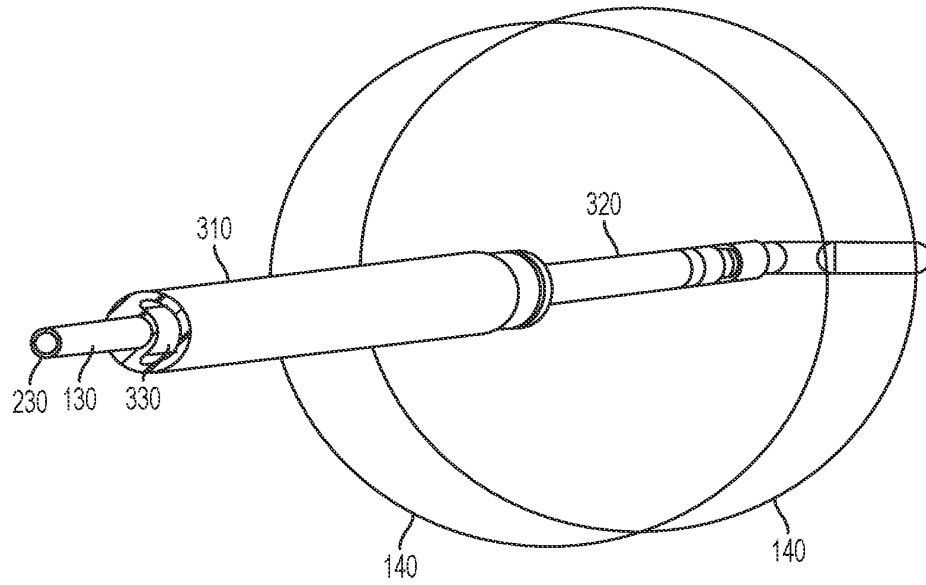


FIG. 9B

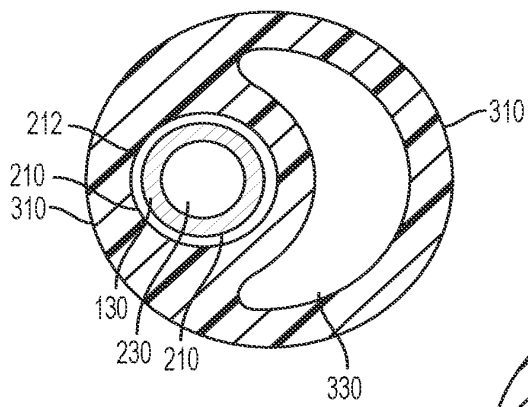


FIG. 9C

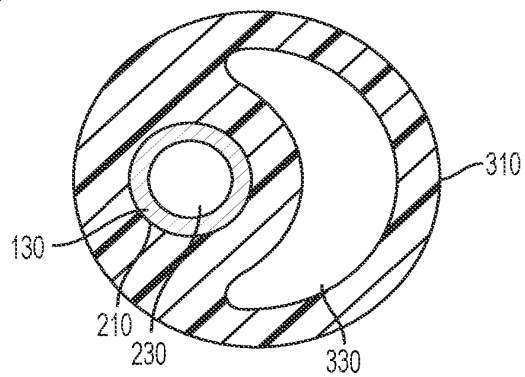
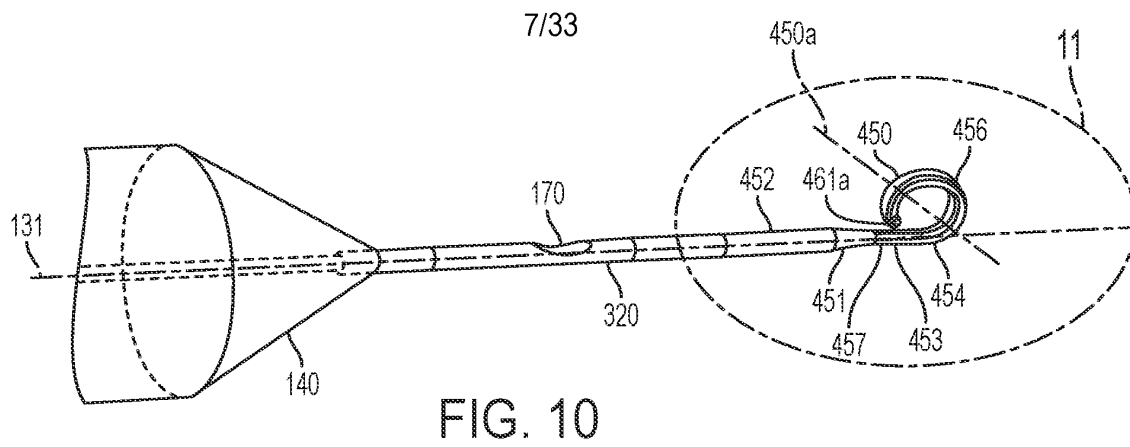
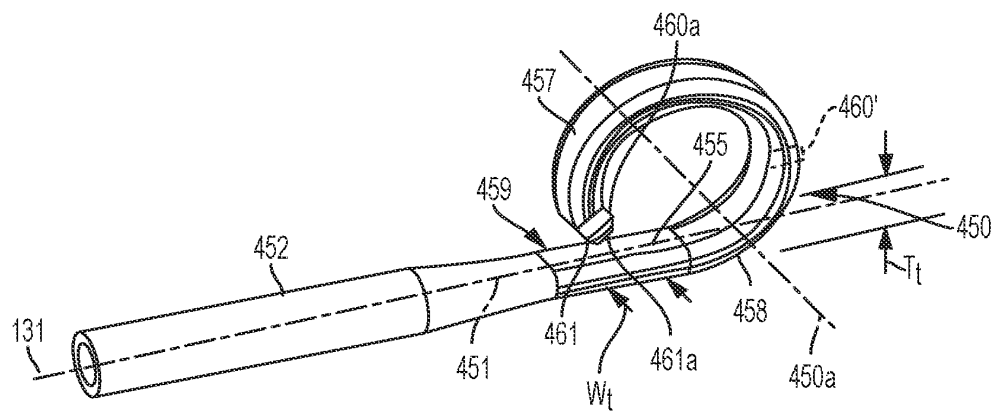
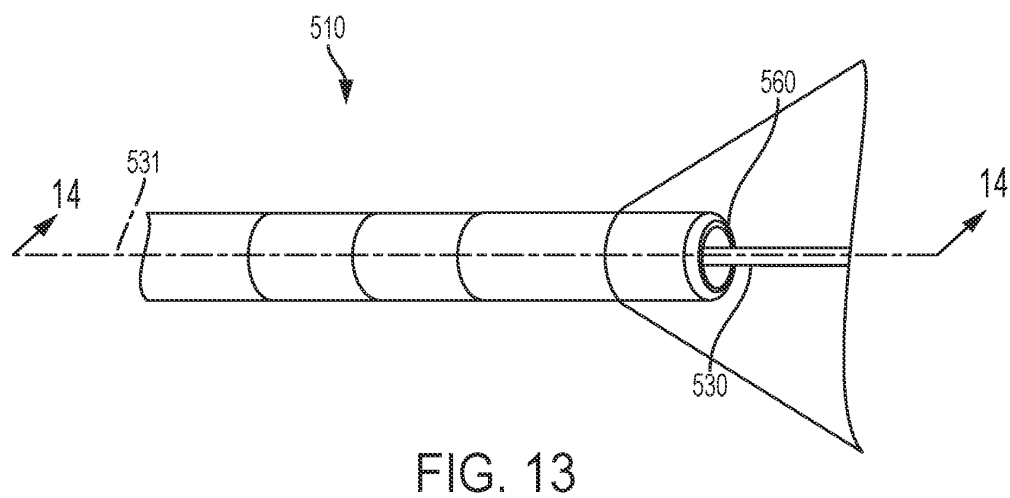


FIG. 9D



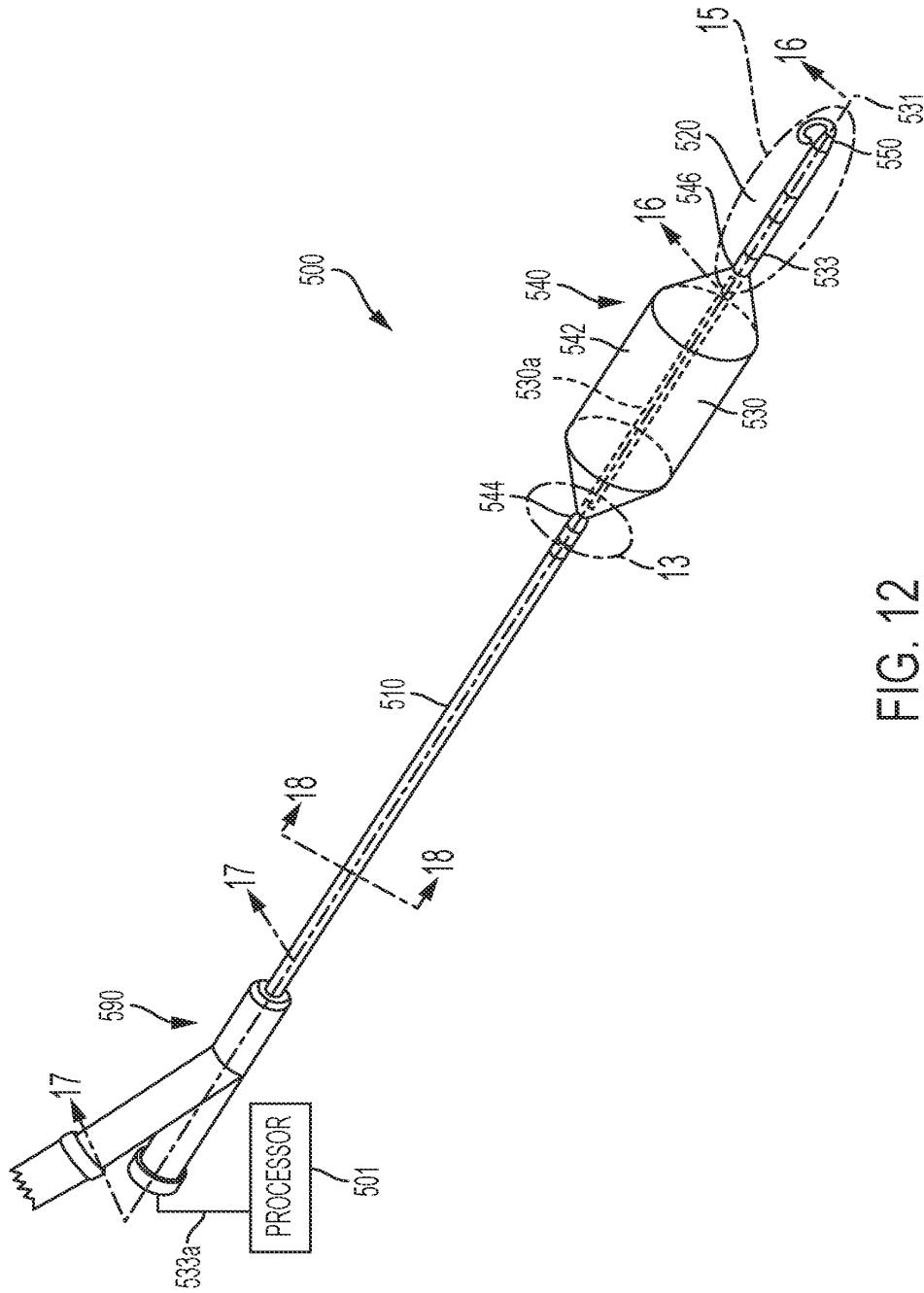


FIG. 12

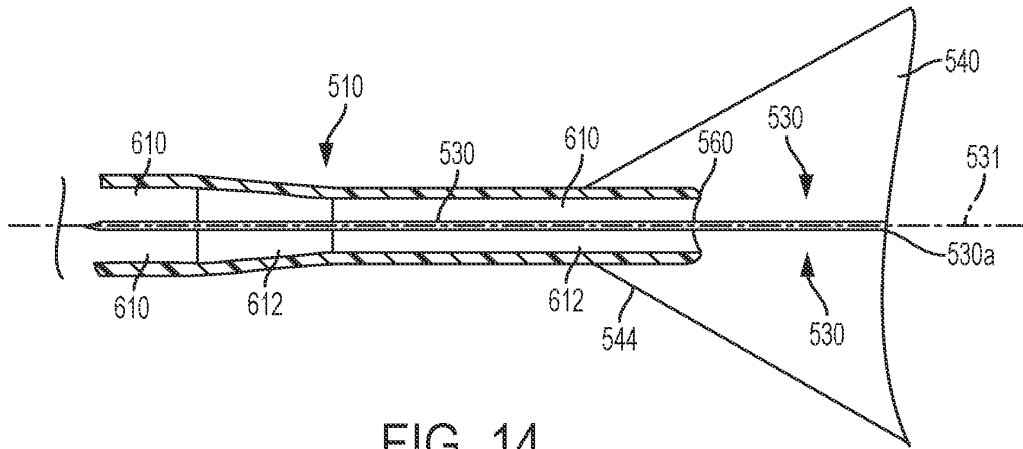


FIG. 14

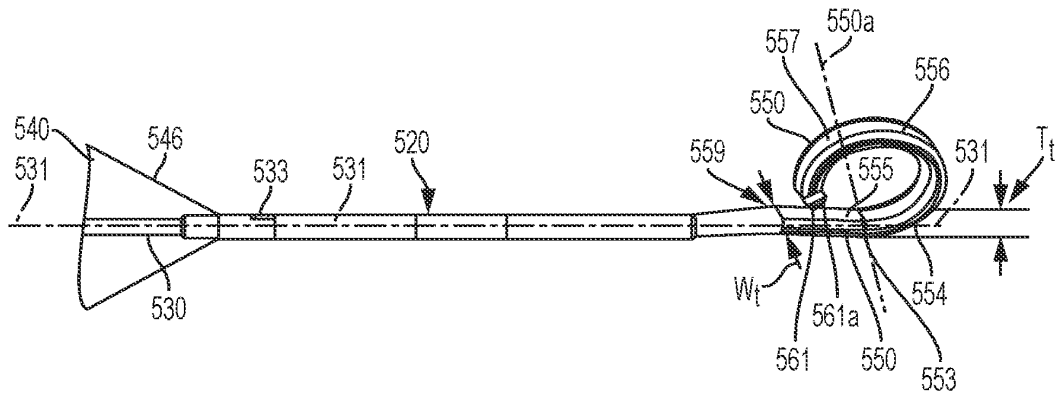
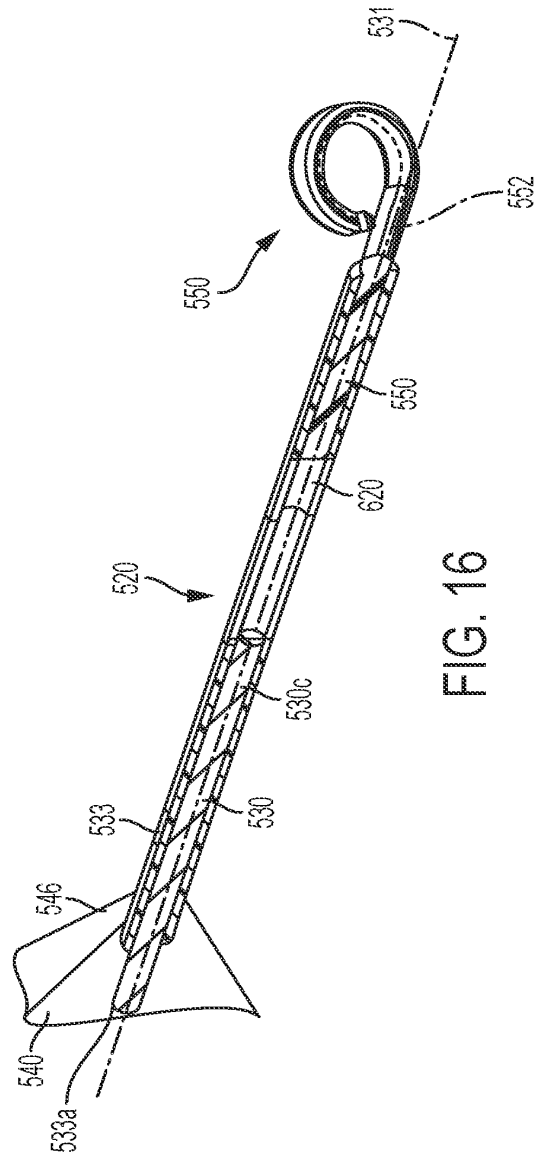
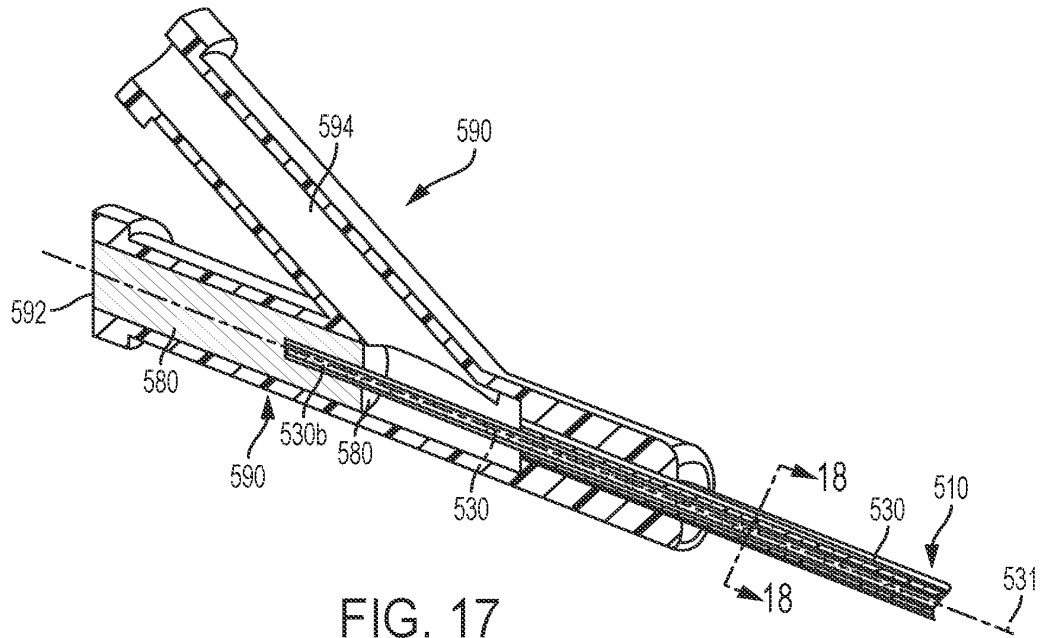
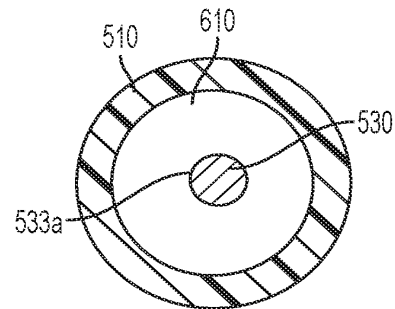


FIG. 15





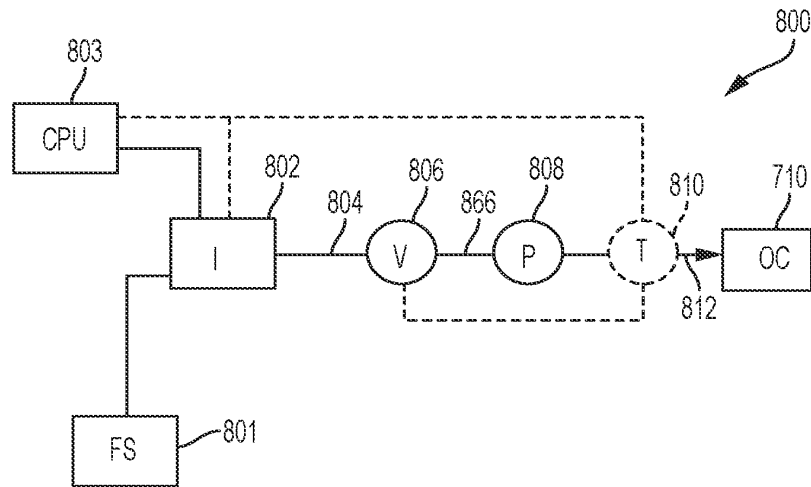


FIG. 21

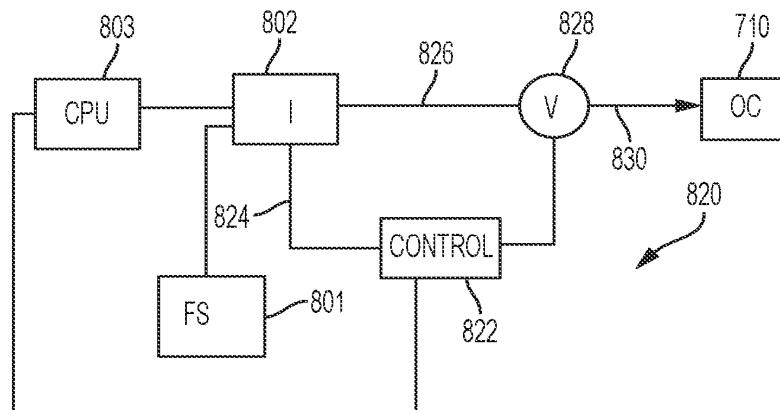


FIG. 22

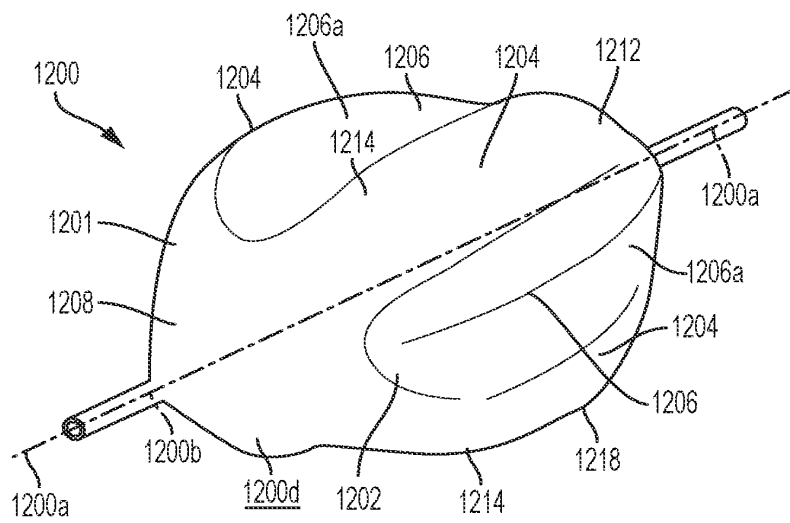


FIG. 26

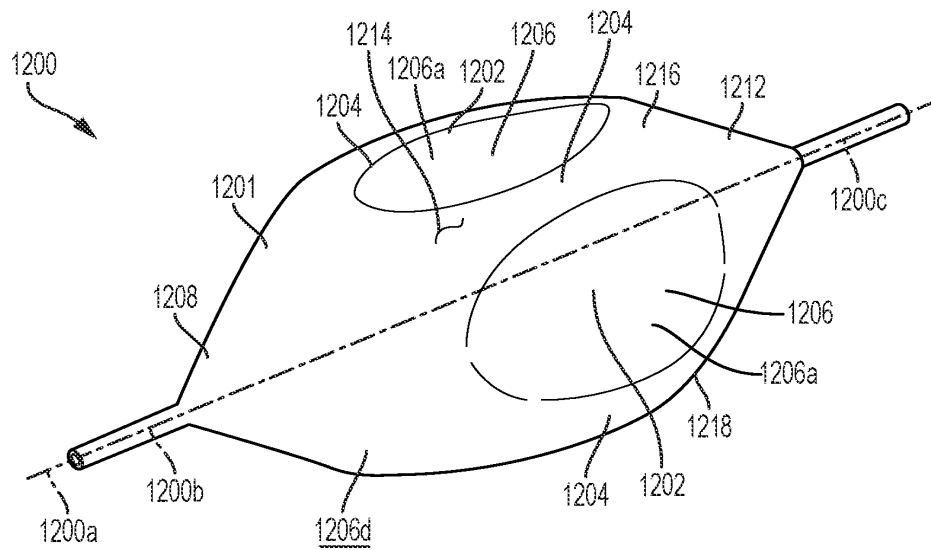


FIG. 27

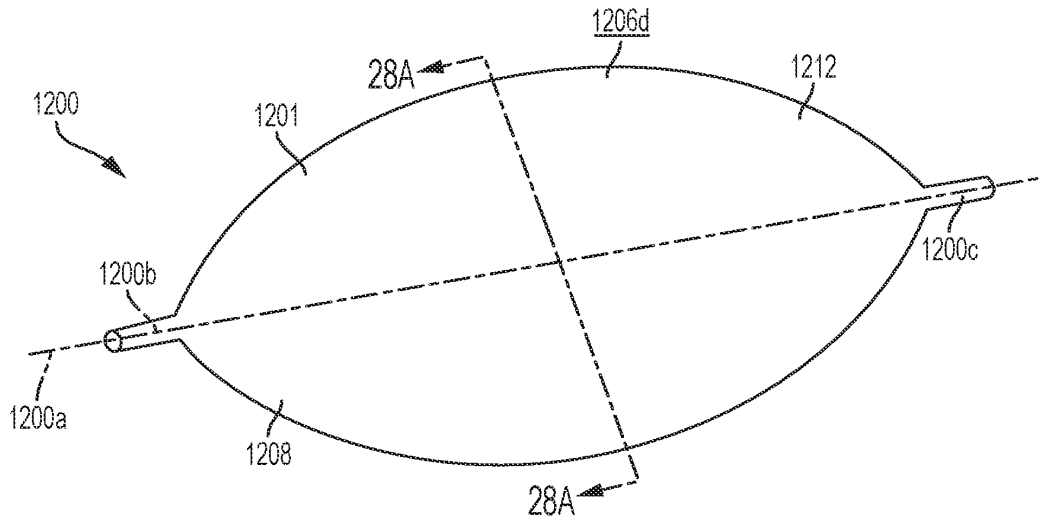


FIG. 28

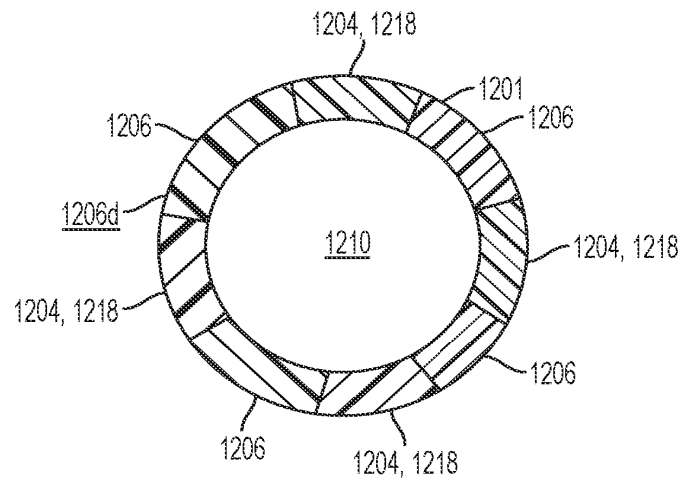


FIG. 28A

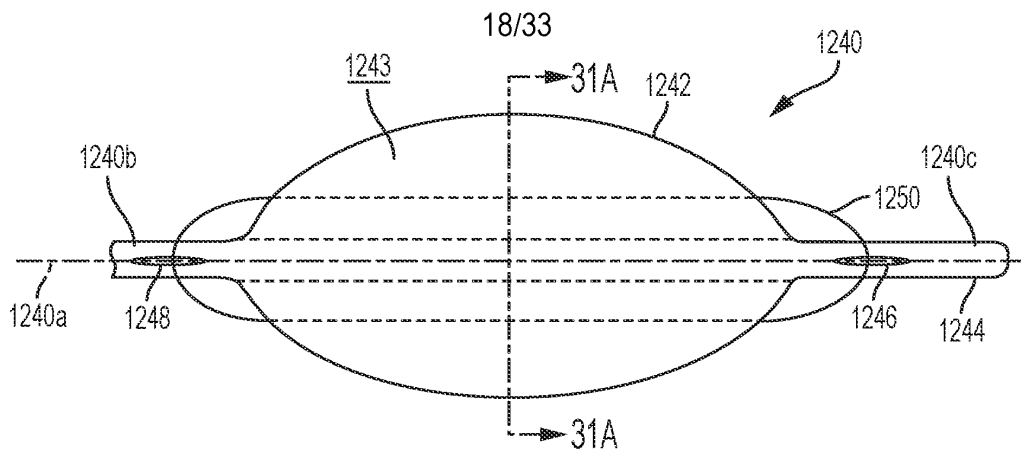


FIG. 31

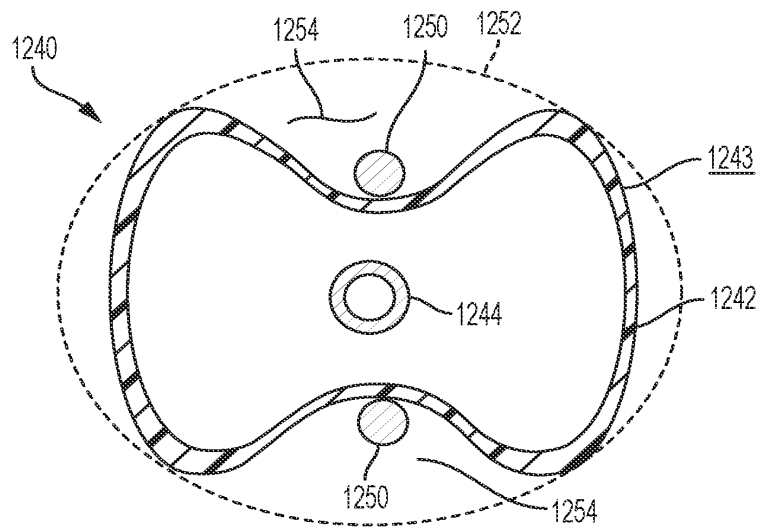


FIG. 31A

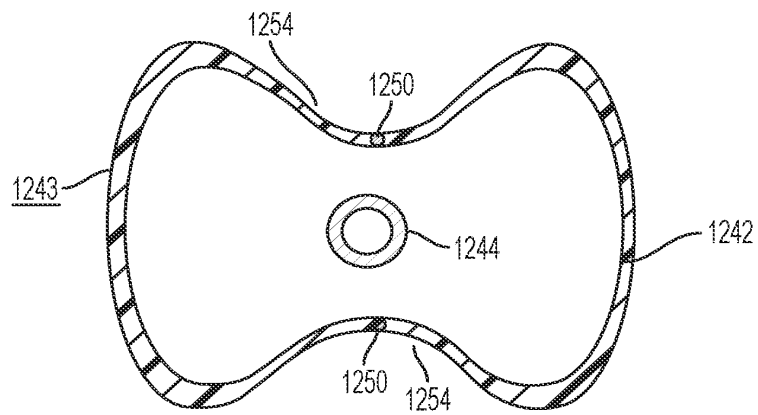


FIG. 31B

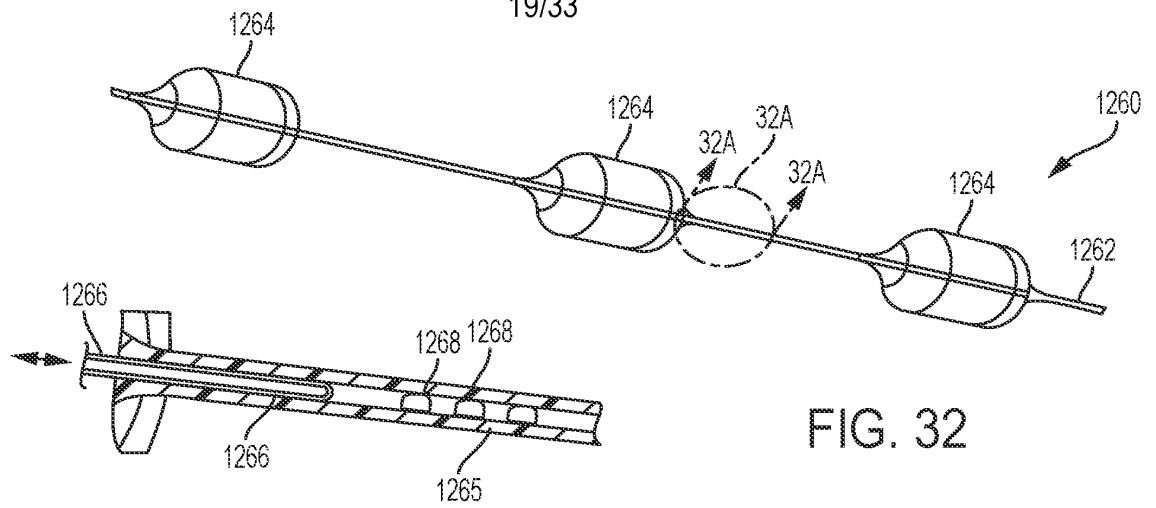


FIG. 32

FIG. 32A

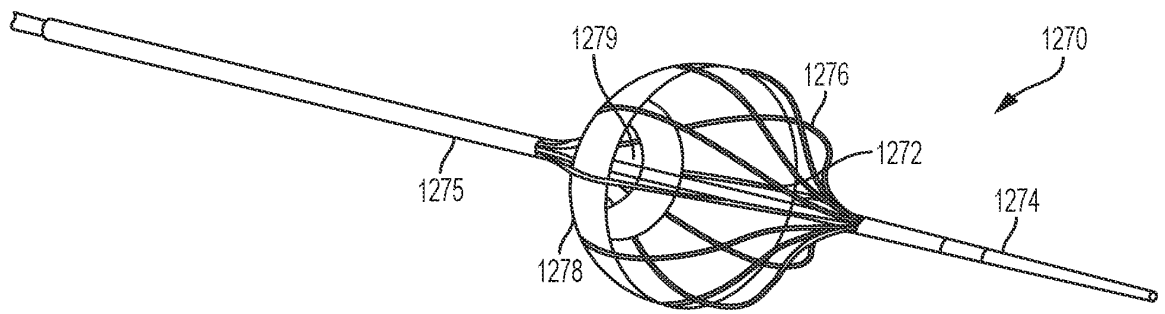


FIG. 33

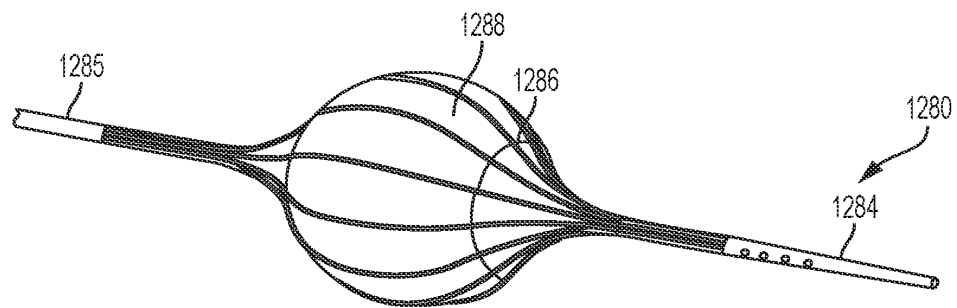


FIG. 34

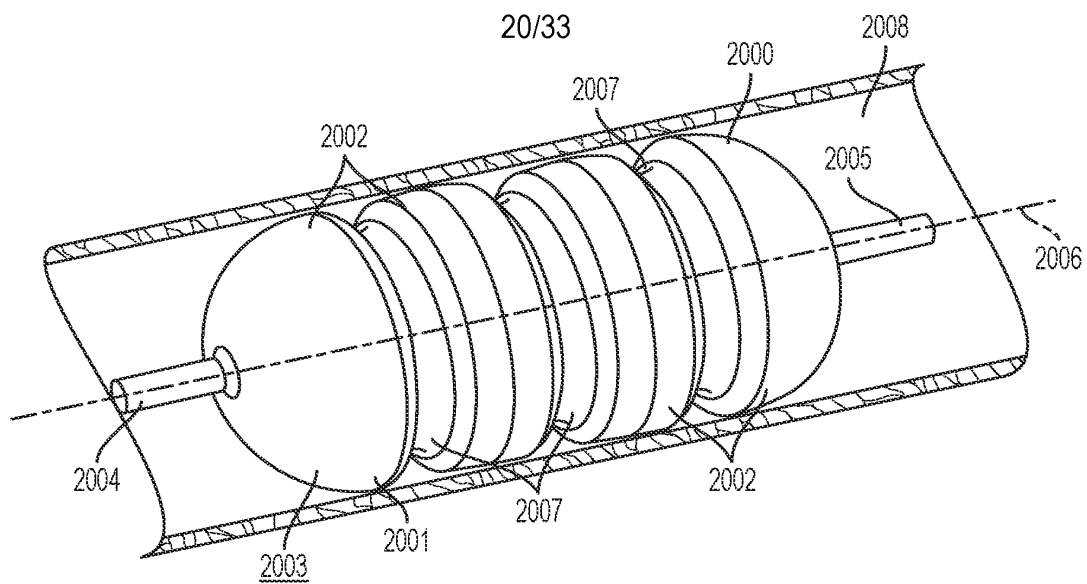


FIG. 35A

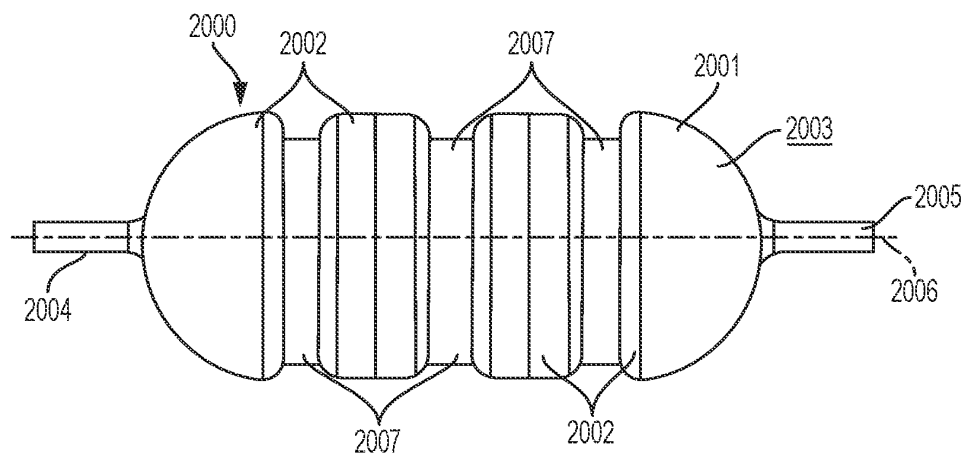


FIG. 35B

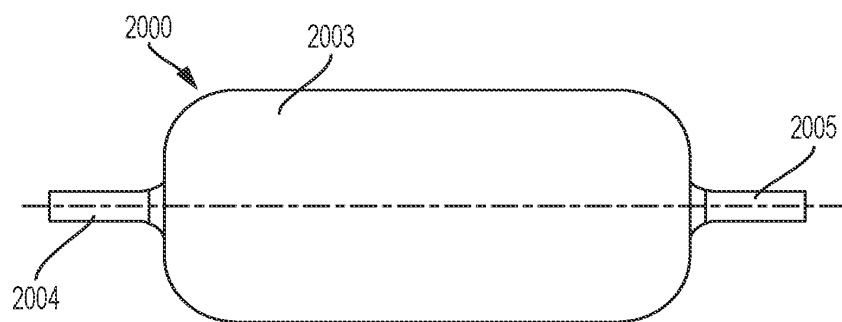


FIG. 35C

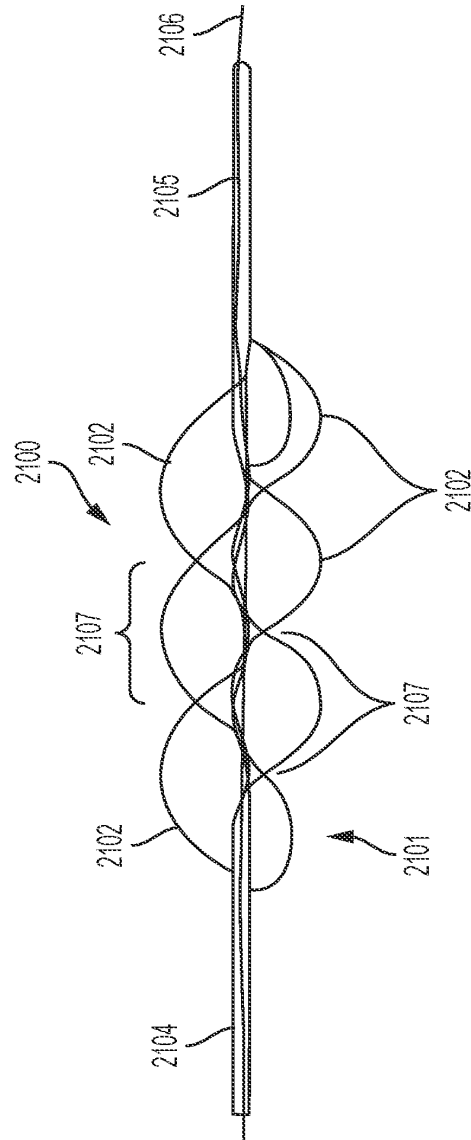
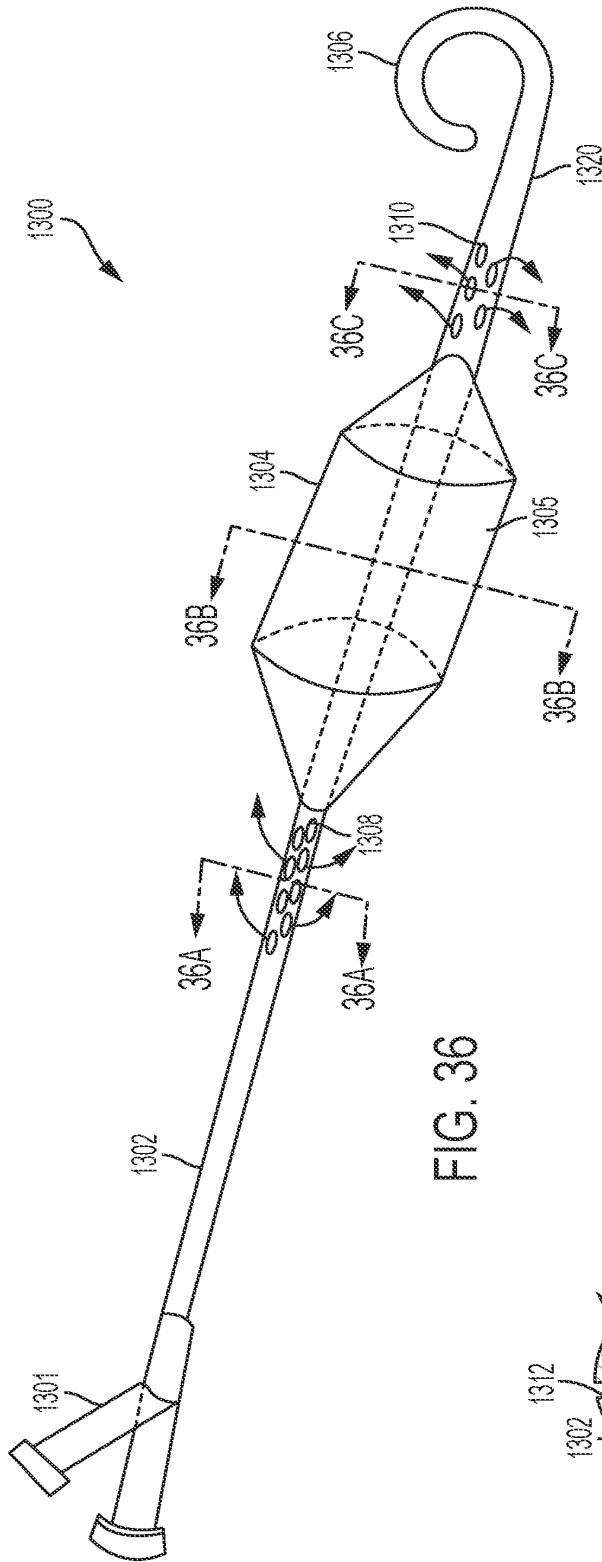
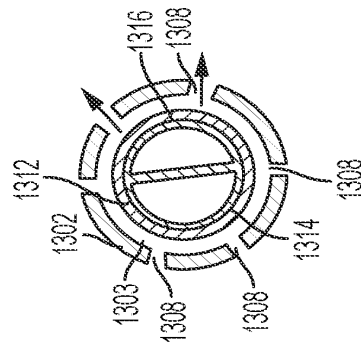
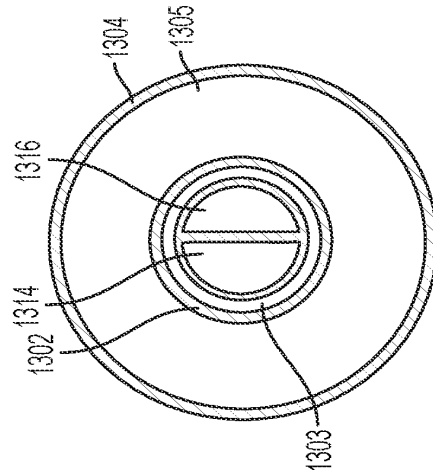
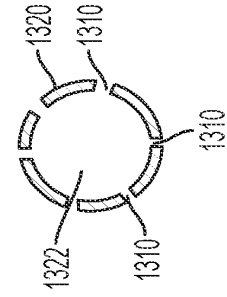
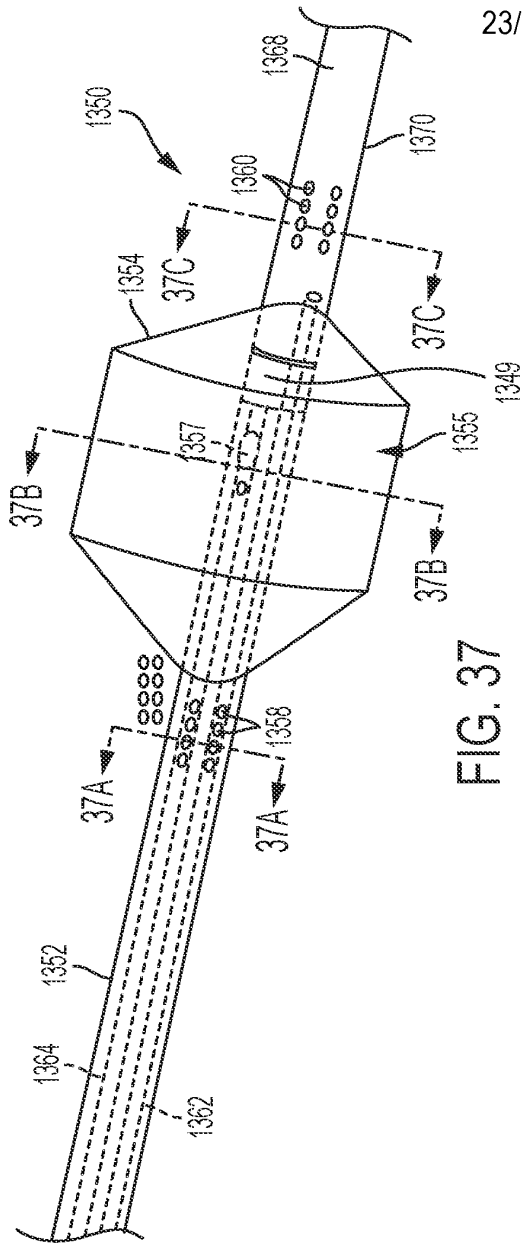
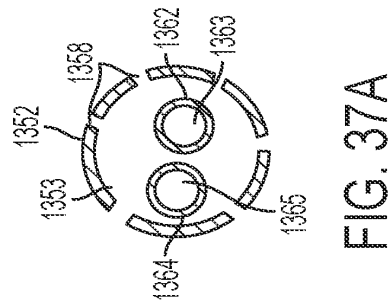
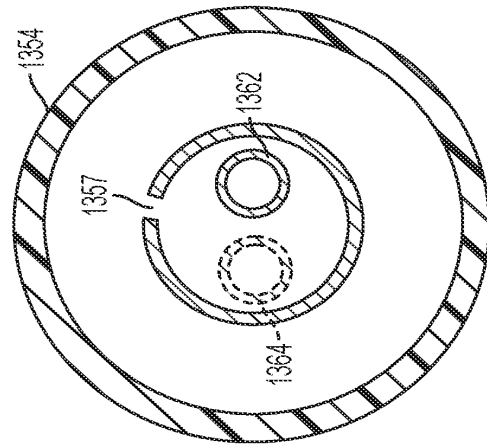
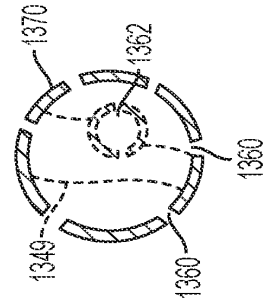
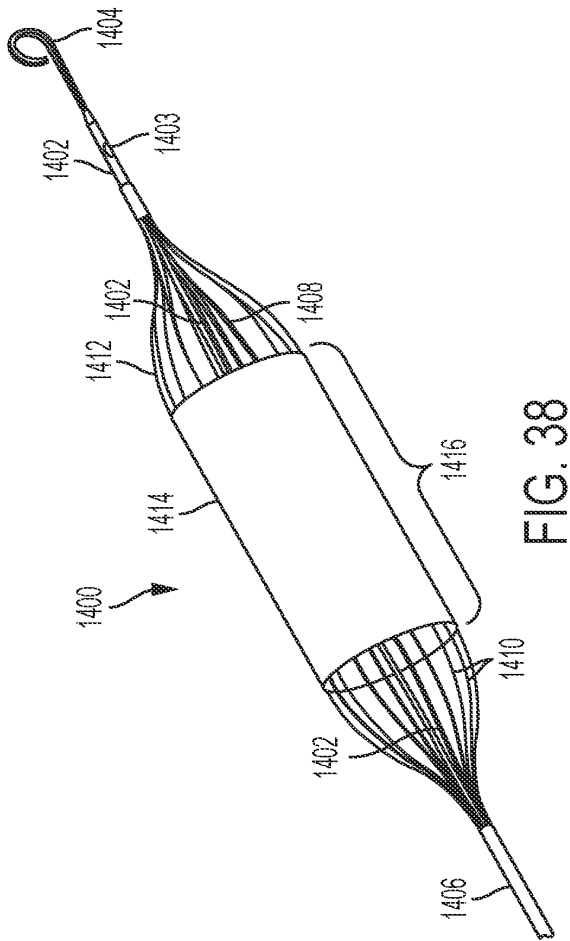
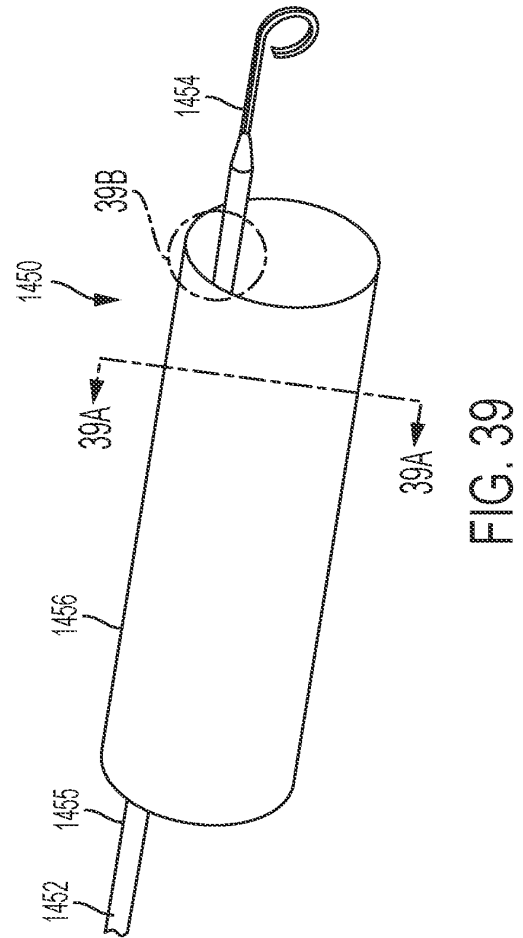


FIG. 35D







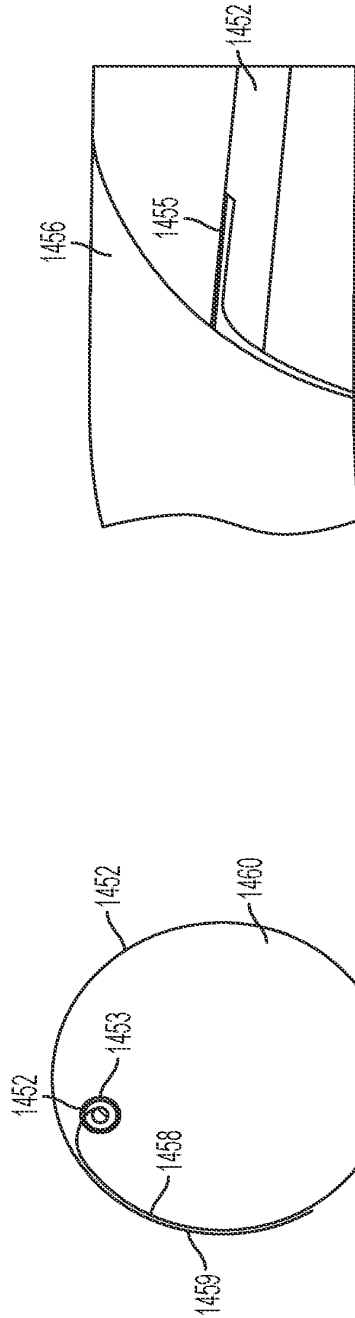


FIG. 39A

FIG. 39B

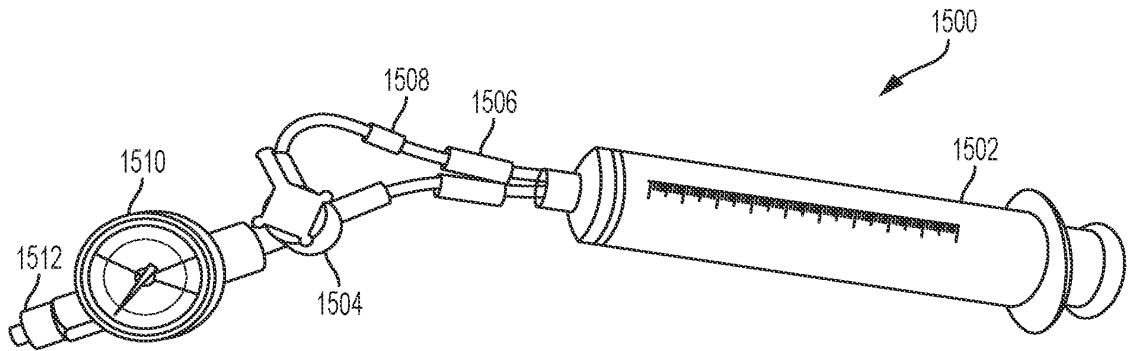


FIG. 40

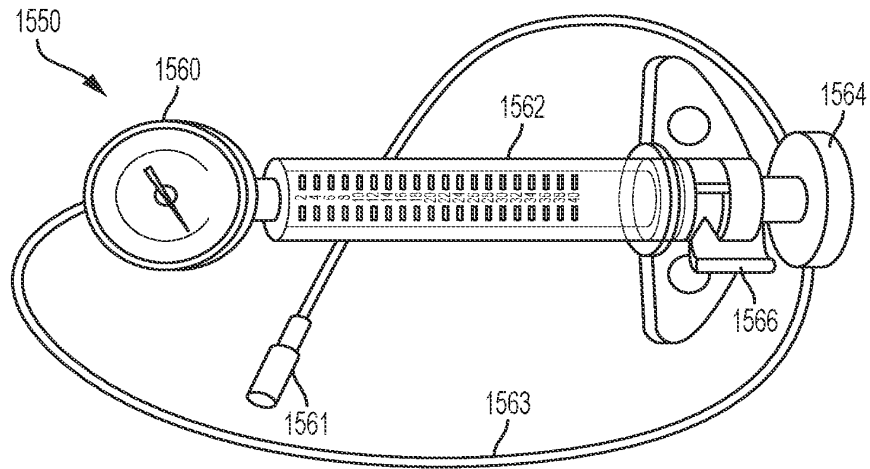


FIG. 41

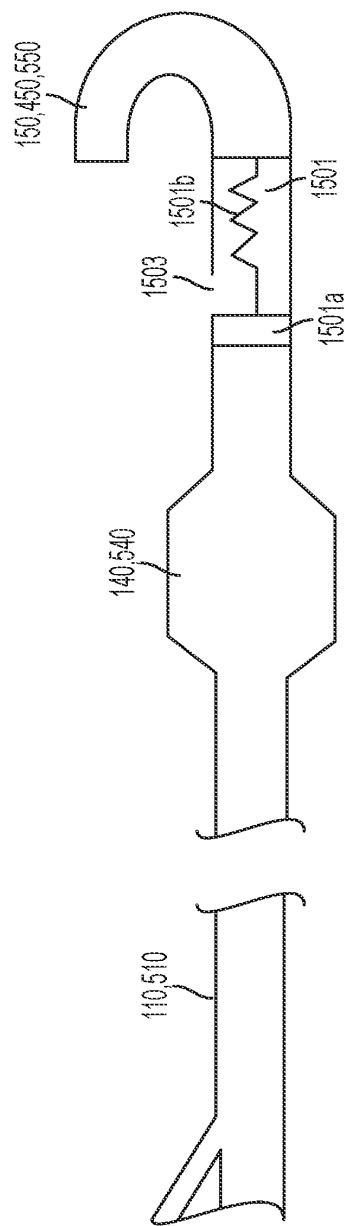


FIG. 41A

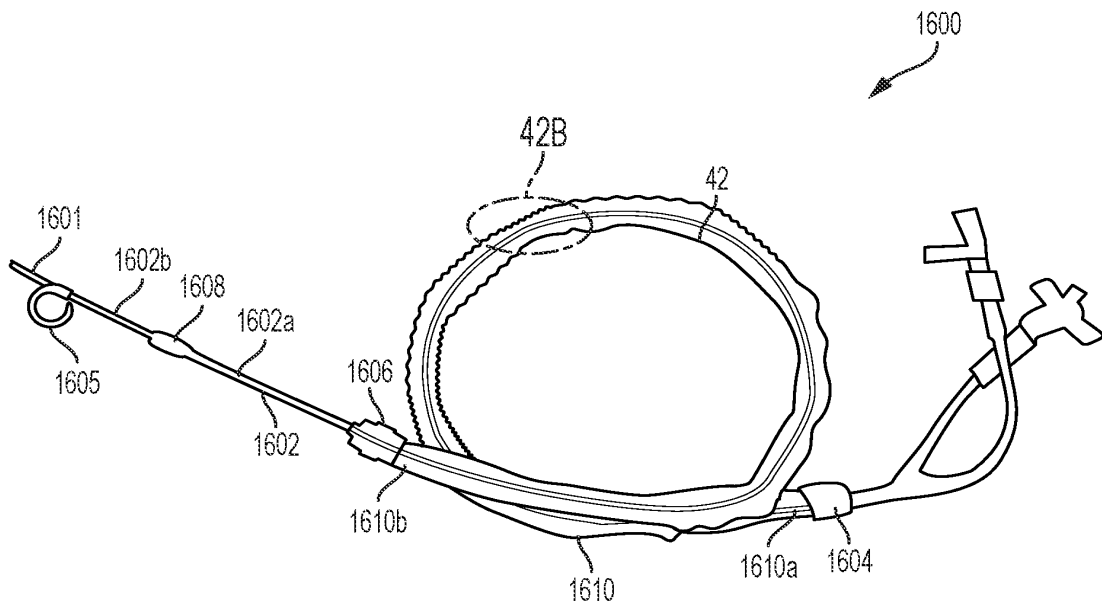


FIG. 42A

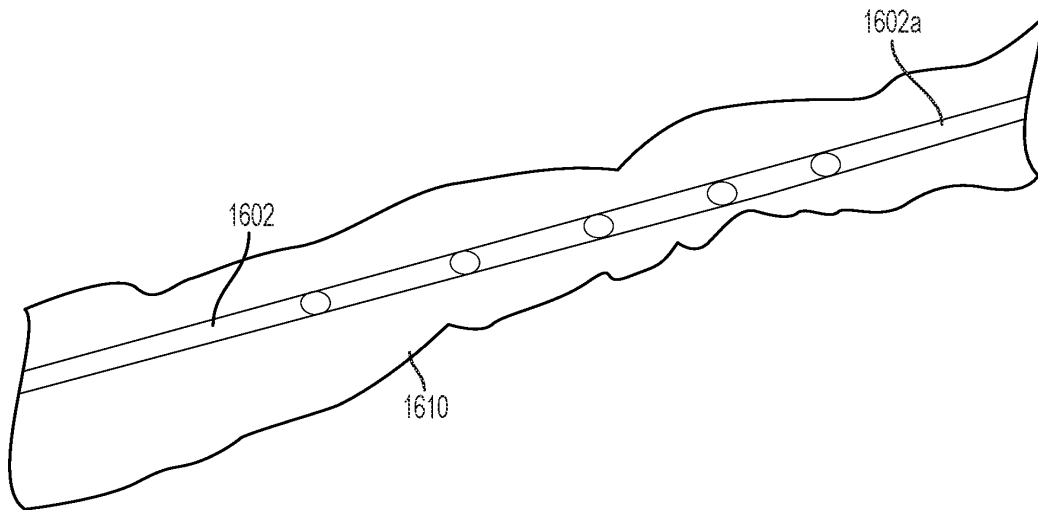


FIG. 42B

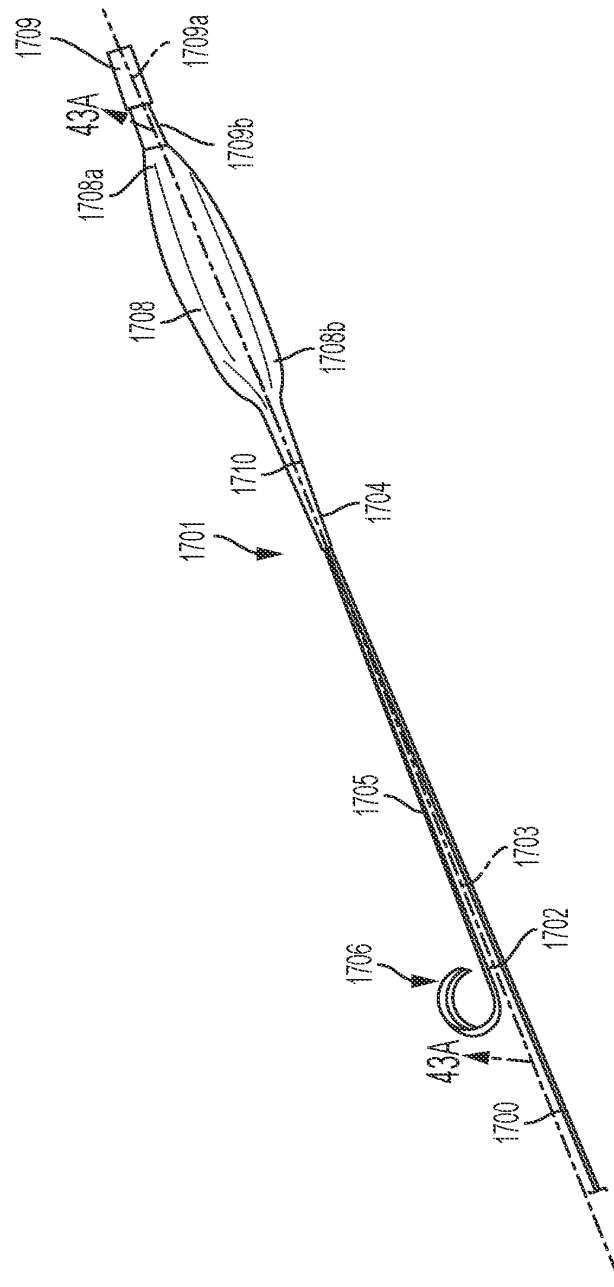


FIG. 43

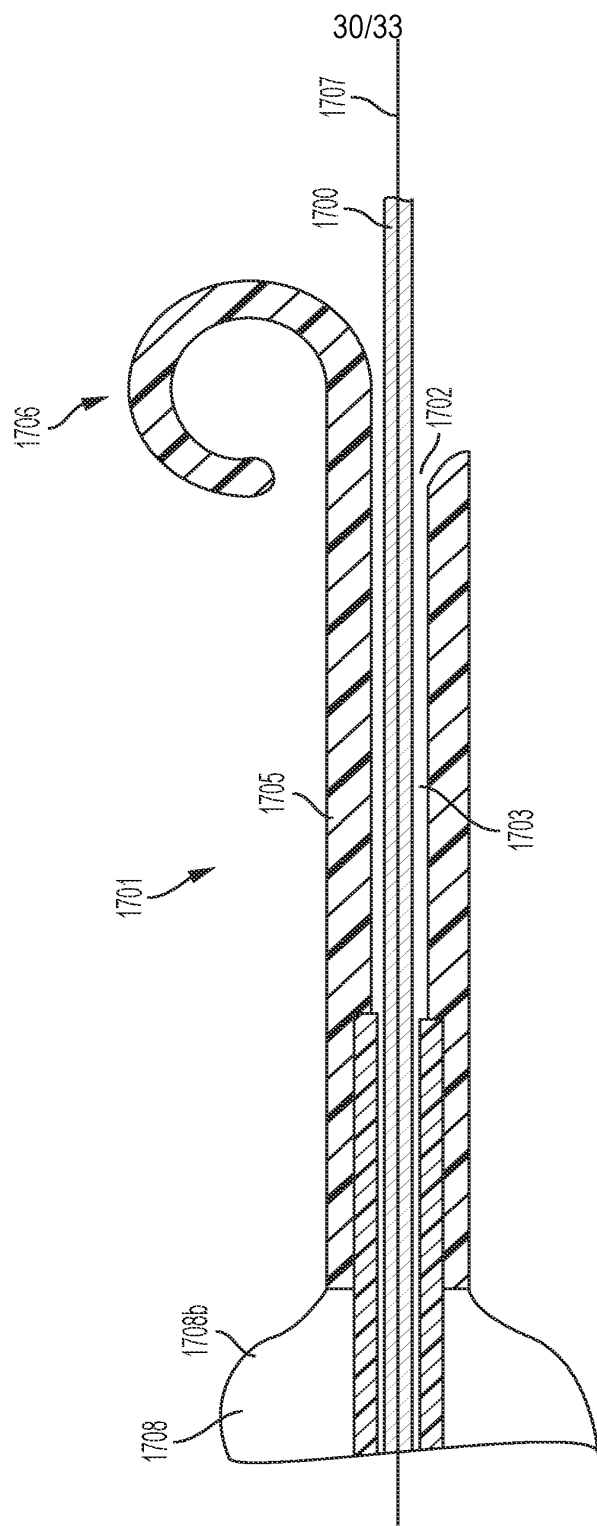
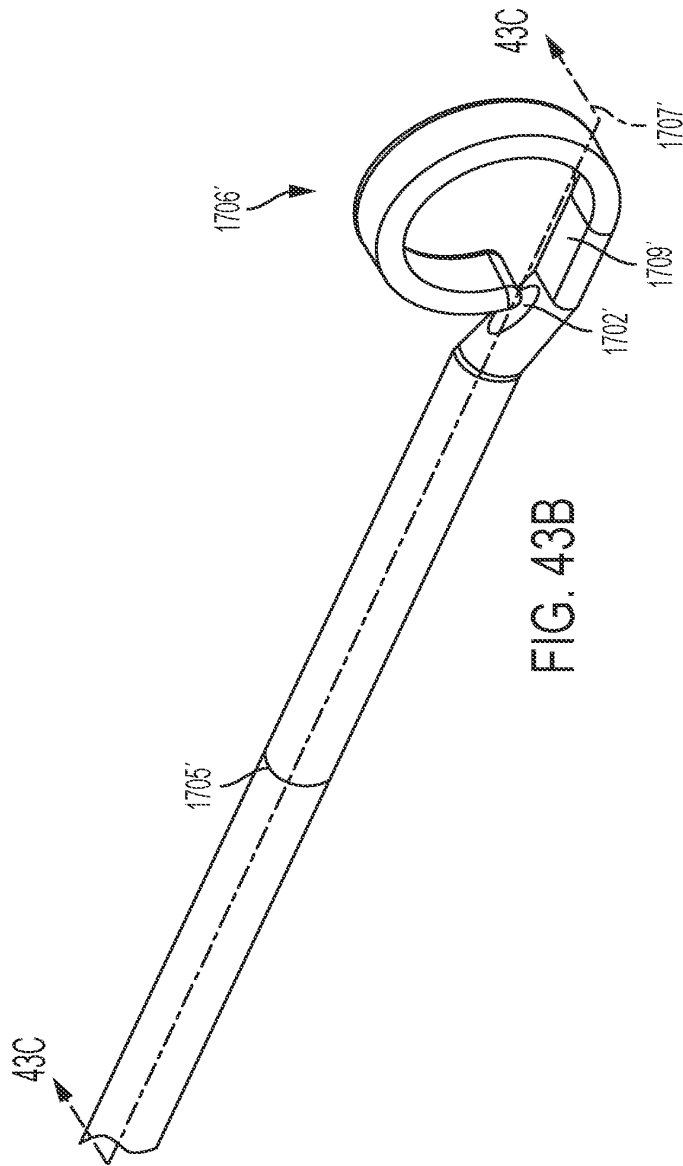
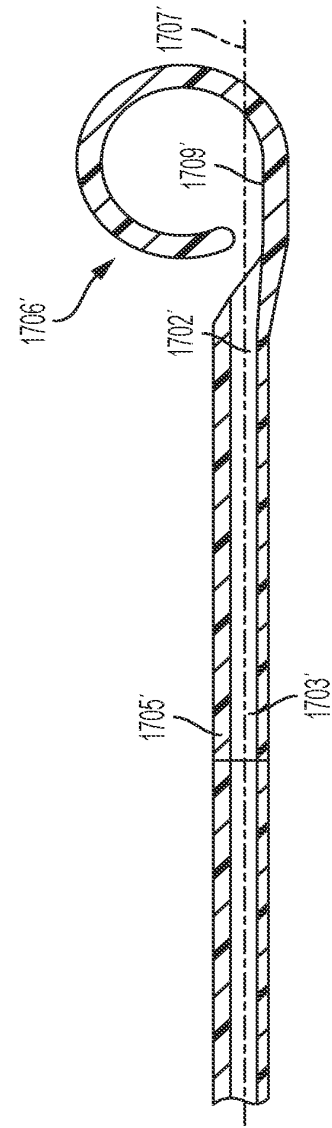


FIG. 43A



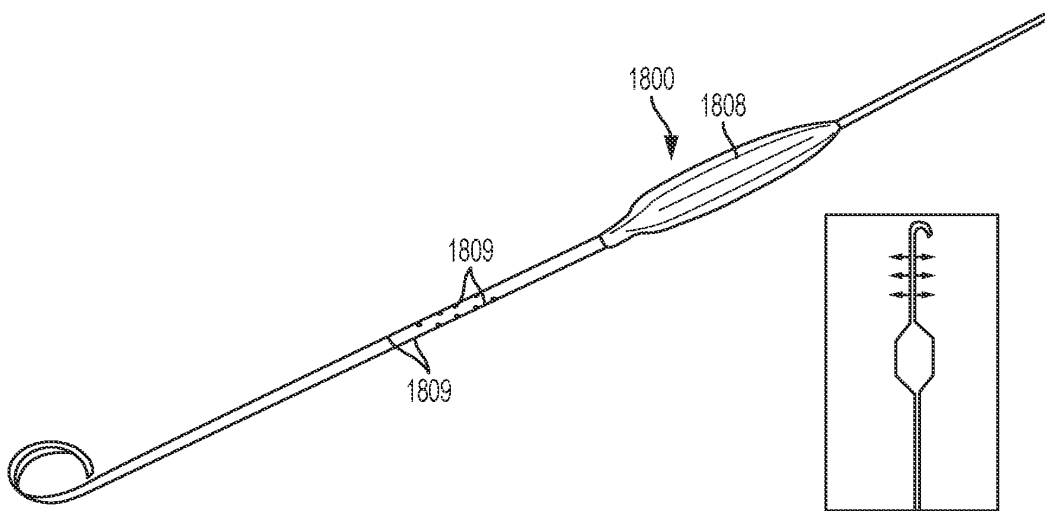


FIG. 44

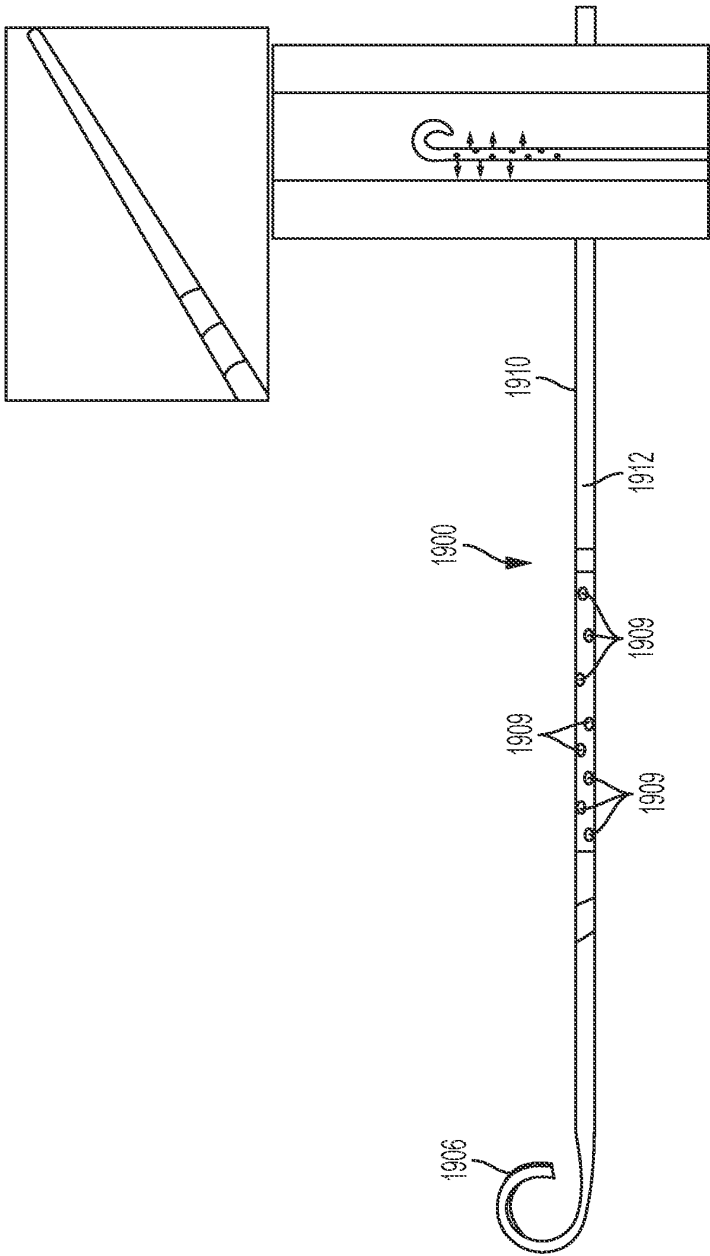


FIG. 45



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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
17/563,669	12/28/2021	3783	830	688961-25U7	10	1

CONFIRMATION NO. 4495

FILING RECEIPT



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Date Mailed: 01/13/2022

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Inventor(s)

Curtis J. FRANKLIN, Lakewood, CO;
David SPENCER, Boerne, TX;
Todd J. KRUMMENACHER, Lakewood, CO;

Applicant(s)

Prytime Medical Devices, Inc., Boerne, TX;

Power of Attorney: The patent practitioners associated with Customer Number 00570

Domestic Priority data as claimed by applicant

This application is a CON of 16/133,193 09/17/2018
which is a CON of 15/551,504 08/16/2017 PAT 10149962
which is a 371 of PCT/US16/23223 03/18/2016
which claims benefit of 62/204,804 08/13/2015
and claims benefit of 62/136,571 03/22/2015
and claims benefit of 62/136,123 03/20/2015
and claims benefit of 62/136,152 03/20/2015
and claims benefit of 62/136,180 03/20/2015
and claims benefit of 62/136,230 03/20/2015
and claims benefit of 62/136,326 03/20/2015
and claims benefit of 62/136,370 03/20/2015
and claims benefit of 62/136,390 03/20/2015
and claims benefit of 62/135,552 03/19/2015
and claims benefit of 62/135,528 03/19/2015

and claims benefit of 62/135,576 03/19/2015
and claims benefit of 62/135,603 03/19/2015
and claims benefit of 62/135,609 03/19/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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Permission to Access Search Results: Yes

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/563,669**

Projected Publication Date: 04/21/2022

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

Preliminary Class

604

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

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page 2 of 4

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/563,669	
APPLICATION AS FILED - PART I							
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	10	minus 20 = *	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1	minus 3 = *	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL	
APPLICATION AS AMENDED - PART II							
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		OTHER THAN SMALL ENTITY
	Total (37 CFR 1.16(i))	*	Minus **	=	x =		RATE(\$)
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		ADDITIONAL FEE(\$)
	Application Size Fee (37 CFR 1.16(s))						
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
				TOTAL ADD'L FEE		TOTAL ADD'L FEE	
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		OTHER THAN SMALL ENTITY
	Total (37 CFR 1.16(i))	*	Minus **	=	x =		RATE(\$)
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =		ADDITIONAL FEE(\$)
	Application Size Fee (37 CFR 1.16(s))						
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
				TOTAL ADD'L FEE		TOTAL ADD'L FEE	
<div style="font-size: x-small;"> * If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1. </div>							

Doc code: IDS

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PTO/SB/08a (02-18)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	8951565		2015-02-10	McCarthy	
	2	8545382		2013-10-01	Suzuki et al.	
	3	8430899		2013-04-30	Dae et al.	
	4	8814900		2014-08-26	Fleming, III	
	5	6423031		2002-07-23	Donlon	
	6	8655798		2014-02-18	Humphrey et al.	
	7	8672868		2014-03-18	Simons	
	8	8747358		2014-06-10	Trombley, III et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

	9	6735532		2004-05-11	Freed et al.	
	10	4464172		1984-08-07	Lichtenstein	
	11	6736790		2004-05-18	Barbut et al.	
	12	6161547		2000-12-19	Barbut	
	13	6165199		2000-12-26	Barbut	
	14	6146370		2000-11-14	Barbut	
	15	6733513		2004-05-11	Boyle et al.	
	16	7892469		2011-02-22	Lim et al.	
	17	5282479		1994-02-01	Havran	
	18	5447503	A	1995-09-05	Miller	
	19	5522400		1996-06-04	Williams	

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	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

	20	6011988		2000-01-04	Lynch et al.	
	21	8948848		2015-02-03	Merhi	
	22	6796959		2004-09-28	Davis et al.	
	23	7951186		2011-05-31	Eidenschink et al.	
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	28	6248121		2001-06-19	Nobles	
	29	6231572		2001-05-15	Hart et al.	
	30	6102930		2000-08-15	Simmons, Jr.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
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	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

	31	5135494		1992-08-04	Engelson et al.	
	32	4983166		1991-01-08	Yamawaki	
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	41	6679860		2004-01-20	Stiger	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17563669
	Filing Date		2021-12-28
	First Named Inventor	Curtis J. FRANKLIN	
	Art Unit		N/A
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number		688961-25U7

	42	6695811		2004-02-24	Samson et al.	
	43	6719270		2004-04-13	Ozawa	
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	45	7959644		2011-06-14	Shriver	
	46	8088103		2012-01-03	Teeslink et al.	
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	51	4926885		1990-05-22	Hinkle	
	52	4823469		1989-04-25	Broselow	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

53	2156289	1939-05-02	HOY EDWARD W	
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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

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

See attached certification statement.

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

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SIGNATURE

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

Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2022-01-28
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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

Privacy Act Statement

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

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

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

Docket No.: 688961-25U7
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Curtis J. FRANKLIN et al.

Application No.: 17/563,669

Confirmation No.: 4495

Filed: December 28, 2021

Art Unit: N/A

For: SYSTEM AND METHOD FOR LOW-PROFILE Examiner: Not Yet Assigned
OCCLUSION BALLOON CATHETER

INFORMATION DISCLOSURE STATEMENT (IDS)

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

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d) (37 C.F.R. § 1.97(b)(1)).

In accordance with 37 C.F.R. § 1.98(d)(1), the foreign and non-patent literature references listed on the attached PTO/SB/08 were previously cited by or submitted to the Office in prior application numbers 16/133,193 filed September 17, 2018 and 15/551,504 filed August 16, 2017 and relied on in the above-identified application for an earlier effective filing date under 35 U.S.C. § 120:

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

Application No. 17/563,669

Docket No.: 688961-25U7

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1017, under Order No. 688961.0168 from which the undersigned is authorized to draw.

Dated: January 28, 2022

Respectfully submitted,

By /Ragi A.I. Elias/
Ragi A. I. Elias
Registration No.: 67,772
PANITCH SCHWARZE BELISARIO & NADEL LLP
Two Commerce Square
2001 Market Street, Suite 2800
Philadelphia, Pennsylvania 19103
(215) 965-1221
(215) 965-1331 (Fax)
relias@panitchlaw.com (E-Mail)

Electronic Acknowledgement Receipt	
EFS ID:	44862876
Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Katie Carlson
Filer Authorized By:	Ragi A.I. Elias
Attorney Docket Number:	688961-25U7
Receipt Date:	28-JAN-2022
Filing Date:	28-DEC-2021
Time Stamp:	13:16:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	ISR_WO.PDF	910833	no	15
			b264208499f914f3cb2d85c532f147409095c192		
Warnings:					

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	Information_Disclosure_Statement_Fillable_PDF.pdf	1041982	no	25
			2a60dc9947206f6a12de7ef7e61cc7a2dca3b805		
Warnings:					
Information:					
3	Transmittal Letter	IDS_Transmittal.PDF	45078	no	2
			5b2c255482658bfa1374741ba8dbdc010a36776f		
Warnings:					
Information:					
Total Files Size (in bytes):			1997893		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

RECEIVED

OCT 23 2019

PANITCH SCHWARZE
BELISARIO & NADEL

To: Dennis J. Butler
Panitch Schwarze Belisario & Nadel LLP
Two Commerce Square
2001 Market Street, Suite 2800
Philadelphia, Pennsylvania 19103
United States of America

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	
Applicant's or agent's file reference 688961-122WO	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US19/45252	International filing date (day/month/year) 06 August 2019 (06.08.2019)
Applicant PRYTIME MEDICAL DEVICES, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
(Facsimile No.: +41 22 338 82 70)

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
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Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To: Dennis J. Butler
Panitch Schwarze Belisario & Nadel LLP
Two Commerce Square
2001 Market Street, Suite 2800
Philadelphia, Pennsylvania 19103
United States of America

Date of mailing
(day/month/year) **18 OCT 2019**

Applicant's or agent's file reference
688961-122WO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US19/45252

International filing date
(day/month/year) **06 August 2019 (06.08.2019)**

Applicant
PRYTIME MEDICAL DEVICES, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
(Facsimile No.: +41 22 338 82 70)

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/tune_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer
Shane Thomas
Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 688961-122WO		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US19/45252	International filing date (day/month/year) 06 August 2019 (06.08.2019)	(Earliest) Priority Date (day/month/year) 06 August 2018 (06.08.2018)	
Applicant PRYTIME MEDICAL DEVICES, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the **figure** of the **drawings** to be published with the abstract is Figure No. 1
☐ as suggested by the applicant.
☒ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/45252

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/12; A61M 25/10 (2019.01)

CPC - A61B 17/12036, 17/12109, 17/12136; A61M 25/1002

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/149653 A2 (PRYTIME MEDICAL DEVICES, INC.) 22 September 2016; paragraphs [0157], [0163]-[0164], [0170], [0227]; figures 1, 3-5	1-7
-		8-20
Y	US 2014/0243873 A1 (PRYOR MEDICAL DEVICES, INC.) 28 August 2014; paragraph [0061]	8-20
A	WO 2017/210584 A1 (PRYTIME MEDICAL DEVICES, INC.) 07 December 2017; entire document	1-20
A	US 2008/0097300 A1 (ESKAROS, S et al.) 24 April 2008; entire document	1-20
A	US 2015/0272732/A1 (LOMA VISTA MEDICAL, INC.) 01 October 2015; entire document	1-20

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

30 September 2019 (30.09.2019)

Date of mailing of the international search report

18 OCT 2019

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Dennis J. Butler
Panitch Schwarze Belisario & Nadel LLP
Two Commerce Square
2001 Market Street, Suite 2800
Philadelphia, Pennsylvania 19103
United States of America

Date of mailing
(day/month/year) **18 OCT 2019**

Applicant's or agent's file reference
688961-122WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US19/45252

International filing date (day/month/year)

06 August 2019 (06.08.2019)

Priority date (day/month/year)

06 August 2018 (06.08.2018)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61B 17/12; A61M 25/10 (2019.01)

CPC - A61B 17/12036, 17/12109, 17/12136; A61M 25/1002

Applicant

PRYTIME MEDICAL DEVICES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43 bis. 1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

30 September 2019 (30.09.2019)

Authorized officer

Shane Thomas

PCT Help Desk

Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US19/45252

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US19/45252

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6, 8-20	YES
	Claims	1-5, 7	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-5 and 7 lack novelty under PCT Article 33(2) as being anticipated by WO 2016/149653 A2 to Prytime Medical Devices, Inc. (hereinafter 'Prytime').

As per claim 1, Prytime discloses an occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter (an occlusion catheter system for partial or full occlusion of a blood vessel, wherein the blood vessel will inherently have a diameter; abstract; paragraph [0022]), the occlusion catheter system comprising: a proximal catheter shaft having a proximal lumen (the occlusion catheter system 100 comprises a catheter member 110 (proximal catheter shaft) having lumen 210; paragraph [0163]; figures 1, 3); a central shaft positioned partially within the proximal lumen and spaced from the proximal catheter shaft (catheter member 130 (central shaft) is positioned within lumen 210 and is shown spaced from the catheter member 110; paragraph [0163]; figure 3); a distal catheter shaft attached to a distal end of the central shaft (catheter member 120 (distal catheter shaft) is attached to the catheter member 130 (central shaft); paragraph [0163]; figures 1, 4-5); and an occlusion balloon having a proximal end and a distal end (occlusion balloon 1201 comprising proximal end 1208 and a distal end 1212; paragraph [0227]; figures 23-24 – Note how the balloon 1201 may be utilized with the preferred occlusion catheter system 100 by mounting the proximal and distal ends 1208, 1212 to the associated catheters; paragraph [0227]), the occlusion balloon connected at the proximal end to the proximal catheter shaft and at the distal end to the distal catheter shaft (the occlusion balloon is connected at the proximal end to the proximal catheter shaft and at the distal end to the distal catheter shaft; paragraphs [0164], [0227]), the occlusion balloon configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces (the occlusion balloon 1201 defines flow channels 1206a at folds in the balloon 1201 when partially inflated, as shown in figures 23-25, and so the occlusion balloon is capable of defining flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces; paragraphs [0227]-[0229]; figures 23-25), the occlusion balloon positionable in a folded configuration around the central shaft, the proximal catheter shaft, the distal catheter shaft (the occlusion balloon 1201 is positionable in a collapsed configuration wherein the balloon 1201 is folded, and wherein the balloon is capable of being positioned around catheter members 130 (central shaft), 110 (proximal catheter shaft), and 120 (distal catheter shaft); paragraph [0164]; figure 1 – Note how the balloon 1201 may be utilized with the preferred occlusion catheter system 100 by mounting the proximal and distal ends 1208, 1212 to the associated catheters; paragraph [0227]) and the occlusion balloon in the folded configuration having an outer diameter less than seven French gauge (the occlusion balloon 1201 is folded to have substantially the same diameter as the proximal and distal catheters, and wherein the balloon catheter system 100, when in the uninflated condition, is of sufficiently small cross-segmental dimension to pass through a 6-8 French percutaneous sheath; paragraphs [0170], [0227] – Note how the balloon 1201 may be utilized with the preferred occlusion catheter system 100 by mounting the proximal and distal ends 1208, 1212 to the associated catheters; paragraph [0227]).

As per claim 2, Prytime discloses the occlusion catheter system of claim 1. Prytime further discloses wherein the occlusion balloon is comprised of a non-compliant balloon (paragraph [0160]).

As per claim 3, Prytime discloses the occlusion catheter system of claim 1. Prytime further discloses wherein the occlusion balloon is comprised of a semi-compliant balloon (the balloon can be constructed on partially compliant material; paragraph [0160]).

As per claim 4, Prytime discloses the occlusion catheter system of claim 1. Prytime further discloses wherein the occlusion balloon is comprised of a compliant balloon (paragraph [0160]).

As per claim 5, Prytime discloses the occlusion catheter system of claim 1. Prytime further discloses an inflation hub connected to a proximal end of the proximal catheter shaft and to a proximal end of the central shaft (hub 190 for connecting to an inflation source is connected to a proximal end of catheter member 110, as shown in figure 1, and wherein lumen 230 of catheter member 130 (central shaft) is connected at the proximal end to hub 190; paragraphs [0163], [0165]; figures 1, 5).

As per claim 7, Prytime discloses the occlusion catheter system of claim 1. Prytime further discloses wherein the occlusion balloon has a blown diameter greater than the vessel diameter (since the balloon can transition to its full inflation state to completely occlude a blood vessel, the occlusion balloon is capable of comprising a blown diameter greater than the vessel diameter of which the balloon occlusion catheter system is inserted into; paragraph [0231]; figure 28).

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US19/45252

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 6 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 6 is indefinite for the following reason(s): Claim 6 refers to "the inflation hub". There is a lack of antecedent basis for this limitation in the claim. For the purpose of this opinion, as best understood, claim 6 is interpreted to depend on claim 5.

Form PCT/ISA/237 (Box No. VIII) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US19/45252

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
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-Continued from Box V: Citations and Explanations-

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over Prytime.

As per claim 6, Prytime discloses the occlusion catheter system of claim 5. Prytime does not disclose in the embodiment of figure 1 a pressure relief valve attached to the inflation hub, the pressure relief valve in fluid communication with an inflation cavity of the occlusion balloon. However, Prytime discloses in a separate embodiment a pressure relief valve attached to the inflation hub (a pressure relief port is formed through the wall of the hub; paragraphs [0158]-[0159]), the pressure relief valve in fluid communication with an inflation cavity of the occlusion balloon (the pressure relief port is in fluid communication with the occlusion balloon via the inflation/deflation lumen; paragraph [0159]). It would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the balloon catheter occlusion system 100 of Prytime, to include the pressure relief port as taught in a different embodiment, in order to relieve pressure from the balloon to prevent it from rupturing and injuring the patient (Prytime; paragraph [0157]).

Claims 8-20 lack an inventive step under PCT Article 33(3) as being obvious over Prytime in view of US 2014/0243873 A1 to Pryor Medical Devices, Inc. (hereinafter 'Pryor').

As per claim 8, Prytime an occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter (an occlusion catheter system 100 for partial or full occlusion of a blood vessel, wherein the blood vessel will inherently have a diameter; abstract; paragraphs [0022], [0163]) accessed with an introducer sheath having an inner introducer diameter of seven French or less (the balloon catheter system 100, when in the uninflated condition (folded), is of sufficiently small cross-segmental dimension to pass through a 6-8 French percutaneous sheath; paragraph [0170]), the occlusion catheter system comprising: a proximal catheter shaft having a proximal lumen (the occlusion catheter system 100 comprises a catheter member 110 (proximal catheter shaft) having lumen 210; paragraph [0163]; figures 1, 3); a central shaft positioned partially within the proximal lumen (catheter member 130 (central shaft) is positioned within lumen 210 and is shown spaced from the catheter member 110; paragraph [0163]; figure 3); a distal catheter shaft attached to a distal end of the central shaft (catheter member 120 (distal catheter shaft) is attached to the catheter member 130 (central shaft); paragraph [0163]; figures 1, 4-5); and an occlusion balloon having a proximal end and a distal end (occlusion balloon 1201 comprising proximal end 1208 and a distal end 1212; paragraph [0227]; figures 23-24 - Note how the balloon 1201 may be utilized with the preferred occlusion catheter system 100 by mounting the proximal and distal ends 1208, 1212 to the associated catheters; paragraph [0227]), the proximal end connected to the proximal catheter shaft and the distal end connected to the distal catheter shaft (the occlusion balloon is connected at the proximal end to the proximal catheter shaft and at the distal end to the distal catheter shaft; paragraphs [0164], [0227]), the occlusion balloon having a blown diameter (as shown; figures 28, 28A; paragraph [0228]), the occlusion balloon positionable in a folded configuration (as shown; figures 23-25) wherein the occlusion balloon is folded around the central shaft (the occlusion balloon is positionable around catheter members 130 (central shaft), 110 (proximal catheter shaft), and 120 (distal catheter shaft); paragraph [0164]; figure 1 -Note how the balloon 1201 may be utilized with the occlusion catheter system 100 by mounting the proximal and distal ends 1208, 1212 to the associated catheters; paragraph [0227]) and an inflated configuration wherein the occlusion balloon is expanded to the blown diameter (as shown; figures 28, 28A), the distal catheter shaft, the occlusion balloon in the folded configuration and the proximal catheter shaft movable through the introducer sheath for introduction into the vessel (the balloon catheter system 100, when in the uninflated condition (folded), is of sufficiently small cross-segmental dimension to pass through a 6-8 French percutaneous sheath into the blood vessel; paragraph [0170]). Prytime does not disclose the occlusion balloon having a blown diameter of approximately twenty-five to thirty-five millimeters (25-35 mm). Pryor discloses the occlusion balloon having a blown diameter of approximately twenty-five to thirty-five millimeters (25-35 mm) (an occlusion balloon 14 that can expand to a maximum diameter of 26 mm; paragraph [0061]). Since Prytime discloses wherein the occlusion balloon catheter can be used as an aortic occlusion balloon catheter (Prytime; paragraph [0153]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the occlusion catheter system of Prytime, wherein the occlusion balloon has a blown diameter of approximately twenty-five to thirty-five millimeters (25-35 mm), as taught by Pryor, for the advantage of expanding to a diameter that can conform to the shape of the aorta, thereby obstructing blood flow through the aorta (Pryor; paragraph [0061]).

As per claim 9, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 8. Prytime further discloses further comprising: an inflation hub connected to a proximal end of the proximal catheter shaft and to a proximal end of the central shaft (hub 190 for connecting to an inflation source is connected to a proximal end of catheter member 110, as shown in figure 1, and wherein lumen 230 of catheter member 130 (central shaft) is connected at the proximal end to hub 190; paragraph [0163]; figures 1, 5), the inflation hub including a balloon extension line (hub 190 comprises a second fluid pathway 194 in fluid communication with lumen 210 of the catheter member 110, wherein lumen 210 is in fluid communication with the occlusion balloon for inflating and deflating the occlusion balloon; paragraphs [0165], [0176]; figures 3, 6) and an arterial line extension line (fluid pathway 192 connected to an external pressure sensor for measuring arterial pressure; paragraphs [0174], [0176], [0181]; figure 6), the balloon extension line in fluid communication with the proximal lumen (fluid pathway 194 in fluid communication with lumen 210 of the catheter member 110; paragraphs [0165], [0176]; figures 3, 6), the proximal lumen in fluid communication with an inflation cavity of the occlusion balloon (lumen 210 is in fluid communication with the interior space of the occlusion balloon; paragraph [0165]; figure 3).

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US19/45252

Supplemental Box

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As per claim 10, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 9. Prytime does not disclose wherein the balloon extension line includes an inflation valve and a pressure relief valve, the inflation valve positioned closer to the occlusion balloon than the pressure relief valve. However, Prytime discloses in a different embodiment wherein the balloon extension line includes a pressure relief valve (a pressure relief port is formed through the wall of the hub, and since the pressure relief port is in fluid communication with the occlusion balloon via the inflation/deflation lumen, the pressure relief port would inherently be formed through the wall of the second fluid pathway 194 of the hub 190; paragraphs [0158]-[0159]). It would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the balloon catheter occlusion system 100 of Prytime, to include the pressure relief port as taught in a different embodiment, in order to relieve pressure from the balloon to prevent it from rupturing and injuring the patient (Prytime; paragraph [0157]). Additionally, Pryor discloses wherein the balloon extension line includes an inflation valve (Pryor discloses an inflation valve connected to the balloon extension line (an occlusion catheter comprising a branch 54 (balloon extension line) having a one-way valve 60 for permitting passage of inflation fluid therethrough; figure 10; paragraph [0064]). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the occlusion catheter system of Prytime, with an inflation valve connected to the balloon extension line, as taught by Pryor, for the advantage of quickly and easily controlling the inflation of the occlusion balloon, as is well-known within the art. Furthermore, since the valve 60 of Pryor is located distally on the branch 54 closest to the occlusion balloon (Pryor; figure 10), it would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified Prytime such that the inflation valve of Pryor is positioned closer to the occlusion balloon than the pressure relief valve, since such a modification can be achieved without significantly altering the function of the device of Prytime. Moreover, such a modification involves a mere change to the placement of valves, and thus would have required only routine skill in the art.

As per claim 11, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 9. Prytime further discloses wherein the central shaft is comprised of a hypotube (catheter member 130 is a tube made of stainless steel metal; paragraph [0171]; figure 3), the hypotube including a hypotube lumen (lumen 230; paragraph [0163]; figure 3), the hypotube lumen in fluid communication with the arterial line extension line (lumen 230 is in fluid communication with fluid pathway 192 (arterial extension line); paragraph [0176]; figure 6).

As per claim 12, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 8. Prytime further discloses wherein the occlusion balloon is configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces (the occlusion balloon 1201 defines flow channels 1206a at folds in the balloon 1201 when partially inflated, as shown in figures 23-25, and so the occlusion balloon is capable of define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces; paragraphs [0227]-[0229]; figures 23-25).

As per claim 13, the combination of Prytime and Pryor discloses the occlusion system of claim 12. Prytime further discloses wherein the occlusion balloon is configured to fully occlude the vessel and is in facing engagement with the inner surfaces in the inflated configuration (occlusion balloon 1201 comprises a full inflation configuration with no flow channel 1206a, as shown in figures 28 and 28A, such that the vessel may be completely occluded when the balloon 1201 is inflated to the fully inflated configuration; paragraphs [0228], [0231]; figures 28, 28A).

As per claim 14, the combination of Prytime and Pryor discloses the occlusion system of claim 8. Prytime further discloses wherein the proximal catheter shaft includes depth markings (the outer catheter shaft (proximal catheter shaft) of balloon catheter system 100 includes length markers to indicate to the physician the insertion depth of the balloon catheter system 100; paragraph [0207]).

As per claim 15, the combination of Prytime and Pryor discloses the occlusion system of claim 14. Prytime does not disclose wherein the depth markings include a zone I range and a zone III range. Pryor discloses wherein the depth markings include a zone I range (the occlusion catheter comprises markings for zone 138 between the celiac (zone I) and the lowest renal artery; paragraphs [0059], [0073]) and a zone III range (the occlusion catheter comprises markings for the common iliac artery zone 141 between the aortic bifurcation 37 (zone II) and a distal end of the femoral artery 13; paragraphs [0059], [0073], [0077]). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the occlusion system of Prytime, wherein the depth markings include a zone I range and a zone III range, as taught by Pryor, for the advantage of determining where the distal end of the occlusion system is located within the body relative to clinically important branch points (Pryor; paragraph [0077]).

As per claim 16, the combination of Prytime and Pryor discloses the occlusion system of claim 8. Prytime does not disclose wherein the blown diameter is approximately thirty millimeters (30 mm). Pryor discloses wherein the blown diameter is approximately thirty millimeters (30 mm) (an occlusion balloon 14 that can expand to a maximum diameter of 26 mm (approximately 30 mm); paragraph [0061]). Since Prytime discloses wherein the occlusion balloon catheter can be used as an aortic occlusion balloon catheter (Prytime; paragraph [0153]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the occlusion catheter system of Prytime, wherein the occlusion balloon has a blown diameter of approximately 30 mm, as taught by Pryor, for the advantage of expanding to a diameter that can conform to the shape of the aorta, thereby obstructing blood flow through the aorta (Pryor; paragraph [0061]).

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US19/45252

Supplemental Box

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As per claim 17, Prytime disclose an occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter (an occlusion catheter system for partial or full occlusion of a blood vessel; abstract; paragraph [0022]), the occlusion catheter system comprising: a proximal catheter shaft having a proximal lumen (the occlusion catheter system 100 comprises a catheter member 110 (proximal catheter shaft) having lumen 210; paragraph [0163]; figures 1, 3); a central shaft positioned partially within the proximal lumen and spaced from the proximal catheter shaft (catheter member 130 (central shaft) is positioned within lumen 210 and is shown spaced from the catheter member 110; paragraph [0163]; figure 3); an inflation hub connected to a proximal end of the proximal catheter shaft and to a proximal end of the central shaft (hub 190 is connected to a proximal end of catheter member 110, as shown in figure 1, and wherein lumen 230 of catheter member 130 (central shaft) is connected at the proximal end to hub 190; paragraph [0163]; figures 1, 5), the inflation hub including a balloon extension line (hub 190 comprises a second fluid pathway 194 in fluid communication with lumen 210 of the catheter member 110, wherein lumen 210 is in fluid communication with the occlusion balloon for inflating and deflating the occlusion balloon; paragraphs [0165], [0176]; figures 3, 6); a distal catheter shaft attached to a distal end of the central shaft (catheter member 120 (distal catheter shaft) is attached to the catheter member 130 (central shaft); paragraph [0163]; figures 1, 4-5); an occlusion balloon having an inflation cavity, a proximal end and a distal end (occlusion balloon 1201 comprising proximal end 1208 and a distal end 1212, and would inherently comprise an interior inflation cavity; paragraph [0227]; figures 23-24 – Note how the balloon 1201 may be utilized with the occlusion catheter system 100 by mounting the proximal and distal ends 1208, 1212 to the associated catheters; paragraph [0227]), the occlusion balloon connected at the proximal end to the proximal catheter shaft and at the distal end to the distal catheter shaft (the occlusion balloon is connected at the proximal end to the proximal catheter shaft and at the distal end to the distal catheter shaft; paragraphs [0164], [0227]), the occlusion balloon configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces (the occlusion balloon 1201 defines flow channels 1206a at folds in the balloon 1201 when partially inflated, as shown in figures 23-25, and so the occlusion balloon is capable of defining flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces; paragraphs [0227]-[0229]; figures 23-25). Prytime does not disclose an inflation valve connected to the balloon extension line; and a pressure relief valve connected to the balloon extension line, the pressure relief valve configured to release pressure from the inflation cavity below a rupture pressure of the occlusion balloon. Pryor discloses an inflation valve connected to the balloon extension line (an occlusion catheter comprising a branch 54 (balloon extension line) having a one-way valve 60 for permitting passage of inflation fluid therethrough; figure 10; paragraph [0064]). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the occlusion catheter system of Prytime, with an inflation valve connected to the balloon extension line, as taught by Pryor, for the advantage of easily controlling the inflation of the occlusion balloon, as is well-known within the art. Additionally, Prytime discloses within another embodiment a pressure relief valve connected to the balloon extension line (a pressure relief port is formed through the wall of the hub, wherein the pressure relief port would inherently be formed within the hub having the fluid pathway (balloon extension line) in communication with the occlusion balloon; paragraphs [0158]-[0159]), the pressure relief valve configured to release pressure from the inflation cavity below a rupture pressure of the occlusion balloon (the bias of the pressure relief member is less than or equal to a predetermined pressure known to protect the device from overpressure and burst; paragraphs [0157]-[0159]). It would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the balloon catheter occlusion system 100, to include the pressure relief port as taught in a different embodiment, in order to relieve pressure from the balloon to prevent it from rupturing and injuring the patient (Prytime; paragraph [0157]).

As per claim 18, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 17. Prytime does not disclose wherein the occlusion balloon has a blown diameter of approximately thirty millimeters. Pryor discloses wherein the occlusion balloon has a blown diameter is approximately thirty millimeters (30 mm) (an occlusion balloon 14 that can expand to a maximum diameter of 26 mm (approximately 30 mm); paragraph [0061]). Since Prytime discloses wherein the occlusion balloon catheter can be used as an aortic occlusion balloon catheter (Prytime; paragraph [0153]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the occlusion catheter system of Prytime, wherein the occlusion balloon has a blown diameter of approximately 30 mm, as taught by Pryor, for the advantage of expanding to a diameter that can conform to the shape of the aorta, thereby obstructing blood flow through the aorta (Pryor; paragraph [0061]).

As per claim 19, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 17. Prytime further discloses a pressure sensor attached to the occlusion catheter system (the first fluid pathway 192 of the proximal hub 190 may be connected to an external pressure sensor; paragraphs [0168], [0176]).

As per claim 20, the combination of Prytime and Pryor discloses the occlusion catheter system of claim 17. Prytime further discloses wherein the occlusion balloon is comprised of a semi-compliant balloon (the balloon can be constructed on partially compliant material; paragraph [0160]).

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

PCT Recordation of Search History

Case/PCT Application Number: PCT/US19/45252

CLIN Number/Technical Field of PCT Application: 002

Dates During Which the Search was Conducted: 24 September 2019 – 30 September 2019

Date of Completion of Recordation of Search History Form: 30 September 2019

Research Analyst Initials: KMB

Search Approval Official (SAO) Initials: JMP

Field of Search/Classification Information:

IPC(8) Classifications: A61B17/12, A61M25/10 (2019.01)

CPC Classifications: A61B17/12022, A61B17/12027, A61B17/12031, A61B17/12036, A61B17/1204, A61B17/12109, A61B17/12136, A61M25/10, A61M25/1002, A61M2025/1004, A61M25/10185, A61M25/10186, A61M25/1034, A61M2025/1052, A61M2025/1059, A61M2025/1081, A61M2025/1086, A61M2025/1095, A61M2025/1097

Databases Searched (Patent and Non-Patent Literature (NPL), Including Sub-Databases and Files Searched) and Search Terms Used:

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Orbit; PubMed; EBSCO; Google/Google Scholar;

KEYWORDS: occlusion, catheter, balloon, inflatable, expandable, blood vessel, artery, vein, aorta, block, fold, pleat, overlap, ruffle, partial

Database Search String Recordation, Including Dates of Searches:

Patent Database Search Strategy/Results:

Orbit (26 September 2019)

Search String	Results
A61B17/12136 AND TACD: (partial+)	919
A61B17/12136 AND TACD: (partial+) AND (fold+)	402
A61B17/12136	1309
A61B17/12036	408
A61M2025/1004	305
A61M2025/1052	1160
A61M2025/1059	174

PatSeer

ID	Search String	Records	Created Date
L21	L9 AND TACD: (balloon OR inflat* OR expan*) W10 (fold* OR pleat* OR ruffi* OR overlap* OR channel) AND (blood) AND (vessel OR arter* OR vein OR aort*)	4391	30-Sep-19
L20	L9 AND TACD: (partial*) W10 (balloon OR inflat* OR expan*) W10 (fold* OR pleat* OR ruffi* OR overlap* OR channel) AND (blood) AND (vessel OR arter* OR vein OR aort*)	287	30-Sep-19
L19	L9 AND TACD: (partial*) W10 (balloon OR inflat* OR expan*) W10 (fold* OR pleat* OR ruffi* OR overlap*) AND (blood) AND (vessel OR arter* OR vein OR aort*)	221	30-Sep-19
L18	TACD: (catheter) AND (occlu*) AND (partial*) AND (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffi* OR overlap*) AND (blood) AND (vessel OR arter* OR vein OR aort*)	15562	30-Sep-19
L17	TACD: (catheter) AND (occlu*) AND (partial*) AND (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffi* OR overlap*) W10 (blood) AND (vessel OR arter* OR vein OR aort*)	1234	30-Sep-19
L16	L9 AND TACD: (catheter) AND (occlu*) AND (partial*) AND (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffi* OR overlap*) W10 (blood) AND (vessel OR arter* OR vein OR aort*)	263	27-Sep-19
L15	L9 AND TACD: (catheter) AND (occlu*) W10 (partial*) W10 (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffi* OR overlap*) AND (vessel OR arter* OR vein OR aort*)	277	27-Sep-19
L14	L9 AND TACD: (catheter) AND (occlu*) W10 (partial*) AND (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffi* OR overlap*)	898	27-Sep-19
L13	L9 AND TACD: (catheter) AND (occlu*) W10 (partial*) AND (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffi* OR overlap*)	3774	27-Sep-19

L12	L9 AND TACD: (catheter) AND (occlu*) AND (partial*) W10 (balloon OR inflat* OR expan*) W10 (fold* OR pleat* OR ruffi* OR overlap*)	152	26-Sep-19
L11	L9 AND TACD: (catheter) AND (occlu*) AND (partial*) W10 (balloon OR inflat* OR expan*)	2472	26-Sep-19
L10	L9 AND TACD: (catheter) AND (occlu*) W10 (partial*) W10 (balloon OR inflat* OR expan*)	513	26-Sep-19
L9	CPC: (A61B17/12022 OR A61B17/12027 OR A61B17/12031 OR A61B17/12036 OR A61B17/1204 OR A61B17/12109 OR A61B17/12136 OR A61M25/10 OR A61M25/1002 OR A61M25/1004 OR A61M25/10185 OR A61M25/10186 OR A61M25/1034 OR A61M25/1052 OR A61M25/1059 OR A61M25/1081 OR A61M25/1086 OR A61M25/1095 OR A61M25/1097) OR IC: (A61B17/12 OR A61M25/10)	29101	24-Sep-19
L8	TAC: (catheter) AND (occlu*) W10 (partial*) W10 (balloon OR inflat* OR expan*)	182	24-Sep-19
L7	TAC: (catheter) AND (occlu*) AND (partial*) W10 (balloon OR inflat* OR expan*)	487	24-Sep-19
L6	TAC: (catheter) AND (occlu*) W10 (partial*) AND (balloon OR inflat* OR expan*) W10 (fold*)	16	24-Sep-19
L5	TAC: (catheter) AND (occlu*) AND (partial*) AND (balloon OR inflat* OR expan*) AND (fold*)	155	24-Sep-19
L4	TA: (catheter) AND (occlu*) AND (partial*) AND (balloon OR inflat* OR expan*) AND (fold*)	3	24-Sep-19
L3	L2 AND TACD: (catheter) AND (occlu*) AND (balloon OR inflat*)	9	24-Sep-19
L2	INV: (FRANKLIN W2 Curt*) OR (REYNOLDS W2 Jeremy) OR (POINTER W2 Eric) OR (GARLAND W2 Matt*) OR (KRUMMENACHER W2 Todd)	288	24-Sep-19
L1	AASN: PRYTIME	10	24-Sep-19

Non-Patent Literature (NPL) Search Strategy/Results:

Google/Google Scholar (27 September 2019):

- occlusion balloon catheter folds partial occlusion blood vessel
- partially occluded balloon catheter folds channel blood
- partial occlusion catheter balloon pleated
- partial occlusion balloon catheter hub pressure relief valve

PubMed (27 September 2019):

- occlusion balloon catheter folds partial occlusion blood vessel
- partially occluded balloon catheter folds channel blood
- partial occlusion catheter balloon pleated
- partial occlusion balloon catheter hub pressure relief valve

EBSCO (27 September 2019):

- (catheter) AND (occlu*) AND (partial*) AND (balloon OR inflat* OR expan*) AND (fold*)
- (catheter) AND (occlu*) N10 (partial*) AND (balloon OR inflat* OR expan*) AND (fold*)
- (catheter) AND (occlu*) AND (partial*) N10 (balloon OR inflat* OR expan*) AND (fold* OR pleat* OR ruffl* OR overlap*) AND (blood) AND (vessel OR arter* OR vein OR aort*)

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 17/563,669		Filing Date 12/28/2021		☐ To be Mailed	
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO									
APPLICATION AS FILED - PART I									
		(Column 1)		(Column 2)					
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)	
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A			
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A			
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A			
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 =	*			x \$50 =			
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =	*			x \$240 =			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL			
APPLICATION AS AMENDED - PART II									
		(Column 1)		(Column 2)	(Column 3)				
AMENDMENT	02/10/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 11	Minus	** 20	= 0		x \$50 =		0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x \$240 =		0
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		0	
		(Column 1)		(Column 2)	(Column 3)				
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x \$0 =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x \$0 =		
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LDRC			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/EVA V GILLIS/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

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Docket No.: 688961-25U7
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Curtis J. FRANKLIN et al.

Application No.: 17/563,669

Confirmation No.: 4495

Filed: December 28, 2021

Art Unit: 3783

For: SYSTEM AND METHOD FOR LOW-PROFILE Examiner: Not Yet Assigned
OCCCLUSION BALLOON CATHETER

FIRST PRELIMINARY AMENDMENT UNDER 37 C.F.R. 1.115

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendment to the Claims is reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Amendment to and Listing of the Claims:

In accordance with 37 C.F.R. § 1.121(c), this listing of claims will replace all prior versions and listings of claims in the application. Please amend claim 1, wherein underlining indicates additions and strikethrough indicates deletions, and add new claim 11, so that the claims read as follows:

1. (Currently Amended) An occlusion catheter system comprising:
a proximal hub; ~~having~~
a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device;
a proximal catheter section in fluid communication with the proximal hub;
a distal catheter section distally terminating with an atraumatic tip;
an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being constructed of a compliant biocompatible material;
at least one length marking on an exterior of the proximal catheter shaft to indicate an insertion depth of the occlusion catheter system;
a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon; and
a solid wire extending within the proximal catheter section, the occlusion balloon and the distal catheter section,
the occlusion balloon, the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.
2. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.
3. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

4. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.

5. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

6. (Original) The occlusion catheter system of claim 1, wherein the solid wire is secured to the proximal hub.

7. (Original) The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.

8. (Original) The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.

9. (Original) The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon;

10. (Original) An inflation control system kit comprising:
the occlusion catheter system of claim 1; and
a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.

11. (New) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.

REMARKS

With entry of the foregoing amendment, claims 1-10, as amended, and new claim 11, are pending in the application. No new matter is added by any of the above amendments. Entry of this amendment and early examination of this application is respectfully solicited.

Dated: February 10, 2022

Respectfully submitted,

Electronic signature: /Ragi A.I. Elias/
Ragi A. I. Elias
Registration No.: 67,772
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Electronic Acknowledgement Receipt	
EFS ID:	44965758
Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Angela Kryszczak
Filer Authorized By:	Ragi A.I. Elias
Attorney Docket Number:	688961-25U7
Receipt Date:	10-FEB-2022
Filing Date:	28-DEC-2021
Time Stamp:	13:46:08
Application Type:	Utility under 35 USC 111(a)

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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Preliminary_Amendment.PDF	25909	yes	4
			c7f5a67018c0841b18ada9cfc2e9fb56074e1c8e		

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Preliminary Amendment	1	1	
Claims	2	3	
Applicant Arguments/Remarks Made in an Amendment	4	4	

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7

CONFIRMATION NO. 4495

PUBLICATION NOTICE

570

PANITCH SCHWARZE BELISARIO & NADEL LLP
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 2800
PHILADELPHIA, PA 19103



OC000000133318218*

Title:SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

Publication No.US-2022-0118221-A1

Publication Date:04/21/2022

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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Doc code: IDS

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PTO/SB/08a (02-18)

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	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

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	1	9925417	WO	A1	1999-05-27	Boston Scient Corp		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17563669
	Filing Date		2021-12-28
	First Named Inventor	Curtis J. FRANKLIN	
	Art Unit	3783	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	688961-25U7	

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	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

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

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

OR

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See attached certification statement.

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

☒ A certification statement is not submitted herewith.

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Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2022-07-15
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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EFS ID:	46201450
Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Katie Carlson
Filer Authorized By:	Ragi A.I. Elias
Attorney Docket Number:	688961-25U7
Receipt Date:	15-JUL-2022
Filing Date:	28-DEC-2021
Time Stamp:	14:33:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	WO9925417A1.pdf	1527244	no	33
			9946e4341a56c5c44358860b4fd9da18f7b8be8d		
Warnings:					

Information:					
2	Non Patent Literature	ISR_WO_060822.PDF	617574	no	9
			57f2a8f78375f6374acff5eeac51f889cc4ef6eb		
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<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 25/10	A1	(11) International Publication Number: WO 99/25417 (43) International Publication Date: 27 May 1999 (27.05.99)
(21) International Application Number: PCT/US98/22997 (22) International Filing Date: 30 October 1998 (30.10.98) (30) Priority Data: 969,904 13 November 1997 (13.11.97) US (71) Applicant: BOSTON SCIENTIFIC CORPORATION [US/US]; One Boston Scientific Place, Natick, MA 01760-1537 (US). (72) Inventors: BAMPOS, Pattiann; One Prospect Street, Wake- field, MA 01880 (US). BARRY, Ralph, J.; 79 Warner Street, Hudson, MA 01749 (US). CAMPBELL, Andrew, J.; 253 Franklin Street, Reading, MA 01867 (US). HAMIL- TON, Bruce, S.; 22 Veritas Avenue, Lowell, MA 01854 (US). MANETAKIS, Emmanuel; 10 Eugene Road, Burling- ton, MA 01803 (US). (74) Agents: CROMPTON, David, M. et al.; Crompton, Seager & Tufte, LLC, Suite 895, 331 Second Avenue South, Minneapolis, MN 55401-2246 (US).		(81) Designated States: AL, AU, BA, BB, BG, BR, CA, CN, CU, CZ, EE, GE, HU, ID, IL, IS, JP, KP, KR, LC, LK, LR, LT, LV, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, SL, TR, TT, UA, UZ, VN, YU, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>
(54) Title: CATHETER BALLOON HAVING SELECTED FOLDING CHARACTERISTICS		
(57) Abstract <p>A balloon and method of manufacture for use in catheters for medical procedures, in particular percutaneous transluminal coronary angioplasty and other cardiovascular interventions. The balloon incorporates an inflatable membrane having a number of perpendicular ribs which have a higher resistance to collapse during deflation. A number of longitudinal ribs are provided which are preferably equidistantly spaced about a longitudinal axis and which extend between a proximal and distal end of the balloon. A number of triangular indentations are provided, wherein each triangular indentation is preferably equidistantly positioned between adjacent longitudinal ribs and each triangular indentation extends along a portion of the balloon between the proximal and distal ends. Each triangular indentation may extend through a perpendicular rib to reduce the resistance of the perpendicular rib to collapse during deflation. The number of triangular indentations enhance the collapse of the balloon from an expanded configuration to a folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome.</p>		

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BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

CATHETER BALLOON HAVING SELECTED FOLDING**CHARACTERISTICS**Technical Field

This invention relates to the field of medical devices, and more particularly, to the field of catheters such as balloon catheters having inflatable and collapsible balloons which are inserted into lumens of the human body, such as the arterial system to perform a variety of medical procedures. Specifically, the invention is directed to an improved balloon catheter incorporating a balloon shape which, during inflation, collapses to a low profile for improved catheter movement in the arterial system after a first inflation.

10 Background of the Invention

The use of balloon catheters for treatment in the vascular system or other lumens of the body is well known in the field of medicine. Percutaneous transluminal angioplasty (PTA) is a procedure used for the treatment of the vascular system which opens blockages in the artery. One approach which has been used in the prior art for the treatment of blockages in arteries is a dilatation balloon catheter. The dilatation balloon catheter has an inflatable balloon member proximate a distal end which is positioned across a stenosis or blockage. The catheter is inserted into the vascular system and guided to position the balloon, whereupon a fluid is injected through an inflation lumen contained within the catheter to inflate the balloon. The inflation of the balloon causes an outward expansion which opens the stenosis.

It is desirable that the dilatation balloon have a low profile while deflated to increase the ease with which the dilatation balloon can be passed through arteries having small lumens and across a stenosis. The low profile is also desirable to minimize the force required to remove the balloon catheter. Thus, low range sheath withdrawal forces for balloon catheters has always been a desirable design goal. One approach which has been used is to fold the balloon flat prior to a treatment such as PTA. This results in two wings being formed, which may be brought together in order to reduce the overall diameter of the preinflated balloon. A sleeve may be installed around the balloon in order to hold the wings together when the balloon is in the preinflated configuration. The balloon is inflated during treatment. Once the treatment is complete, the balloon must be deflated. Often times the deflated balloon does not return to a diameter small enough to fit within a guide catheter. Often times the result of deflating the balloon by pulling

a vacuum is that the balloon can flatten in a phenomena known as "winging", in which the flat lateral portions of the deflated balloon extend outward beyond the diameter of the balloon when in its inflated and preinflated condition. The presence of the wings and edges can interfere with the ease of withdrawal, both through a guide catheter and
5 through a body vessel such as an artery. Thus, a low profile upon deflation is desirable to increase the ease of retraction by decreasing contact with the vessel walls.

Several attempts have been made in the prior art to provide a dilatation balloon having a reduced profile when in a deflated state. Campbell et al. (U.S. Patent No. 5,458,572) disclose a balloon having an array of longitudinally and circumferentially
10 arranged ribs. The ribs are either more stiff or less stiff than a wall of the balloon. Upon evacuation of an inflation fluid from the balloon, either portions of the wall between the ribs will collapse between the ribs, or the ribs will collapse within the wall.

Campbell et al. (U.S. Patent No. 5,456,666) disclose a balloon formed of a continuous balloon material which has a generally cylindrical shape and four ribs formed
15 within a body. The ribs are longitudinally and equidistantly spaced about an axis which extends from the proximal end to the distal end of the balloon. The ribs are formed of stressed balloon material. Webs of less stressed balloon material are disposed between the ribs, whereupon the ribs and the webs form the balloon which is expandable from a folded condition to an expanded condition having a diameter substantially greater than
20 the folded condition. After completion of a treatment, the balloon is reverted back to a folded condition where the webs between the ribs collapse inwardly towards the axis. .

Montano (U.S. Patent No. 4,941,877) discloses a balloon which defines transition zones at respective ends of the balloon which have flutes which are generally longitudinally directed at an angle to a balloon axis. The balloon can assume a collapsed
25 position in which the collapsed transition zones collapse in a preferred cross section, rather than a flat collapsed configuration.

These prior art approaches attempt to improve the folding characteristics of the balloon by utilizing either longitudinally directed ribs within the mid region of the balloon, or by utilizing generally longitudinal fluted regions defined in the transition
30 zones. The ribs or fluted regions attempt to induce the collapse of the balloon to a predetermined configuration by creating longitudinally oriented stressed regions in the balloon material.

Summary of the Invention

The present invention overcomes the disadvantages of the prior art by providing a balloon catheter and method of manufacture which incorporates an inflatable balloon having a number of perpendicular ribs which have a high resistance to collapse during deflation. A number of longitudinal ribs are provided which are equidistantly spaced about a longitudinal axis and which extend between a proximal and distal end of the balloon. A number of triangular indentations are provided, wherein each triangular indentation is equidistantly positioned between adjacent longitudinal ribs and each triangular indentation extends along a portion of the balloon between the proximal and distal ends. Each triangular indentation may extend through a perpendicular rib to reduce the resistance of the perpendicular rib to collapse during deflation. The number of triangular indentations enhance the collapse of the balloon from an expanded configuration to a folded configuration because the triangular indentations along the rib weaken or lessen the resistance to folding along that rib. In this way, the resistance of the number of ribs to collapse has been overcome. In the folded configuration, the balloon has a low profile to minimize the balloon withdrawal force.

In a preferred embodiment, a balloon is provided which is formed of a flexible material which defines an inflation chamber which is adapted for inflation from a folded configuration to an expanded configuration, and deflation back to a preferred folded configuration. The balloon has a generally cylindrical shape about a longitudinal axis which extends between a proximal and distal end. In a preferred embodiment, the flexible material may be polyethylene terephthalate or any other suitable material. A number of longitudinal ribs are provided which are formed in the flexible material of the inflation chamber and which extend longitudinally between the proximal and distal end. The number of longitudinal ribs are equidistantly spaced about the longitudinal axis.

A number of perpendicular ribs can also be provided which are formed in the flexible material of the inflation chamber which intersect the number of longitudinal ribs. The number of perpendicular ribs are perpendicular to the longitudinal axis. The number of perpendicular ribs have a high resistance to collapse during deflation of the balloon.

In a preferred embodiment, a number of triangular indentations are provided which are formed in the flexible material of the inflation chamber, where each triangular indentation is equidistantly positioned between two adjacent ones of the number of

longitudinal ribs. Each triangular indentation extends longitudinally a portion of the length between the proximal and distal end of the balloon. The number of triangular indentations enhance the collapse of the inflation chamber from the expanded configuration to the folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome. In a preferred embodiment, the total number of longitudinal ribs is four and the number of triangular indentations is four at each end of the balloon for a total of eight. In a preferred embodiment, the balloon comprises a reduced diameter or proximal transition region adjacent the proximal end, a reduced diameter distal transition region adjacent the distal end, and a body portion positioned between the proximal transition region and the distal transition region. In a preferred embodiment, the number of perpendicular ribs comprises a first plurality of the number of perpendicular ribs positioned in a first plane perpendicular to the longitudinal axis, where the first portion of the number of perpendicular ribs joins the proximal transition region to the proximal end body. The number of perpendicular ribs also comprises a second plurality of the number of perpendicular ribs positioned in a second plane perpendicular to the longitudinal axis, where the second portion of the number of perpendicular ribs joins the distal transition region to the distal end body. In a preferred embodiment, the first plurality of the number of perpendicular ribs is four and the second plurality of the number of perpendicular ribs is four. Each of the number of triangular indentations is an inwardly directed fold where the fold is directed towards the longitudinal axis and has a crease which is generally parallel to the longitudinal axis in a radial direction to the longitudinal axis.

In a preferred embodiment, a first portion of the number of triangular indentations is positioned near the proximal end of the balloon, where the crease of each one of the first portion of the number of triangular indentations extends through a particular one of the first plurality of the number of perpendicular ribs. A second portion of the number of triangular indentations is positioned near the distal end of the balloon, where the crease of each one of the second portion of the number of triangular indentations extends through a particular one of the second plurality of the number of perpendicular ribs. The crease of each one of the first portion of the number of triangular indentations extending through the particular one of the first plurality of the number of perpendicular ribs in addition to the crease of each one of the second portion of the number of triangular

indentations extending through the particular one of the second plurality of the number of perpendicular ribs reduces the resistance of the number of perpendicular ribs to collapse during deflation and enhances the collapse of the inflation chamber from the expanded configuration to the folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome.

It is understood that within the scope of this invention are several embodiments which have triangular indentations located at any number of locations on the balloon. In an alternative embodiment of the present invention, a first portion of the number of triangular indentations is positioned within the proximal transition region where the crease of each one of the first portion of the number of triangular indentations extends from the proximal end of the balloon to a corresponding particular one of the first portion of the number of perpendicular ribs. The crease of each one of the first portion of the number of triangular indentations, however, does not extend through the corresponding particular one of the first plurality of the number of perpendicular ribs. A second portion of the number of triangular indentations is positioned within the distal transition region where the crease of each one of the second portion of the number of triangular indentations extends from the distal end of the balloon to a corresponding particular one of the second plurality of the number of perpendicular ribs. The crease of each one of the second portion of the number of triangular indentations, however, does not extend through the corresponding particular one of the second plurality of the number of perpendicular ribs. In this alternative embodiment, the crease of each one of the first portion of the number of triangular indentations, and the crease of each one of the second portion of the number of triangular indentations, enhance the collapse of the inflation chamber from the expanded configuration to the folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome.

In a second alternative embodiment, each one of the number of triangular indentations is positioned within the body portion of the balloon and the crease of each one of the number of triangular indentations extends from a proximal end to a distal end of the body. The crease of each one of the number of triangular indentations, however, does not intersect the corresponding particular one of the first plurality of the number of perpendicular ribs or the corresponding particular one of the second plurality of the number of perpendicular ribs. The crease of each one of the number of triangular

indentations enhances the collapse of the inflation chamber from the expanded configuration to the folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome.

5 In a third alternative embodiment of the present invention, the crease of each one of the number of triangular indentations extends from a proximal end of the body to a distal end of the body. The crease of each one of the number of triangular indentations intersects and extends through a corresponding particular one of the first plurality of the number of perpendicular ribs and a corresponding particular one of the second plurality of the number of perpendicular ribs to reduce the resistance of the number of perpendicular ribs to collapse during deflation. The crease of each one of the number of triangular indentations enhances the collapse of the inflation chamber from the expanded configuration to the folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome.

10 In a fourth alternative embodiment, the crease of each one of the number of triangular indentations extends from the proximal end of the balloon to the distal end of the balloon. The crease of each one of the number of triangular indentations intersects the corresponding particular one of the first plurality of the number of perpendicular ribs and the corresponding particular one of the second plurality of the number of perpendicular ribs to reduce the resistance of the number of perpendicular ribs to collapse during deflation. The crease of each one of the number of triangular indentations enhances the collapse of the inflation chamber from the expanded configuration to the folded configuration once the resistance of the number of perpendicular ribs to collapse has been overcome.

Brief Description of the Drawings

25 Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

30 Fig. 1 is a perspective view of a balloon adapted to fold to a predetermined configuration in a preferred embodiment of the present invention;

Fig. 2 is a partial perspective view of an end of the balloon of Fig. 1 illustrating

the collapse of the inflation chamber during deflation;

Fig. 3 is an end view of an inflated balloon showing the generally cylindrical shape of the balloon;

Fig. 4 is an end view of a deflated balloon showing a quad-folded configuration;

5 Fig. 5 is a cross-section view of the balloon of Fig. 2 taken along line 5-5 of Fig. 2;

Fig. 6 is a cross-section view of the balloon of Fig. 2 taken along line 6-6 of Fig. 2;

10 Fig. 7 is a plan view of one half of a mold for forming the balloon of a preferred embodiment;

Fig. 8 is a cross-sectional view of the mold of Fig. 7 taken along line 8-8 of Fig. 7;

Fig. 9 is a cross-section view of the mold of Fig. 7 taken along line 9-9 of Fig. 7;

15 Fig. 10 is a perspective view of an end of a balloon showing an alternative embodiment of the present invention;

Fig. 11 is a plan view of one half of a mold for forming the balloon of an alternative embodiment;

Fig. 12 is a cross-section view of the mold of Fig. 11 taken along line 12-12 of Fig. 11;

20 Fig. 13 is a cross-section view of the mold of Fig. 11 taken along line 13-13 of Fig. 11;

Fig. 14 is a perspective view of a third alternative embodiment of the present invention;

25 Fig. 15 is a perspective view of a fourth alternative embodiment of the present invention; and

Fig. 16 is a perspective view of a fifth alternative embodiment of the present invention.

Detailed Description of the Preferred Embodiments

30 Referring now to the drawings, wherein like reference numerals refer to like elements throughout the several views, Fig. 1 is a perspective view of a balloon adapted to fold to a predetermined configuration in a preferred embodiment of the present invention. Fig. 1 illustrates generally a balloon 10 for a balloon catheter having a

proximal end 12 and a distal end 14. Distal tip 16 is affixed at distal end 14. Shaft 18 couples to proximal end 12 of balloon 10. Shaft 18 also couples to a hub assembly (not shown). In the preferred embodiment, shaft 18 includes an inner shaft (not shown) disposed within outer shaft 18. The inner shaft extends through the length of the balloon
5 from proximal end 12 through distal tip 16 to provide a guide wire lumen for guiding the balloon catheter over a guide wire (not shown). The annular space formed between the inner shaft and the outer shaft 18 forms an inflation lumen in fluid communication with balloon 10 to inflate and deflate balloon 10.

Balloon 10 is formed of a flexible material 24 which may be polyethylene
10 terephthalate. The flexible material may also be a polyester ether block copolymer such as ARNITEL, available from DSM NV, Inc., or in the alternative, SELAR, available from DuPont. The balloon can be any polymeric material, such as polyamide, polyimide, polyethylene, liquid crystal polymer, polybutylone, terephthalate, or polyethylene naphthalate. Coextrusions of these materials are also possible. Flexible material 24
15 defines an inflation chamber 26 (see, Fig. 3). Balloon 10 is adapted for inflation from a deflated state 28 to an inflated state 30 (see, Figs. 4 and 3, respectively). The expanded configuration shown in Fig. 3 has a generally cylindrical shape indicating a fully inflated balloon, while the balloon of Figure 1 is shown partially inflated to detail its molded shape.

20 A longitudinal axis 34 extends between proximal end 12 and distal end 14. Longitudinal ribs 36 are formed in flexible material 24 of balloon 10 and extend longitudinally from proximal end 12 and distal end 14. The term ribs is used herein to define an angle transition or change on the longitudinal surface of the balloon. In Figure 1, this angle change is 90°. Longitudinal ribs 36 are equidistantly spaced about
25 longitudinal axis 34. Proximal perpendicular ribs 38 and distal perpendicular ribs 40 intersect with longitudinal ribs 36. Perpendicular ribs 38 and perpendicular ribs 40 are perpendicular to longitudinal axis 34. Perpendicular ribs 38 and perpendicular ribs 40 have a higher resistance to collapse during deflation of balloon 10.

Proximal triangular indentations 42 and distal triangular indentations 44 are
30 formed in flexible material 24 of balloon 10. Each proximal triangular indentation 42 is equidistantly positioned between two adjacent ones of proximal longitudinal ribs 36 and extends longitudinally at least a portion of the length between proximal end 12 and distal

end 14. Each distal triangular indentation 44 is equidistantly positioned between two adjacent ones of distal longitudinal ribs 36 and extends longitudinally at least a portion of the length between proximal end 12 and distal end 14. Triangular indentations 42 and triangular indentations 44 enhance the collapse of inflation chamber 26 from inflated state 30 to deflated state 28 once the resistance of perpendicular ribs 38 and perpendicular ribs 40 to collapse has been overcome as balloon 10 is deflated. It is believed the triangular indentations are stress concentrations that interrupt the natural resistance associated with the perpendicular ribs. They create a weak spot or stress concentration that serves as a hinge for the perpendicular rib to collapse.

10 Balloon 10, as shown in Fig. 1, has four longitudinal ribs 36, four proximal perpendicular ribs 38 and four distal perpendicular ribs 40. Balloon 10 further comprises a reduced diameter proximal transition region 46 adjacent proximal end 12, a reduced diameter distal transition region 48 adjacent distal end 14, and a body 50 positioned between proximal transition region 46 and distal transition region 48. Perpendicular ribs 15 38 are positioned in a first plane 52 which is perpendicular to longitudinal axis 34, wherein perpendicular ribs 38 join proximal transition region 46 to body 50. Perpendicular ribs 40 are positioned in a second plane 54 which is perpendicular to longitudinal axis 34, wherein perpendicular ribs 40 join distal transition region 48 to body 50. Perpendicular ribs 38 comprise four perpendicular ribs which intersect 20 longitudinal ribs 36. Perpendicular ribs 40 comprise four perpendicular ribs which intersect longitudinal ribs 36. Triangular indentations 42 and triangular indentations 44 are each inwardly directed folds, wherein each fold is directed towards longitudinal axis 34. Each triangular indentation 42 has a crease 56 and each triangular indentation 44 has a crease 58. Crease 56 and crease 58 extend longitudinally at an angle radially toward 25 longitudinal axis 34.

Fig. 2 is a partial perspective view of an end of the balloon of Fig. 1. Fig. 2 shows generally the proximal transition region 46 and a portion of body 50 of Fig. 1 to illustrate the quad-folding nature of balloon 10 as balloon 10 is deflated from an inflated state 30 to a deflated state 28. Balloon 10 can exist in a variety of different stages of inflation. The fully pressurized state of inflation is shown in Fig. 3. Fig. 1 shows balloon 30 10 in a relaxed or non-pressurized state 60. Fig. 2 shows balloon 10 in a partially depressurized or partially deflated state 62. Fig. 4 shows balloon 10 in a deflated state

28 in which balloon 10 is in a quad-folded configuration. Fig. 2 shows triangular indentations 42 positioned near proximal end 12 of balloon 10, wherein creases 56 of triangular indentations 42 extend through perpendicular ribs 38. When balloon 10 begins to be deflated under vacuum and goes from a non-pressurized state 60 to a partially depressurized state 62, creases 56 extending through perpendicular ribs 38 are further extended outside of triangular indentations 42 both into body 50 as creases 64 and into proximal transition region 46 as creases 66. As balloon 10 is deflated from non-pressurized state 60 to partially depressurized state 62, triangular indentations 42 extending through perpendicular ribs 38 reduce the resistance of perpendicular ribs 38 to collapse during deflation in order that creases 56 may extend into body 50 (see, creases 64) and into proximal transition region 46 (see, creases 66). This enhances the collapse of inflation chamber 26 of balloon 10 from the expanded configuration shown as inflated state 30 to the folded configuration shown as deflated state 28 once the resistance of perpendicular ribs 38 to collapse has been overcome by deflation.

Fig. 3 is an end view of an inflated balloon showing the generally cylindrical shape of the balloon. Fig. 3 shows balloon 10 in the expanded configuration or inflated state 30 in which balloon 10 has a generally cylindrical shape. To achieve the inflated state, an inflation fluid applied under pressure causes balloon 10 to expand to a level of pressurization where longitudinal ribs 36 become less pronounced. Fig. 3 illustrates inner shaft 20 and guide wire lumen 21. In operation, balloon 10 in a deflated state 28 may be inserted across a tight stenosis wherein subsequent pressurization increases the diameter of balloon 10 as shown by inflated state 30. Once the inflation fluid is withdrawn under vacuum, balloon 10 deflates to the quad-folded configuration or deflated state 28 shown in Fig. 4.

Fig. 4 illustrates that once inflation fluid has been withdrawn under vacuum, balloon 10 refolds into a quadra-folded configuration to minimize patient trauma during withdrawal. The patient trauma is minimized by minimizing the profile of balloon 10. Figs. 5 and 6 illustrate how triangular indentations 42 in combination with longitudinal ribs 36 and perpendicular ribs 38 achieve this quadra-fold configuration which minimizes the profile of balloon 10.

Fig. 5 is a cross-sectional view of the balloon of Fig. 2 taken along line 5-5 of Fig. 2. The plane of 5-5 of Fig. 2 is also first plane 52. Fig. 5 shows creases 56 of

triangular indentations 42 extending through perpendicular ribs 38 to reduce the resistance of perpendicular ribs to collapse during deflation resulting in creases 56 extending into body 50 (see, creases 64) and into proximal transition region 46 (see, creases 66). Perpendicular ribs 38 provide rigidity to allow the transfer of creases 56 into
5 body 50 and proximal transition region 46 so that once the perpendicular resistance to collapse has been broken or reduced, creases 56 extending into body 50 and proximal transition region 46 will enhance and further induce the quad-folding nature of balloon 10.

Fig. 6 is a cross-sectional view of the balloon of Fig. 2 taken along line 6-6 of
10 Fig. 2. Fig. 6 shows balloon 10 in a partially depressurized state 62, wherein creases 64 have transferred from triangular indentations 42 into body 50. Creases 64 have enhanced and induced the quad-folding nature of balloon 10 by drawing in towards longitudinal axis 34 as balloon 10 is deflated to deflated state 28.

Fig. 7 is a plan view of one-half of a mold for forming the balloon of a preferred
15 embodiment. Mold casing 70 shown in Fig. 7 has a cavity 72 for receiving the balloon material. Cavity 72 has corners 78 corresponding to longitudinal ribs 36. It is understood that the half of the mold casing not shown is symmetrical in construction to mold casing 70 and thus not described. Cavity 72 also has end 80 and end 82. End 80 corresponds with proximal transition region 46 and end 82 corresponds with distal
20 transition region 48. Protrusions 84 correspond with triangular indentations 42 and protrusions 86 correspond with triangular indentations 44. Edges 88 correspond to perpendicular ribs 38 and edges 90 correspond to perpendicular ribs 40.

Mold casing 70 is coupled to its mating half so that a cavity is formed having four corners 78 and four side walls 92. Corners 78 form a 90° angle with opposing side walls
25 92 in body region 94, proximal region 96 and distal region 98. Thus, once balloon 10 is positioned within cavity 72 and mold casing 70 is coupled to its mating half via mounting apparatus 100, a polymeric material is injected inside to expand balloon 10 until flexible material 24 is urged against the interior of cavity 72. Preferably with heat being applied to the mold to maintain fluidity and shape flexible material 24, corners 78 form
30 longitudinal ribs 36, edges 88 form perpendicular ribs 38, edges 90 form perpendicular ribs 40, protrusions 84 form triangular indentations 42 and protrusions 86 form triangular indentations 44. Mold casing 70 in combination with its mating half form four

longitudinal ribs 36, four perpendicular ribs 38, four perpendicular ribs 40, four triangular indentations 42, and four triangular indentations 44, all of which enhance and induce the quadra-folding nature of balloon 10 into the quadra-folded configuration or deflated state 28.

5 Fig. 8 is a cross-sectional view of the mold of Fig. 7 taken along line 8-8 of Fig. 7. Mold casing 70 shown in Fig. 8 has a 90° angle between opposing side walls 92. Protrusions 86 extend above side walls 92 so that edges 88 may form creases 56.

 Fig. 9 is a cross-sectional view of the mold of Fig. 7 taken along line 9-9 of Fig. 7. Fig. 9 shows a view of cavity 72 rotated 45° along longitudinal axis 34 to illustrate the
10 symmetrical relationship of side walls 92. As shown in Fig. 8, opposing side walls 92 create 90° angles therebetween to form the balloon 10 of Fig. 1.

 Fig. 10 is a perspective view of an end of a balloon showing an alternative embodiment of the present invention. Fig. 10 shows triangular indentations 104 positioned within proximal transition region 106 of balloon 114. Creases 108 of
15 triangular indentations 104 extend from proximal end 110 to an adjacent corresponding one of perpendicular ribs 112. Balloon 114 has longitudinal ribs 116 positioned as in balloon 10 of Fig. 1. Since creases 108 do not intersect perpendicular ribs 112, creases 118 are formed within proximal transition region 106 to join creases 108 to longitudinal ribs 116 to enhance the quad-folding nature of balloon 114.

20 The alternative embodiment shown in Fig. 10 has a distal transition region, not shown, which is shaped similarly to proximal transition region 106 and is thus not described. Balloon 114 is shown in a non-pressurized state 120. When balloon 114 is deflated to the quad-folded configuration in deflated state 28 shown in Fig. 4, creases 108 enhance the collapse of inflation chamber 122 of balloon 114 from an expanded
25 configuration or inflated state 30 to a quad-folded configuration of deflated state 28 by extending creases 108 through perpendicular ribs 112 once the resistance of perpendicular ribs 112 to collapse has been overcome during deflation. Creases 108 then extend to body 124 between longitudinal ribs 116 to induce the refolding of balloon 114 into deflated state 28 as shown in Fig. 4.

30 Fig. 11 is a plan view of one half of a mold for forming the balloon of the alternate embodiment. Fig. 11 shows half of a mold casing 130. The half of the mold casing 130 shown in Fig. 11 is symmetrical with respect to the features of balloon 114

in Fig. 10 in comparison to the other half of the mold casing which is not shown. Thus, only mold casing 130 is described herein. Cavity 132 of mold casing 130 has proximal region 134, body region 136, and distal region 138. In cavity 132, side walls 140 are opposing at a 90° angle. Corners 142 correspond to longitudinal ridges 116. Proximal region 134 has edges 144 which correspond to perpendicular ribs 112. Distal region 138 has edges 146. Proximal region 134 has protrusions 148 which correspond to triangular indentations 104. Distal region 138 has protrusions 150. Mounting apparatus 158 are used to attach mold casing 130 shown in Fig. 11 to the other half which is not shown.

Fig. 12 is a cross-sectional view of the mold of Fig. 11 taken along line 12-12 of Fig. 11. Fig. 12 shows protrusions 148 which correspond to triangular indentations 104. Side walls 140 are shown opposing at a 90° angle. Ridges 160 correspond to creases 108 as shown extending up to channel 152. Fig. 12 also illustrates corners 142 which correspond to longitudinal ribs 116.

Fig. 13 is a cross-sectional view of the mold of Fig. 11 taken along line 13-13 of Fig. 11. Fig. 13 shows side walls 140 of body region 136 and proximal region 134 and distal region 136. Proximal region 134 has edge 144 which corresponds to perpendicular ribs 112. Distal region 136 has edge 146. Protrusion 148 of proximal region 134 corresponds to triangular indentation 104. Rib 160 corresponds with crease 108 and is shown extending up to channel 152. Distal region 136 has rib 162. The view shown in Fig. 13 along line 13-13 of Fig. 12 illustrates that cavity 132 and balloon 114 are symmetrical with respect to a 45° rotation along longitudinal axis 164.

Fig. 14 is a perspective view of a third alternative embodiment of the present invention. Fig. 14 shows balloon 170 in a non-pressurized state 60. Balloon 170 has a body 172, a proximal transition region 174 and a distal transition region 176. Body 172 has triangular indentations 178. Triangular indentations 178 each have a crease 180. Longitudinal ribs 182 are shown in the third alternative embodiment as defining a beveled or rounded edge. The rounded edges define a radius at the edge of each fold when balloon 170 is quad-folded into the deflated state 28 to reduce trauma to the patient's vascular system by minimizing the balloon profile. In the third alternative embodiment, triangular indentations 178 are positioned within body 172, and creases 180 of triangular indentations 178 extend from a proximal end 192 of body 172 to a distal end 190 of body 172. Creases 180 of each of the number of triangular indentations 178 do

not intersect perpendicular ribs 192 or perpendicular ribs 194. Creases 180 of each of the number of triangular indentations 178 enhance the collapse of balloon 170 from an expanded configuration or inflated state 30 to a folded configuration or deflated state 28 once the resistance of perpendicular ribs 192 and perpendicular ribs 194 to collapse has
5 been overcome by extending creases 180 into proximal transition region 174 and distal transition region 176 to enhance or further induce the quad-folding of balloon 170.

Fig. 15 is a perspective view of a fourth alternative embodiment of the present invention. Fig. 15 shows a balloon 200 having a body 202, a proximal transition region 204, and a distal transition region 206. Balloon 200 is in a non-pressurized state 60.
10 Triangular indentations 208 have creases 210 and are positioned in body 202 of balloon 200 between longitudinal ribs 212. Longitudinal ribs 212 reduce patient trauma due to a radius which is located at the edge of each fold by minimizing the balloon profile when balloon 200 is in the deflated state 28. Longitudinal ribs 212 extend from proximal end 214 to distal end 216. Proximal end 218 of body 200 has perpendicular ribs 220. Distal
15 end 222 of body 202 has perpendicular ribs 224. Creases 210 of triangular indentations 208 extend from proximal end 218 of body 202 to distal end 222 of body 202 and intersect perpendicular ribs 220 and perpendicular ribs 224 to reduce the resistance of perpendicular ribs 220 and perpendicular ribs 224 to collapse during deflation. Creases 210 of triangular indentations 208 enhance the collapse of balloon 200 from an expanded
20 configuration or inflated state 30 to the quadra-folded configuration or the deflated state 28 once the resistance of perpendicular ribs 220 and perpendicular ribs 224 to collapse has been overcome during deflation.

Fig. 16 is a perspective view of a fourth alternate embodiment of the present invention. Fig. 16 shows balloon 230 which has a body 232, a proximal transition region 234, and a distal transition region 236. Balloon 230 is in a non-pressurized state 60.
25 Triangular indentations 238 extend from proximal end 240 to distal end 242. Triangular indentations 238 each have one of creases 244. Perpendicular ribs 246 are located at a proximal end 248 of body 232. Perpendicular ribs 250 are located at a proximal end 252 of body 232. Longitudinal ribs 254 extend from proximal end 240 to distal end 242 of
30 balloon 230. Triangular indentations 238 are equidistantly spaced between adjacent longitudinal ribs 254. Creases 244 of triangular indentations 238 extending from proximal end 240 to distal end 242 intersect perpendicular ribs 246 and perpendicular ribs

250 to reduce the resistance of perpendicular ribs 246 and perpendicular ribs 250 to collapse during deflation. Creases 244 of triangular indentations 238 enhance the collapse of balloon 230 from an expanded configuration or inflated state 30 to a quad-folded configuration or deflated state 28 once the resistance of perpendicular ribs 246 and
5 perpendicular ribs 250 to collapse has been overcome during deflation of balloon 230.

Having thus described the preferred embodiments of the present invention, those of skill in the art will readily appreciate that yet other embodiments may be made and used within the scope of the claims hereto attached.

What is claimed:

1. A balloon for a catheter, comprising:
 - a. an inflatable membrane formed of a flexible material defining an inflation chamber which is adapted for inflation from a folded configuration to an expanded configuration and deflation back to a folded configuration, said
5 balloon having a longitudinal axis extending between a proximal and a distal end;
 - b. a number of longitudinal ribs formed in said flexible material of said inflation chamber which extend longitudinally between said proximal and
10 said distal end;
 - c. a number of perpendicular ribs formed in said flexible material of said inflation chamber which extend between said number of longitudinal ribs, said number of perpendicular ribs being generally perpendicular to said longitudinal axis, said number of perpendicular ribs having a higher
15 resistance to collapse during deflation; and
 - d. a number of indentations formed in said flexible material of said inflation chamber, each indentation positioned between two adjacent ones of said number of longitudinal ribs and extending longitudinally at least a portion
20 of the length between said proximal end and said distal end, said number of indentations enhancing said collapse of said inflation chamber from said expanded configuration to said folded configuration.
2. The balloon of claim 1 wherein said flexible material is formed of polyethylene terephthalate.
- 25 3. The balloon of claim 1 wherein said number of longitudinal ribs is eight and said number of indentations is eight.
4. The balloon of claim 1 wherein said balloon comprises a reduced diameter proximal transition region adjacent said proximal end, a reduced diameter distal
30 transition region adjacent said distal end, and a body positioned between said proximal transition region and said distal transition region.

5. The balloon of claim 4 wherein said number of perpendicular ribs comprises a first plurality of said number of perpendicular ribs positioned in a first plane perpendicular to said longitudinal axis, said first plurality of said number of perpendicular ribs joining said proximal transition region to said body, a second plurality of said number of perpendicular ribs positioned in a second plane perpendicular to said longitudinal axis, said second plurality of said number of perpendicular ribs joining said distal transition region to said body.
6. The balloon of claim 5 wherein said first plurality of said number of perpendicular ribs is four and said second plurality of said number of perpendicular ribs is four.
7. The balloon of claim 5 wherein each one of said number of indentations is an inwardly directed fold, said fold being directed towards said longitudinal axis and having a crease which extends generally longitudinally at a radial angle toward said longitudinal axis.
8. The balloon of claim 7 wherein a first portion of said number of said indentations is positioned near said proximal end of said balloon, said crease of each one of said first plurality of said number of indentations extending through a particular one of said first portion of said number of perpendicular ribs, a second portion of said number of said indentations being positioned near said distal end of said balloon, said crease of each one of said second portion of said number of indentations extending through a particular one of said second plurality of said number of perpendicular ribs to reduce said resistance of said number of perpendicular ribs to collapse during deflation and enhancing said collapse of said inflation chamber from said expanded configuration to said folded configuration.
9. The balloon of claim 7 wherein a first portion of said number of said indentations is positioned within said proximal transition region, said crease of each one of said first portion of said number of indentations extending from said proximal end of said balloon to a corresponding particular one of said first plurality of said number of perpendicular ribs, said crease of each one of said first portion of said

number of indentations not extending through said corresponding particular one of said first plurality of said number of perpendicular ribs, a second portion of said number of said indentations is positioned within said distal transition region, said crease of each one of said second portion of said number of indentations extending from said distal end of said balloon to a corresponding particular one of said second plurality of said number of perpendicular ribs, said crease of each one of said second portion of said number of indentations not extending through said corresponding particular one of said second plurality of said number of perpendicular ribs.

10. The balloon of claim 7 wherein said crease of each one of said number of indentations extends from a proximal end of said body to a distal end of said body, said crease of each one of said number of indentations intersecting a corresponding particular one of said first plurality of said number of perpendicular ribs and a corresponding particular one of said second portion of said number of perpendicular ribs to reduce said resistance of said number of perpendicular ribs to collapse during deflation, said crease of each one of said number of indentations enhancing said collapse of said inflation chamber from said expanded configuration to said folded configuration.

11. The balloon of claim 7 wherein said number of said indentations is positioned within said body, said crease of each one of said number of indentations extending from a proximal end of said body to a distal end of said body, said crease of each one of said number of indentations not intersecting a corresponding particular one of said first plurality of said number of perpendicular ribs or a corresponding particular one of said second plurality of said number of perpendicular ribs, said crease of each one of said number of indentations enhancing said collapse of said inflation chamber from said expanded configuration to said folded configuration.

12. The balloon of claim 7 wherein said crease of each one of said number of indentations extends from a proximal end of said balloon to a distal end of said

balloon, said crease of each one of said number of indentations intersecting and extending through a corresponding particular one of said first plurality of said number of perpendicular ribs and a corresponding particular one of said second plurality of said number of perpendicular ribs to reduce said resistance of said number of perpendicular ribs to collapse during deflation.

13. A balloon for a catheter, comprising:
- a. an inflatable membrane for attachment to a catheter shaft for introduction into a human body conduit, said inflatable membrane formed of a flexible material defining an inflation chamber which is adapted for inflation from a folded configuration to an expanded configuration and deflation back to a folded configuration, said balloon having a longitudinal axis extending between a proximal and a distal end;
 - b. a number of ribs formed in said flexible material of said inflatable membrane, said number of ribs being equidistantly spaced and extending generally along said longitudinal axis; and
 - c. a number of folds formed in said flexible material of said inflatable member, each fold extending longitudinally at least a portion of the length between said proximal end and said distal end of said balloon, said fold being inwardly directed towards said longitudinal axis and having a crease which extends generally longitudinally at a radial angle to said longitudinal axis.
14. The balloon of claim 13 wherein said flexible material is polyethylene terephthalate.
15. The balloon of claim 13 wherein said number of ribs comprise a number of longitudinal ribs formed in said flexible material of said inflatable membrane which extend longitudinally between said proximal and said distal end.
16. The catheter of claim 15 wherein said number of longitudinal ribs is four.

17. The balloon of claim 15 wherein said balloon comprises a reduced diameter proximal transition region adjacent said proximal end, a reduced diameter distal transition region adjacent said distal end, and a body portion positioned between said proximal transition region and said distal transition region.
- 5 18. The balloon of claim 17 wherein said number of ribs further comprise a number of perpendicular ribs formed in said flexible material of said inflation chamber which intersect said number of longitudinal ribs, said number of perpendicular ribs being perpendicular to said longitudinal axis and having a higher resistance to collapse during deflation.
- 10 19. The balloon catheter of claim 18 wherein said number of perpendicular ribs comprise a first plurality of said number of perpendicular ribs positioned in a first plane perpendicular to said longitudinal axis, said first plurality of said number of perpendicular ribs joining said proximal transition region to said body, a
- 15 of perpendicular ribs joining said proximal transition region to said body, a second plurality of said number of perpendicular ribs positioned in a second plane perpendicular to said longitudinal axis, said second plurality of said number of perpendicular ribs joining said distal transition region to said body.
- 20 20. The balloon of claim 19 wherein said first plurality of said number of perpendicular ribs is four and said second plurality of said number of perpendicular ribs is four.
- 25 21. The balloon of claim 19 wherein a first portion of said number of folds is positioned near said proximal end of said balloon, each particular one of said first portion of said number of folds extending through a particular one of said first plurality of said number of perpendicular ribs, a second portion of said number of folds being positioned near said distal end of said balloon, each particular one of said second portion of said number of folds extending through a particular one of said second plurality of said number of perpendicular ribs to enhance said
- 30 collapse of said inflation chamber from said expanded configuration to said folded configuration.

22. The balloon of claim 19 wherein a first portion of said number of folds is positioned within said proximal transition region, said first portion of said number of folds extending from said proximal end of said balloon to a corresponding particular one of said first plurality of said number of perpendicular ribs, said first portion of said number of folds not extending through said corresponding particular one of said first plurality of said number of perpendicular ribs, a second portion of said number of folds is positioned within said distal transition region, said second portion of said number of folds extending from said distal end of said balloon to a corresponding particular one of said second plurality of said number of perpendicular ribs, said second portion of said number of folds not extending through said corresponding particular one of said second plurality of said number of perpendicular ribs to enhance said collapse of said inflation chamber from said expanded configuration to said folded configuration.
23. The balloon of claim 19 wherein said number of folds is positioned within said body, said number of folds extending from a proximal end of said body to a distal end of said body, said number of folds intersecting a corresponding particular one of said first plurality of said number of perpendicular ribs and a corresponding particular one of said second plurality of said number of perpendicular ribs to reduce said resistance of said number of perpendicular ribs to collapse during deflation.
24. The balloon of claim 19 wherein said number of folds is positioned within said body, said number of folds extending from a proximal end of said body to a distal end of said body, said number of folds not intersecting a corresponding particular one of said first plurality of said number of perpendicular ribs and a corresponding particular one of said second plurality of said number of perpendicular ribs.
25. The balloon of claim 19 wherein said number of folds extends from said proximal end of said balloon to said distal end of said balloon, said number of folds

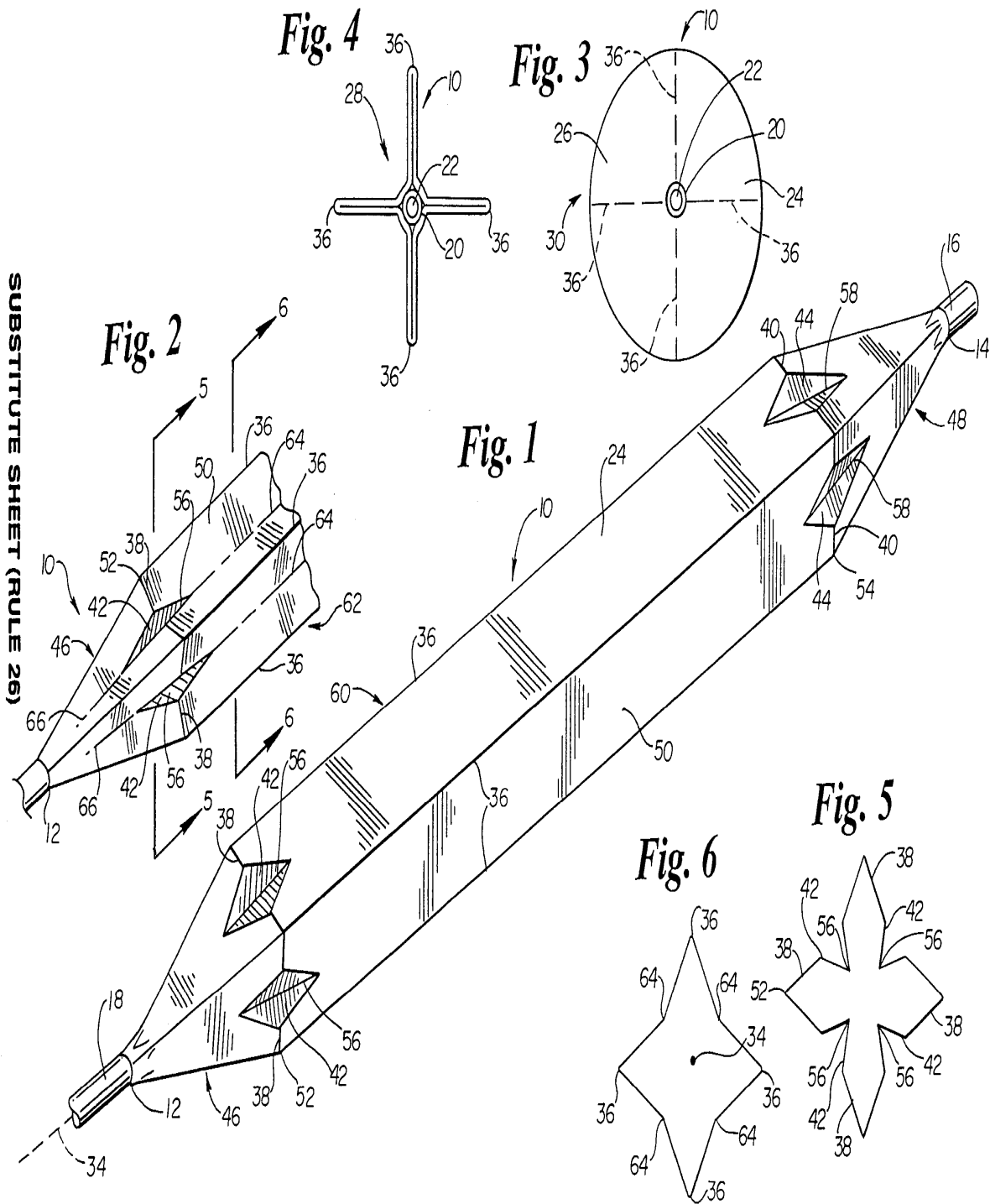
extending through a particular one of said first plurality of said number of perpendicular ribs and a particular one of said second plurality of said number of perpendicular ribs to reduce said resistance of said number of perpendicular ribs to collapse during deflation.

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26. A method for forming a number of indentations in an inflatable balloon for a balloon catheter, said balloon formed of a flexible material defining an inflation chamber which is adapted for inflation from a folded configuration to an expanded configuration and deflation back to a folded configuration, said balloon
- 10 having a longitudinal axis extending between a proximal and a distal end, said balloon having a reduced diameter proximal transition region adjacent said proximal end, a reduced diameter distal transition region adjacent said distal end, and a body positioned between said proximal transition region and said distal transition region, said method comprising the steps of:
- 15 a. providing a mold having a proximal and a distal end and a number of protrusions formed therein;
- b. inserting a polymeric material into said mold and expanding said material until said flexible material is urged against an interior surface of said mold, said mold being shaped to form a number of longitudinal ribs in
- 20 said flexible material which extend longitudinally between said proximal and said distal end of said balloon, said number of longitudinal ribs being equidistantly spaced about said longitudinal axis, said mold also being shaped to form a number of perpendicular ribs in said flexible material which extend between said number of longitudinal ribs, said number of
- 25 perpendicular ribs being perpendicular to said longitudinal axis, said number of perpendicular ribs having a higher resistance to collapse during deflation of said balloon, said number of protrusions forming a plurality of indentations in said flexible material of said inflation chamber, each indentation equidistantly positioned between two adjacent ones of said
- 30 number of longitudinal ribs and extending longitudinally a length between said proximal end and said distal end, said number of indentations enhancing said collapse of said balloon.

27. The method in accordance claim 26, wherein each one of said number of indentations comprise an inwardly directed fold, said fold being directed towards said longitudinal axis of said balloon and having a crease which extends longitudinally at a radial angle to said longitudinal axis.

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SUBSTITUTE SHEET (RULE 26)

Fig. 7

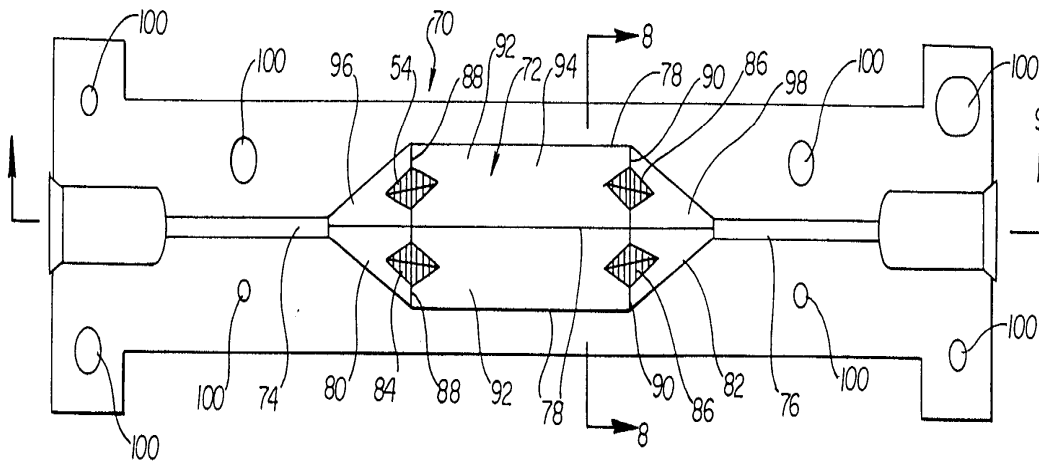


Fig. 9

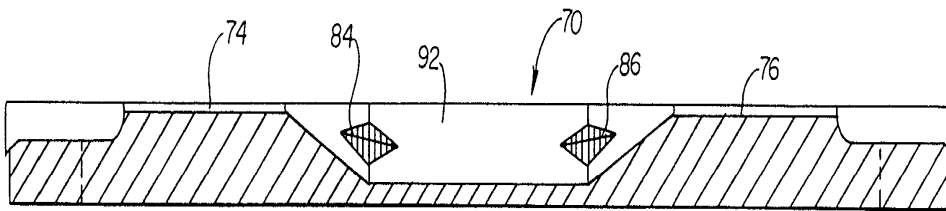


Fig. 8

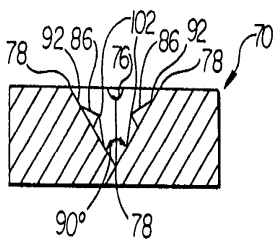


Fig. 10

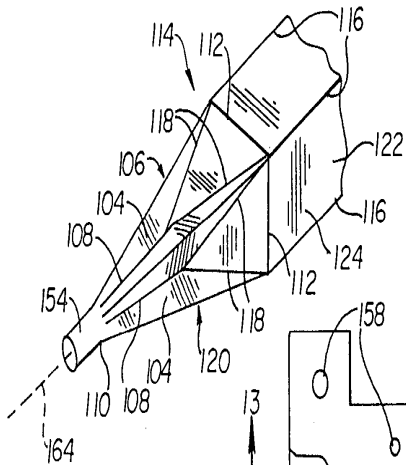


Fig. 11

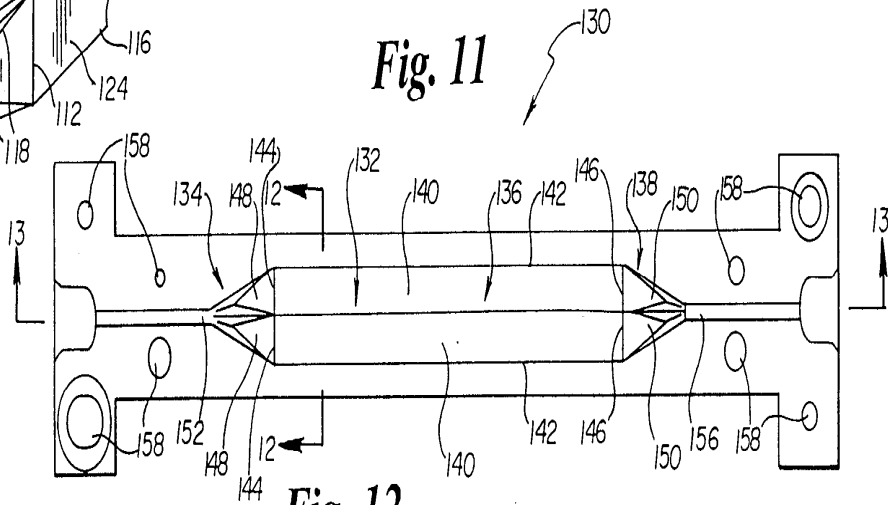


Fig. 12

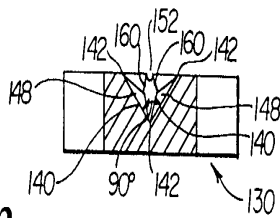
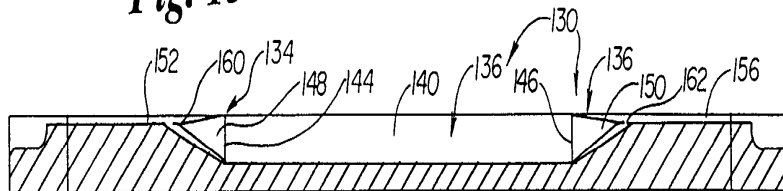
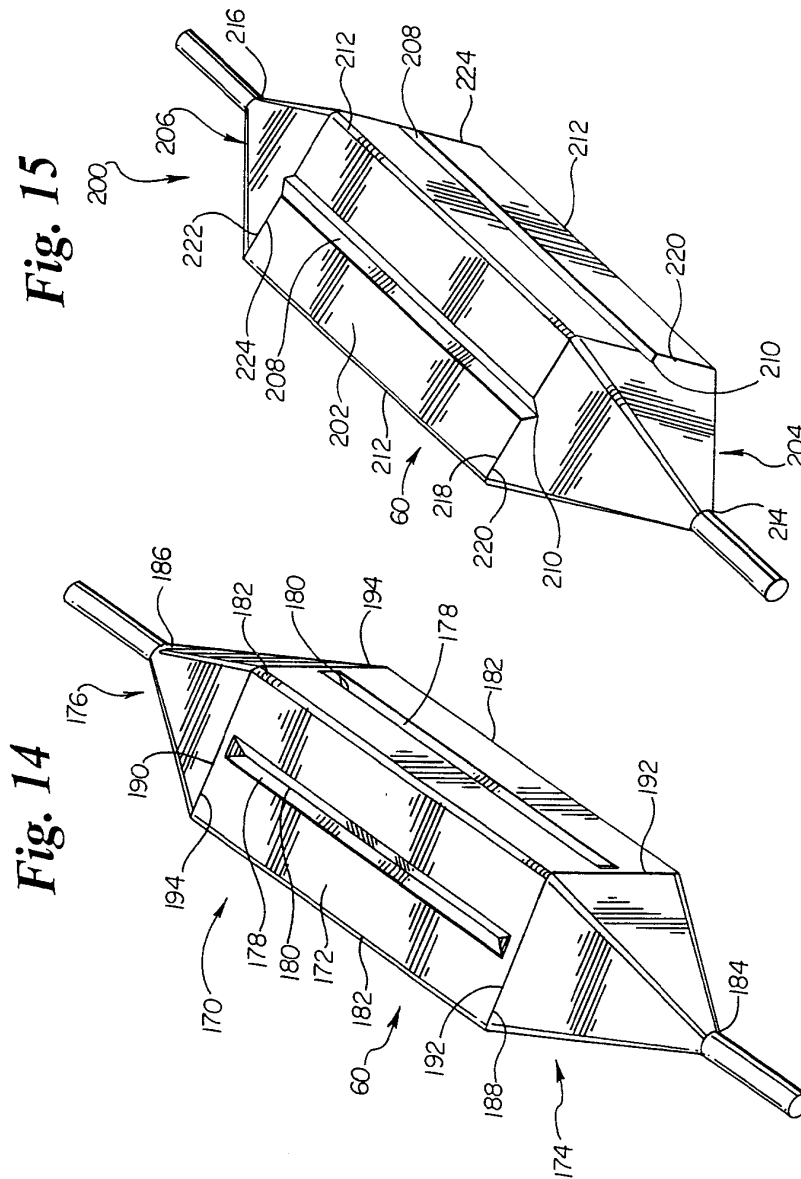


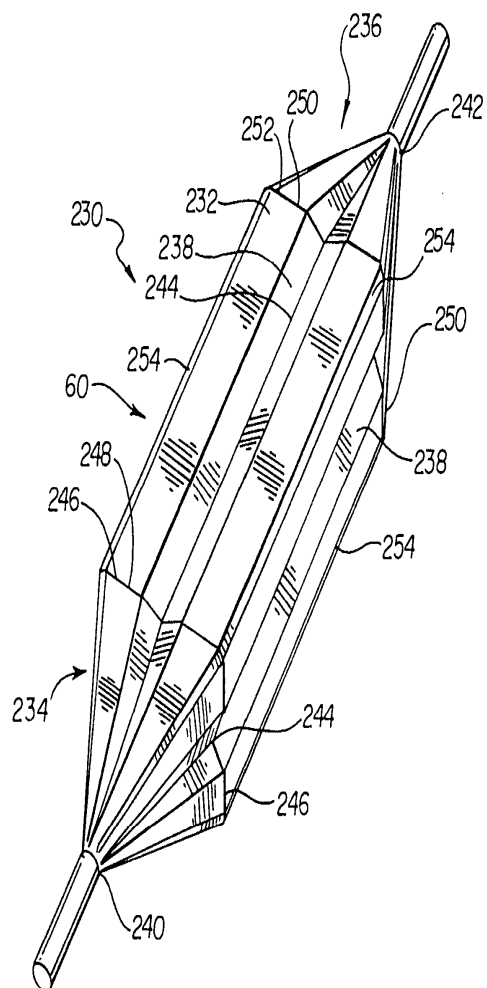
Fig. 13





SUBSTITUTE SHEET (RULE 26)

Fig. 16



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/22997

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 458 572 A (CAMPBELL ET AL.) 17 October 1995 see abstract; claims 1-5,15; figures 1-3 ---	1-27
A	US 5 041 125 A (MONTANO JR) 20 August 1991 see abstract; claims 1-7; figures 1-8 ---	1-27
A	US 5 456 666 A (CAMPBELL ET AL.) 10 October 1995 see abstract; figures 1-7 ---	1-27
A	US 5 318 587 A (DAVEY) 7 June 1994 see abstract; figures 1-7 ---	1-27
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

23 March 1999

Date of mailing of the international search report

31/03/1999

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Michels, N

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/22997

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 565 799 A (INTERVENTIONAL TECHNOLOGIES) 20 October 1993 see abstract; claims 1-3,8,9; figures 1,2A,B	26,27
A	US 4 796 629 A (GRAYZEL) 10 January 1989	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/22997

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5458572	A	17-10-1995	EP 0768904 A JP 10506296 T WO 9601133 A	23-04-1997 23-06-1998 18-01-1996
US 5041125	A	20-08-1991	US 4941877 A	17-07-1990
US 5456666	A	10-10-1995	CA 2187082 A EP 0758914 A JP 9512190 T WO 9528985 A US 5478319 A	02-11-1995 26-02-1997 09-12-1997 02-11-1995 26-12-1995
US 5318587	A	07-06-1994	DE 69011784 D EP 0414350 A JP 3092173 A	29-09-1994 27-02-1991 17-04-1991
EP 0565799	A	20-10-1993	US 5209799 A AU 2845592 A CA 2083352 C DE 69213212 D DE 69213212 T ES 2094886 T JP 2604532 B JP 5293174 A US 5336234 A	11-05-1993 21-10-1993 06-12-1994 02-10-1996 30-01-1997 01-02-1997 30-04-1997 09-11-1993 09-08-1994
US 4796629	A	10-01-1989	WO 8809682 A	15-12-1988

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: RAGI A. I. ELIAS
 PANITCH SCHWARZE BELISARIO & NADEL
 LLP
 TWO COMMERCE SQUARE
 2001 MARKET STREET, SUITE 2800
 PHILADELPHIA, PA 19103

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
 (day/month/year)

JUN 08 2022

Applicant's or agent's file reference

688961-156WO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/US2022/020704

International filing date
 (day/month/year)

17 March 2022

Applicant
 PRYTIME MEDICAL DEVICES, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
 The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
 (Facsimile No.: +41 22 338 82 70)

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of **18 months from the priority date**, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date**, the applicant may request that a **supplementary international search** be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
 Commissioner for Patents
 P.O. Box 1450, Alexandria, VA 22313-1450
 Facsimile No. 571-273-8300

Authorized officer

Harry Kim

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: RAGI A. I. ELIAS
PANITCH SCHWARZE BELISARIO & NADEL
LLP
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 2800
PHILADELPHIA, PA 19103

Date of mailing
(day/month/year)

JUN 08 2022

Applicant's or agent's file reference

688961-156WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2022/020704

International filing date (day/month/year)

17 March 2022

Priority date (day/month/year)

18 March 2021

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61B 17/12; A61B 17/22; A61M 25/00; A61M 25/10 (2022.01)

CPC - A61B 17/12136; A61B 17/12031; A61B 17/12109; A61M 2025/1052 (2022.05)

Applicant

PRYTIME MEDICAL DEVICES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

12 May 2022

Authorized officer

Harry Kim

PCT Helpdesk: 571-272-4300

Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2022/020704

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2022/020704

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-17	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest:

Regarding claim 1, the prior art of record, individually or in combination, does not teach or fairly suggest a vascular occlusion catheter for at least partial occlusion of a target vessel having an internal vessel wall, the vascular occlusion catheter system comprising: a proximal outer shaft; a distal outer shaft distally terminating with an atraumatic tip; an occlusion balloon connected to the proximal outer shaft at a proximal neck and the distal outer shaft at a distal neck; the proximal outer shaft having a first internal lumen and a second internal lumen, the first internal lumen being in fluid communication with the occlusion balloon; the distal outer shaft having a distal internal lumen; a hypotube having an internal hypotube lumen, the hypotube extending through the first internal lumen, through the occlusion balloon and into communication with the distal internal lumen, the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter; a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft, wherein the second internal lumen and the hypotube extend into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition.

Claims 2-12 depend from claim 1, and therefore meet the criteria set out in PCT Article 33(2)-(3) for at least the same reasons as claim 1.

The following prior art is made of record to support and further define the reasons that claim 1 meets the criteria set out in PCT Article 33(2)-(3):

US 10,368,872 to Prytime Medical Devices, Inc. (hereafter Prytime Medical Devices '872) teaches a vascular occlusion catheter for at least partial occlusion of a target vessel having an internal vessel wall (Title; Abstract), the vascular occlusion catheter system comprising: a proximal outer shaft (Fig. 1D shows a proximal outer shaft proximal element 12b); a distal outer shaft distally terminating with an atraumatic tip (Fig. 1D shows a distal outer shaft at 170 terminating at atraumatic tip 12c); an occlusion balloon connected to the proximal outer shaft at a proximal neck (Fig. 1D shows an occlusion balloon at 140 connected to the outer shaft near the proximal neck at 12b) and the distal outer shaft at a distal neck (Fig. 1D shows the occlusion balloon at 140 connected to the distal outer shaft 170 at the distal neck); the proximal outer shaft having a first internal lumen (Fig. 1B shows the proximal outer shaft 12b with a first internal lumen at 171) and a second internal lumen (Fig. 1B shows a second internal lumen 15 of 12a), the first internal lumen being in fluid communication with the occlusion balloon (Fig. 1B shows the first internal lumen in fluid communication with balloon 140); the distal outer shaft having a distal internal lumen (Fig. 1C shows the distal shaft portion of 12a extending through to an opening 170); a hypotube having an internal hypotube lumen (Col. 10, Lns. 4-5, an inflation catheter member 12 having a stiffener member or hypotube 12a), the hypotube extending through the first internal lumen (Fig. 1B shows the proximal outer shaft 12b with a first internal lumen at 171 where hypotube 12a extends through), through the occlusion balloon and into communication with the distal internal lumen (Fig. 1C shows the hypotube 12a extending through the occlusion balloon 140 and into communication with the distal lumen), the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter (Col. 41, Lns. 18-24, a metallic center rod 77 that is positioned in the hypotube lumen 15 of the stiffener member 1812a. The center rod 77 may be positioned in the hypotube lumen 15 when the hypotube lumen 15 is not being utilized for guidewires, pressure sensing or other functional reasons related to the preferred systems to prevent blood from pooling and clotting in the hypotube lumen 15), and a pressure sensor (Col. 4, Lns. 28-30, The distal pressure sensor is attached to the inflation catheter member between the proximal balloon end and the atraumatic tip), but fails to explicitly disclose the vascular occlusion catheter including a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft, wherein the second internal lumen and the hypotube extend into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition.

US 9,211,396 to Aboytes teaches a vascular occlusion catheter for at least partial occlusion of a target vessel having an internal vessel wall (Title; Abstract), the vascular occlusion catheter system comprising: a proximal outer shaft (Fig. 2A shows a proximal outer shaft proximal element 232); a distal outer shaft distally terminating with an atraumatic tip (Fig. 2A shows a distal outer shaft at 236 terminating at atraumatic tip); an occlusion balloon connected to the proximal outer shaft at a proximal neck (Fig. 2A shows an occlusion balloon at

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

226 connected to the outer shaft near the proximal neck at 238) and the distal outer shaft at a distal neck (Fig. 2A shows the occlusion balloon at 226 connected to the distal outer shaft 236 at the distal neck 234); the proximal outer shaft having a first internal lumen (Fig. 2D shows the proximal outer shaft 232 with a first internal lumen at 233) and a second internal lumen (Fig. 2D shows a second internal lumen 223 of 222), the first internal lumen being in fluid communication with the occlusion balloon (Figs. 2A and 2B shows the first internal lumen in fluid communication with balloon 226); a hypotube having an internal hypotube lumen (Col. 4, Lns. 24-29, Control of the expansion of the expandable member can be achieved by axial adjustment of the relative positions of the hypotube and core wire, and by moving the hypotube or core wire relative to one another radially as described in more detail herein), the hypotube extending through the first internal lumen (Col. 9, Ln. 66 to Col. 10, Ln. 7, The tubular member 122 can be, for example, a hypotube, and the elongate member 124 can be, for example, a core wire. The actuation member 120 can optionally be coupled on a proximal end portion to a controller device 130, such as, for example, a hand-held controller. The recanalization device 100 can be used with a catheter or sheath 132 to, for example, deliver a distal portion of the recanalization device 100 to a treatment site within a vessel, as described in more detail herein), but fails to explicitly disclose the vascular occlusion catheter including the distal outer shaft having a distal internal lumen; through the occlusion balloon and into communication with the distal internal lumen, the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter; a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft, wherein the second internal lumen and the hypotube extend into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition.

None of the cited prior art references taken alone or in combination disclose or suggest the specific elements of a vascular occlusion catheter including a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft, wherein the second internal lumen and the hypotube extend into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition as recited above, and none of the cited references cure the deficiencies of Prytime Medical Devices '872 and Aboytes discussed in this written opinion.

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INTERNATIONAL SEARCHING AUTHORITY**

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In case the space in any of the preceding boxes is not sufficient.

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Regarding claim 13, the prior art of record, individually or in combination, does not teach or fairly suggest a vascular occlusion catheter for at least partial occlusion of a target vessel having an internal vessel wall, the vascular occlusion catheter system comprising: an inflation hub having an inflation shaft extending therefrom; a proximal outer shaft; a distal outer shaft distally terminating with an atraumatic tip; and an occlusion balloon connected to the proximal outer shaft and the distal outer shaft; the proximal outer shaft having a first internal lumen and a second internal lumen, the first internal lumen being in fluid communication with the occlusion balloon; the distal outer shaft having a distal internal lumen; a hypotube having an internal hypotube lumen, the hypotube extending through the first internal lumen, through the occlusion balloon and into communication with the distal internal lumen, the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter; a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft and having an internal hub frame, (i) the first internal lumen and the hypotube extending into the display hub and being secured to the internal hub frame, (ii) the inflation shaft extending into the display hub and being secured to the internal hub frame, the internal hub frame fluidly connecting the inflation hub with the first internal lumen, (iii) the second internal lumen extending into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and (iv) the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition.

Claims 14-17 depend from claim 13, and therefore meet the criteria set out in PCT Article 33(2)-(3) for at least the same reasons as claim 13.

The following prior art is made of record to support and further define the reasons that claim 13 meets the criteria set out in PCT Article 33 (2)-(3):

Prytime Medical Devices '872 teaches a vascular occlusion catheter for at least partial occlusion of a target vessel having an internal vessel wall (Title; Abstract), the vascular occlusion catheter system comprising: a proximal outer shaft (Fig. 1D shows a proximal outer shaft proximal element 12b); a distal outer shaft distally terminating with an atraumatic tip (Fig. 1D shows a distal outer shaft at 170 terminating at atraumatic tip 12c); an occlusion balloon connected to the proximal outer shaft at a proximal neck (Fig. 1D shows an occlusion balloon at 140 connected to the outer shaft near the proximal neck at 12b) and the distal outer shaft at a distal neck (Fig. 1D shows the occlusion balloon at 140 connected to the distal outer shaft 170 at the distal neck); the proximal outer shaft having a first internal lumen (Fig. 1B shows the proximal outer shaft 12b with a first internal lumen at 171) and a second internal lumen (Fig. 1B shows a second internal lumen 15 of 12a), the first internal lumen being in fluid communication with the occlusion balloon (Fig. 1B shows the first internal lumen in fluid communication with balloon 140); the distal outer shaft having a distal internal lumen (Fig. 1C shows the distal shaft portion of 12a extending through to an opening 170); a hypotube having an internal hypotube lumen (Col. 10, Lns. 4-5, an inflation catheter member 12 having a stiffener member or hypotube 12a), the hypotube extending through the first internal lumen (Fig. 1B shows the proximal outer shaft 12b with a first internal lumen at 171 where hypotube 12a extends through), through the occlusion balloon and into communication with the distal internal lumen (Fig. 1C shows the hypotube 12a extending through the occlusion balloon 140 and into communication with the distal lumen), the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter (Col. 41, Lns. 18-24, a metallic center rod 77 that is positioned in the hypotube lumen 15 of the stiffener member 1812a. The center rod 77 may be positioned in the hypotube lumen 15 when the hypotube lumen 15 is not being utilized for guidewires, pressure sensing or other functional reasons related to the preferred systems to prevent blood from pooling and clotting in the hypotube lumen 15), and a pressure sensor (Col. 4, Lns. 28-30, The distal pressure sensor is attached to the inflation catheter member between the proximal balloon end and the atraumatic tip), but fails to explicitly disclose the vascular occlusion catheter including an inflation hub having an inflation shaft extending therefrom; the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter; a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft and having an internal hub frame, (i) the first internal lumen and the hypotube extending into the display hub and being secured to the internal hub frame, (ii) the inflation shaft extending into the display hub and being secured to the internal hub frame, the internal hub frame fluidly connecting the inflation hub with the first internal lumen, (iii) the second internal lumen extending into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and (iv) the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition.

Aboytes teaches a vascular occlusion catheter for at least partial occlusion of a target vessel having an internal vessel wall (Title; Abstract), the vascular occlusion catheter system comprising: a proximal outer shaft (Fig. 2A shows a proximal outer shaft proximal element 232); a distal outer shaft distally terminating with an atraumatic tip (Fig. 2A shows a distal outer shaft at 236 terminating at atraumatic tip); an occlusion balloon connected to the proximal outer shaft at a proximal neck (Fig. 2A shows an occlusion balloon at 226 connected to the outer shaft near the proximal neck at 238) and the distal outer shaft at a distal neck (Fig. 2A shows the occlusion balloon at 226 connected to the distal outer shaft 236 at the distal neck 234); the proximal outer shaft having a first internal lumen (Fig. 2D shows the proximal outer shaft 232 with a first internal lumen at 233) and a second internal lumen (Fig. 2D shows a second internal lumen 223 of 222), the first internal lumen being in fluid communication with the occlusion balloon (Figs. 2A and 2B shows the first internal lumen in fluid communication with balloon 226); a hypotube having an internal hypotube lumen (Col. 4, Lns. 24-29, Control of the expansion of the expandable member can be achieved by axial adjustment of the relative positions of the hypotube and core wire, and by moving the hypotube or core wire relative to one another radially as described in more detail herein), the hypotube extending through the first internal lumen (Col. 9, Ln. 66 to Col. 10, Ln. 7, The tubular member 122 can be, for example, a hypotube, and the elongate member 124 can be, for example, a core wire. The actuation member 120 can optionally be coupled on a proximal end portion to a controller device 130, such as, for example, a hand-held controller. The recanalization device 100 can be used with a catheter or sheath 132 to, for example, deliver a distal portion of the recanalization device 100 to a treatment site within a vessel, as described in more detail herein), but fails to explicitly disclose the vascular occlusion catheter including the distal outer shaft having a distal internal lumen; through the occlusion balloon and into communication with the distal internal lumen, an inflation hub having an inflation shaft extending therefrom; the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter; a first window formed in the proximal outer shaft; a proximal sensor

Form PCT/ISA/237 (Supplemental Box) (revised January 2019)

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INTERNATIONAL SEARCHING AUTHORITY**

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Supplemental Box

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being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft and having an internal hub frame, (i) the first internal lumen and the hypotube extending into the display hub and being secured to the internal hub frame, (ii) the inflation shaft extending into the display hub and being secured to the internal hub frame, the internal hub frame fluidly connecting the inflation hub with the first internal lumen, (iii) the second internal lumen extending into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and (iv) the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition.

None of the cited prior art references taken alone or in combination disclose or suggest the specific elements of a vascular occlusion catheter including an inflation hub having an inflation shaft extending therefrom; the hypotube operating as the primary load-bearing chassis of the vascular occlusion catheter; a first window formed in the proximal outer shaft; a proximal sensor being positioned within the second internal lumen facing the first window; a second window formed in distal outer shaft; a distal sensor being positioned within the distal internal lumen facing the second window; and a display hub positioned along the proximal outer shaft and having an internal hub frame, (i) the first internal lumen and the hypotube extending into the display hub and being secured to the internal hub frame, (ii) the inflation shaft extending into the display hub and being secured to the internal hub frame, the internal hub frame fluidly connecting the inflation hub with the first internal lumen, (iii) the second internal lumen extending into the display hub, the display hub being electrically connected with the proximal sensor via the second internal lumen, and (iv) the display hub being electrically connected with the distal sensor via the internal hypotube lumen and the distal internal lumen; wherein the occlusion balloon, the proximal outer shaft and the distal outer shaft have a greatest outer diameter of seven French (7 Fr) or less in an uninflated condition as recited above, and none of the cited references cure the deficiencies of Prytime Medical Devices '872 and Aboytes discussed in this written opinion.

Claims 1-17 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 688961-156WO		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2022/020704	International filing date (day/month/year) 17 March 2022	(Earliest) Priority Date (day/month/year) 18 March 2021	
Applicant PRYTIME MEDICAL DEVICES, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II):

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 30

- ☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/020704

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/12; A61B 17/22; A61M 25/00; A61M 25/10 (2022.01)

CPC - A61B 17/12136; A61B 17/12031; A61B 17/12109; A61M 2025/1052 (2022.05)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

see Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

see Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 10,368,872 B2 (PRYTIME MEDICAL DEVICES, INC.) 06 August 2019 (06.08.2019) entire document	1-17
A	US 9,211,396 B2 (ABOYTES) 15 December 2015 (15.12.2015) entire document	1-17
A	US 8,021,330 B2 (MCANDREW) 20 September 2011 (20.09.2011) entire document	1-17
A	US 9,474,882 B2 (PRYTIME MEDICAL DEVICES, INC.) 25 October 2016 (25.10.2016) entire document	1-17
P, A	US 2021/0290243 A1 (PRYTIME MEDICAL DEVICES INC.) 23 September 2021 (23.09.2021) entire document	1-17

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

12 May 2022

Date of mailing of the international search report

JUN 08 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Harry Kim

Telephone No. PCT Helpdesk: 571-272-4300

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

U.S.PATENTS						Remove
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	1	20110172696	A1	2011-07-14	Jeffrey et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17563669
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	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	688961-25U7	

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EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
<small> ¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached. </small>			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2022-08-25
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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

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

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

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

Electronic Acknowledgement Receipt	
EFS ID:	46482811
Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Katie Carlson
Filer Authorized By:	Ragi A.I. Elias
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Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Angela Kryszczak
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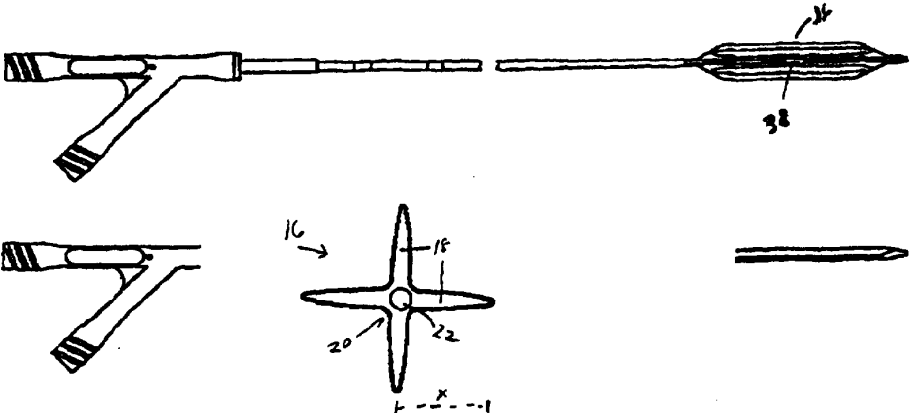
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(51) International Patent Classification ⁶ : A61M 29/00	A1	(11) International Publication Number: WO 97/25093 (43) International Publication Date: 17 July 1997 (17.07.97)
(21) International Application Number: PCT/US96/20302 (22) International Filing Date: 20 December 1996 (20.12.96) (30) Priority Data: 08/582,722 4 January 1996 (04.01.96) US (71) Applicant: LEOCOR, INC. [US/US]; 1301 Regent's Park Drive, Houston, TX 77058 (US). (72) Inventor: WIJAY, Bandula; 1903 Carriage Creek Drive, Friendswood, TX 77546 (US). (74) Agent: ROSENBLATT, Steve; Rosenblatt & Redano, P.C., Suite 500, One Greenway Plaza, Houston, TX 77046 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: FLUTED BALLOON CATHETER  (57) Abstract <p>The present invention provides a catheter (10) with at least one lumen (22) therethrough, and a balloon (16) sealingly engaged in fluid communication with the lumen (22). The balloon (16) has a predetermined folding pattern with at least three collapsible grooves or depressions (20). Upon deflation, the grooves or depressions (20) automatically collapse inward, resulting in a folded configuration which can be twisted into a very low profile configuration. The catheter body (10) preferably is made of polyether ether ketone ("PEEK"), and the fluted balloon (16) preferably is made of polyvinylidene fluoride ("PVDF") and polyurethane.</p>		

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TITLE: FLUTED BALLOON CATHETER

INVENTOR: BANDULA WIJAY

Field of the Invention

5 The present invention relates generally to the field of surgery, and particularly to instruments for facilitating the performance of surgery related to the flow of blood. More particularly, the invention relates to balloon catheters that have a predetermined folding pattern for ease in removing or
10 relocating the balloon after insertion into a blood vessel. Upon deflation, the balloons collapse according to the predetermined folding pattern to result in a low profile configuration.

Background of the Invention

15 When a patient is afflicted with an obstructed coronary artery, the artery typically is dilated using a procedure known as percutaneous transluminal coronary angioplasty ("PTCA"). PTCA is performed using a "balloon" catheter (or a PTCA catheter). A balloon catheter consists, very basically,
20 of an inflatable balloon and a means for guiding the balloon to the target occlusion and for inflating the balloon to dilate the artery at the point of the occlusion. Preferably, the catheter also permits simultaneous monitoring of aortic pressure and/or simultaneous dye injections to clarify the
25 vascular anatomy.

 Once it is determined that PTCA is called for, a guiding catheter typically is introduced through a sheath which guides

-2-

the catheter to the aortic origin of the vessel to be dilated. Once the guidewire reaches the lesion, the guiding catheter supports the balloon catheter as it is threaded onto the guidewire until the "balloon" portion of the catheter reaches
5 the occlusion. The balloon portion then is inflated from an external port, resulting in compression of the atheromatous lesion in a manner perpendicular to the vessel, thus dilating the lumen.

Clinical experience has revealed that a balloon catheter
10 system having the lowest profile is desirable in order to facilitate the passage of the balloon across severe and remote vascular obstructions. Known angioplasty catheters have been shipped to doctors and hospitals in sterilized condition with the balloon deflated and in a "wing-folded" condition.
15 Essentially, wing folding involves flattening of the balloon along the catheter body and folding the balloon over onto the catheter body in two segments which resemble wings coming from a fuselage. In the past, the catheters were wing-folded in the factory prior to shipment.

20 One problem encountered with wing-folded balloons was that the doctor and/or technician generally had to inject a contrast fluid to displace gas in the balloon. As a result, the balloon lost its low profile, "wing-folded" configuration. In order to avoid the need to displace gas in the balloon,
25 manufacturers could prefill the balloon with contrast fluid and place a sleeve over the balloon to maintain the low profile, wing-folded position.

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Although "wing-folded" balloons have a low profile during insertion, the balloons unfold upon inflation. After the target blood vessel is dilated, the balloon must again be returned to a low profile for ease in removing the catheter and/or repositioning to dilate a different blood vessel. Unfortunately, it is difficult to manipulate a deflated balloon positioned inside of a blood vessel to achieve a low profile configuration. A balloon having a construction that would automatically return to a low profile configuration upon deflation would be very advantageous.

Summary of the Invention

The present invention provides a catheter with at least one lumen therethrough and a balloon sealingly engaged in fluid communication with the lumen. The balloon has a predetermined folding pattern with at least three collapsible grooves or depressions. Upon deflation, the grooves or depressions automatically collapse inward, resulting in a folded configuration which can be twisted into a very low profile configuration. The catheter body preferably is made of polyetheretherketone ("PEEK"), and the fluted balloon preferably is made of polyvinylidene fluoride ("PVDF"), polyurethane, and polyester terephthalate.

Brief Description of the Drawings

Fig. 1 is a schematic diagram of a balloon angioplasty catheter according to the present invention wherein the balloon is inflated.

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Fig. 2 is a schematic diagram of a balloon angioplasty catheter according to the present invention wherein the balloon is deflated.

Fig. 3 is a schematic diagram of a balloon angioplasty catheter according to the present invention wherein the balloon is deflated and has been folded in on itself.

Fig. 4 is a blow up of the balloon depicted in Fig. 1 indicating a cross section at line B-B.

Fig. 4A is a schematic cross section along line B-B in Fig. 4.

Fig. 4B is a schematic cross section of the section in Fig. 4A when the balloon unfolded.

Fig. 5 is a blow up of the balloon portion of the catheter in Fig. 2 indicating a cross section at line A-A.

Fig. 5A is a cross section along line A-A in Fig. 5 when the balloon has one predetermined folding pattern.

Fig. 5B is a cross section along line B-B in Fig. 5 when the balloon has another predetermined folding pattern.

Fig. 6A is a side view of a balloon catheter having a necked down catheter body, a necked down perfusion lumen, and an inner strengthening wire.

Fig. 6B is a blowup of the necked down region of the catheter shown in Fig. 6A, with the internal lumens and wire depicted as dotted lines.

Fig. 6C is a cross section along line C-C in Fig. 6B.

-5-

Fig. 7A is a side view of a balloon catheter having a necked down catheter body, a perfusion lumen that is not necked down, and an inner strengthening wire.

Fig. 7B is a blowup of the necked down region of the catheter shown in Fig. 7A, with the internal lumens and wire shown as dotted lines.

Fig. 7C is a cross section along line D-D in Fig. 7B.

Fig. 8 is a schematic diagram of a typical balloon with no predetermined folding pattern which has been "wing folded."

Fig. 9 is a schematic of a cross section through an inflated balloon.

Fig. 10 is a schematic of a typical balloon with no predetermined folding pattern after deflation.

Detailed Description of the Invention

Fig. 1 depicts a balloon catheter system 10 which includes a proximal section 12 secured proximally to a fitting 14. Many suitable fittings 14 are known in the art. The particular fitting that is used with the catheter is not critical to the invention; however, the fitting must have certain features in order to be compatible with the catheter. The fitting 14 must include a mechanism 13 for inserting and maneuvering a guidewire (not shown) and also for pumping perfused blood, drugs, and/or dyes, preferably through another lumen (22 in Figs. 4-7) in the proximal section 12 and out the distal portion of the catheter 10. The fitting 14 also should have a mechanism 15 to inflate the balloon.

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The fitting 14 preferably should be insert-molded using known methods to process high-density polyethylene. At the distal end of the catheter 10 is a balloon 15. In a preferred embodiment, the balloon is made of polyvinylidene fluoride ("PVDF"), preferably KYANAR™ (a product available from Pennwalt Corporation), polyurethane, polyester terephthalate, or blends thereof. These plastics are available from numerous sources, such as Pennwalt Corporation. Various blends of these materials may be used to alter the properties of the balloon. A preferred blend of materials for the balloon is 40 wt% KYANAR™, 5 wt% polyurethane, and 44 wt% polyester terephthalate.

A balloon made of a polymeric mix containing PVDF is preferred because such balloons are strong, can be biaxially oriented, and have good memory characteristics. The balloon also can be made of other suitable materials, including but not limited to, polyethylene, polyurethane, or polyester. Polyethylene and polyurethane balloons tend to have thick walls which withstand high pressures and distend considerably in response to internal pressure. Polyester balloons and balloons made of a blend containing PVDF, have significantly thinner walls but nevertheless will withstand high pressures and distend only minimally with increased internal pressure. The balloon may be made in a variety of sizes between about 1.5-10.0 mm using known procedures.

In the typical balloon catheter, the balloon 16 is molded to have a smooth, flexible surface with no predetermined

-7-

folding pattern. Upon inflation, a cross section of a typical balloon would have a substantially rounded outer circumference, as broadly depicted in Fig. 9. Upon deflation, balloons molded with no predetermined folding pattern will
5 flatten out into a "pancake" form, as broadly depicted in Fig. 10. In the past, manufacturers have "wing-folded" deflated balloons such as that shown in Fig. 10 to result in "wing-folded" configuration substantially as illustrated in Fig. 8.

In Fig. 8, E is a portion of the catheter body that forms
10 a lumen which may extend through the balloon to the distal tip of the catheter in order to perfuse various substances. D is the folded balloon. Wing folding is the technique of using digital manipulation or a machine to grab the balloon D above and below the elongated body E and, in effect, fold the
15 balloon into a pair of winglike segments above and below the elongated body E. These two wing segments are folded over the elongated body E as shown in Fig. 8.

In contrast, the balloons of the present invention are molded to have a predetermined folding pattern. The
20 predetermined folding pattern preferably has at least three grooves or depressions 20 which (a) upon inflation, are pressed outward to result in a balloon with a substantially rounded circumference, as depicted in Fig. 9, and (b) upon deflation, pulled inward to result in a collapsed
25 configuration, such as that shown in Fig. 4B, so that the balloon 16 can be twisted and/or more easily and consistently

-8-

manipulated into a low profile, folded configuration, such as that shown in Fig. 4A.

In a preferred embodiment, the predetermined folding pattern has four lobes 18 with a groove or depression 20
5 between each lobe (Figs. 4A, 4B, 5A, 5B). The balloon is molded in a manner that results in "plump" lobes 18 similar to those shown in Figs. 5A and 5B; however, upon deflation, the lobes 18 collapse into a configuration closer to that shown in Fig. 4B. The deflated balloon shown in Fig. 4B can relatively
10 easily be twisted to have the low profile configuration shown in Fig. 4A.

A predetermined folding pattern with four lobes 18 is preferred because it should reduce the widest "diameter" of the deflated, unfolded balloon by about one-half. A deflated
15 balloon with no predetermined folding pattern will assume the "pancake"-like configuration depicted in Fig. 10. The "pancake"-like configuration of a deflated balloon with no predetermined folding pattern has a diameter at its widest point equal to about 4 times the radius of the inflated
20 balloon (x in Fig. 4B). This widest point is indicated in Fig. 10 at line $4x$. In contrast, a deflated balloon which has a preferred predetermined folding pattern into four lobes, such as the "lobed" configurations shown in Figs. 4B, 5A, and 5B, has a diameter at its widest point equal to about two
25 times the radius of the inflated balloon ($2x$ in Fig. 4B). When deflated, the maximum diameter of the balloon preferably

-9-

should be between about 0.02-0.035 inches, preferably about 0.03 inches.

Persons of ordinary skill in the art will recognize that the predetermined folding pattern could have more than three
5 grooves or depressions, or could have a different configuration--such as a star shape--and still result in a deflated balloon which could be folded into a configuration with a relatively low profile.

The balloon of the present invention may be used with a
10 catheter body 10 having any number of configurations. Preferred configurations are depicted in Figs. 6-7. The body of the catheter 10 depicted in Figs. 6-7 preferably should be between about 135-140 cm long, and approximately 2 cm of this length should be housed within the fitting 14. In a preferred
15 embodiment, the body 10 has a coaxial construction with an outer wall 23 surrounding an outer lumen 24 and an inner wall 21 surrounding an inner lumen 22 (Fig. 6C). A preferred embodiment has a metal wire 26 (Figs. 6-7) disposed in the outer lumen 24 to impart additional stiffness to the catheter
20 body 10. The metal wire 26 preferably is tapered at its distal end for a length of about 10 cm from a normal diameter of about 0.014 inches to a final diameter at its distal end of about 0.005 inches. This taper increases the flexibility and maneuverability of the distal end of the catheter. A
25 preferred material for the metal wire 26 is stainless steel.

In a preferred embodiment, the catheter body 10 preferably consists of extruded tubing made of

-10-

polyetheretherketone ("PEEK"), which also adds stiffness to the catheter body 10. Reinforcement may be provided along the first 2.0-2.4 cm of the proximal section 12 as it exits the fitting to provide strain relief. The proximal section 12 of the catheter 10 preferably should have a diameter of between about 3.0-3.5 French. The proximal section 12 preferably has the configuration shown in more detail in Figs. 6-7.

Fig. 6B is a blow-up of the necked down region 30 of the catheter body 10 of Fig. 6A with the lumens 22, 24 and the wire 26 depicted as dotted lines. The smaller diameter, necked down region of the balloon 31 preferably is about 20 cm long. The inner lumen 22 in Fig. 6 also is necked down at regions 28, and the wire 26 is shown disposed in the outer lumen 24. Fig. 6C depicts the inner lumen 22, the outer lumen 24, and the wire 26 in cross section. Figs. 7A-7C depict a preferred embodiment which is substantially the same as that depicted in Figs. 6A-6C, except that the inner lumen 22 is not necked down.

The catheter body 10 can be unitary or formed as multiple components attached by suitable means that are known in the art. For example, the proximal section 12 may be formed as a single unit which may be joined to a separate, smaller diameter unit at the necked down region 30 using known means, such as heat bonding, fusing, or using a biocompatible glue. In a preferred embodiment, the separate, smaller diameter, more distal unit is made of polyethylene.

-11-

The balloon 16 has an elongated shape which defines an annular cavity 36 between the balloon 16 and the inner wall 21. The balloon 16 may be sealingly engaged with the catheter body using conventional means. Preferably, the proximal end 32 (Fig. 1) of the balloon 16 should extend about 2 mm proximally over the outer wall 23 at the distal end of the catheter body 10 and the overlapping portions should be heat-fused or bonded by other means. In a preferred embodiment, the outer wall 23 does not extend through the balloon, but ends substantially where the balloon 16 is engaged with the outer wall 23. Preferably, only the inner wall 21 extends through the balloon 16. Preferably, approximately 2-4 mm of the distal ends 34 of the balloon 16 and the inner wall 21 are sealingly engaged using known means, preferably heat-fusing or adhesive bonding.

A guidewire may be inserted through the inner lumen 22 to guide the catheter when it is inserted into a blood vessel or other body cavity. Preferably, the inner lumen 22 should have a diameter that is large enough to permit a suitable guidewire (not shown) to move relatively freely within the lumen 22. The inner lumen 22 also should be large enough to permit active perfusion of blood/fluids with flowrates up to about 100 cc/min. and to permit insertion of a guidewire, but small enough to maintain a low catheter profile. A preferable diameter for the inner lumen is about 0.014 inch. The outer lumen 24 should be as small as possible, but large enough to

-12-

retain the metal wire 26 and also permit a sufficient amount of inflation fluid to flow to the balloon 16.

Although the construction of the catheter body 10 is described as substantially "coaxial," it is not necessary for the inner lumen 22 and the outer lumen 24 to have x and y axes that completely coincide. As used herein, the term "substantially coaxial" means that the inner lumen 22 and the outer lumen 24 have x and y axes that are substantially parallel in construction, at least when the catheter is relaxed. During the insertion process, the outer wall 23 may become twisted in relation to the inner wall 21 so that the x and y axes are temporarily dislocated.

In actual manufacture, the catheter assemblies may be stored as two subassemblies until it is known what size of balloon 16 is required. A first subassembly can be the proximal section 12 of the catheter body 10, including the inner wall 21 surrounding the inner lumen 22 that will extend through the balloon 16. A radiopaque marker 38 may be attached to the inner wall 21 at a desired location. Typically, the radiopaque marker should be placed at a location that will be at or near the center of the balloon 16 after final assembly. This first subassembly then may be stored in stock.

Independently, the balloon 16 may be stored in stock as a second subassembly. After it is decided what size of catheter is needed, a correctly sized balloon can be fused to the first subassembly, as already described.

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The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing
5 from the spirit of the invention.

WE CLAIM:

1 1. A catheter, comprising:
2 a body comprising a proximal end, a distal end, and at
3 least one lumen therethrough;
4 a balloon with a predetermined folding pattern
5 comprising at least three collapsible depressions,
6 said balloon being supported by said distal end of
7 said body and sealingly engaged in fluid
8 communication with said lumen.

1 2. The catheter of claim 1 wherein
2 said body has at least two lumens therethrough, one of
3 said lumens being a perfusion lumen and another of
4 said lumens being an inflation lumen; and
5 said balloon is sealingly engaged with said inflation
6 lumen and said perfusion lumen extends through said
7 balloon to a distal end of said catheter.

1 3. The catheter of claim 1 further comprising a wire
2 disposed within said body to strengthen said catheter.

1 4. The catheter of claim 3 wherein said wire has a
2 proximal and a distal end and said wire is tapered at said
3 distal end.

1 5. The catheter of claim 2 further comprising a wire
2 disposed in said inflation lumen.

1 6. The catheter of claim 5 wherein said wire has a
2 proximal and a distal end and said wire is tapered at said
3 distal end.

1 7. The catheter of claim 1 wherein said body comprises
2 a portion having a decreased diameter at said distal end.

1 8. The catheter of claim 7 wherein said decreased
2 diameter portion of said catheter comprises polyethylene.

1 9. The catheter of claim 3 wherein said body comprises
2 a portion having a decreased diameter at said distal end.

1 10. The catheter of claim 9 wherein said decreased
2 diameter portion of said catheter comprises polyethylene.

1 11. The catheter of claim 5 wherein said body comprises
2 a portion having a decreased diameter at said distal end.

1 12. The catheter of claim 11 wherein said decreased
2 diameter portion of said catheter comprises polyethylene.

1 13. The catheter of claim 1 wherein said balloon
2 comprises polyvinylidene fluoride.

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1 14. The catheter of claim 1 wherein said body comprises
2 polyetheretherketone.

1 15. The catheter of claim 13 wherein said body comprises
2 polyetheretherketone.

1 16. The catheter of claim 3 wherein said balloon
2 comprises polyvinylidene fluoride.

1 17. The catheter of claim 3 wherein said body comprises
2 polyetheretherketone.

1 18. The catheter of claim 16 wherein said body comprises
2 polyetheretherketone.

1 19. The catheter of claim 9 wherein said balloon
2 comprises polyvinylidene fluoride.

1 20. The catheter of claim 9 wherein said body comprises
2 polyetheretherketone.

1 21. The catheter of claim 19 wherein said body comprises
2 polyetheretherketone.

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1 22. A device for dilating stenotic lesions in body
2 cavities comprising a body with a lumen therethrough and a
3 balloon sealingly engaged in fluid communication with said
4 lumen wherein said body comprises polyetheretherketone.

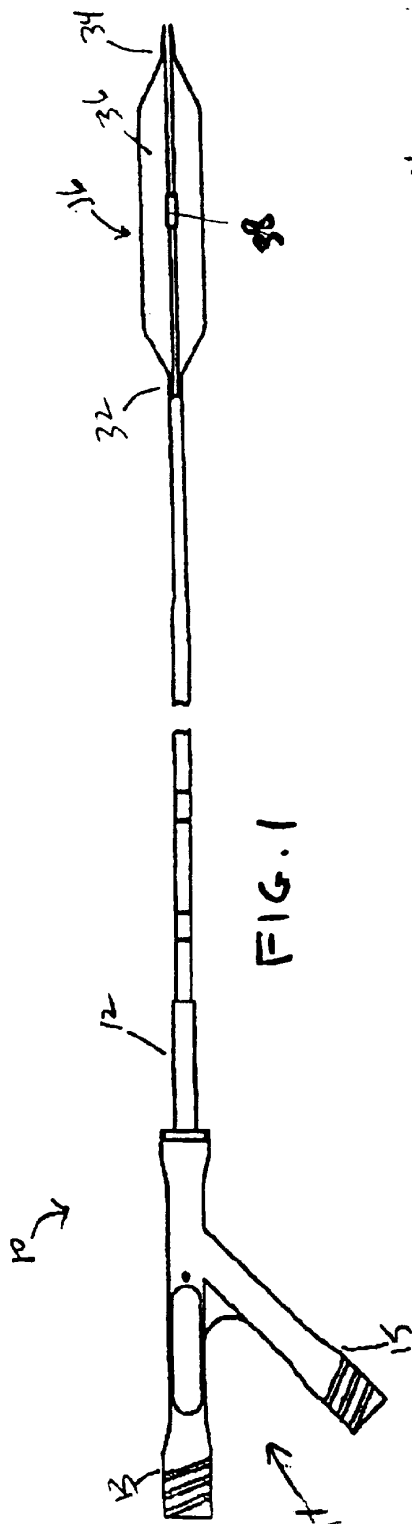
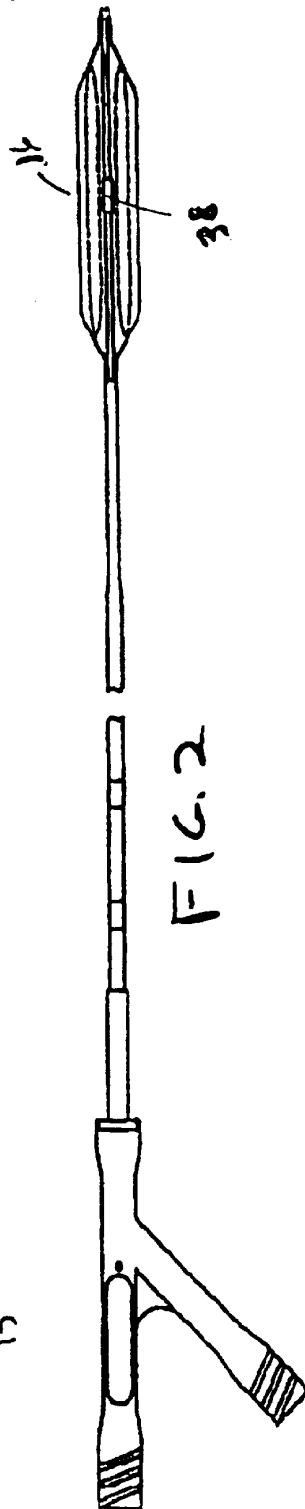
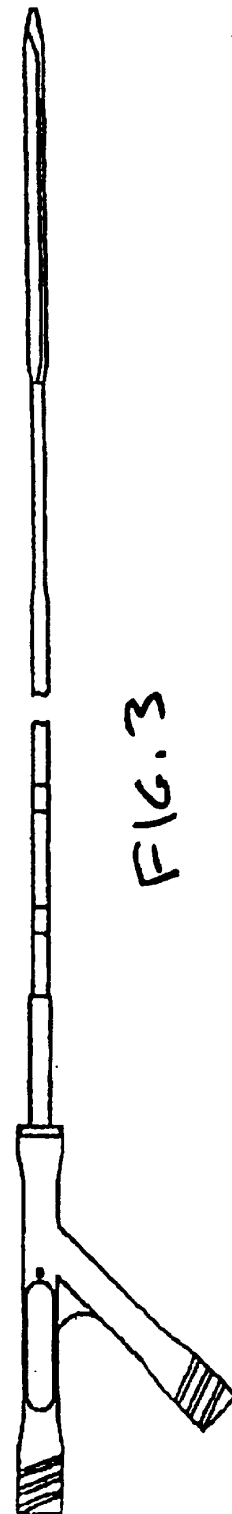
1 23. The device of claim 22 wherein said balloon has a
2 predetermined folding pattern comprising at least three
3 collapsible depressions.

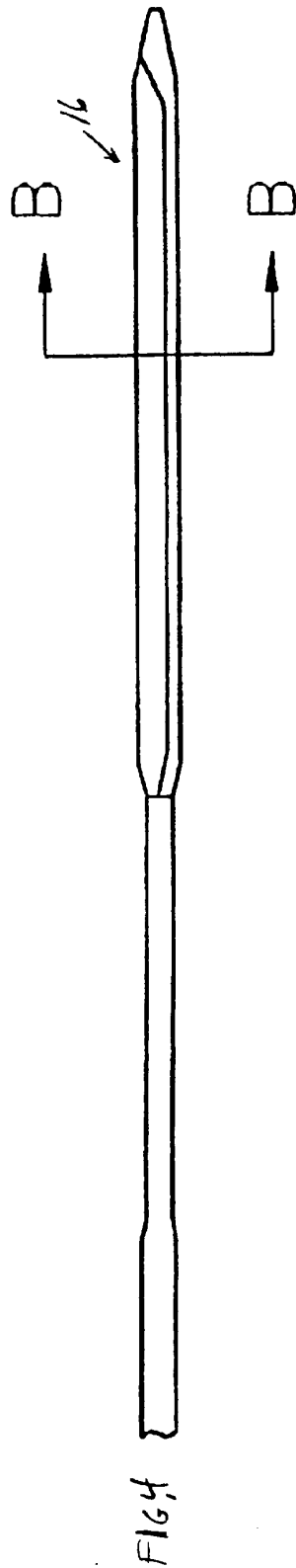
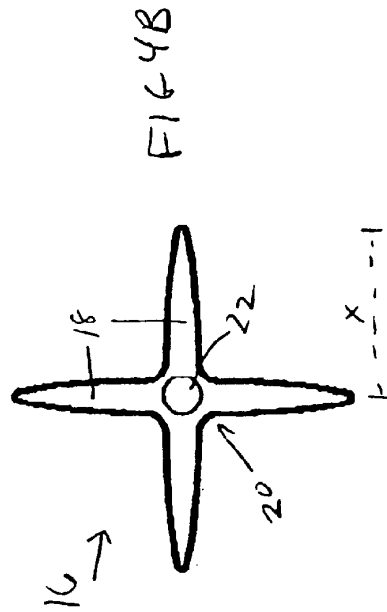
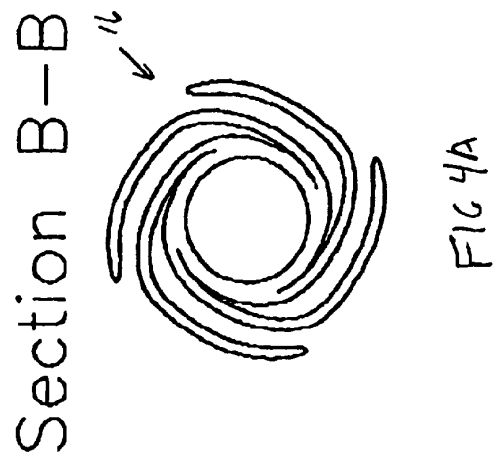
1 24. The device of claim 23 wherein said balloon
2 comprises polyvinylidene fluoride.

1 25. A device for dilating stenotic lesions in body
2 cavities comprising a body with a lumen therethrough and a
3 balloon sealingly engaged in fluid communication with said
4 lumen wherein said balloon comprises polyvinylidene fluoride.

1 26. The device of claim 25 wherein said balloon has a
2 predetermined folding pattern comprising at least three
3 collapsible depressions.

1 27. A device for dilating stenotic lesions in body
2 cavities comprising a body with a lumen therethrough and a
3 balloon sealingly engaged in fluid communication with said
4 lumen wherein said balloon has a predetermined folding pattern
5 comprising at least three collapsible depressions.





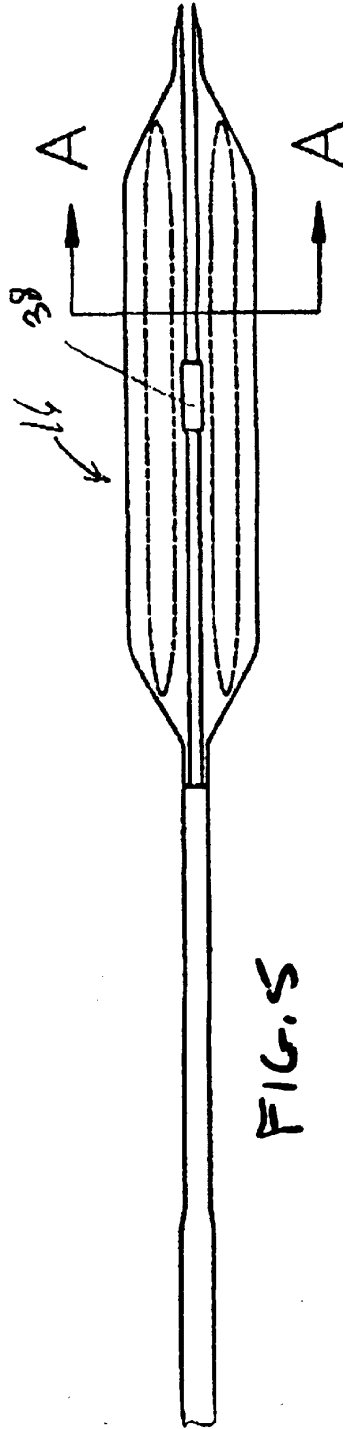


FIG. 5

Section A-A

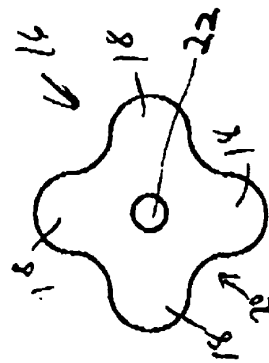


FIG. 5A

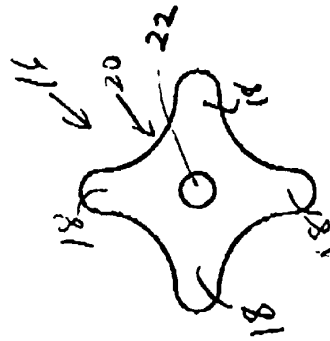
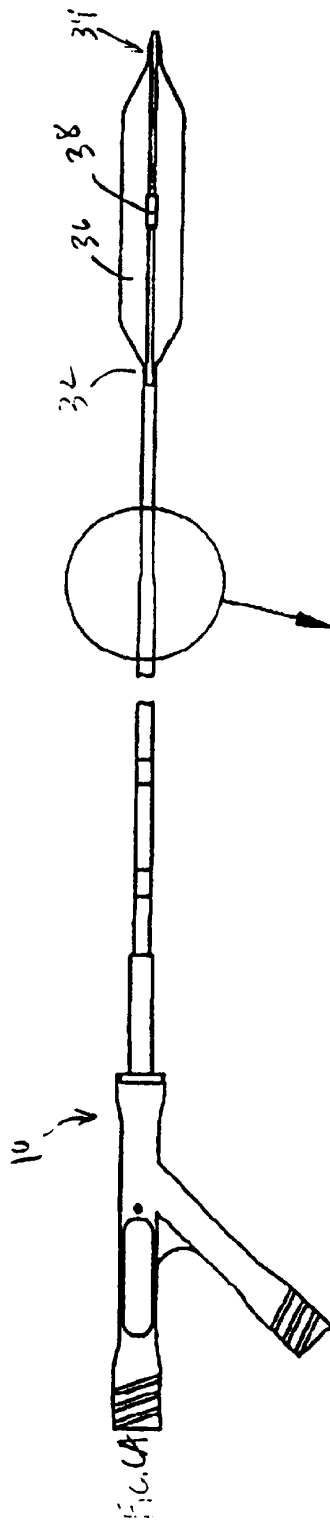
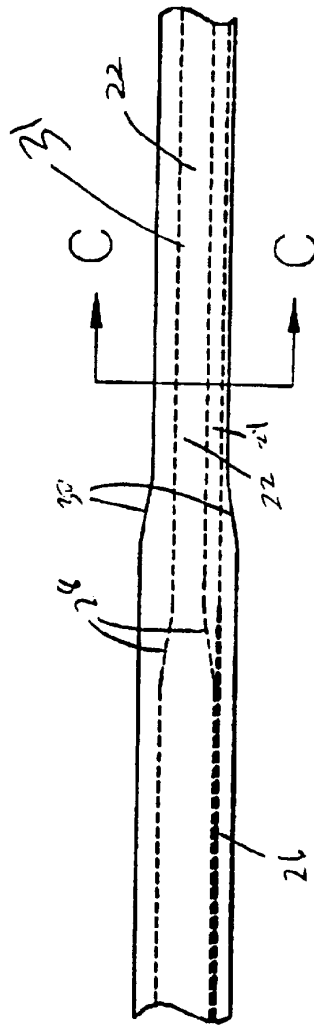
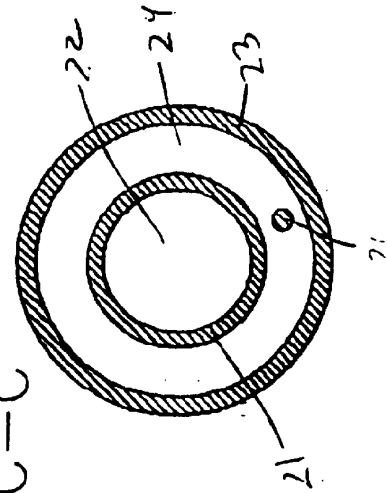
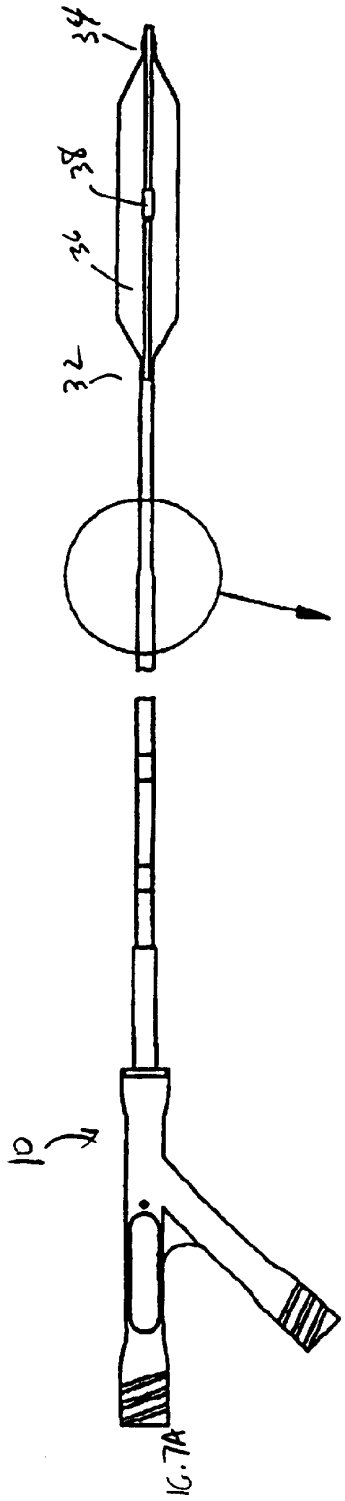
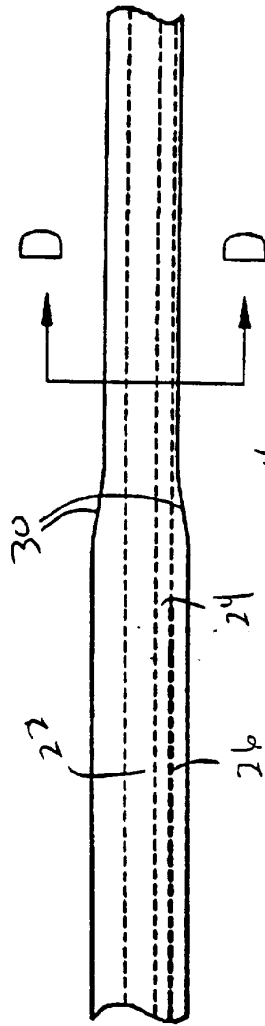


FIG. 5B

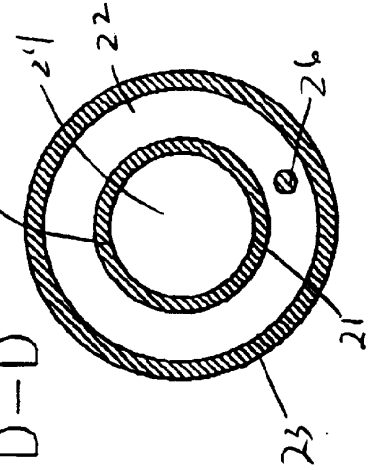


Section C-C





Section D-D



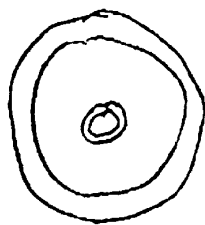


FIG. 9

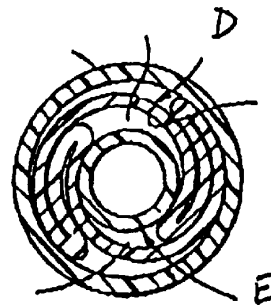


FIG. 8

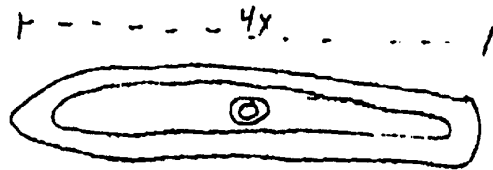


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20302

A. CLASSIFICATION OF SUBJECT MATTER IPC(6) : A61M 29/00 US CL : 604/96; 606/194 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/96; 606/194 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched 606/191, 192, 198 Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) APS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,087,246 A (SMITH) 11 February 1992. entire document.	1-27 ----- 1-21, 23, 24, 26, 27
X,P ---- Y,P	US 5,554,121 A (AINSWORTH et al) 10 September 1996. entire document.	22 ----- 1-3, 7-10, 14, 15, 17-21, 23, 24
☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents. "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "A" document defining the general state of the art which is not considered to be of particular relevance "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "E" earlier document published on or after the international filing date "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "&" document member of the same patent family "P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 27 MARCH 1997		Date of mailing of the international search report 16 APR 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer <i>Ellen TAO</i> ELLEN TAO Telephone No. (703) 308-2109

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20302

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E ----- Y,E	US 5,609,606 A (O'BOYLE) 11 March 1997. entire document.	25 ----- 1, 3, 13, 15, 16, 18, 19, 21, 24
Y	US 5,425,711 A (RESSEMANN et al) 20 June 1995. entire document.	1-6, 11, 12

Form PCT/ISA/210 (continuation of second sheet)(July 1992)*

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

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	2	5295995		1994-03-22	Kleiman, Jay H.	
	3	6007517		1999-12-28	Anderson, R. David	

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	Filing Date	2021-12-28
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2023-05-02
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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

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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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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.

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Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Angela Kryszczak
Filer Authorized By:	Ragi A.I. Elias
Attorney Docket Number:	688961-25U7
Receipt Date:	02-MAY-2023
Filing Date:	28-DEC-2021
Time Stamp:	10:33:13
Application Type:	Utility under 35 USC 111(a)

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495
570 7590 06/20/2023 PANITCH SCHWARZE BELISARIO & NADEL LLP TWO COMMERCE SQUARE 2001 MARKET STREET, SUITE 2800 PHILADELPHIA, PA 19103			EXAMINER DOUBRAVA, JOHN A	
			ART UNIT 3783	PAPER NUMBER
			NOTIFICATION DATE 06/20/2023	DELIVERY MODE ELECTRONIC

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

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

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

usptomail@panitchlaw.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Amendment

2. This office action is responsive to the amendment filed on February 10, 2022. As directed by the amendment: claim 1 has been amended, no claims have been cancelled, and claim 11 have been added. Thus, claims 1-11 are presently pending in this application.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. **Therefore, the asymmetrical balloon of claim 2 and the balloon comprising a conically shaped portion facing a spherically shaped portion of claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.**

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. **Claims 1-11 are** objected to because of the following informalities: in line 15 "the occlusion balloon" is recited twice, but should only be recited once. **Claims 2-11** are objected to because they depend from claim 1. Appropriate correction is required.
5. **Claim 9** is objected to because of the following informalities: punctuation, specifically, the claim should end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 103

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

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 1, 4-6 and 9-11** are rejected under 35 U.S.C. 103 as being unpatentable over Kantor US 2004/0039332 A1 in view of Mallaby 2010/0204712 A1 in view of Jeffrey et al. (Jeffrey) US 2011/0172696 A1 in view of Klocke et al. (Klocke) US 2019/0366046 A1.

9. **Regarding claim 1**, Kantor discloses an occlusion catheter system (catheter 300, P0037 and shown in Fig. 3) comprising: a proximal hub (hub 310, P0037); a proximal catheter section (shaft 304, P0073 and shown in Fig. 6) in fluid communication with the proximal hub; a distal catheter section (inner member 606, P0073), an intervening occlusion balloon (balloon 312, P0073) connecting the proximal catheter section with the distal catheter section, the occlusion balloon being constructed of a compliant biocompatible material (polyethylene, P0034, and see Haarmann-Thiemann US 2016/0051386 P0049); a lumen (inflation lumens, P0071) extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon; and a solid wire (guidewire 302, P0062 with solid cross-section shown in Fig. 5) extending within the proximal catheter section, the occlusion balloon and the distal catheter section (Fig. 3), the occlusion balloon, the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration (P0070).

10. Kantor does not explicitly teach a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device.

11. However, Mallaby teaches a microcatheter comprising a flow valve (valve 32, P0049 and shown in Fig. 1) configured to selectively fluidly communicate the proximal hub with an inflation device (balloon inflation syringe 34, P0049).

12. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to modify the hub of Kantor with the valve and syringe of Mallaby for the purpose of controlling fluid flow as taught by Mallaby, P0049.

13. Kantor does not teach a distal catheter section distally terminating with an atraumatic tip.

14. However, Jeffrey teaches a catheter having a soft distal tip wherein the distal catheter section is distally terminating with an atraumatic tip (sleeve 34, P0033-0034 and shown in Fig. 2A).

15. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to combine the catheter of Kantor with the sleeve of Jeffrey for the purpose of minimizing the risks to vessel injury or rupture, as taught by Jeffrey P0006-0007.

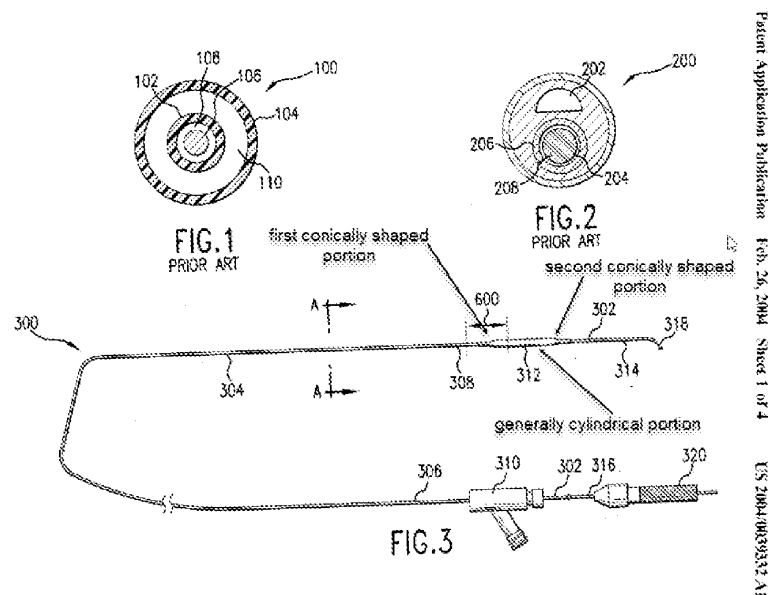
16. Kantor does not teach at least one length marking on an exterior of the proximal catheter shaft to indicate an insertion depth of the occlusion catheter system.

17. However, Klocke teaches a catheter with markings having at least one length marking (marks 32, P0023) on an exterior of the catheter shaft (Fig. 7A) to indicate an insertion depth of the occlusion catheter system (P0024).

17. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to combine the catheter of Kantor with the marks of

Klocke for the purpose of assessing the amount to which the catheter has been introduced to the treatment area, as taught by Klocke P0024.

18. **Regarding claim 4**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion (Kantor, see annotated Fig. 3 below).



19.

20. **Regarding claim 5**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion (Kantor, see annotated Fig. 3 above).

21. **Regarding claim 6**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1, wherein the solid wire is secured to

the proximal hub (Mallaby, Fig. 2, showing guide wire lock 72 for locking the guidewire to the hub).

22. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to modify the hub of Kantor with the guidewire lock of Mallaby for the purpose of ensuring that the guidewire remains stationary when needed to prevent unintended advancement of the guidewire and the potential for injury.

23. **Regarding claim 9**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1, further comprising a proximal radio opaque marker (Klocke, proximate radiopaque marker 40, P0027 and see annotated Fig. 8 below) proximate a proximal end of the occlusion balloon and a distal radio opaque marker (Klocke, proximate radiopaque marker 40, P0027 and see annotated Fig. 8 below) proximate a distal end of the occlusion balloon;

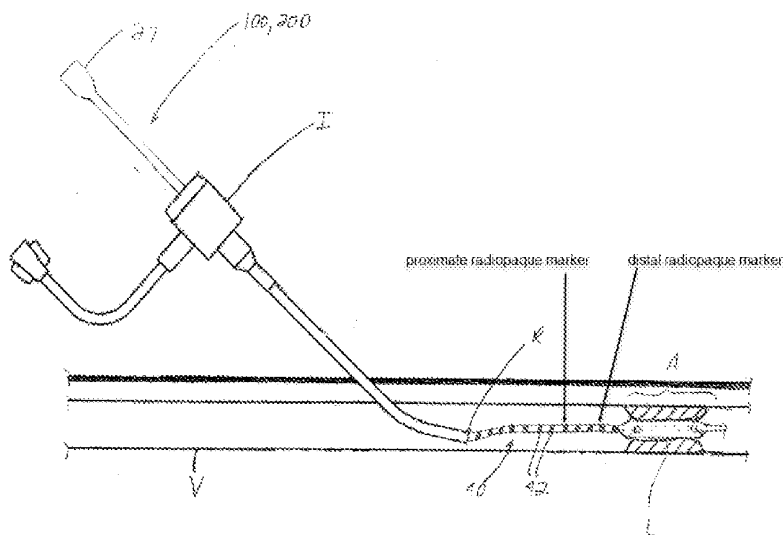


FIG. 8

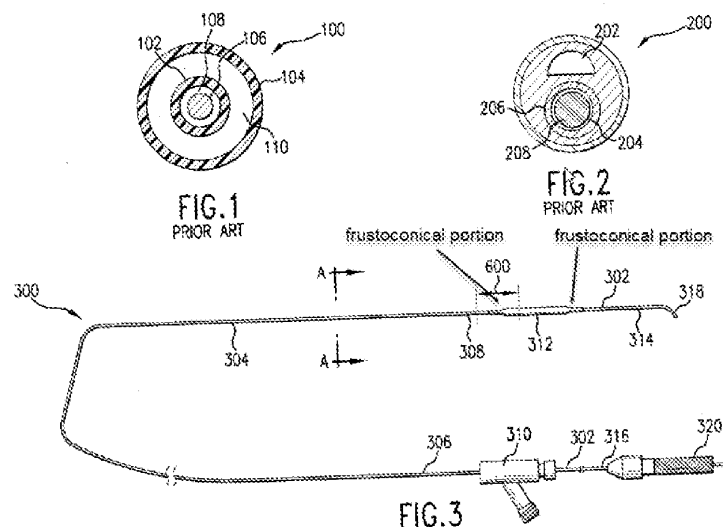
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24.

25. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to modify the catheter of Kantor with radiopaque markings as taught by Klocke for the purpose of providing for additional markings to ensure proper placement of the catheter in vivo, Klocke P0027.

26. **Regarding claim 10**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches an inflation control system kit comprising: the occlusion catheter system of claim 1; and a syringe containing a fluid (Mallaby, balloon inflation syringe 34, P0049), the syringe being configured to fluidly connect with an inlet of the proximal hub (Mallaby, Fig. 1).

27. **Regarding claim 11**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions (Kantor, see annotated Fig. 3 below).



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28.

29. **Claim 2** is rejected under 35 U.S.C. 103 as being unpatentable over Kantor in view of Mallaby in view of Jeffrey in view of Klocke in view of Hamilton et al. (Hamilton) US 6,129,737.

30. **Regarding claim 2**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1.

31. Kantor in view of Mallaby in view of Jeffrey in view of Klocke does not teach wherein the occlusion balloon is asymmetrical.

32. However, Hamilton teaches an asymmetric dilatation balloon (asymmetric balloon 12, col 2 ln 53-54 and shown in Figs. 1-1A).

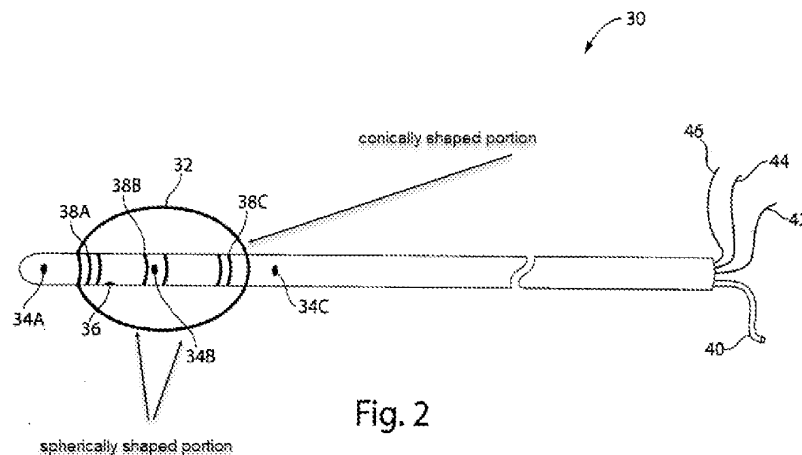
33. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to modify the shape of the balloon of Kantor as taught by Hamilton for the purpose of atraumatic withdrawal of the balloon as well as for the dilatation of a stenosis in an area where there is little distal clearance beyond a stenosis or lesion because of a physiological feature, as well as decreased inflation/deflation times, as taught by Hamilton col 2 ln 54-67.

34. **Claim 3** is rejected under 35 U.S.C. 103 as being unpatentable over Kantor in view of Mallaby in view of Jeffrey in view of Klocke in view of Mashimo et al. (Mashimo) US 2010/0113939 A1.

35. **Regarding claim 3**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1.

36. Kantor in view of Mallaby in view of Jeffrey in view of Klocke does not teach wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

37. However, Mashimo teaches a smart balloon catheter wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion (see annotated Fig. 2 below).



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38.

39. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to modify the balloon of Kantor with the balloon of Mashimo for the purpose of reducing the common risks of improper dilation, Mashimo P0001.

40. **Claims 7-8** are rejected under 35 U.S.C. 103 as being unpatentable over Kantor in view of Mallaby in view of Jeffrey in view of Klocke in view of Lentz US 2008/0287786 A1.

41. **Regarding claim 7**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1.

42. Kantor teaches that the guidewire uses radiopaque markers P0037, but is silent with regard to wherein the solid wire is constructed of a metal.

43. Lentz teaches use of stainless steel for radiopaque markers, P0057.

44. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to utilize stainless steel as taught by Lentz for the radiopaque markers of Kantor since stainless steel is a well known material in the art for use as a radiopaque marker.

45. **Regarding claim 8**, Kantor in view of Mallaby in view of Jeffrey in view of Klocke teaches the occlusion catheter system of claim 1.

46. Kantor teaches that the guidewire uses radiopaque markers P0037, but is silent with regard to wherein the solid wire is constructed of a stainless steel.

47. Lentz teaches use of stainless steel for radiopaque markers, P0057.

48. It would have been obvious to one having ordinary skill in the art before the effective filing date of the invention to utilize stainless steel as taught by Lentz for the radiopaque markers of Kantor since stainless steel is a well known material in the art for use as a radiopaque marker.

Conclusion

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN A DOUBRAVA whose telephone number is (408)918-7561. The examiner can normally be reached M-F 9-5 Pacific Time.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nathan Price can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/J.A.D./
Examiner, Art Unit 3783

/LAURA A BOUCHELLE/
Primary Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/563,669		Applicant(s)/Patent Under Reexamination FRANKLIN et al.	
	Examiner JOHN A DOUBRAVA		Art Unit 3783	Page 1 of 1

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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

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Symbol	Date	Examiner
A61M25/ 0068, 0074, 1002, 1006	06/12/2023	JAD
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Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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Search Notes		
Search Notes	Date	Examiner
Searched Search, NPL, Inventors and Assignee.	06/12/2023	JAD

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/J.A.D./ Examiner, Art Unit 3783	
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Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

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Art Unit	N/A
Examiner Name	Not Yet Assigned
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Name/Print	Ragi A. I. Elias	Registration Number	67,772

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	Art Unit	3783
	Examiner Name	Not Yet Assigned
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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

Application Number	17563669
Filing Date	2021-12-28
First Named Inventor	Curtis J. FRANKLIN
Art Unit	3783
Examiner Name	Not Yet Assigned
Attorney Docket Number	688961-25U7

CERTIFICATION STATEMENT

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OR

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See attached certification statement.

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Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2023-02-27
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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Doc code: IDS

PTO/SB/08a (02-18)

Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

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	1	20110172696	A1	2011-07-14	Jeffrey et al.	

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Examiner Signature	/JOHN A DOUBRAVA/	Date Considered	06/12/2023
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Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2022-08-25
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5250070		1993-10-05	Parodi, Juan C.	
	2	5295995		1994-03-22	Kleiman, Jay H.	
	3	6007517		1999-12-28	Anderson, R. David	

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	130	("20070043409" "20070129466" "20070135830" "20090171293" "20090312807" "20100268017" "8419648" "9474882" "20040254528" "20050059931" "5505702" "6190356" "7763043" "20020193735" "20030167038" "20040073162" "20050148812" "20070043307" "20080027356" "20080082046" "20080082119" "20080243067" "20080262477" "20090026595" "20090062666" "20090265951" "20090287079" "20100016735" "20100041984" "20100234915" "20100262076" "20100280451" "20110196412" "20110295301" "20110295302" "20110301630" "20120101413" "20120108979" "20120116352" "2012012911" "20120215166" "20120271231" "20120302994" "20130102926" "20130102929" "20130190619" "20130281869" "20130289607" "20140243873" "20140249504" "20140316012" "20140378869" "20150012031" "20150039012" "20150367098" "20160000446" "2156289" "4464172" "4713888" "4777951" "4823469" "4865549" "4926885" "4983166" "5135494" "5282479" "5320605" "5383856" "5447503" "5522400" "5718678" "5738652" "5911702" "6011988" "6013019" "6102930" "6146370" "6161547" "6165199" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669	(US-PGPUB; USPAT)	OR	ON	ON	2018/05/31 10:50 AM

		679" "6679860" "6695811" "6719270" "6719720" "6733513" "6735532" "6736790" "6746462" "6796959" "6936056" "7341571" "7434326" "7503904" "7503909" "7892469" "7909810" "7951186" "7951819" "7959644" "8088103" "8162879" "8241241" "8262611" "8430899" "8499681" "8545382" "8655798" "8672868" "8747358" "8814900" "8900214" "8948848" "8951565" "9131874" "9414843" "D748257" "20030032974" "20050261725" "20070219488" "20120109057").P N.					
L2	2	((("PRYTIME") near3 ("MEDICAL") near3 ("DEVICES") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2018/05/31 10:50 AM
L3	563	((("FRANKLIN") near3 ("Curtis")) OR ((("SPENCER") near3 ("David")) OR ((("KRUMMENACHER") near3 ("Todd")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:51 AM
L4	563	((("FRANKLIN") near3 ("Curtis")) OR ((("SPENCER") near3 ("David")) OR ((("KRUMMENACHER") near3 ("Todd")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:51 AM
L5	688	L1 or L2 or L3	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:51 AM
L6	0	604/096.010	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:52 AM
L7	0	604/096	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:52 AM
L8	12594	A61M25/0068.cpc. or A61M25/0074.cpc. or A61M25/1002.cpc. or A61M25/1006.cpc. or A61M2025/0002.cpc. or A61M2025/1052.cpc. or A61M2025/1059.cpc. or A61M2025/1081.cpc. or A61M2025/1086.cpc.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:54 AM

L9	58	L5 and L8	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:54 AM
L10	12536	L8 not L9	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:55 AM
L11	13224	L5 or L10	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:55 AM
L12	2	L11 and (atraumatic adj tip) same circular same solid	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:56 AM
L13	132184	L11 and tipsame circular same solid	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:56 AM
L14	19	L11 and (tip same circular same solid)	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:57 AM
L15	9	L11 and (tip same circular same solid) and balloon	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:59 AM
L16	8863929	ep "1094861"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:02 AM
L17	8863919	ep "1094861" and boston adj scientific	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:02 AM
L18	8863919	ep "1094861" and (boston adj scientific).as.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:03 AM
L19	9625	(boston adj scientific).as.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:03 AM
L20	0	(boston adj scientific).as. and "1094861"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:03 AM
L21	1	"1999003348".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:05 AM
L22	0	"19999903438".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:06 AM
L23	0	"19983442198".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:06 AM
L24	2212	L19 and (catheter tip designs for improved stent crossing).ti.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:07 AM
L25	2081	L19 and (catheter tip designs stent).ti.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:08 AM
L26	1176	L19 and (tip designs	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31

		stent).ti.	USOCR; EPO; JPO; DERWENT)				11:08 AM
L27	176	L19 and (tip designs).ti.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:08 AM
L28	2	"6517515".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:14 AM
L29	229	("3631848" "3766915" "3788326" "3911927" "3915171" "4085185" "4195637" "4249536" "4251305" "4307722" "4323071" "4385635" "4413989" "4425919" "4530698" "4531512" "4531943" "4540404" "4551292" "4581019" "4582181" "4588399" "4596563" "4610662" "4616653" "4636272" "4636346" "4676229" "4699611" "4706670" "4739768" "4748982" "4753765" "4759748" "4764324" "4777951" "4782834" "4790331" "4798586" "4808164" "4817613" "4819751" "4820349" "4846174" "4848344" "4863442" "4884573" "4886506" "4898896" "4906244" "4917666" "4921483" "4943278" "4946466" "4950227" "4955377" "4960410" "4964409" "4964853" "4976720" "4983168" "4990139" "4994018" "5002559" "5007434" "5047045" "5050606" "5054501" "5055101" "5078702" "5078727" "5093546" "5100381" "5104377" "5108416" "5120308" "5122125" "5139496" "5143093" "5147377" "5154725" "5156594" "5156612" "5158548" "5159937" "5163906" "5171221" "5171230" "5176637" "5180585" "5209728" "5213574" "5221270" "5226888" "5226889" "5234416" "5240537" "5254091"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:15 AM

		"5256144" "5258160" "5259839" "5261878" "5270086" "5279559" "5279561" "5279562" "5290295" "5304134" "5304198" "5316706" "5318032" "5318527" "5318529" "5318532" "5320604" "5324257" "5324259" "5324263" "5327885" "5328468" "5334148" "5334168" "5335410" "5338296" "5342389").PN. OR ("5344400" "5346505" "5370615" "5370655" "5387193" "5389087" "5397306" "5399164" "5403292" "5405338" "5405380" "5407432" "5411477" "5415664" "5423754" "5423771" "5425709" "5425712" "5445646" "5449373" "5454788" "5454795" "5458573" "5458613" "5470322" "5480383" "5496271" "5496294" "5503263" "5509910" "5520644" "5531685" "5531715" "5538513" "5540236" "5542924" "5542937" "5549552" "5549556" "5554121" "5554139" "5569218" "5588965" "5591129" "5605543" "5624449" "5643209" "5645528" "5647857" "5674198" "5716373" "5718686" "5725513" "5728063" "5776100" "5891110" "5971955" "6048338" "6102891" "6113579" "6287320" "RE33166").PN. OR ("6517515").URPN.					
L30	141	L29 and catheter.ti.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:16 AM
L31	877	A6125/0071.cpc. or A61M25/0026.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:37 AM
L32	0	A6125/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:47 AM
L33	2138	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:47 AM
L34	2018	A61M25/0068.cpc. not	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31

L35	28	L31 ("4795446" "4842585" "5100390" "5167645" "5183470" "5295980" "6186987" "6254578").PN. OR ("6979318").URPN.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	11:47 AM 2018/05/31 11:56 AM
L36	261	("3631848" "3766915" "3788326" "3911927" "4085185" "4195637" "4249536" "4251305" "4307722" "4323071" "4385635" "4413989" "4425919" "4530698" "4531512" "4531943" "4540404" "4551292" "4581019" "4582181" "4588399" "4596563" "4616653" "4636272" "4636346" "4676229" "4699611" "4706670" "4739768" "4748982" "4753765" "4759748" "4764324" "4777951" "4782834" "4790331" "4798586" "4808164" "4817613" "4819751" "4820349" "4846174" "4848344" "4863442" "4884573" "4886506" "4898896" "4906244" "4917666" "4921483" "4943278" "4946466" "4950227" "4955377" "4960410" "4964409" "4964853" "4976720" "4983168" "4994018" "5002559" "5007434" "5047045" "5050606" "5054501" "5055101" "5078702" "5078727" "5093546" "5100381" "5108416" "5120308" "5122125" "5139496" "5143093" "5147377" "5154725" "5156594" "5156612" "5158548" "5159937" "5163906" "5171221" "5171230" "5176637" "5180585" "5209728" "5213574" "5221270" "5226888" "5226889" "5234416" "5240537" "5254091" "5256144" "5258160" "5259839" "5261878" "5270086" "5279559"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 12:03 PM

		"5279561" "5279562" "5290295" "5304134" "5304198" "5316706" "5318032" "5318527" "5318529" "5318532" "5324257" "5324259" "5324263" "5327885" "5328468" "5334148" "5334168" "5335410" "5338296" "5342386" "5344400" "5346505" "5370615" "5370655" "5387193").PN. OR ("5389087" "5397306" "5399164" "5403292" "5405338" "5405380" "5407432" "5411477" "5415664" "5423754" "5423771" "5425709" "5425712" "5445646" "5449373" "5454788" "5454795" "5458573" "5458613" "5470322" "5480383" "5496271" "5496294" "5503263" "5509910" "5520644" "5531685" "5531715" "5538513" "5540236" "5542924" "5542937" "5549552" "5549556" "5554121" "5554139" "5569218" "5591129" "5605543" "5624449" "5643209" "5645528" "5647857" "5716373" "5725513" "5728063" "5776100" "5931829" "B14323071" "Re33166").PN. OR ("6113579").URPN.					
L37	1	(11/619979).APP.	(USPAT; USOCR)	OR	ON	ON	2018/05/31 12:48 PM
L38	20	("20010021840" "20020055771" "20030149467" "20050045183" "20050209676" "20060276808" "2862498" "3710777" "3754554" "3884242" "4819619" "5207232" "5273527" "5685824" "5720275" "5791341" "5873362" "6096052" "6432116").PN. OR ("8961532").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 12:48 PM
L39	886	A61M2025/1093.cpc.	(US-PGPUB; USPAT;	OR	ON	ON	2018/06/01

L40	130	("20070043409" "20070135830" "20090171293" "20090312807" "20100268017" "8419648" "9474882" "20040254528" "2005059931" "5505702" "6190356" "7763043" "20020193735" "20030167038" "20040073162" "20050148812" "20070043307" "20080027356" "20080082046" "20080082119" "20080243067" "20080262477" "20090026595" "20090062666" "20090265951" "20090287079" "20100016735" "20100041984" "20100234915" "20100262076" "20100280451" "20110196412" "20110295301" "20110295302" "201110301630" "2012010413" "20120108979" "2012010120116352" "2012012911" "20120215166" "20120271231" "20120302994" "20130102926" "20130102929" "20130190619" "20130281869" "20130289607" "20140243873" "20140249504" "20140316012" "20140378869" "20150012031" "20150039012" "20150367098" "20160000446" "2156289" "4464172" "4713888" "4777951" "4823469" "4865549" "4926885" "4983166" "5135494" "5282479" "5320605" "5383856" "5447503" "5522400" "5718678" "5738652" "5911702" "6011988" "6013019" "6102930" "6146370" "6161547" "6165199" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669679" "6679860" "6695811" "6719270" "6719720" "6733513" "6735532" "6736790" "6746462" "	USOCR) (US-PGPUB; USPAT)	OR	OFF	OFF	09:03 AM 2018/06/05 04:01 PM
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L48	1	((("PRYOR") near3 ("MEDICAL") near3 ("DEVICES") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2018/06/06 03:25 PM
L49	72	("FRANKLIN") near3 ("Curtis").INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/06/06 03:27 PM
L50	14	("FRANKLIN") near3 ("Curtis").INV. and catheter	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/06/06 03:27 PM
L51	2	"9687333".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/07/09 10:49 AM
L52	153	("20080097300 "20150272732 "20080243221 "20110144742 "20140364835 "20160375230 "2015158529 "20020007146 "20020062119 "20120209176 "20130172786 "20130338637 "5047045 "20020193735 "20030032974 "20030167038 "20040073162 "20040082935 "20040254528 "20050059931 "20050148812 "20050261725 "20070043307 "20070043409 "20070129466 "20070135830 "20070219466 "20070219488 "20080027356 "20080082046 "20080082119 "20080243067 "20080262477 "20090026595 "20090062666 "20090171272 "20090171293 "20090265951 "2009028	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/14 03:09 PM

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L53	5	48848" "8951565" "9131874" "9414843" "9474882" "9687333" "D748257").PN. (("20120302994") or ("6579221") or ("6013019") or ("20110251497") or ("7341571")).PN.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/14 04:32 PM
L54	1	(13/481532).APP.	(USPAT; USOCR)	OR	ON	ON	2021/07/14 04:35 PM
L55	287	("20010001812" "20010029362" "20010037085" "20020018866" "20020082549" "20020165523" "20030009151" "20030032920" "20030055447" "20030055448" "20030105426" "20030139762" "20040059291" "20040059292" "20040064130" "20040068240" "20040097892" "20040116956" "20040131808" "20040167441" "20040170782" "20040173935" "20040181206" "20040191443" "20040215141" "20040267195" "20040267280" "20050015048" "20050043679" "20050124976" "20050131445" "20050148997" "20050154414" "20050186370" "20050228429" "20050238833" "20050261725" "20050277878" "20060008606" "20060136032" "20060165926" "20060175739" "20060282041" "20070016165" "20070021772" "20070060863"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/14 04:35 PM

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		"20080262470"					
		"20090005754"					
		"20090036829"					
		"20090156998"					
		"20090223624"					
		"20090247946"					
		"20090264822"					
		"20100010439"					
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		"5277199"					
		"5290232").PN. OR					
		("5290306" "5300025"					
		"5304134" "5312430"					
		"5318032" "5318526"					
		"5342386" "5358486"					
		"5364357" "5370655"					
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		"5423754" "5425712"					
		"5447497" "5451233"					
		"5454789" "5458615"					
		"5470315" "5476477"					
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		"5490837" "5496275"					
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		"5512051" "5526823"					
		"5538513" "5545134"					
		"5549552" "5554121"					
		"5556383" "5569195"					

		"5587125"	"5599326"				
		"5613979"	"5620649"				
		"5622665"	"5632760"				
		"5643209"	"5649909"				
		"5658264"	"5690613"				
		"5728063"	"5743874"				
		"5743875"	"5749849"				
		"5755690"	"5759173"				
		"5766151"	"5769817"				
		"5769819"	"5775327"				
		"5779731"	"5782811"				
		"5791036"	"5792124"				
		"5792144"	"5795325"				
		"5795341"	"5797887"				
		"5814016"	"5820594"				
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		"5879499"	"5902290"				
		"5908406"	"5911715"				
		"5916193"	"5947939"				
		"5964778"	"6004289"				
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		"6071266"	"6086556"				
		"6102890"	"6124007"				
		"6132824"	"6136258"				
		"6146356"	"6165166"				
		"6165195"	"6168588"				
		"6171275"	"6171278"				
		"6179810"	"6179856"				
		"6193686"	"6197015"				
		"6210396"	"6217565"				
		"6242063"	"6245053"				
		"6251093"	"6264063"				
		"6265016"	"6306097"				
		"6306124"	"6308342"				
		"6358227"	"6364894"				
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		"6579259"	"6585687"				
		"6585688"	"6589207"				
		"6589226")	PN. OR				
		("6620127"	"6620128"				
		"6626889"	"6629961"				
		"6645422"	"6663614"				
		"6673291"	"6673302"				
		"6695809"	"6702802"				
		"6718211"	"6733487"				
		"6756094"	"6777644"				
		"6793647"	"6796958"				
		"6796960"	"6835189"				
		"6837890"	"6863678"				
		"6875197"	"6887219"				
		"6890395"	"6893456"				

		"6911038" "6913600" "6918920" "6923822" "6946092" "6951555" "6951675" "6964750" "6979342" "7026026" "7029732" "7037291" "7037295" "7074206" "7108877" "7112357" "7141059" "7147817" "7163523" "7195638" "7273485" "7303798" "7322959" "7335185" "7341571" "7549975" "7556634" "7662130" "7828766" "7833193" "7833597" "7862541" "7906066" "7967836" "8048058" "8052638" "8070719").PN. OR ("10406329").URPN.					
L56	8	((("Prytime") near3 ("Medical") near3 ("Devices") near3 ("Inc"))).AS,AANM.	(USPAT)	OR	ON	ON	2021/11/23 11:01 AM
L57	673	((("FRANKLIN") near3 ("Curtis")) OR (("SPENCER") near3 ("David")) OR (("KRUMMENACHER") near3 ("Todd"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/11/23 11:01 AM
L58	153	("20080097300" "20150 272732" "20080243221 " "20110144742" "2014 0364835" "2016037523 0" "5158529" "2002000 7146" "20020062119" " 20120209176" "201301 72786" "20130338637" " "5047045" "200201937 35" "20030032974" "20 030167038" "20040073 162" "20040082935" "2 0040254528" "2005005 9931" "20050148812" " 20050261725" "200700 43307" "20070043409" " "20070129466" "20070 135830" "20070219466 " "20070219488" "2008 0027356" "2008008204 6" "20080082119" "200 80243067" "200802624 77" "20090026595" "20 090062666" "20090171 272" "20090171293" "2 0090265951" "2009028 7079" "20090312807" "	(US-PGPUB; USPAT)	OR	ON	ON	2021/11/23 11:02 AM

		20100016735 "201000 41984 "20100234915" "20100262076 "20100 268017 "20100280451 "20110196412 "2011 0295301 "2011029530 2 "20110301630 "201 20101413 "201201089 79 "20120109057 "20 120116352 "20120130 359 "20120172911 "2 0120215166 "2012027 1231 "20120302994 " 20130102926 "201301 02929 "20130190619" "20130281869 "20130 289607 "20140221898 "20140243873 "2014 0249504 "2014031601 2 "20140378869 "201 50012031 "201500390 12 "20150367098 "20 160000446 "2156289" "4464172 "4713888 "4 777951 "4823469 "48 65549 "4926885 "498 3166 "5135494 "5169 386 "5282479 "53206 05 "5383856 "544750 3 "5505702 "5522400" "5571093 "5718678 " 5738652 "5911702 "6 011988 "6013019 "61 02930 "6113579 "614 6370 "6161547 "6165 199 "6190356 "62315 72 "6248121 "628043 4 "6423031 "6453572" "6575932 "6579221 " 6602270 "6656153 "6 666814 "6669679 "66 79860 "6695811 "671 9270 "6719720 "6733 513 "6735532 "67367 90 "6746462 "679695 9 "6936056 "6979318" "7341571 "7434326 " 7503904 "7503909 "7 763043 "7892469 "79 09810 "7951186 "795 1819 "7959644 "8088 103 "8162879 "82412 41 "8262611 "841964 8 "8430899 "8499681" "8545382 "8655798 " 8672868 "8747358 "8 814900 "8900214 "89 48848 "8951565 "913				
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		1874" "9414843" "9474882" "9687333" "D748257").PN.					
L59	2818	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L60	1655	A61M25/0074.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L61	3455	A61M25/1002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L62	644	A61M25/1006.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L63	944	A61M2025/0002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L64	2670	A61M2025/1052.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L65	386	A61M2025/1059.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L66	953	A61M2025/1081.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L67	762	A61M2025/1084.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:04 AM
L68	1676	A61M2025/1086.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:04 AM
L69	6	((("20160213893") or ("20030032974") or ("20120109057") or ("20070219488") or ("20050261725") or ("5830181"))).PN.	(US-PGPUB; USPAT)	OR	ON	ON	2021/11/23 04:30 PM
L70	1	("20070135830").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:35 PM
L71	2	((("6113579") or ("5047045"))).PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:38 PM
L72	6	((("20040082935") or ("5169386") or ("20120330359") or ("9687333") or ("8419648") or ("20090312807"))).PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:42 PM
L73	1	("6579221").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:47 PM
L74	0	("60130019").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:50 PM
L75	1	("6013019").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:50 PM
L76	1	("8419648").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:50 PM
L77	1	("9687333").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:52 PM
L78	0	("(US-20180117279-\$orUS-20020169457-	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/03 10:27 AM

L79	19	\$orUS-20060167421- \$orUS-20070060911- \$orUS-20140221898- \$orUS-20070219466- \$orUS-20180140806- \$orUS-20170043123- \$orUS-20160213893- \$).did.or(US-6517515- \$orUS-5645528-\$orUS- 5425709-\$orUS- 4777951-\$orUS- 5571093-\$orUS- 9211389-\$orUS- 6979318-\$orUS- 6254578-\$orUS- 6113579-\$orUS- D748257-\$).did.or(WO- 9944666-\$).did.).PN. (US-20180117279-\$ or US-20020169457-\$ or US-20060167421-\$ or US-20070060911-\$ or US-20140221898-\$ or US-20070219466-\$ or US-20180140806-\$ or US-20170043123-\$ or US-20160213893- \$).did. or (US-6517515- \$ or US-5645528-\$ or US-5425709-\$ or US- 4777951-\$ or US- 5571093-\$ or US- 9211389-\$ or US- 6979318-\$ or US- 6254578-\$ or US- 6113579-\$ or US- D748257-\$).did. or (WO-9944666-\$).did.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/03 10:28 AM
L80	1	(14/917286).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/07 09:47 AM
L81	1	(14/917286).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/07 09:48 AM
L82	142	("20020193735" "20030032974" "20030167038" "20040073162" "20040082935" "20040254528" "20050059931" "20050148812" "20050261725" "20070043307" "20070043409" "20070129466" "20070135830" "20070219466" "20070219488"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 09:48 AM

		"20080027356"					
		"20080082046"					
		"20080082119"					
		"20080243067"					
		"20080262477"					
		"20090026595"					
		"20090062666"					
		"20090171272"					
		"20090171293"					
		"20090265951"					
		"20090287079"					
		"20090312807"					
		"20100016735"					
		"20100041984"					
		"20100234915"					
		"20100262076"					
		"20100268017"					
		"20100280451"					
		"20110196412"					
		"20110295301"					
		"20110295302"					
		"20110301630"					
		"20120101413"					
		"20120108979"					
		"20120109057"					
		"20120116352"					
		"20120130359"					
		"20120172911"					
		"20120215166"					
		"20120271231"					
		"20120302994"					
		"20130102926"					
		"20130102929"					
		"20130190619"					
		"20130281869"					
		"20130289607"					
		"20140221898"					
		"20140243873"					
		"20140249504"					
		"20140316012"					
		"20140378869"					
		"20150012031"					
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		"20150367098"					
		"20160000446"					
		"2156289" "4464172"					
		"4713888" "4777951"					
		"4823469" "4865549"					
		"4926885" "4983166"					
		"5047045" "5135494"					
		"5169386" "5282479"					
		"5320605" "5383856"					
		"5447503" "5505702"					
		"5522400" "5571093"					
		"5718678" "5738652"					
		"5911702" "6011988"					
		"6013019" "6102930"					
		"6113579" "6146370"					

		"6161547" "6165199" "6190356" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669679" "6679860" "6695811" "6719270" "6719720" "6733513").PN. OR ("6735532" "6736790" "6746462" "6796959" "6936056" "6979318" "7341571" "7434326" "7503904" "7503909" "7763043" "7892469" "7909810" "7951186" "7951819" "7959644" "8088103" "8162879" "8241241" "8262611" "8419648" "8430899" "8499681" "8545382" "8655798" "8672868" "8747358" "8814900" "8900214" "8948848" "8951565" "9131874" "9414843" "9474882" "9687333" "D748257").PN. OR ("10569062").URPN.					
L83	0	L82 and rboa	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 10:02 AM
L84	1	L82 and reboa	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 10:03 AM
L85	28	A61M\$.cpc. and (catheter same reboa)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 10:07 AM
L86	1	(14/990465).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/07 10:15 AM
L87	23	("20020188344" "20030083617" "20030195382" "20030212361" "20040010282" "20040172055" "20060282115" "20090082800" "20120078343" "20130102926" "20140243873" "20140350523" "20150104331" "4456011" "5320604" "6135981" "6743196" "6743208" "7198632"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 10:15 AM

		"7220269" "7771448" "7927346" "8257421").PN. OR ("10279094").URPN.					
L88	2823	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 12:54 PM
L89	1206	A61B17/12036.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 12:55 PM
L90	38	L88 and L89	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:18 PM
L91	1662	A61M25/0074.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:23 PM
L92	0	A61M25/1084.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:24 PM
L93	839	A61M25/10184.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:24 PM
L94	36	L89 and L93	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:25 PM
L95	1679	A61M2025/1086.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:33 PM
L96	238	L95 and grooves	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:33 PM
L97	34	A61B\$.cpc. and (catheter same reboa)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:34 PM
L98	28	A61M\$.cpc. and (catheter same reboa)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:34 PM
L99	8	L97 not L98	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:34 PM
L100	77	L95 and flute	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 02:58 PM
L101	69	L100 not L96	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 02:59 PM
L102	228	("2330399" "2486056" "3409016" "3557794" "3822593" "4018231" "4141364" "4178939" "4248246" "4275591" "4276874" "4292974" "4346698" "4416267" "4444186" "4449532" "4572186" "4573470" "4576142" "4592744" "4601713" "4636201" "4681092" "4711181" "4738666" "4743258" "4762125" "4762130" "4771776" "4796629" "4820349" "4846174" "4846344" "4846801" "4881547" "4896669" "4906244" "4921483" "4930341" "4935190" "4938676" "4941877"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 03:09 PM

L103	2	"4994072" "5015230" "5015231" "5017325" "5037392" "5041125" "5087246" "5147302" "5192296" "5195970" "5196024" "5209799" "5226887" "5250070" "5254091" "5295995" "5306246" "5308356" "5318587" "5320634" "5336178" "5336472" "5342301" "5342307" "5350361" "5370614" "5411477" "5423745" "5456666" "5458572" "5470313" "5478319" "5490839" "5658311" "5718684" "5853389").PN. OR ("6013055").URPN. "4195637".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 03:17 PM
L104	307	("3086525" "3498286" "3635223" "3831588" "3837347" "3924632" "3941119" "3978863" "4033331" "4057065" "4072146" "4088135" "4114603").PN. OR ("4195637").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 03:23 PM
L105	1	(13/777667).APP.	(US-PGPUB; USOCR)	OR	ON	ON	2021/12/07 04:54 PM
L106	404	(perfusion with dilatation) same catheter	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 04:56 PM
L107	0	L106 and reboa	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 04:56 PM
L108	328	(perfusion with dilatation) same catheter	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:56 PM
L109	252	(perfusion with dilatation) and catheter.ab.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:57 PM
L110	706	(perfusion with occlusion) and catheter.ab.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:59 PM
L111	486	(perfusion with occlusion) with balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:59 PM
L112	275	L111 and catheter.ab.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:59 PM
L113	12	L112 and (balloon with (flute or groove))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 05:00 PM

L114	947	A61M2025/0002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:29 PM
L115	2674	A61M2025/1052.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:30 PM
L116	0	A61M2025/1025.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:30 PM
L117	387	A61M2025/1059.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:31 PM
L118	3778	L114 or L115 or L117	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:32 PM
L119	111	L118 and (pressure near1 relief near1 valve)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:33 PM
L120	4	(US-20070135830-\$ or US-20120302994-\$).did. or (US-6013055-\$ or US-5558644-\$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/08 01:13 PM
L121	0	L120 and sensor	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:13 PM
L122	53	(US-20180117279-\$ or US-20020169457-\$ or US-20060167421-\$ or US-20070060911-\$ or US-20140221898-\$ or US-20070219466-\$ or US-20180140806-\$ or US-20170043123-\$ or US-20160213893-\$ or US-20120302994-\$ or US-20110251497-\$ or US-20120109057-\$ or US-20070219488-\$ or US-20050261725-\$ or US-20030032974-\$ or US-20070135830-\$ or US-20090312807-\$ or US-20040082935-\$ or US-20120330359-\$ or US-20160206798-\$ or US-20140243873-\$ or US-20150142045-\$).did. or (US-6517515-\$ or US-5645528-\$ or US-5425709-\$ or US-4777951-\$ or US-5571093-\$ or US-9211389-\$ or US-6979318-\$ or US-6254578-\$ or US-6113579-\$ or US-D748257-\$ or US-7341571-\$ or US-6579221-\$ or US-6013019-\$ or US-	(US-PGPUB; USPAT; DERWENT)	OR	ON	ON	2021/12/08 01:13 PM

		5830181-\$ or US- 5047045-\$ or US- 9687333-\$ or US- 8419648-\$ or US- 5169386-\$ or US- 9474882-\$ or US- 5250070-\$ or US- 6013055-\$ or US- 5295995-\$ or US- 4195637-\$ or US- 5423745-\$ or US- 5516336-\$ or US- 5087246-\$).did. or (US- 4944745-\$ or US- 7195612-\$ or US- 5308356-\$ or US- 5558644-\$).did. or (WO-9944666-\$).did.					
L123	10	L122 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:14 PM
L124	2	"20190015630".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:18 PM
L125	1	L124 and (back adj flow)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:19 PM
L126	0	L122 and (back adj flow)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:21 PM
L127	2	L122 and (check adj valve)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:21 PM
L128	1	L124 and (distal adj pressure adj sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 02:18 PM
L129	1	L124 and (pressure adj sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 02:20 PM
L130	153	("20080097300" "20150 272732" "20080243221 " "20110144742" "2014 0364835" "2016037523 0" "5158529" "2002000 7146" "20020062119" " 20120209176" "201301 72786" "20130338637" " "5047045" "200201937 35" "20030032974" "20 030167038" "20040073 162" "20040082935" "2 0040254528" "2005005 9931" "20050148812" " 20050261725" "200700 43307" "20070043409" "	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/09 04:25 PM

		"20070129466" "20070 135830" "20070219466 " "20070219488" "2008 0027356" "2008008204 6" "20080082119" "200 80243067" "200802624 77" "20090026595" "20 090062666" "20090171 272" "20090171293" "2 0090265951" "2009028 7079" "20090312807" " 20100016735" "201000 41984" "20100234915" " "20100262076" "20100 268017" "20100280451 " "20110196412" "2011 0295301" "2011029530 2" "20110301630" "201 20101413" "201201089 79" "20120109057" "20 120116352" "20120130 359" "20120172911" "2 0120215166" "2012027 1231" "20120302994" " 20130102926" "201301 02929" "20130190619" " "20130281869" "20130 289607" "20140221898 " "20140243873" "2014 0249504" "2014031601 2" "20140378869" "201 50012031" "201500390 12" "20150367098" "20 160000446" "2156289" " "4464172" "4713888" "4 777951" "4823469" "48 65549" "4926885" "498 3166" "5135494" "5169 386" "5282479" "53206 05" "5383856" "544750 3" "5505702" "5522400" "5571093" "5718678" " 5738652" "5911702" "6 011988" "6013019" "61 02930" "6113579" "614 6370" "6161547" "6165 199" "6190356" "62315 72" "6248121" "628043 4" "6423031" "6453572" "6575932" "6579221" " 6602270" "6656153" "6 666814" "6669679" "66 79860" "6695811" "671 9270" "6719720" "6733 513" "6735532" "67367 90" "6746462" "679695 9" "6936056" "6979318" "7341571" "7434326" "				
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		7503904 "7503909 "7 763043 "7892469 "79 09810 "7951186 "795 1819 "7959644 "8088 103 "8162879 "82412 41 "8262611 "841964 8 "8430899 "8499681" "8545382 "8655798 "8 8672868 "8747358 "8 814900 "8900214 "89 48848 "8951565 "913 1874 "9414843 "9474 882 "9687333 "D7482 57").PN.					
L131	37	L130 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 04:39 PM
L132	9	L131 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 04:56 PM
L133	2	"20080015404".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:03 PM
L134	0	L133 and (pressure near1 sensor) and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:04 PM
L135	0	L133 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:04 PM
L136	0	L133 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:04 PM
L137	1	"20110196297".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L138	0	L137 and (pressure near1 sensor) and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L139	0	L137 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L140	0	L137 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L141	1	(12/855473).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/09 05:09 PM
L142	5	("4934996").PN. OR ("8262580").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09 05:09 PM
L143	6	L137 or L142	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09 05:10 PM
L144	5	L143 and (blood near1 pressure)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09 05:10 PM
L145	1	L144 and sensor	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09

L146	10	(US-20140364835-\$ or US-20120215166-\$ or US-20110295301-\$ or US-20080015404-\$ or US-20110295302-\$ or US-20030032974-\$ or US-20120172911-\$).did. or (US-8419648-\$ or US-4934996-\$ or US-6656153-\$).did.	USOCR) (US-PGPUB; USPAT)	OR	ON	ON	05:10 PM 2021/12/10 09:17 AM
L147	3	L146 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 09:18 AM
L148	8	L146 and (blood near1 pressure)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 09:21 AM
L149	3	L147 and L148	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 09:21 AM
L150	6	(US-20070135830-\$ or US-20120302994-\$ or US-20190015630-\$).did. or (US-6013055-\$ or US-5558644-\$ or US-8419648-\$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/10 03:24 PM
L151	243	engel near1 matthew	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 03:50 PM
L152	135	doubrava near1 john	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 03:52 PM
L153	0	(08/969904).APP.	(US-PGPUB; USOCR)	OR	ON	ON	2021/12/14 09:30 AM
L154	0	(08/372741).APP.	(US-PGPUB; USOCR)	OR	ON	ON	2021/12/14 09:31 AM
L155	7	(US-20070135830-\$ or US-20120302994-\$ or US-20190015630-\$ or US-20110295302-\$).did. or (US-6013055-\$ or US-5558644-\$ or US-8419648-\$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 01:26 PM
L156	3	L155 and (proximal same (pressure near1 sensor))	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 01:27 PM
L157	1	L155 and (compliant near1 balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:27 PM
L158	60	(US-20180117279-\$ or US-20020169457-\$ or US-20060167421-\$ or US-20070060911-\$ or US-20140221898-\$ or US-20070219466-\$ or	(US-PGPUB; USPAT; DERWENT)	OR	ON	ON	2021/12/14 02:28 PM

L159	7	US-20180140806-\$ or US-20170043123-\$ or US-20160213893-\$ or US-20120302994-\$ or US-20110251497-\$ or US-20120109057-\$ or US-20070219488-\$ or US-20050261725-\$ or US-20030032974-\$ or US-20070135830-\$ or US-20090312807-\$ or US-20040082935-\$ or US-20120330359-\$ or US-20160206798-\$ or US-20140243873-\$ or US-20150142045-\$ or US-20190015630-\$ or US-20140364835-\$ or US-20080015404-\$ or US-20110196297-\$).did. or (US-20110295302-\$).did. or (US-6517515-\$ or US-5645528-\$ or US-5425709-\$ or US-4777951-\$ or US-5571093-\$ or US-9211389-\$ or US-6979318-\$ or US-6254578-\$ or US-6113579-\$ or US-D748257-\$ or US-7341571-\$ or US-6579221-\$ or US-6013019-\$ or US-5830181-\$ or US-5047045-\$ or US-9687333-\$ or US-8419648-\$ or US-5169386-\$ or US-9474882-\$ or US-5250070-\$ or US-6013055-\$ or US-5295995-\$ or US-4195637-\$ or US-5423745-\$ or US-5516336-\$ or US-5087246-\$).did. or (US-4944745-\$ or US-7195612-\$ or US-5308356-\$ or US-5558644-\$ or US-4934996-\$ or US-6248121-\$).did. or (WO-9944666-\$).did. L158 and (compliant near1 balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:28 PM
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L160	546	A61M\$.cpc. and (PET same (semi near1 compliant))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:33 PM
L161	511	A61M\$.cpc. and (PET same (semi near1 compliant) same balloon)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:34 PM
L162	508	A61M\$.cpc. and (PET same (semi near1 compliant) same balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:34 PM
L163	336	L162 and catheter.ab.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:35 PM
L164	215	L163 and angioplasty	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:35 PM
L165	3	L158 and wireless	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:40 PM
L166	14	L158 and (proximal same (pressure near1 sensor))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:53 PM
L167	324	A61M\$.cpc. and (proximal same (pressure near1 sensor)) and catheter.ab. and balloon.ab.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 03:12 PM
L168	99	L167 and angioplasty	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 03:13 PM
L169	53	L168 and (blood near1 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 03:45 PM
L170	1	(13/481532).APP.	(USPAT; USOCR)	OR	OFF	OFF	2022/07/12 01:31 PM
L171	288	("20010001812" "20010029362" "20010037085" "20020018866" "20020082549" "20020165523" "20030009151" "20030032920" "20030055447" "20030055448" "20030105426" "20030139762" "20040059291" "20040059292" "20040064130" "20040068240" "20040097892" "20040116956" "20040131808" "20040167441" "20040170782")	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/07/12 01:31 PM

		"20040173935"					
		"20040181206"					
		"20040191443"					
		"20040215141"					
		"20040267195"					
		"20040267280"					
		"20050015048"					
		"20050043679"					
		"20050124976"					
		"20050131445"					
		"20050148997"					
		"20050154414"					
		"20050186370"					
		"20050228429"					
		"20050238833"					
		"20050261725"					
		"20050277878"					
		"20060008606"					
		"20060136032"					
		"20060165926"					
		"20060175739"					
		"20060282041"					
		"20070016165"					
		"20070021772"					
		"20070060863"					
		"20070142771"					
		"20070167973"					
		"20070191813"					
		"20070240817"					
		"20080015499"					
		"20080045895"					
		"20080045928"					
		"20080065188"					
		"20080262470"					
		"20090005754"					
		"20090036829"					
		"20090156998"					
		"20090223624"					
		"20090247946"					
		"20090264822"					
		"20100010439"					
		"20100130925"					
		"20100189876"					
		"20100285085"					
		"20110022150"					
		"20110070355"					
		"20110172696"					
		"20110315301"					
		"20120065586"					
		"20120143129"					
		"4425919" "4563181"					
		"4596563" "4721117"					
		"4775371" "4782834"					
		"4820349" "4877031"					
		"4886506" "4892519"					
		"4952357" "4976690"					
		"4976720" "5047045"					
		"5061273" "5078702"					

		"5085649" "5112304" "5156594" "5176661" "5195969" "5205822" "5207700" "5217434" "5217482" "5250059" "5256144" "5270086" "5277199" "5290232").PN. OR ("5290306" "5300025" "5304134" "5312430" "5318032" "5318526" "5342386" "5358486" "5364357" "5370655" "5378238" "5395336" "5423754" "5425712" "5447497" "5451233" "5454789" "5458615" "5470315" "5476477" "5478320" "5484409" "5490837" "5496275" "5499980" "5507768" "5512051" "5526823" "5538513" "5545134" "5549552" "5554121" "5556383" "5569195" "5587125" "5599326" "5613979" "5620649" "5622665" "5632760" "5643209" "5649909" "5658264" "5690613" "5728063" "5743874" "5743875" "5749849" "5755690" "5759173" "5766151" "5769817" "5769819" "5775327" "5779731" "5782811" "5791036" "5792124" "5792144" "5795325" "5795341" "5797887" "5814016" "5820594" "5833657" "5879369" "5879499" "5902290" "5908406" "5911715" "5916193" "5947939" "5964778" "6004289" "6004339" "6010521" "6021340" "6024693" "6024722" "6027510" "6036670" "6056719" "6059751" "6059770" "6071266" "6086556" "6102890" "6124007" "6132824" "6136258" "6146356" "6165166" "6165195" "6168588" "6171275" "6171278" "6179810" "6179856" "6193686" "6197015"				
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L172	2	"6210396" "6217565" "6242063" "6245053" "6251093" "6264063" "6265016" "6306097" "6306124" "6308342" "6358227" "6364894" "6416494" "6482348" "6495090" "6495127" "6500148" "6508784" "6575934" "6575958" "6579259" "6585687" "6585688" "6589207" "6589226").PN. OR ("6620127" "6620128" "6626889" "6629961" "6645422" "6663614" "6673291" "6673302" "6695809" "6702802" "6718211" "6733487" "6756094" "6777644" "6793647" "6796958" "6796960" "6835189" "6837890" "6863678" "6875197" "6887219" "6890395" "6893456" "6911038" "6913600" "6918920" "6923822" "6946092" "6951555" "6951675" "6964750" "6979342" "7026026" "7029732" "7037291" "7037295" "7074206" "7108877" "7112357" "7141059" "7147817" "7163523" "7195638" "7273485" "7303798" "7322959" "7335185" "7341571" "7549975" "7556634" "7662130" "7828766" "7833193" "7833597" "7862541" "7906066" "7967836" "8048058" "8052638" "8070719").PN. OR ("10406329").URPN. ((US-6013055-A).did. AND USPT.dbnm.) OR ((US-20110172696- A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA,	OR	ON	ON	2022/12/21 05:45 PM
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L173	3	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1).did. AND PGPB.dbnm.)	VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/21 05:48 PM
L174	40	(Artificial Intelligence) More like doc: US-6013055-A Text: (EP-1030708-B1 OR EP-1030708-A1 OR WO-9925417-A1 OR DE-69832811-T2 OR DE-69731561-T2 OR US-5954740-A OR EP-1007134-A1 OR WO-9811933-A1 OR US-4941877-A OR US-20030236495-A1 OR EP-1007134-B1 OR US-5041125-A OR US-6110192-A OR EP-1620160-B1 OR EP-1620160-A1 OR US-6355013-B1 OR US-7306616-B2 OR US-20060015134-A1 OR WO-9725093-A1 OR CA-2568727-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/21 06:02 PM
L175	156	("20210290243" OR "8021330" OR "9211396" OR "20080097300" OR "20150272732" OR "20080243221" OR "20110144742" OR "20140364835" OR "20160375230" OR "5158529" OR "20020007146" OR "20020062119" OR "20120209176" OR "20130172786" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/21 07:04 PM

		"20130338637" OR "5047045" OR "20020193735" OR "20030032974" OR "20030167038" OR "20040073162" OR "20040082935" OR "20040254528" OR "20050059931" OR "20050148812" OR "20050261725" OR "20070043307" OR "20070043409" OR "20070129466" OR "20070135830" OR "20070219466" OR "20070219488" OR "20080027356" OR "20080082046" OR "20080082119" OR "20080243067" OR "20080262477" OR "20090026595" OR "20090062666" OR "20090171272" OR "20090171293" OR "20090265951" OR "20090287079" OR "20090312807" OR "20100016735" OR "20100041984" OR "20100234915" OR "20100262076" OR "20100268017" OR "20100280451" OR "20110196412" OR "20110295301" OR "20110295302" OR "20110301630" OR "20120101413" OR "20120108979" OR "20120109057" OR "20120116352" OR "20120130359" OR "20120172911" OR "20120215166" OR "20120271231" OR "20120302994" OR "20130102926" OR "20130102929" OR "20130190619" OR "20130281869" OR "20130289607" OR "20140221898" OR "20140243873" OR "20140249504" OR "20140316012" OR "20140378869" OR				
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		"20150012031" OR "20150039012" OR "20150367098" OR "20160000446" OR "2156289" OR "4464172" OR "4713888" OR "4777951" OR "4823469" OR "4865549" OR "4926885" OR "4983166" OR "5135494" OR "5169386" OR "5282479" OR "5320605" OR "5383856" OR "5447503" OR "5505702" OR "5522400" OR "5571093" OR "5718678" OR "5738652" OR "5911702" OR "6011988" OR "6013019" OR "6102930" OR "6113579" OR "6146370" OR "6161547" OR "6165199" OR "6190356" OR "6231572" OR "6248121" OR "6280434" OR "6423031" OR "6453572" OR "6575932" OR "6579221" OR "6602270" OR "6656153" OR "6666814" OR "6669679" OR "6679860" OR "6695811" OR "6719270" OR "6719720" OR "6733513" OR "6735532" OR "6736790" OR "6746462" OR "6796959" OR "6936056" OR "6979318" OR "7341571" OR "7434326" OR "7503904" OR "7503909" OR				
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		"7763043" OR "7892469" OR "7909810" OR "7951186" OR "7951819" OR "7959644" OR "8088103" OR "8162879" OR "8241241" OR "8262611" OR "8419648" OR "8430899" OR "8499681" OR "8545382" OR "8655798" OR "8672868" OR "8747358" OR "8814900" OR "8900214" OR "8948848" OR "8951565" OR "9131874" OR "9414843" OR "9474882" OR "9687333" OR "D748257").pn.					
L176	3	("9211396" "8021330" "20210290243").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/12/21 07:04 PM
L177	4	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/22 01:39 PM
L178	5	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA,	OR	ON	ON	2022/12/22 01:39 PM

L179	5	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/23 12:26 PM
L180	69	((US-5250070-A OR US-7195612-B2 OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-5169386-A OR US-8419648-B2 OR US-9687333-B2 OR US-5308356-A OR US-5558644-A OR US-4934996-A OR US-6248121-B1 OR US-7862541-B2 OR US-5047045-A OR US-6517515-B1 OR US-5645528-A OR US-5425709-A OR US-4777951-A OR US-5571093-A OR US-9211389-B2 OR US-6979318-B1 OR US-6254578-B1 OR US-6113579-A OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-8021330-B2 OR US-9211396-B2).did. AND USPT.dbnm.) OR ((US-20140243873-A1 OR US-20160206798-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:18 PM

L181	7	OR US-20120330359-A1 OR US-20040082935-A1 OR US-20150142045-A1 OR US-20190015630-A1 OR US-20140364835-A1 OR US-20080015404-A1 OR US-20110196297-A1 OR US-20110295302-A1 OR US-20030083579-A1 OR US-20100113939-A1 OR US-20110224606-A1 OR US-20110172696-A1 OR US-20180117279-A1 OR US-20020169457-A1 OR US-20060167421-A1 OR US-20070060911-A1 OR US-20140221898-A1 OR US-20070219466-A1 OR US-20180140806-A1 OR US-20090312807-A1 OR US-20070135830-A1 OR US-20030032974-A1 OR US-20050261725-A1 OR US-20070219488-A1 OR US-20120109057-A1 OR US-20110251497-A1 OR US-20120302994-A1 OR US-20160213893-A1 OR US-20170043123-A1 OR US-20210290243-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) ((US-6013055-A OR US-5558644-A OR US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK,	OR	ON	ON	2023/04/10 07:31 PM
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L182	6	L181 AND angioplasty	TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:31 PM
L183	6	L182	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:31 PM
L184	4	L182 AND (polyethylene OR polyurathane OR polyester)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:36 PM
L185	2	((US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA,	OR	ON	ON	2023/04/10 07:39 PM

L186	2	L185	EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:39 PM
L187	295	("1115224" "2701559" "4018231" "4141364" "4471776" "4878495" "4881939" "4927412" "5002531" "5041125" "5090958").pn. OR ("5250070").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:39 PM
L188	113	("2930377" "3889686" "4040413" "4183102" "4233983" "4329993" "4423725" "4581017" "4601713" "4661094" "4710181" "4738666" "4787388" "4790315" "4795427" "4877031" "4878495" "4892519" "4909252" "5102416" "5167628").pn. OR ("5295995").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:39 PM
L189	36	(Artificial Intelligence) More like doc: US-5295995-A Text: (WO-9405365-A1 OR US-6007517-A OR EP-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2023/04/10 07:39 PM

L190	38	<p>0688233-A4 OR EP-0688233-A1 OR WO-9501200-A1 OR US-5571089-A OR US-5344402-A OR JP-2001513374-A OR US-5522800-A OR JP-H08504652-A OR US-5542926-A OR JP-2865426-B2 OR JP-H06233822-A OR JP-2607896-Y2 OR EP-0526102-A1 OR US-5716340-A OR WO-9516487-A1 OR CA-2074304-C OR US-5558642-A OR EP-0526102-B1).did.</p> <p>(Artificial Intelligence) More like doc: US-5250070-A</p> <p>Text: (EP-0735906-A1 OR WO-9517223-A1 OR EP-0735906-B1 OR US-5545132-A OR US-5273536-A OR US-20040098018-A1 OR FR-2753907-A1 OR EP-1009469-A1 OR WO-9814233-A1 OR JP-H09506805-A OR JP-2001501115-A OR US-5718684-A OR EP-0746362-A1 OR EP-0746362-A4 OR DE-102012001188-A1 OR EP-0746362-B1 OR US-5951514-A OR WO-9834670-A2 OR JP-2005224635-A OR JP-3694524-B2).did.</p>	<p>IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)</p> <p>(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)</p>	OR	ON	ON	2023/04/10 07:39 PM
L191	676	L187 L188 L189 L190	<p>(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT;</p>	OR	ON	ON	2023/04/10 07:40 PM

L192	222	L191 AND angioplasty	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:40 PM
L193	4	L191 AND (partial near1 inflation)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:40 PM
L194	180	L192	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:41 PM
L195	13	L194 AND (flow near1 channel)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:42 PM
L196	266	("4581017" "4601713" "4762129" "4771777" "4790315" "4819751" "4850969" "4909252" "4909781" "4944745" "4983167" "4988356" "4994033" "5040548" "5046503" "5049131" "5061273" "5078685" "5102403" "5108370" "5116318" "5135535" "5147377" "5154725" "5156594" "5158540" "5171222" "5180367" "5205822" "5232445" "5267958" "5284473" "5295959" "5295995" "5308356" "5318535" "5324269" "5336184" "5342297" "5346505" "5370617" "5378237" "5383856" "5383890" "5395333" "5395353" "5403274" "5409458" "5411478" "5425709" "5425714" "5433706" "5470314" "5472425" "5484411" "5484412" "5489271" "B14581017").pn. OR ("6007517").urpn. AND (PGPB USPT USOC).dbnm.	OR	ON	ON	2023/04/10 07:46 PM	

L197	36	(Artificial Intelligence) More like doc: US-6007517-A Text: (EP-0362268-A1 OR AU-614976-B2 OR US- 5462530-A OR US- 4958634-A OR JP- 2007512931-A OR EP- 0362268-B1 OR EP- 1708779-A4 OR WO- 9320882-A1 OR EP- 1708779-A2 OR US- 20050124939-A1 OR EP-0590140-A1 OR US-20060259062-A1 OR US-5295995-A OR EP-0853956-A2 OR US-5522800-A OR EP- 0688233-A4 OR WO- 9501200-A1 OR EP- 0688233-A1 OR US- 5571089-A OR US- 5324259-A).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:46 PM
L198	536	L196 L197	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:46 PM
L199	336	L198	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN))	OR	ON	ON	2023/04/10 07:46 PM
L200	233	L199 AND angioplasty	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:46 PM

L201	2	L200 AND (partial near1 inflation)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L202	6	L200 AND (flow near1 channel)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L203	8	L201 L202	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L204	8	L203	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L205	3	((US-5250070-A OR US-5295995-A OR US-6007517-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:48 PM
L206	3	L205	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:49 PM
L207	1974	(angioplasty near1 balloon) AND apposition	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:01 PM
L208	72	L207 AND (flow near1 channel)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:01 PM
L209	9	L207 AND (partial near1 inflation)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:02 PM
L210	7	((US-6013055-A OR US-5558644-A OR US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV,	OR	ON	ON	2023/04/10 08:14 PM

		PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L211	201	(thermoplastic near1 polymer) AND balloon AND angioplasty AND (semi near1 compliant)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:18 PM
L212	25	L211 AND (thermoplastic near1 polymer) SAME (semi near1 compliant)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:25 PM
L213	25	L211 AND ((thermoplastic near1 polymer) SAME (semi near1 compliant))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:26 PM
L214	7	((US-6013055-A OR US-5558644-A OR US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 08:39 PM
L215	1	("10149962" "116772951").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:41 PM
L216	0	("11677951").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:41 PM
L217	0	L215 AND marking	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:42 PM
L218	1	L215 AND marker	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:47 PM
L219	8	((US-5250070-A OR US-5295995-A OR US-6007517-A OR US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20030083579-A1 OR US-20110172696-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2023/06/10 02:23 PM

		AND EPAB.dbnm.)	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L220	1	("20190366046").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:26 PM
L221	0	("2015015046").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:29 PM
L222	1	("20150015046").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:29 PM
L223	1	("20150150436").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:29 PM
L224	3	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/10 02:30 PM
L225	2	L224 AND atraumatic	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/10 02:35 PM
L226	1	L224 AND compliant	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2023/06/10 02:36 PM

L227	0	L224 AND french	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/10 02:39 PM
L228	0	(balloon AND catheter) AND (6 near1 (french OR fr))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L229	114824	(balloon AND catheter)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L230	0	6 near1 (french OR fr)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L231	0	6 near1 french	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L232	0	6 near1 fr	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:41 PM
L233	15101	L229 AND french	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:41 PM
L234	0	L233 AND 6	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:41 PM
L235	15047	L233 AND "6"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L236	8811	("6" near1 (french OR fr))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L237	3312	L229 AND L236	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L238	1348	L237 AND hub	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L239	642	L238 AND stiff	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:48 PM
L240	1025	L238 AND stiff\$4	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:48 PM
L241	21	L238 AND stiffener	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:48 PM
L242	1025	L240	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:53 PM

L243	1348	L238	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:53 PM
L244	295	L238 AND (hub WITH (wire OR stiffener))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:57 PM
L245	83	L244 NOT (guide near1 wire)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 03:00 PM
L246	295	L244	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 04:13 PM
L247	5	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 01:00 PM
L248	1	L247 AND french	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 01:00 PM
L249	5	L247	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:17 PM

L250	32	(Artificial Intelligence) More like doc: US-20170296798-A1 Text: (WO-2019010077-A1 OR EP-3648828-A1 OR CA-3068925-A1 OR EP-4183440-A1 OR EP-3648828-B1 OR US-11027104-B2 OR US-20210322738-A1 OR JP-2020527964-A OR JP-2023072042-A OR US-20210228847- A1 OR US- 20190175885-A1 OR US-10864357-B2 OR US-20170354803-A1 OR US-10039906-B2 OR US-20160158502- A1 OR US-9126018-B1 OR US-9399118-B2 OR US-9241699-B1 OR US-20170043141-A1 OR US-9662480- B2).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:18 PM
L251	15	((US-5250070-A OR US-5295995-A OR US- 6007517-A OR US- 6013055-A OR US- 5558644-A OR US- 4369790-A).did. AND USPT.dbnm.) OR ((US- 20030083579-A1 OR US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:20 PM
L252	79	((US-9211389-B2 OR US-6113579-A OR US- 6254578-B1 OR US- 6979318-B1 OR US- 5571093-A OR US- 4777951-A OR US- 5425709-A OR US- 5645528-A OR US- 6517515-B1 OR US- 5047045-A OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2023/06/12 02:21 PM

		7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US- 5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US- 6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20110172696- A1 OR US-	NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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L253	18	20110224606-A1 OR US-20100113939-A1 OR US-20030083579- A1 OR US- 20110295302-A1 OR US-20080015404-A1 OR US-20140364835- A1 OR US- 20190015630-A1 OR US-20150142045-A1 OR US-20040082935- A1 OR US- 20110196297-A1 OR US-20210290243-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) L252 AND french	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:21 PM
L254	9	L253 AND "6" near1 french	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO;	OR	ON	ON	2023/06/12 02:21 PM

L255	3312	(balloon AND catheter) AND ("6" near1 (french OR fr))	JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:27 PM
L256	260	L255 AND (core near1 wire)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:27 PM
L257	2	("5549557" "5549556").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:37 PM
L258	260	L256	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:37 PM
L259	96942	guide near1 wire	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:24 PM
L260	52052	L259 AND catheter	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:24 PM
L261	975	L260 AND ((guide near1 wire) WITH lock)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:25 PM
L262	662	L261 AND balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:25 PM
L263	260	L262 AND radiopaque	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:26 PM
L264	19	L263 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:27 PM
L265	5245	L260 AND (radio near1 (paque OR opaque))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:39 PM
L266	318	(L265 AND ("6" near1 (fr OR french)))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:39 PM
L267	10	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 04:41 PM
L268	10	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2023/06/12 04:42 PM

L269	10	A1 OR US-20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.) (((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.)	NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT)	OR	ON	ON	2023/06/12 04:51 PM
L270	169	("5250070" OR "5295995" OR "6007517" OR "5087246" OR "5425711" OR "5554121" OR "5609606" OR "20110172696" OR "10368872" OR "20210290243" OR "8021330" OR "9211396" OR "20020007146" OR "20020062119" OR "20020193735" OR "20030032974" OR "20030083579" OR "20030167038" OR "20040073162" OR "20040082935" OR "20040254528" OR "20050059931" OR "20050148812" OR "20050261725" OR "20070043307" OR "20070043409" OR "20070129466" OR "20070135830" OR "20070219466" OR "20070219488" OR "20080027356" OR "20080082046" OR "20080082119" OR "20080097300" OR "20080243067" OR		OR	ON	ON	2023/06/12 06:55 PM

		"20080243221" OR "20080262477" OR "20090026595" OR "20090062666" OR "20090171272" OR "20090171293" OR "20090265951" OR "20090287079" OR "20090312807" OR "20100016735" OR "20100041984" OR "20100113939" OR "20100234915" OR "20100262076" OR "20100268017" OR "20100280451" OR "20110144742" OR "20110196412" OR "20110295301" OR "20110295302" OR "20110301630" OR "20120101413" OR "20120108979" OR "20120109057" OR "20120116352" OR "20120130359" OR "20120172911" OR "20120209176" OR "20120215166" OR "20120271231" OR "20120302994" OR "20130102926" OR "20130102929" OR "20130172786" OR "20130190619" OR "20130281869" OR "20130289607" OR "20130338637" OR "20140221898" OR "20140243873" OR "20140249504" OR "20140316012" OR "20140364835" OR "20140378869" OR "20150012031" OR "20150039012" OR "20150272732" OR "20150367098" OR "20160000446" OR "20160375230" OR "2156289" OR "4464172" OR "4713888" OR "4777951" OR "4823469" OR "4865549" OR "4926885" OR "4983166" OR				
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		"5047045" OR "5135494" OR "5158529" OR "5169386" OR "5282479" OR "5320605" OR "5383856" OR "5447503" OR "5505702" OR "5522400" OR "5558644" OR "5571093" OR "5718678" OR "5738652" OR "5911702" OR "6011988" OR "6013019" OR "6013055" OR "6102930" OR "6113579" OR "6146370" OR "6161547" OR "6165199" OR "6190356" OR "6231572" OR "6248121" OR "6280434" OR "6423031" OR "6453572" OR "6575932" OR "6579221" OR "6602270" OR "6656153" OR "6666814" OR "6669679" OR "6679860" OR "6695811" OR "6719270" OR "6719720" OR "6733513" OR "6735532" OR "6736790" OR "6746462" OR "6796959" OR "6936056" OR "6979318" OR "7341571" OR "7434326" OR "7503904" OR "7503909" OR "7763043" OR "7892469" OR "7909810" OR "7951186" OR "7951819" OR "7959644" OR "8088103" OR "8162879" OR				
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		"8241241" OR "8262611" OR "8419648" OR "8430899" OR "8499681" OR "8545382" OR "8655798" OR "8672868" OR "8747358" OR "8814900" OR "8900214" OR "8948848" OR "8951565" OR "9131874" OR "9414843" OR "9474882" OR "9687333" OR "D748257").pn.					
L271	9	((("Prytime") near3 ("Medical") near3 ("Devices") near3 ("Inc"))).AS,AANM.	(USPAT)	OR	ON	ON	2023/06/12 07:02 PM
L272	716	((("FRANKLIN") near3 ("Curtis")) OR (("SPENCER") near3 ("David")) OR (("KRUMMENACHER") near3 ("Todd"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/06/12 07:02 PM
L273	3106	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L274	1873	A61M25/0074.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L275	3727	A61M25/1002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L276	697	A61M25/1006.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L277	2921	A61M2025/1052.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:08 PM
L278	1355	A61B17/12036.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:08 PM
L279	6044	L275 OR L277	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:09 PM
L280	3727	L279 AND L275	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:10 PM
L284	50	L280 AND (asymmetric\$2 near1 balloon)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:12 PM
L285	2	L284 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:12 PM
L286	50	L284	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:13 PM
L287	727	L272 L271 L270	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:18 PM

L288	634	L287 NOT (guide near1 wire)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:18 PM
L289	139	L288 AND wire	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:18 PM
L290	55	L289 AND balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:19 PM
L291	213	L273 AND L277	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:36 PM
L292	16	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1 OR US-20130338637-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A OR US-5087246-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 07:48 PM
L293	4	L292 AND compliant	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:33 PM
L294	90	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO,	OR	ON	ON	2023/06/12 11:35 PM

	5047045-A OR US- 7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US- 5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US- 6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 5690613-A OR US- 5464394-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR	MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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L296	5547	balloon SAME (compliant WITH (pet OR polyethylene OR pvc OR polypropylene OR nylon OR pebax))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:53 PM
L297	1182	balloon SAME (compliant WITH pebax)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:54 PM
L298	219	L296 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:54 PM
L299	111	L296 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/12 11:54 PM
L300	18	((US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2023/06/13 12:00 AM

L301	1	20140243873-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20120302994-A1 OR US-20090018500-A1 OR US-20130338637- A1 OR US- 20110224606-A1 OR US-20160051386- A1).did. AND PGPB.dbnm.) OR ((US- 5464394-A OR US- 5087246-A).did. AND USPT.dbnm.) L300 AND (insertion near1 depth)	IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:02 AM
L302	18	((US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20140243873-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20120302994-A1 OR US-20090018500-A1 OR US-20130338637- A1 OR US- 20110224606-A1 OR US-20160051386- A1).did. AND	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:01 AM

L303	4	PGPB.dbnm.) OR ((US-5464394-A OR US-5087246-A).did. AND USPT.dbnm.) ((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM
L304	0	L303 AND asymmetric\$2	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM
L305	29	((US-5250070-A OR US-5295995-A OR US-6007517-A OR US-6013055-A OR US-5558644-A OR US-4369790-A OR US-5690613-A OR US-5464394-A OR US-5087246-A).did. AND USPT.dbnm.) OR ((US-20030083579-A1 OR US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM

L306	2	A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-A1 OR US-20140243873-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) (L305 AND asymmetric\$2)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM
L307	4	L303	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:15 AM
L308	61	(angioplasty WITH catheter) AND (asymmetric\$2 near1 balloon)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/13 11:17 AM
L309	5	((US-20040039332-A1 OR US-20190366046-A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/06/13 11:26 AM

L310	30	20100204712-A1 OR US-20110172696-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:32 AM
		((US-5250070-A OR US-5295995-A OR US-6007517-A OR US-6013055-A OR US-5558644-A OR US-4369790-A OR US-5690613-A OR US-5464394-A OR US-5087246-A OR US-6129737-A).did. AND USPT.dbnm.) OR ((US-20030083579-A1 OR US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-A1 OR US-20140243873-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L311	20	L310 AND angioplasty	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2023/06/13 11:34 AM

L312	92	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-5047045-A OR US-7195612-B2 OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-7862541-B2 OR US-5250070-A OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-5169386-A OR US-8419648-B2 OR US-9687333-B2 OR US-6248121-B1 OR US-4934996-A OR US-5558644-A OR US-5308356-A OR US-8021330-B2 OR US-9211396-B2 OR US-10149962-B2 OR US-4369790-A OR US-5476450-A OR US-5690613-A OR US-5464394-A OR US-6129737-A OR US-6007517-A).did. AND USPT.dbnm.) OR ((US-20070219466-A1 OR US-20140221898-A1 OR US-20070060911-	CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:35 AM
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		A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20110295302- A1 OR US- 20040082935-A1 OR US-20110172696-A1 OR US-20110224606- A1 OR US- 20100113939-A1 OR US-20030083579-A1 OR US-20110196297- A1 OR US- 20080015404-A1 OR US-20140364835-A1 OR US-20190015630- A1 OR US- 20150142045-A1 OR US-20210290243-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20150342581-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20090018500-A1 OR US-20130338637-A1 OR US-20160051386- A1 OR US- 20190076152-A1).did.				
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L313	59	AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)					
		L312 AND angioplasty	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:35 AM
L314	7	((US-20040039332-A1 OR US-20190366046- A1 OR US- 20100204712-A1 OR US-20110172696-A1 OR US-20100113939- A1 OR US- 20120109057-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:43 AM
L315	6	((US-20040039332-A1 OR US-20190366046- A1 OR US- 20100204712-A1 OR US-20110172696-A1 OR US-20100113939- A1).did. AND PGPB.dbnm.) OR ((US- 6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:59 AM
L316	1	L315 AND metal	(US-PGPUB; USPAT; USOCR; FIT (AU, AP,	OR	ON	ON	2023/06/13 12:05 PM

L317	92	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-5047045-A OR US-7195612-B2 OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-7862541-B2 OR US-5250070-A OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-5169386-A OR US-8419648-B2 OR US-9687333-B2 OR US-6248121-B1 OR US-4934996-A OR US-5558644-A OR US-5308356-A OR US-8021330-B2 OR US-9211396-B2 OR US-10149962-B2 OR US-4369790-A OR US-5476450-A OR US-5690613-A OR US-5464394-A OR US-6129737-A OR US-6007517-A).did. AND USPT.dbnm.) OR ((US-20070219466-A1 OR	AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:06 PM
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		US-20140221898-A1 OR US-20070060911-A1 OR US-20060167421-A1 OR US-20020169457-A1 OR US-20180140806-A1 OR US-20180117279-A1 OR US-20090312807-A1 OR US-20070135830-A1 OR US-20030032974-A1 OR US-20050261725-A1 OR US-20070219488-A1 OR US-20120109057-A1 OR US-20110251497-A1 OR US-20120302994-A1 OR US-20160213893-A1 OR US-20170043123-A1 OR US-20140243873-A1 OR US-20160206798-A1 OR US-20120330359-A1 OR US-20110295302-A1 OR US-20040082935-A1 OR US-20110172696-A1 OR US-20110224606-A1 OR US-20100113939-A1 OR US-20030083579-A1 OR US-20110196297-A1 OR US-20080015404-A1 OR US-20140364835-A1 OR US-20190015630-A1 OR US-20150142045-A1 OR US-20210290243-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-					
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L318	1	A1 OR US-20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) L317 AND (metal WITH (guide near1 wire))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:07 PM
L319	2	(L317 AND (stainless WITH (guide near1 wire)))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/13 12:07 PM
L320	92	((US-9211389-B2 OR US-6113579-A OR US- 6254578-B1 OR US- 6979318-B1 OR US- 5571093-A OR US- 4777951-A OR US- 5425709-A OR US- 5645528-A OR US- 6517515-B1 OR US- 5047045-A OR US- 7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US- 5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:17 PM

		6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 5690613-A OR US- 5464394-A OR US- 6129737-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20110295302- A1 OR US- 20040082935-A1 OR US-20110172696-A1 OR US-20110224606- A1 OR US- 20100113939-A1 OR US-20030083579-A1 OR US-20110196297- A1 OR US- 20080015404-A1 OR US-20140364835-A1 OR US-20190015630- A1 OR US- 20150142045-A1 OR US-20210290243-A1 OR US-20190366046- A1 OR US-				
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L321	39	20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20150342581-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20090018500-A1 OR US-20130338637-A1 OR US-20160051386- A1 OR US- 20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) L320 AND stainless	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:17 PM
L322	9	L321 AND radio	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:17 PM
L323	1117	(radio SAME stainless)	(US-PGPUB; USPAT;	OR	ON	ON	2023/06/13

L324	726	AND (guide near1 wire) L323 AND balloon AND catheter	USOCR) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	12:19 PM 2023/06/13 12:19 PM
L325	7	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:27 PM
L326	7	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:52 PM
L327	8	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1 OR US-20160051386-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:59 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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N41	4666	A61M2025/1093.cpc. or A61M25/0068.cpc. or A61M25/0071.cpc. or A61M25/0026.cpc. or A61M2025/0002.cpc. or A61M2025/1052.cpc. or A61M2025/1059.cpc. or A61M2025/1081.cpc. or A61M2025/1086.cpc. or A61M25/0074.cpc. or A61M25/1002.cpc. or A61M25/1006.cpc.	(USPAT)	OR	OFF	OFF	2018/06/06 09:41 AM
N42	0	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and occlusion and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and flattened and solid and beyond	(USPAT)	OR	OFF	OFF	2018/06/06 09:43 AM
N43	0	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and occlusion and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and flattened and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:43 AM
N44	2	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and occlusion and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:43 AM
N45	10	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:45 AM

N46	0	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid not N45	(USPAT)	OR	OFF	OFF	2018/06/06 09:52 AM
N47	5	A61M\$.cpc. and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid not N45	(USPAT)	OR	OFF	OFF	2018/06/06 09:53 AM
N48	0	A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND radially AND projecting AND landing AND inflation AND partial AND apposition AND curvilinear AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:05 PM
N49	0	A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND radially AND projecting AND landing AND inflation AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:05 PM
N50	0	A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND landing AND inflation AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:05 PM
N51	4	A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND inflation AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:06 PM

Doc code: IDS

PTO/SB/08a (02-18)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 11/30/2020. OMB 0651-0031

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	688961-25U7

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10368872		2019-08-06	Franklin et al.	
	2	9211396		2015-12-15	Aboytes	
	3	8021330		2011-09-20	McAndrew	

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20210290243	A1	2021-09-23	FRANKLIN et al.	

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	1	9925417	WO	A1	1999-05-27	Boston Scient Corp		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17563669
	Filing Date		2021-12-28
	First Named Inventor	Curtis J. FRANKLIN	
	Art Unit	3783	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	688961-25U7	

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	1	Int'l Search Report and Written Opinion issued June 8, 2022 in Int'l Application No. PCT/US2022/020704	
	2	European Search Report Issued May 31, 2022 in European Application No. 19846055.2	
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Examiner Signature		/JOHN A DOUBRAVA/	Date Considered 06/12/2023
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

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

Application Number	17563669
Filing Date	2021-12-28
First Named Inventor	Curtis J. FRANKLIN
Art Unit	3783
Examiner Name	Not Yet Assigned
Attorney Docket Number	688961-25U7

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2022-07-15
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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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.

Bibliographic Data

Application No: 17/563,669

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged:

Examiner's Signature

Initials

Title:

SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION
BALLOON CATHETER

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/28/2021	604	3783	688961-25U7
RULE			

APPLICANTS

Prytime Medical Devices, Inc., Boerne, TX, UNITED STATES

INVENTORS

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David SPENCER, Boerne, TX, UNITED STATES

Todd J. KRUMMENACHER, Lakewood, CO, UNITED STATES

CONTINUING DATA

This application is a CON of 16133193 09/17/2018 PAT 11672951

16133193 is a CON of 15551504 08/16/2017 PAT 10149962

15551504 is a 371 of PCT/US16/23223 03/18/2016

PCT/US16/23223 has PRO of 62204804 08/13/2015

PCT/US16/23223 has PRO of 62136571 03/22/2015

PCT/US16/23223 has PRO of 62136180 03/20/2015

PCT/US16/23223 has PRO of 62136370 03/20/2015

PCT/US16/23223 has PRO of 62136152 03/20/2015

PCT/US16/23223 has PRO of 62136123 03/20/2015

PCT/US16/23223 has PRO of 62136326 03/20/2015

PCT/US16/23223 has PRO of 62136390 03/20/2015

PCT/US16/23223 has PRO of 62136230 03/20/2015

PCT/US16/23223 has PRO of 62135576 03/19/2015

PCT/US16/23223 has PRO of 62135552 03/19/2015

PCT/US16/23223 has PRO of 62135609 03/19/2015

PCT/US16/23223 has PRO of 62135528 03/19/2015

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FOREIGN APPLICATIONS

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UNITED STATES

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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

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	Art Unit	3783
	Examiner Name	J. A. Doubrava
	Attorney Docket Number	688961-25U7

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10449337		2019-10-22	Kassab et al.	
	2	10279094		2019-05-07	Williams et al.	
	3	10143789		2018-12-04	Frost, Habib	
	4	10111669		2018-10-30	Eliason et al.	
	5	3585983		1971-06-22	Kantrowitz et al.	

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	1	20220000486	A1	2022-01-06	Williams et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17563669	
	Filing Date		2021-12-28	
	First Named Inventor	Curtis J. FRANKLIN		
	Art Unit	3783		
	Examiner Name	J. A. Doubrava		
	Attorney Docket Number	688961-25U7		

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	3	20030083617	A1	2003-05-01	St. Germain et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	2020033372	WO	A1	2020-02-13	Prytime Medical Devices, Inc		
	2	2019095049	WO	A1	2019-05-23	Three Rivers Cardiovascular Systems Inc		

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	M. Austin Johnson et al. (published on May 27, 2016). Partial Resuscitative Balloon Occlusion of the Aorta (P-REBOA): Clinical Technique and Rationale, J Trauma Acute Care Surg, 81(5) Suppl 1:S133-S137	
	2	Rachel M. Russo et al. (presented at the Military Surgical Symposium, Nashville, TN in April 2015, published on April 29, 2016). Partial Resuscitative Endovascular Balloon Occlusion of the Aorta in Swine Model of Hemorrhagic Shock, J Am Coll Surg, 223:359-368	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17563669
	Filing Date		2021-12-28
	First Named Inventor	Curtis J. FRANKLIN	
	Art Unit	3783	
	Examiner Name	J. A. Doubrava	
	Attorney Docket Number	688961-25U7	

3	Rachel M. Russo et al. (published on December 14, 2015. Extending the Golden Hour: Partial Resuscitative Endovascular Balloon Occlusion of the Aorta in a Highly Lethal Swine Liver Injury Model, J Trauma Acute Care Surg (80)3:372-380
4	Extended Search Report issued May 10, 2023 in European Application No. 22743436.2

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	Attorney Docket Number	688961-25U7

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Application Number:		17563669		
Filing Date:		28-Dec-2021		
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First Named Inventor/Applicant Name:		Curtis J. FRANKLIN		
Filer:		Ragi A.I. Elias/Angela Kryszczak		
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- (74) Agent: **BUTLER, Dennis, J.** et al.; Panitch Schwarze Belisario & Nadel LLP, Two Commerce Square, 2001 Market Street, Suite 2800, Philadelphia, PA 19103 (US).
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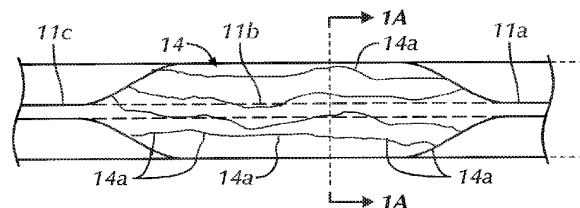


FIG. 1

(57) Abstract: An occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter includes a proximal catheter shaft having a proximal lumen and a hypotube positioned partially within the proximal lumen and spaced from the proximal catheter shaft. The catheter system also includes a distal catheter shaft attached to a distal end of the hypotube and an occlusion balloon connected at a proximal end to the proximal catheter shaft and at a distal end to the distal catheter shaft. The occlusion balloon is configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces.



TITLE OF THE INVENTION

System and Method for Low Profile Occlusion Balloon Catheter

BACKGROUND OF THE INVENTION

5 **[0001]** The present invention pertains generally to vascular occlusion catheters and methods of vascular pre-conditioning while controlling occlusion and perfusion during an occlusion procedure. Pre-conditioning is employed to mitigate ischemia before, during and/or after a vascular occlusion procedure, as well as used to reduce or ameliorate the onset of hypertension during or reduce or ameliorate the onset of hypotension after a
10 vascular occlusion procedure. Vascular occlusions may be indicated in either the venous system and/or the arterial system. Endoarterial occlusion is a procedure in which a blood vessel is at least partially occluded in order to restrict blood flow upstream or downstream of the occlusion site for purposes of a vascular procedure or repair. It is known that transient hypertension is a risk factor in arterial occlusion, particularly aortic
15 occlusion. Transient hypertension occurs when the blood pressure upstream of the occlusion site rises to a potentially unsafe level during the time duration of the occlusion. Upon completion of a procedure requiring arterial occlusion, particularly aortic occlusion, care must be taken during the process of reestablishing blood flow to reduce or ameliorate the onset of hypotension. Thus, arterial occlusion carries with it two twin
20 risks, hypertension during the occlusion and hypotension as the occlusion is withdrawn and blood flow restored that must be managed. Partial occlusion of the aorta is also preferred to mitigate the risk of ischemia below the site of the occlusion to limit or eliminate lack of blood flow to organs and tissue below the occlusion location.

25 **[0002]** In addition to hypotension and hypertension, techniques allowing partial flow of blood and related fluids past the occlusion member may be desirable to provide at least partial blood flow to portions of the patient's body downstream of the occlusion member. At least partial perfusion past the occlusion member can provide the benefits of focusing or directing a majority of blood flow to the brain, heart and lungs or other upstream portions of the patient, but also potentially increasing the amount of time the occlusion
30 member can be implanted in the patient, by providing at least partial blood flow to the

patient's organs downstream of the occlusion member, such as to the patient's liver, digestive tract, kidneys and legs.

5 **[0003]** Referring to Fig. 1PA, partial perfusion may be accomplished by reducing the size of an occlusion member or occlusion balloon 1 that is attached to a catheter 2. The occlusion balloon 1 may, for example, be partially deflated to allow blood to flow between outer surfaces 1a of the occlusion balloon 1 and inner surfaces 3a of a vessel 3 within which the occlusion balloon 1 is positioned. This, for example, deflation of the occlusion balloon 1 may cause the occlusion balloon 1 to lose contact with the inner surface 3a of the vessel 3, thereby causing movement of the occlusion balloon 1 and
10 partial vibration between the vessel 3 and the occlusion balloon 1 that is undesirable. Such loss of contact with the inner surfaces 3a of the vessel 3 by the occlusion balloon 1 is represented in Fig. 1PA, by a cylindrical channel 4 defined between the outer surface 1a of the occlusion balloon 1 and the inner surfaces 3a of the vessel 3. Loss of contact with the inner surface 3a of the vessel 3 by the occlusion balloon 1 may also result in the
15 occlusion balloon 1 and attached catheter 2 being urged downstream in the vessel 3, thereby moving the occlusion balloon 1 out of its preferred placement. It would be desirable to design, develop and implement an occlusion balloon catheter that maintains contact with the vessel 3 during partial perfusion to reduce or eliminate such vibrations and movement of the occlusion member during partial perfusion.

20 **[0004]** Temporary aortic occlusion as an operative method to increase proximal or central perfusion to the heart and brain or other major organs in the setting of shock due to major trauma is generally known. Despite potential advantages over thoracotomy with aortic clamping, resuscitative endovascular balloon occlusion of the aorta ("REBOA") for trauma has not been widely adopted.

25 **[0005]** Many attempts have been made at developing technologies to control non-compressible abdominal hemorrhage. For example, non-occlusive, abdominal tamponade procedures have been developed to address the problem of non-compressible hemorrhage, such as introducing an expandable, biocompatible foam into the abdominal cavity to apply pressure to the abdominal organs and vasculature. Pharmacological
30 efforts have also been developed to address the problem of non-compressible hemorrhage. Conventional REBOA procedures are typically performed in an operating

room and with the aid of fluoroscopy or other imaging.

[0006] Devices that automate inflation and deflation of a balloon are generally known. Intra-aortic balloon counterpulsation catheters for blood pressure augmentation coordinated with electrocardiography signals are also known. Over-inflation safety
5 devices are also known, such as a pressure-relief valve coupled to an inflation lumen that opens when pressure within the inflation lumen exceeds a threshold pressure, but relative pressure within the occlusion balloon is necessary to maintain occlusion of the blood vessel.

[0007] It would be desirable to design, develop and implement a system that
10 intermittently and automatically releases an occlusion balloon or member by releasing apposition of the occlusion balloon or member against the vascular wall and allowing perfusion past the occlusion balloon or member in response to a physiological parameter, then re-establishing occlusion in response to potential changes in the physiological parameter, either during a vascular repair procedure to control hypertension or post-repair
15 procedure to control hypotension. It would also be desirable to design, develop and implement a system that allows perfusion past the occlusion balloon or member while maintaining engagement between the occlusion balloon or member and the walls of the vasculature, preferably an artery and more preferably the aorta, to prevent vibration, movement, sliding or shifting of the occlusion balloon or member as blood flows past the
20 occlusion balloon. In addition, it is desirable to design, develop and implement an occlusion balloon that permits relatively fine control of a pressure ratio between proximal and distal sides of the occlusion balloon and, therefore, relatively fine control of blood flow across the occlusion balloon through the vessel. The preferred embodiments of the present invention address certain of these limitations of the prior art occlusion systems.

[0008] In addition, it is desirable to design, develop and implement an occlusion
25 balloon that permits relatively fine control of a pressure ratio between proximal and distal sides of the occlusion balloon and, therefore, relatively fine control of blood flow across the occlusion balloon through the vessel. Existing occlusion balloons are difficult to modulate pressure drop across the balloon and modulation can result in movement of the
30 balloon under blood pressure in the balloon. A relatively small change in balloon volume or internal pressure often results in drastic changes in blood pressure between proximal

and distal sides of the occlusion balloon, resulting in full occlusion or a relatively high rate of volumetric blood flow across the balloon. It is desirable to design, develop and deploy an occlusion system that is less sensitive to slight pressure changes in the occlusion balloon and provides a more gradual change in blood flow past the occlusion balloon. It is also desired to create catheters with occlusion members that perform both partial and full occlusion. This would allow more gradual transitions between full and no occlusion and also provide surgeons more time to prevent fatal loss of blood in patients. The preferred present invention addresses these shortcomings of prior art occlusion balloons.

10 **[0009]** A majority of catheters with balloons attached thereto or integrated therewith are bonded together using a lap or overlap weld, wherein the material of the balloon overlaps an end or portion of the catheter. The overlapped portions are then welded or otherwise bonded together to secure the balloon to the catheter. This lap weld causes the profile of the catheter to be greatest at the lap weld because of the overlap of material in
15 this area of the catheter system. Any increase in the size or diameter of the catheter shaft results in an increase in size or counterpart dimension of an introducer sheath through which the catheter is introduced into the patient's body. Alternatively, the catheter shaft may be necked or have a reduced diameter portion at its end where the overlap weld is located in attempts to maintain the overall diameter of the catheter system at the lap weld.
20 This necking of the catheter shaft, however, reduces the flow of inflation medium into and out of the balloon through a reduced diameter internal catheter shaft lumen at the necking area, which is undesirable. In addition, the thickness of the catheter shaft and balloon material may only be reduced to dimensions that allow the catheter and balloon to support the pressures expected within the catheter and the balloon, so that reducing the
25 thickness of the catheter or balloon material is limited by these structural performance parameters. It would be desirable to design, construct and implement a balloon catheter system that minimizes the thickness of the catheter shaft in the weld or connection area with the balloon, while maintaining the size of the internal lumen that extends through this area of the catheter.

30

BRIEF SUMMARY OF THE INVENTION

[0010] Non-compliant or semi-compliant balloons may have certain advantages in REBOA procedures, such as ease of use, because the non-compliant or semi-compliant nature of the balloon causes the internal balloon pressure to increase dramatically once slack in the folds of the non-compliant or semi-compliant balloon is overcome during inflation. Compliant balloons may also be preferred for use in certain REBOA procedures, such as partial occlusion of a vessel where an oversized balloon is inserted into the vessel.

[0011] The preferred catheter systems described herein perform partial and full occlusion of a patient's vessel, preferably a large vessel such as various locations in the patient's aorta, including the descending thoracic aorta and the abdominal aorta. A variety of compliant, semi-compliant and non-compliant balloons may be utilized with the preferred occlusion catheter systems to occlude or partially occlude relatively large vessels in the patient's circulatory system. The preferred compliant, semi-compliant and non-compliant balloons preferably perform well during smooth control tests, preferably exhibiting the ability to gradually transition pressure in the vessel between full and no occlusion, such that transition between full and partial occlusion of the vessel is readily controllable to avoid quick or immediate transitions between full occlusion and virtually no occlusion in the vessel.

[0012] Certain non-compliant or semi-compliant balloons were relatively easy to use because of the non-compliant or semi-compliant nature of the balloon, which caused the internal balloon pressure to increase dramatically once the "slack" was taken out of the balloon during inflation. While the non-compliant or semi-compliant balloons were effective for performing full occlusion in the tubes or virtual vessels up to, but not exceeding, their blown diameter, these non-compliant balloons generally cannot occlude tubes larger than their blown diameter or at least somewhat larger than their blown diameter, because the non-compliant balloons do not stretch significantly in the radial direction to come into facing engagement with a full diametric slice or portion of the internal walls of the vessel.

[0013] As a preferred example of testing a non-compliant or semi-compliant balloon with the preferred occlusion catheter systems, a non-compliant or semi-compliant balloon

with a blown diameter of twenty millimeters (20mm) and a blown length of twenty millimeters (20 mm) was able to partially occlude a simulated vessel comprised of a tube having a fifteen and one-half millimeter (15.5 mm) inner diameter. In contrast, the same twenty millimeter (20 mm) non-compliant or semi-compliant balloon had a limited ability to gradually transition between partial and full occlusion in a simulated vessel comprised of a tube having a nineteen millimeter (19 mm) inner diameter. As the non-compliant or semi-compliant balloon is inflated, the folds of the twenty millimeter (20mm) balloon in in the fifteen and one-half millimeter (15.5 mm) tube or simulated vessel defines flow channels with the inner surfaces of the tube or vessel that permit some flow to go past the balloon, even when the outer surface of the balloon is touching the wall of the tube or simulated vessel. In contrast, in the nineteen millimeter (19 mm) tube or simulated vessel, there are very few flow channels created by the folds in the balloon because nearly all of the folds are expanded at this greater diameter, so partial occlusion of the tube or simulated vessel is limited. The twenty millimeter (20 mm) diameter non-compliant or semi-compliant balloon also does not substantially occlude a tube or simulated vessel larger than approximately twenty millimeters (20 mm). The twenty millimeter (20 mm) non-compliant or semi-compliant balloon, accordingly, is not preferred for REBOA procedures when the patient's vessel has an inner diameter in the range of twenty to thirty or more millimeters (20-30+ mm).

[0014] In the above-described preferred catheter system example, the occlusion balloon is constructed of a low-compliance, semi-compliant or non-compliant polyethylene terephthalate ("PET") balloon, but is not so limited. The occlusion balloon may also be constructed of a nylon, urethane, polyether block amide ("PEBA") or PEBAX material or other similar materials. When the example catheter system is used in vessels or sample vessels smaller in diameter than the blown diameter, the blood vessel or sample vessel is the only material pushing back radially when the balloon inflates. The blood vessel can tolerate some stretching but too much can rupture or cause a dissection. The user preferably stops inflating before this pressure gets too high or a safety feature is incorporated into the catheter system to prevent over-inflation of the occlusion balloon, such as a pop-off or pressure release valve.

[0015] In a preferred embodiment, a relatively large diameter, such as a blown

diameter of approximately twenty-five to thirty-five millimeters (~25-35 mm), non-compliant or semi-compliant balloon is mounted near the distal end of the catheter system. A pressure-relief or pop-off valve is mounted at the catheter hub in line or in fluid communication with the balloon inflation lumen at a location of the catheter shaft, hub, extension line, stopcock or proximal to the stopcock of the catheter system to prevent the balloon from overinflating.

[0016] The relatively large diameter, non-compliant or semi-compliant balloon, such as, but not limited to, having a blown diameter of approximately twenty-five to thirty-five millimeters (~25-35 mm), would have folds in almost all aortas. Greater than ninety-five percent of normal aortas have a diameter of twenty-five millimeters (25 mm) or smaller, so the relatively large diameter balloon would have folds when encountering the inner walls of the aorta during inflation or before full inflation. Accordingly, the relatively large non-compliant or semi-compliant balloon incorporated into the system or a non-compliant or semi-compliant balloon that is configured to have a blown diameter of approximately ten to sixty percent (10-60%) greater than an inner diameter of the associated vessel is functional for partially occluding the vessels, particularly for partial occlusion utilizing folds in the partially inflated balloon to create flow channels with the inner surface of the vessel. The non-compliant or semi-compliant, twenty-five to thirty-five millimeter (~25-35 mm) occlusion balloon, specifically is generally effective for a majority of aortas. The pressure relief valve preferably prevents the user from overinflating the balloon, which could cause aortic rupture/dissection or balloon rupture, but still allow all aortas, generally regardless of size, to be occluded. The preferred catheter system also include a P-tip, hypotube/wire positioned centrally within the catheter system, marks on the outer shaft for placement of the occlusion balloon in a preferred zone of the aorta, no guidewires, and marker bands for visualization of the placement of the balloon.

[0017] In a preferred embodiment, the occlusion catheter system is configured for full or partial occlusion of a vessel having a vessel diameter. The occlusion catheter system includes a proximal catheter shaft having a proximal lumen and a hypotube positioned partially within the proximal lumen and spaced from the proximal catheter shaft. The hypotube may also be described as a central shaft. The central shaft may have an internal

lumen or may be substantially solid between its proximal and distal ends with both configurations of the central shaft providing strength and stiffness to the preferred catheter for insertion into the patient's vessel. The catheter system also includes a distal catheter shaft attached to a distal end of the hypotube and an occlusion balloon connected at a proximal end to the proximal catheter shaft and at a distal end to the distal catheter shaft. The occlusion balloon has a blown diameter greater than the vessel diameter. The occlusion balloon is configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces.

10 BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0018] The foregoing summary, as well as the following detailed description of preferred embodiments of the instrument, system and method of the present application, will be better understood when read in conjunction with the appended drawings. For the purposes of illustrating the preferred occlusion catheter system, there are shown in the drawings preferred embodiments. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown. In the drawings:

15 [0019] Fig. 1PA is a side perspective, partially cut-away view of a prior art occlusion balloon catheter implanted in a vessel with partial inflation allowing flow around an entire periphery of the occlusion balloon and a cross-sectional view taken along line X-X of the vessel and catheter;

20 [0020] Fig. 1 is a magnified, side elevational view of a non-compliant or semi-compliant occlusion balloon in a simulated vessel in accordance with a first preferred catheter system of the present invention, wherein the occlusion balloon is inflated to come into contact with the simulated vessel, with folds formed in the balloon, thereby creating flow channels;

25 [0021] Fig. 1A is a cross-sectional view of the balloon of Fig. 1 inflated to a partially occluded configuration, taken along line X-X of Fig. 1;

[0022] Fig. 1B is a cross-sectional view of the balloon of Fig. 1 inflated to a full occlusion configuration, taken along line X-X of Fig. 1;

30 [0023] Fig. 1C is a top plan view of a first preferred occlusion catheter system

including the first preferred occlusion balloon of Fig. 1;

[0024] Fig. 1D is a cross-sectional view of a proximal catheter shaft of the occlusion catheter system, taken along line 1D-1D of Fig. 1C;

5 **[0025]** Fig. 1E is a top plan view of the first preferred occlusion catheter system of Fig. 1C implanted in a patient's aorta;

[0026] Fig. 1F is a front elevational view of a control hub attached to a proximal catheter shaft of the occlusion catheter system of Fig. 1C;

[0027] Fig. 1G is a front perspective view of the control hub of Fig. 1F;

10 **[0028]** Fig. 2 is a line chart comparing balloon volume vs. balloon pressure for compliant, semi-compliant and non-compliant occlusion balloons mounted on the first preferred catheter system;

[0029] Fig. 2A is a line chart comparing balloon volume vs. balloon pressure for a standard compliant and twenty-five millimeter (25 mm) non-compliant or semi-compliant occlusion balloons mounted in a fifteen and one-half millimeter (15.5 mm) simulated
15 vessel;

[0030] Fig. 2B is a line chart comparing balloon volume vs. balloon pressure for a standard compliant and twenty-five millimeter (25 mm) non-compliant or semi-compliant occlusion balloons mounted in a nineteen millimeter (19 mm) simulated vessel;

20 **[0031]** Fig. 2C is a line chart comparing balloon volume vs. balloon pressure for a standard compliant occlusion balloon mounted in a twenty-five and four tenths millimeter (25.4 mm) simulated vessel;

[0032] Fig. 3 is a side, cross-sectional view of the catheter system in accordance with the first preferred embodiment of the present invention;

25 **[0033]** Fig. 4 is a magnified, cross-sectional view of a pressure gauge mounted to the catheter system of Fig. 3;

[0034] Fig. 5 is a magnified, cross-sectional view of a threshold pressure sensor mounted to the catheter system of Fig. 3;

[0035] Fig. 6 is an alternative pressure source that may be utilized with the catheter system of Fig. 3;

30 **[0036]** Fig. 7 is a side, cross-sectional view of a distal portion of a catheter system in accordance with a second preferred embodiment of the present invention;

- [0037] Fig. 8 is a side elevational view of the catheter system of Fig. 7;
- [0038] Fig. 9 is a side elevational view of a first alternative preferred occlusion balloon that may be utilized with any of the preferred catheter systems described herein;
- [0039] Fig. 10 is a side elevational view of a second alternative preferred occlusion balloon that may be utilized with any of the preferred catheter systems described herein;
- [0040] Fig. 11 is a side elevational view of a distal portion of a catheter system in accordance with a third preferred embodiment of the present invention;
- [0041] Fig. 12 is a side elevational view of a distal portion of a catheter system in accordance with a fourth preferred embodiment of the present invention;
- 10 [0042] Fig. 13 is a side elevational view of a distal portion of a catheter system in accordance with a fifth preferred embodiment of the present invention;
- [0043] Fig. 14 is a side elevational view of an occlusion balloon of a catheter system in accordance with a sixth preferred embodiment of the present invention;
- [0044] Fig. 14A is a cross-sectional view of the occlusion balloon of Fig. 14, taken
15 along line A-A of Fig. 14;
- [0045] Fig. 15 is a side elevational view of a distal portion of a catheter system in accordance with a seventh preferred embodiment of the present invention;
- [0046] Fig. 16 is a side perspective view of an occlusion catheter system in accordance with an eighth preferred embodiment of the present invention;
- 20 [0047] Fig. 16A is a cross-sectional view of the occlusion catheter system of Fig. 16, taken along line 16A-16A of Fig. 16;
- [0048] Fig. 17 is a magnified cross-sectional view of a portion of the occlusion catheter system of Fig. 16, taken from within shape 17 of Fig. 16A; and
- [0049] Fig. 18 is a magnified cross-sectional view of a portion of the occlusion
25 catheter system of Fig. 16, taken from within shape 18 of Fig. 16A.

DETAILED DESCRIPTION OF THE INVENTION

- [0050] Certain terminology is used in the following description for convenience only and is not limiting. Unless specifically set forth herein, the terms “a”, “an” and “the” are not limited to one element but instead should be read as meaning “at least one”. The
30 words "right", "left", "lower" and "upper" designate directions in the drawings to which

reference is made. The words "inwardly" or "distally" and "outwardly" or "proximally" refer to directions toward and away from, respectively, the patient's body, or the geometric center of the preferred occlusion catheter systems and related parts thereof. The words, "anterior", "posterior", "superior," "inferior", "lateral" and related words and/or phrases designate preferred positions, directions and/or orientations in the human body to which reference is made and are not meant to be limiting. The terminology includes the above-listed words, derivatives thereof and words of similar import.

[0051] It should also be understood that the terms "about," "approximately," "generally," "substantially" and like terms, used herein when referring to a dimension or characteristic of a component of the preferred invention, indicate that the described dimension/characteristic is not a strict boundary or parameter and does not exclude minor variations therefrom that are functionally the same or similar, as would be understood by one having ordinary skill in the art. At a minimum, such references that include a numerical parameter would include variations that, using mathematical and industrial principles accepted in the art (e.g., rounding, measurement or other systematic errors, manufacturing tolerances, etc.), would not vary the least significant digit.

[0052] Referring to Figs. 1-4, a first preferred embodiment of an occlusion catheter system, generally designated 10, includes a proximal catheter shaft 11a, a strong and stiff central shaft or hypotube 11b and a distal catheter shaft 11c. The proximal catheter shaft 11a has a central lumen that surrounds a proximal end of the central shaft 11b and is attached to an inflation hub 12 at its proximal end. In the first preferred embodiment, the central shaft 11b is a hypotube 11b with an internal lumen, typically for collecting pressure data via pressure head, delivering medications or instruments to the distal end of the occlusion catheter system 10 or otherwise providing a lumen to the distal end of the system 10. The central shaft 11b may be solid or have the central lumen of the hypotube 11b and preferably provides strength and stiffness to the system 10 in both configurations.

[0053] Marker bands 11m are preferably attached to the hypotube 11b proximate proximal and distal ends of the occlusion balloon 14 for location and identification of the position of the occlusion balloon 14 using fluoroscopy or other visualization techniques or systems. The proximal catheter shaft 11a also preferably includes depth markings

on its external surface that assists the user in properly placing the catheter system 10 during use by indicating the depth of insertion, as indicated by the depth markings 33. The distal catheter shaft 11c includes an atraumatic tip or a P-tip 13 that unfolds to a generally straight insertion configuration when the catheter is inserted into a vessel 3 and a biased or relaxed configuration when positioned within the patient's vessel 3. An occlusion balloon 14 is connected at a proximal end to an open distal end of the proximal catheter shaft 11a and at a distal end to the distal catheter shaft 11c. A proximal sensor 15a is positioned adjacent the proximal end of the balloon 14 and a distal sensor 15b is positioned adjacent the distal end of the balloon 14. The proximal and distal sensors 15a, 15b are preferably comprised of pressure sensors and may be electronic pressure sensors positioned directly on the catheter shaft, a port for a fluid lumen for measuring pressure based on pressure head, a separate pressure sensor positioned adjacent the catheter shaft or other pressure sensing mechanisms or methods that facilitate pressure or other measurement at the desired locations. The balloon 14 is preferably comprised of a large diameter, semi-compliant or non-compliant balloon 14. A pressure-relief or pop-off valve 16 is preferably connected to a catheter hub 16 at the proximal end of the proximal catheter shaft 11a. The pressure-relief or pop-off valve 16 may be positioned in close relation to the or on the inflation hub 12, such as proximal to the balloon valve or stopcock 12c in a molded pressure relief fitting. The pressure-relief or pop-off valve 16 can be used to prevent the balloon 14 from overinflating.

[0054] In the first preferred embodiment of the occlusion catheter system 10, the occlusion balloon 14 is comprised of a semi-compliant or substantially non-compliant balloon mounted to the proximal and distal catheter shafts 11a, 11c. Although not so limited, a non-compliant or semi-compliant balloon 14 generally has growth of approximately two to seven percent (2-7%) within the working range (balloon pressure) when inflated, a semi-compliant balloon has growth of approximately seven to twenty percent (7-20%) within the working range (balloon pressure) when inflated and a compliant balloon has growth of approximately greater than twenty percent (20%+) within the working range (balloon pressure) when inflated. Compliant balloons 14 may have growth of approximately one to three hundred percent (100-300%) within the working range (balloon pressure) when inflated. The occlusion balloon 14 has a

relatively large blown diameter D, preferably approximately twenty-five to thirty-five millimeters (~25-35mm), that is configured to be approximately ten to sixty percent (10-60%) larger than the vessel 3 into which the balloon 14 is inserted and inflated for occlusion. The semi-compliant balloon 14 is, therefore, only partially inflated when its
5 outer surface comes into full diametric contact with the inside of the target vessel 3 and folds 14a remain at the outer surface of the balloon 14. In this partially inflated configuration, the semi-compliant balloon 14 has a partially inflated diameter d, wherein the folds 14a are formed. These folds 14a create channels 15 with the inner surfaces of the vessel 3 or with portions of the outer surface of the balloon 14 that allow partial
10 perfusion or blood flow past the balloon 14 under the blood pressure within the vessel 3. The cross-hatching within the folds 14a of Fig. 1A represent blood or fluid flowing through the folds 14a, although the folds 14a would otherwise be open in this partially inflated configuration.

[0055] The preferred pressure-relief valve 16 mounted to the catheter hub 12 is
15 configured to prevent the balloon 14 from overinflating so that the balloon 14 does not burst and the vessel 3 is not damaged during the procedure. In the first preferred embodiment, the pressure-relief valve 16 is mounted in the fluid flow path further from the occlusion balloon 14 than the stopcock or balloon valve 12c. If the pressure relief valve 16 is mounted closer to the occlusion balloon 14 in the fluid flow path for inflation
20 of the occlusion balloon 14, the pressure relief valve 16 remains active or able to relieve pressure during the occlusion period. Momentary pressure increases in the vessel 3 during the occlusion period may result in release of pressure by the pressure-relief valve 16. The system 10, however, is not significantly impacted by positioning the pressure-relief valve 16 closer to the occlusion balloon 14 in the fluid flow than the stopcock or
25 balloon valve 12c and is not limited to being positioned either further way from or closer to the occlusion balloon 14 in the fluid flow than the stopcock or balloon valve 12c.

[0056] In the partially inflated configuration when the outer surface of the balloon 14 initially engages the inner surfaces 3a of the vessel 3 (Fig. 1A), the large diameter, semi-compliant balloon 14 has the folds 14a in almost all aortas, approximately greater than
30 ninety-five percent (95%) of the patient population of aortas, which allows for partial occlusion utilizing the oversized, semi-compliant balloon 14 in nearly all patient aortas.

The folds 14a and the inner walls of the vessel 3 define channels 15 that facilitates blood flow past the occlusion balloon 14. The pressure relief valve 16 preferably prevents the user from overinflating the balloon 14, thereby preventing aortic rupture/dissection or rupture of the balloon 14, but still allowing nearly all patient population aortas, to be occluded.

[0057] The preferred catheter system 10 may include the proximal and/or distal pressure sensors 15a, 15b, flow sensors, temperature sensors and other sensors that collect data related to the procedure above and/or below the balloon 14. The system 10 may also include a display on the inflation hub 12 or otherwise positioned for review by the user that is in wired or wireless contact with the pressure sensors 15a, 15b and other sensors so that the user is able to monitor the procedure and characteristics of the patient during the procedure. The use of the pressure sensors 15a, 15b and the related sensors with a controller or control hub 200 may also facilitate closed loop control of the catheter system 10 during use to modulate balloon volume to achieve a desired set point (i.e. proximal/distal blood pressure, temperature, flow, etc.). The pressure sensors 15a, 15b may be comprised of pressure sensors that measure pressure by fluid pressure head, electronic pressure sensors or other sensors that are able to measure pressure of fluid in the patient's vessel 13, within the occlusion balloon 14 or otherwise within the system 10.

[0058] The combination of the pop-off or pressure-relief valve 16 and the non-compliant, semi-compliant or compliant balloon 14, which is properly sized for the vessel 3, allow the user to inflate the balloon 14 safely until the pop-off or pressure-relief valve 16 releases liquid or other inflation medium, as shown in Fig. 2-2B. The preferred occlusion catheter system 10 is configured for all reasonable vessel 3 sizes or diameters of the aorta, generally up to approximately twenty-eight and six tenths millimeters (~28.6 mm). Then when deflating from full occlusion and approaching full occlusion, the folds 14a in the balloon 14 open enough to allow some blood flow in the channels 15 defined by the folds 14a and/or the inner surfaces 3a of the vessel 3, thereby providing the user with a good degree of partial occlusion to limit shock to the patient's system of a quick change in pressure above and below the balloon 14. Specifically, as is shown in Figs. 2-2B, the non-compliant or semi-compliant balloon 14 exhibits a slow and gradual increase in internal balloon pressure during an initial balloon volume increase and then a sharp

increase in pressure with limited increase in balloon volume or inflation fluid introduction after full occlusion. The range of inflation fluid introduction and removal near full occlusion is, therefore, relatively forgiving for the non-compliant or semi-compliant balloon 14 just below full occlusion pressures and volumes, when oversized for the associated vessel 3, allowing the user to readily control partial occlusion below the full occlusion range. The compliant balloon 14 has a more consistent balloon pressure vs. balloon volume slope below and above full occlusion when oversized for the associated vessel 3. When properly sized and configured, the compliant, semi-compliant and non-compliant balloons 14 of the preferred occlusion catheter system 10 provide partial and full occlusion and are prevented from rupture of the balloon 14 and rupture of the vessel 3 by pressure release from the pop-off or pressure-relief valve 16. The semi-compliant or non-compliant balloon 14 also provides a clear tactile indication to the user that the balloon 14 has come into direct facing engagement with the inside surfaces of the vessel 3 that provides an opposite reaction force to the expanding occlusion balloon 14 or has reached its full blown diameter D based on the steep pressure increase with relatively little inflation medium introduction into the balloon 14, as shown in Fig. 2. This facilitates the pressure-relief valve 16 releasing pressure well below an unsafe region of inflation where vessel 3 rupture or balloon rupture could potentially occur.

[0059] Referring to Figs. 2-2C, balloon volume in milliliters (mL) vs. balloon pressure in pounds per square inch (psi) are shown for various occlusion balloon and vessel 3 configurations and scenarios. Fig. 2 shows generic compliant and semi-compliant or non-compliant balloon pressure vs. balloon volume curves wherein the compliant balloon 14 stretches enough to soften at the point when the vessel 3 is occluded and, thus, may rupture before the crack pressure of the pop-off or pressure-relief valve 16 is reached (Fig. 2C), while the non-compliant or semi-compliant balloon 14 actuates the pressure-relief or pop-off valve 16 before either the balloon 14 or vessel 3 rupture. Fig. 2A, shows a non-compliant or semi-compliant twenty-five millimeter (25 mm) balloon 14 and a prior art compliant balloon 14 that both actuate the pressure-relief or pop-off valve 16 before either balloon or vessel 3 rupture. The balloons 14 of Fig. 2A are inserted and actuated in a fifteen and one-half millimeter (15.5 mm) tube or simulated vessel 3 and the pressure-relief or pop-off valve 16 has an actuation range of eight

pounds per square inch with a tolerance of two pounds per square inch ($8 \text{ psi} \pm 2 \text{ psi}$). The compliant balloon 14 reaches full occlusion of the vessel 3 at approximately five and eight tenths milliliters (5.8 mL) and three pounds per square inch (3 psi), while the non-compliant or semi-compliant balloon 14 reached full occlusion of the vessel 3 at approximately eight and eight tenths milliliters (8.8 mL) and two and one tenth pounds per square inch (2.1 psi).

5 [0060] Fig. 2B, shows the same non-compliant or semi-compliant and compliant balloons 14 inflated in a nineteen millimeter tube or simulated vessel 3 with the same the pressure-relief or pop-off valve 16 having the same actuation range of eight pounds per square inch with a tolerance of two pounds per square inch ($8 \text{ psi} \pm 2 \text{ psi}$). The compliant balloon 14 reaches full occlusion of the vessel 3 at approximately seven and eight tenths milliliters (7.8 mL) and three pounds per square inch (3 psi), while the non-compliant or semi-compliant balloon 14 reached full occlusion of the vessel 3 at approximately eleven and eight tenths milliliters (11.8 mL) and two and two tenths pounds per square inch (2.2 psi). Both the compliant and non-compliant or semi-compliant balloons 14 enter the pop-off range prior to rupture, thereby actuating the pop-off or pressure-relief valve 16 before the balloon ruptures.

10 [0061] Fig. 2C, shows the same compliant balloon 14 inflated in a twenty-five and four tenths millimeter (25.4 mm) tube or simulated vessel 3 with the same pressure-relief or pop-off valve 16 having the same actuation range of eight pounds per square inch with a tolerance of two pounds per square inch ($8 \text{ psi} \pm 2 \text{ psi}$). In the scenario and configuration of Fig. 2C, the pressure in the compliant balloon 14 never exceeded the crack pressure for the pop-off or pressure relief valve 16, so the valve 16 does not open and the balloon 14 ruptures. For smaller vessels 3, for example, approximately twenty millimeters (20mm) or smaller, the compliant and non-compliant or semi-compliant balloons 14 function similarly (*i.e.* pressure in the balloons 14 stays low through full occlusion, then starts to increase quickly after full occlusion has been reached). When vessels 3 are larger than about twenty millimeters (20 mm), the compliant balloons 14 no longer have this rapid increase in balloon pressure after full occlusion. The reason is the balloon 14 has stretched enough at that point that the balloon 14 is becoming less stiff as additional volume is added. This results in the balloon pressure staying relatively low, all

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the way to rupture. This configuration and scenario doesn't allow the pop-off valve 16 to open before balloon 14 ruptures, because the pressure is too low to actuate the pop-off valve 16. This effect is highly depending on the blown diameter D of the balloon 14 in comparison to the size. If, as a non-limiting example, a compliant balloon was blown to thirty millimeters (30 mm) and placed in a relatively small vessel 3, such as a fifteen millimeter (15 mm) vessel 3, it is possible that the balloon wouldn't have stretched much by the time it reaches full occlusion and the pressure would rise significantly like a non-compliant or semi-compliant balloon. Both a compliant and non-compliant or semi-compliant balloons could work for this application if it was blown significantly large.

10 **[0062]** For relatively small vessels 3, such as the fifteen and one-half and nineteen millimeter (15 mm and 19 mm) tubes or simulated vessels 3, shown in Figs. 2A and 2B, the compliant and non-compliant or semi-compliant balloons 14 have relatively similarly shaped pressure vs. volume curves. In these simulations, the compliant balloon 14 hasn't significantly stretched when the compliant balloon 14 reaches full occlusion, such that
15 the wall of the compliant balloon 14 is still relatively thick and the pressure in the balloon 14 rises relatively quickly, similar to the non-compliant or semi-compliant balloon 14, although the slope of pressure increase of the non-compliant or semi-compliant balloon 14 is steeper starting at a greater inflation fluid volume. Conversely, for large diameter vessels 3 where the compliant balloon 14 is not oversized for the vessel 3, the compliant
20 balloons 14 can have a shallow slope and the pressure doesn't increase significantly after occlusion, thereby potentially leading to rupture at a relatively low pressure (Fig. 2).

This configuration could lead to the the compliant balloon 14 rupturing before the pop-off valve 16 is actuated. For the pop-off valve 16 to function successfully, meaning the valve 16 always opens before balloon 14 or vessel 3 rupture, the valve 16 remains closed
25 or unactuated during inflation of the balloons 14 to full occlusion and the valve 16 opens or is actuated before either: (1) the balloon 14 ruptures or the blood vessel 3 ruptures.

[0063] Referring to Figs. 4 and 5, the preferred occlusion catheter system 10 may alternatively include a pressure gauge 16a (Fig. 4) or a threshold pressure sensor 16b (Fig. 5) mounted to the hub 12 for monitoring the pressure within the balloon 14. The
30 pressure gauge 16a may include markings or indications related to a safe inflation zone or range for the associated balloon 14 and the threshold pressure sensor 16b may include a

visual indication to notify the user that a maximum pressure has been reached within the balloon 14. The threshold pressure sensor 16b may also indicate to the user that the threshold pressure has been reached by a light, a buzzer, vibration emission or another related indication to the user that the threshold pressure is reached.

5 **[0064]** Referring to Figs. 3, 4 and 6, the first preferred occlusion catheter system 10 includes an inflation pressure source 17 that is preferably comprised of a syringe that may be manually operated by the user. The system 10 is not limited to including the inflation pressure source 17 comprised of the syringe and may include a compressor or other pressure introducing mechanism that is able to provide a pressurized inflation medium
10 into the occlusion balloon 14 through the proximal catheter shaft 11a, which may be controlled by the user manually or via a controller. The system 10 may, alternatively, include a comparatively large syringe 17a with a large bore to limit the amount of pressure that can be inserted into the balloon 14 by a users hand.

15 **[0065]** Referring to Fig. 7, a second preferred occlusion catheter system 20 has a similar construction to the first preferred occlusion catheter system 10 and like reference numbers are utilized to identify like features of the second preferred occlusion catheter system 20 with a number “2” prefix replacing the “1” prefix to distinguish the features of the occlusion catheter system 10 of the first preferred embodiment from the occlusion catheter system 20 of the second preferred embodiment.

20 **[0066]** In the second preferred occlusion catheter system 20, a compliant, large-diameter balloon 24 is mounted to the proximal and distal catheter shafts 21a, 21c in place of the non-compliant or semi-compliant balloon 14 of the first preferred embodiment. When the compliant balloon 24 is inflated in a vessel 3 smaller than the blown diameter D, the folds 24a in the balloon 24 create flow channels for good partial
25 occlusion. When full occlusion has been reached, the balloon 24 stretches axially to facilitate additional inflation medium volume in the balloon 24 without causing the blood vessel 3 to stretch further, as shown in Fig. 7. In addition, the greater length in the contact between the outer surfaces of the balloon 24 and the inner surfaces 3a of the vessel 3 facilitate full occlusion of the vessel 3 as the folds 24a are released or removed
30 as the balloon 24 stretches.

30 **[0067]** Referring to Fig. 8, the second preferred catheter system 20, as well as the

first preferred catheter system 10, may mount the pop-off or pressure-relief valve (not shown) at various locations on the proximal or distal catheter shafts 21a, 21c or on the hub 22. The pop-off or pressure-relief valve may be mounted nearly anywhere on the catheter system 20 that permits communication between the valve and the inflation medium that inflates the balloon 24. For example, the pop-off or pressure-relief valve, as well as the pressure gauge or sensor 16a and the threshold pressure sensor 16b, may be located at the catheter hub 22, in-line with the balloon extension line, at the balloon pressure relief fitting, proximal to the stopcock, on the catheter shaft or near the balloon.

[0068] Referring to Figs. 9 and 10, first and second alternative occlusion balloons 8, 9 may be mounted to any of the preferred occlusion catheter systems, including the first and second preferred occlusion catheter systems 10, 20, described herein. The first and second alternative occlusion balloon 8, 9 are tapered to create an extended range of partial occlusion by allowing the balloon 8, 9 to grow axially. The first and second preferred tapered balloons 8, 9 reduce the likelihood of the balloons 8, 9 “windsocking” or pushing the balloon fluid or inflation medium to the proximal or downstream side of the balloons 8, 9 near the proximal catheter shaft 11a, 21a when the balloons 8, 9 are in the vessel 3 and subjected to blood pressure within the vessel 3.

[0069] Referring to Fig. 11, a third preferred occlusion catheter system 30 has a similar construction to the first and second preferred occlusion catheter systems 10, 20 and like reference numbers are utilized to identify like features of the third preferred occlusion catheter system 30 with a number “3” prefix replacing the “1” and “2” prefixes to distinguish the features of the occlusion catheter systems 10, 20 of the first and second preferred embodiments from the occlusion catheter system 30 of the third preferred embodiment. The third preferred occlusion catheter system 30 includes an occlusion balloon 34 comprised of an oversized, non-compliant or semi-compliant balloon 34x paired with a non-compliant or semi-compliant, smaller diameter spine balloon 34y. In a partially inflated configuration, balloon folds 34a are formed at the outer surface of the oversized, non-compliant or semi-compliant balloon 34x that form flow channels with the inner surfaces 3a of the vessel 3 for partial occlusion capability in small vessels 3. In addition, the spine balloon 34y, the inner surfaces 3a of the vessel 3 and the surfaces of the oversized balloon 34x define flow channels for partial blood flow, particularly when

the occlusion balloon 34 is positioned within a large vessel 3.

[0070] Referring to Fig. 12, a fourth preferred occlusion catheter system 40 has a similar construction to the first, second and third preferred occlusion catheter systems 10, 20, 30 and like reference numbers are utilized to identify like features of the fourth preferred occlusion catheter system 40 with a number “4” prefix replacing the “1,” “2” and “3” prefixes to distinguish the features of the occlusion catheter systems 10, 20, 30 of the first, second and third preferred embodiments from the occlusion catheter system 40 of the fourth preferred embodiment. In the fourth preferred embodiment, a comparatively longer occlusion balloon 44 is mounted to the proximal and distal catheter shafts 41a, 41c. The comparatively longer occlusion balloon 44 is configured to extend the range of partial occlusion because comparatively greater length L makes partial occlusion more gradual. In the fourth preferred embodiment, the occlusion balloon 44 has a length L of approximately thirty to one hundred millimeters (30-100mm) for occlusion of a typical patient’s aorta.

[0071] Referring to Figs. 13-15, fifth, sixth and seventh preferred occlusion catheter systems 50, 60, 70 have a similar constructions compared to the first, second, third and fourth preferred occlusion catheter systems 10, 20, 30, 40 and like reference numbers are utilized to identify like features of the fifth, sixth and seventh preferred occlusion catheter systems 50, 60, 70 with the numbers “5,” “6,” and “7” prefixes replacing the “1,” “2,” “3” and “4” prefixes, respectively to distinguish the features of the occlusion catheter systems 10, 20, 30, 40 of the first, second, third and fourth preferred embodiments from the occlusion catheter systems 50, 60, 70 of the fifth, sixth and seventh preferred embodiments. In the fifth, sixth and seventh preferred embodiments, the systems 50, 60, 70 include an offset occlusion balloon 54, 64, 74 mounted to the proximal catheter shaft 51a, 61a, 71a and the distal catheter shaft 51c, 61c, 71c. The offset occlusion balloons 54, 64, 74 could be utilized with any of the preferred occlusion catheter systems 10, 20, 30, 40, 50, 60, 70 described herein. The fifth, sixth and seventh preferred occlusion balloons 54, 64, 74 are designed and configured to strengthen the occlusion balloons 54, 64, 74 where they stretch the most. In the fifth preferred embodiment, the spine balloon 54y inhibits expansion of the oversized occlusion balloon 54x such that the lower part of the oversized occlusion balloon 54x stretches the most. This effect is caused by the

restraining nature of the non-compliant or semi-compliant spine balloon 54y limits the occlusion balloon 54x from growing in the direction toward the spine balloon 54y. In the sixth preferred embodiment, the occlusion balloon 64 is constructed of a compliant balloon 64, although the balloon 64 may also be non-compliant or semi-compliant, that is
5 designed and configured or blown such that the occlusion balloon 64 is offset relative to the longitudinal axis defined by the proximal and distal catheter shafts 61a, 61c and the hypotube 61b. In the seventh preferred embodiment, the occlusion balloon 74 is constructed of a non-compliant or semi-compliant oversized and offset occlusion balloon 74x and an adjacent spine balloon 74y. The oversized occlusion balloon 74x is designed
10 and configured to be offset from the longitudinal axis defined by the proximal and distal catheter shafts 71a, 71c and the spine balloon 74y is positioned on the limited diameter side of the oversized occlusion balloon 74x.

[0072] Referring to Figs. 16-18, an eighth preferred occlusion catheter system 80 has a similar construction to the first, second, third, fourth, fifth, sixth and seventh preferred
15 occlusion catheter systems 10, 20, 30, 40, 50, 60, 70 and like reference numbers are utilized to identify like features of the eighth preferred occlusion catheter system 80 with a number “8” prefix replacing the “1,” “2,” “3,” “4,” “5,” “6,” and “7” prefixes to distinguish the features of the occlusion catheter systems 10, 20, 30, 40, 50, 60, 70 of the first, second, third, fourth, fifth, sixth and seventh preferred embodiments from the
20 occlusion catheter system 80 of the eighth preferred embodiment.

[0073] In the eighth preferred embodiment, the occlusion balloon 84 has a proximal end 84p and a distal end 84d. To connect the balloon 84 to the proximal catheter 81a and the distal catheter 84c, the balloon proximal end 84p is butt welded to the proximal catheter 81a (Fig. 17) and the balloon distal end 84d is butt welded to the distal catheter
25 81c (Fig. 18). Butt welding the balloon proximal and distal ends 84p, 84d to the proximal and distal catheters 81a, 81c maintains an outer diameter D_o of the catheter to limit the size of the insertion sheath 18 required for introducing the catheter system 80 into the patient. The outer diameter D_o is preferably small enough for insertion into the introducer sheath or insertion catheter 18 having an inner introducer diameter of seven
30 French gauge (7 Fr) or less, such as six French gauge (6 Fr). The seven French (7 Fr) or smaller introducer sheath 18 typically results in the access site through the patient’s skin

and into the vessel 3 being closed by holding manual pressure for a period of time, such as twenty to thirty minutes (20-30 min). If the introducer sheath 18 has the introducer diameter D_R greater than seven French (7 Fr), a surgical repair of the access site may be required, thereby further complicating the procedure. In the first preferred embodiment, the outer diameter D_O of the proximal catheter shaft 11a and the distal catheter shaft 11c are six French gauge (6 Fr) or less to accommodate sliding through the insertion sheath 18 having the inner diameter of seven French gauge (7 Fr) with the occlusion balloon 14 in the folded configuration and retained by the peel away sheath 25 at a diameter of approximately seven French gauge (7 Fr) or less. The outer diameter D_O of six French gauge (6 Fr) or less in combination with the seven French gauge (7 Fr) introducer sheath inner diameter provides an annular space between the proximal catheter shaft 11a and the introducer sheath 18. If the annular gap is flushed and prepared with saline solution, the annular gap facilitates use of fluid column pressure monitoring for measuring blood pressure below the occlusion balloon 14, near the terminus of the introducer sheath 18, if a side arm or port 99 of the introducer sheath 18 is connected to a pressure sensor or monitor 98. The additional pressure monitor (not shown in Fig. 1E) permits the surgeon or medical personnel to measure pressure separate from the pressure sensors 15a, 15b that are on the occlusion catheter system 10. The occlusion catheter system 10 may also include a pressure monitor 98 that is in fluid communication with the hypotube lumen 9a through the arterial line extension line 12b to measure pressure head.

[0074] In addition, the butt welding also facilitates maintaining an inner diameter D_i of the proximal catheter 81a such that flow of inflation medium through the space or proximal lumen between the hypotube 81b and the proximal catheter 81a is not limited or constricted at the connection of the balloon proximal end 84p and the proximal catheter shat 81a. At the proximal side of the balloon 84, the balloon proximal end 84p is preferably positioned against the distal end of the proximal catheter 81a and butt welded with the hypotube 81b positioned within a lumen within the proximal catheter 81a and the balloon proximal end 84p that facilitates flow of the inflation medium into and out of the balloon 84. At the distal side of the balloon 84, the balloon distal end 84d is preferably positioned against the proximal end of the distal catheter 81c and butt welded with the balloon distal end 84d. The distal catheter 84c and the distal balloon end 84d are

also both preferably in facing engagement with and secured, potentially lap welded, to the hypotube 81b to prevent inflation fluid from escaping the distal end of the balloon 84. Minimizing restriction of the lumen between the lumens within the proximal catheter shaft 81a and the balloon proximal end 84p and the hypotube 81b is preferred to facilitate rapid inflation or filling of the balloon 84 with the inflation medium without causing the pop-off or pressure-relief valve 16 to open prematurely, while also maintaining at low profile of the catheter and facilitating rapid deflation of the balloon 84, if necessary.

[0075] The eighth preferred occlusion catheter system 80 may also include a relatively thin reinforcement band 84z that overlaps the butt weld at the connection between the proximal catheter 81a and the balloon proximal end 84p to increase strength and rigidity of the connection without significantly adding to the profile or outer diameter D_o of the catheter system 80 at the proximal end of the balloon 84 and of the distal catheter shaft 81c. The reinforcement band 84z may also be utilized at the distal end of the balloon 84 at the butt weld between the distal catheter shaft 81c and the balloon distal end 84d. The outer diameter D_o is preferably six French gauge (6 Fr) or less for insertion through the seven French gauge (7 Fr) inner diameter of the introducer sheath 18 to utilize the gap between the outer diameter D_o and the inner diameter of the introducer sheath 18 for fluid column pressure monitoring. The diameter at the reinforcement band 84z and the occlusion balloon 14 in the folded configuration is less than seven French gauge (7 Fr) for insertion through the seven French gauge (7 Fr) introducer sheath 18.

[0076] Referring to Figs. 1-6, the occlusion catheter system 10 of the first preferred embodiment is designed to fully or partially occlude the vessel 3 having a vessel diameter D_v accessed with an introducer sheath 18 having an inner introducer diameter D_R of seven French gauge (7 Fr) or less, such as six French gauge (6 Fr). In the first preferred embodiment, the introducer sheath 18 is comprised of a substantially cylindrical sheath that may have a sharpened distal end for insertion through the patient's skin into the vessel 3 and may have a flared or funnel-shaped proximal end for receipt of the straightened P-tip 13, distal catheter shaft 11c, folded occlusion balloon 14, and proximal catheter shaft 11a during the insertion and placement process. The occlusion balloon 14 preferably has a limited thickness to accommodate low-profile the folded configuration for insertion through the seven or six French gauge (7 or 6 Fr) introducer sheath 18 when

folded over the central shaft 11b. In the preferred embodiment, the inner introducer diameter D_R of the seven French gauge (7 Fr) introducer sheath 18 is approximately two and thirty-three hundredths millimeters (2.33 mm) and the inner introducer diameter D_R of the six French gauge (6 Fr) introducer sheath 18 is approximately two and zero

5 hundredths millimeters (2.00 mm). The inner introducer diameter D_R is preferred to minimize the puncture in the patient's skin and vessel 3 and to simplify the procedure, as use of introducer sheath's 18 with inner introducer diameters D_R greater than seven French gauge (7 Fr) typically requires additional and specialized medical personnel. The vessel diameter D_v of zones I and III of over ninety-nine percent (99%) of typical

10 patient's is approximately twenty-six millimeters (26 mm) or less such that the balloon blown diameter D of approximately twenty-five to thirty-five millimeters (25-35 mm) and more preferably thirty millimeters (30 mm) will result in full occlusion of the vessel 3 when the semi-compliant occlusion balloon 14 is inflated to the balloon blown diameter D .

15 **[0077]** The proximal catheter shaft 11a preferably includes a proximal lumen therein formed between inner surfaces of the proximal catheter shaft 11a and outer surfaces of the central shaft 11b. The proximal lumen is preferably in fluid communication with an inflation cavity 14b inside the balloon 14 wherein pressurized fluid is received to blow-up the occlusion balloon 14 during use or to transform the occlusion balloon 14 from the

20 folded configuration, wherein the folded occlusion balloon 14 is folded around the central shaft 11b for insertion through the introducer sheath 18, and the inflated or partially inflated configurations, wherein the occlusion balloon 14 occludes, typically when inflated to the diameter of the blood vessel 3 when the vessel 3 provides an opposition force to further expansion of the occlusion balloon 14, or partially occludes the vessel 13,

25 typically when the folds 14a are retained in the semi-inflated configurations.

[0078] The central shaft or hypotube 11b is positioned partially within the proximal lumen of the proximal catheter shaft 11a, thereby defining the proximal lumen for introduction of the inflation fluid and to provide strength and stiffness to the system 10. The central shaft or hypotube 11b may be substantially solid from its proximal to its

30 distal end or may include the hypotube lumen extending therethrough for pressure measurement by pressure head, introduction of medications to the distal end of the

system 10 or otherwise for access through the hypotube lumen to the distal end of the system 10 beyond the occlusion balloon 14 during operation when the occlusion balloon 14 is inflated. The central shaft or hypotube 11b extends beyond the distal end of the proximal catheter shaft 11a for connection to the distal catheter shaft 11c and spans through the inflation cavity 14b. The hypotube lumen may also be configured for introduction of a guidewire for placement of the catheter system 10 in the patient's vessel 13.

[0079] In the first preferred embodiment, the proximal catheter shaft 11a includes depth markings 33 on an outer surface. The depth markings 33 may be comprised of hashes or line marks at predetermined distances on the length of the proximal catheter shaft 11a, such as markings at every inch or centimeter along the outer surface of the proximal catheter shaft 11a. The depth markings 33 may alternatively be comprised of zone markings, such as zone I and zone III representing locations in the patient's vessel 3, typically the aorta, wherein the occlusion balloon 14 is likely positioned during use. The preferred location of the occlusion balloon 14 in zone I preferably extends from the original of the left subclavian artery to the coeliac artery, zone II preferably extends from the coeliac artery to the most caudal renal artery and zone III preferably extends distally from the most caudal renal artery to the aortic bifurcation.

[0080] The inflation hub 12 of the preferred embodiment is connected to a proximal end of the proximal catheter shaft 11a and to a proximal end of the central shaft or the hypotube 11b. The inflation hub 12 includes a balloon extension line 12a and an arterial line extension line 12b that are positioned generally proximally on the catheter. The balloon extension line 12a and the arterial line extension line 12b are preferably comprised of medical tubing with pressure relief fitting and a balloon valve 12c and a monitor valve 12d thereon, respectively. A syringe or other pressurization device may be attached to the pressure relief fitting of the balloon extension line 12a and the arterial line extension line 12b to pressurize the occlusion balloon 14 or connect to the hypotube lumen 9b through the arterial line extension line 12b. The balloon extension line 12a is in fluid communication with the proximal lumen 9a between the inner surfaces of the proximal catheter shaft and the central shaft 11b and the inflation cavity 14b. The balloon extension line 12a also includes the pressure relief valve 16 thereon that is

positioned proximally relative to the balloon valve 12c, such that the inflation or balloon valve 12c is positioned closer to the occlusion balloon 14 than the pressure relief valve 16. In operation, the pressure relief valve 16 will release inflation fluid pressure only during inflation of the occlusion balloon 14 when the balloon valve 12c is open. The pressure relief valve 16, therefore, does not operate when the balloon valve 12 is closed. The pressure relief valve 16 is preferably comprised of a ball valve that seats on an O-ring and is urged onto the O-ring by a spring for appropriate sealing when the pressure relief valve 16 is not intended to be in the open position.

[0081] In the first preferred embodiment, the occlusion balloon 14 has a proximal end 20a and a distal end 20b. The proximal end 20a is connected to proximal catheter shaft 11a and the distal end 20b is connected to the distal catheter shaft 11c. The occlusion balloon 14 preferably has the blown diameter D of approximately twenty-five to thirty-five millimeters (25-35 mm). The occlusion balloon 14 is positioned in a folded configuration wherein the occlusion balloon 14 is folded around the central shaft or hypotube 11b and an inflated configuration wherein the occlusion balloon 14 is expanded to the blown diameter D. The occlusion balloon 14 is in the folded configuration, the distal catheter shaft 11c and the proximal catheter shaft 11a are movable through the introducer sheath 18 for introduction into the vessel 3. The relatively large occlusion balloon 14, preferably between twenty-five to thirty-five millimeters (25-35 mm), in the folded configuration is insertable through the introducer sheath 18 having the inner introducer diameter D_I of seven French gauge (7 Fr) or less. The procedure to occlude the vessel 3 is substantially less invasive and complicated when utilizing the introducer sheath 18 having the inner introducer diameter D_I of seven French gauge (7 Fr) or less.

[0082] In the preferred embodiment, a peel-away sheath 25 is pre-positioned over the occlusion balloon 14 in the folded configuration to maintain the folded configuration. The pressure relief valve 16 is preferably primed before use by attaching an inflation syringe to the pressure relief fitting of the balloon extension line 12a, opening the balloon valve 12c and injecting inflation fluid until the pressure relief valve 16 opens or releases pressure. Since the peel-away sheath 25 is covering the occlusion balloon 14, the occlusion balloon 14 preferably does not inflate. Negative pressure on the syringe plunger will then be applied to remove the remaining fluid/air from the balloon lumen.

[0083] The pressure relief valve is a safety feature designed to open and vent inflation medium if the balloon is over-inflated. If the balloon is inflated properly (not over-inflated), the pressure relief valve will not need to open. If the valve does open due to over-inflation, it will shut automatically when the balloon lumen has vented sufficient volume.

[0084] This design may be used with a guidewire up to thirty-eight thousandths of an inch (0.038”) in diameter if desired. It is still designed to be used without a guidewire, but warnings regarding use with a guidewire will be removed.

[0085] The proximal and distal sensors 15a, 15b and potentially a pressure sensor within the occlusion balloon 14, preferably transmit signals to a controller or control hub 200 that may be incorporated into the inflation hub 12 and the pressures are preferably displayed as pressure readings on a display screen or display screens mounted to the occlusion catheter system 10, preferably on the control hub 200 or the inflation hub 12. The control hub 200 is preferably mounted on a proximal portion of the inflation hub 12 and includes the integrated LCD screen to display the pressures from the pressure sensors or other sensors 15a, 15b. The display screen of the control hub 200 may display the pulsatile blood pressures 201, 202, 203, 204 above and/or below the occlusion balloon 14, an occlusion percentage 205 in the vessel 13 or other desired pressure, temperature, pH or related patient or system data acquired from the system 10. The control hub 200 may also include a guidewire orifice 206 that accommodated use of a guidewire. The control hub 200 also preferably includes a power button 207 to turn the control hub 200 off and on during use. The balloon extension line 12a also preferably extends from the control hub 200. The control hub 200 may be configured, operate and function similarly to the control hub described in U.S. Patent Application No. 15/573,054, published as U.S. Patent Application Publication No. 2019/0076152 and titled, “System and Method for Low Profile Occlusion Balloon Catheter,” which is incorporated herein by reference in its entirety, particularly with respect to the control hub.

[0086] Monitoring the pressures displayed on the display screen allows the user to observe blood pressure responses to the various inflation configurations of the occlusion balloon 14, in real time and in a convenient location, as the pressurization of the occlusion balloon 14 is modified. The positioning of the control hub 200 on the inflation

hub 12 with the display screen thereon is preferred, versus a vital monitor that may or may not be conveniently located relative to the procedure for observation by the technician or physician. The display of the pressures from the pressure sensors or other sensors 15a, 15b on the display screen with a localized signal processor acts as a means
5 for open-loop feedback of the occlusion catheter system 10. The displays may display the pressure inside the occlusion balloon 14 from an internal balloon pressure sensor, the pressure proximally of the occlusion balloon 14 from the proximal pressure sensor 15a and the pressure distally of the occlusion balloon 14 from the distal pressure sensor 15b. The proximal and distal sensors 15a, 15b are not limited to pressure sensors and may be
10 comprised of alternative sensors for acquiring data related to the system 10 or the patient, such as temperature, pH, flow rate and related data. The sensor data may also be transmitted to a central processor in a wired or wireless manner for depiction, manipulation and/or processing. For example, the collected data may be wirelessly transmitted to a remote central processor for storage and depiction on a larger display,
15 such as a television screen, tablet, vital sign monitor or related equipment for viewing by a larger audience, manipulation and recording or storage. The displays may also include other collected data or calculated information for the user, such as a pressure ratio between the distal and proximal pressure sensors 15a, 15b, an indication of the degree or percentage of occlusion of the vessel 3 based on an algorithm that uses the proximal and
20 distal pressures 15a, 15b to provide an approximation of the degree of occlusion. The degree of occlusion could be displayed as a percentage, on a scale, such as 1-5, as a dial gauge or in other manners that provide an estimation of the degree of occlusion to the user.

[0087] The control hub 200 on the inflation hub 12 preferably includes the controller and a power source. The power source is preferably comprised of a battery or batteries
25 stored in the control hub on the inflation hub 12 to power at least the display screen. The controller may include a circuit board to process signals, make calculations related to the collected data, control the operating components and perform related functions described herein.

30 **[0088]** In a non-limiting, preferred example, as conditions change within the patient with the occlusion balloon 14 positioned in the vessel 3 and in the partially or fully

inflated configurations, the partial and distal sensors 15a, 15b provide passive feedback to the practitioner to indicate the need for changes to the occlusion balloon's 14 volume to manage blood pressure distal and proximal to the occlusion balloon 14. If the occlusion balloon 14 is inflated in a constricted vessel 3, occlusion may be lost as the vessel 3
5 relaxes and the passive feedback can indicate to the practitioner that additional volume or pressure is required in the occlusion balloon 14 to maintain occlusion or a desired level of partial occlusion.

[0089] In operation in a non-limiting example, the controller 200 is preferably connected to the pressure sensors 15a, 15b and other sensors, as is described herein, for
10 management of the occlusion state of the occlusion balloon 14 in a closed loop configuration (full feedback). The controller 200 is powered on by depressing the power button 207 and can be set to maintain the distal and/or proximal pressures or the pressure ratio between the two by continually adjusting the volume or pressure of the fluid introduced into the occlusion balloon 14 using a preferably small, internal, locally
15 powered pump in the controller 200. The controller 200 may be set to maintain the proximal pressure measured by the proximal pressure sensor 15a at approximately zero when maintaining full occlusion and at a pressure greater than zero when maintaining partial occlusion through creation of the blood flow channels at the folds 14a. For partial occlusion, the controller 200 is preferably set to manage the pressure ratio or a pressure
20 ratio within a range, to maintain a user-specified amount of partial occlusion. The controller 200 may also be configured to permit the user to select a distal pressure setpoint that sets a desired pressure for the distal pressure sensor 15b, which is typically the upstream side of the occlusion balloon 14 when the system 10 is positioned in the artery or vessel 3, such as the aorta (Fig. 1E). The controller 200 preferably adjusts the
25 fluid volume in the occlusion balloon 14 until the setpoint is achieved. The controller 200 may also be based on a proximal side setpoint associated with the proximal pressure sensor 14a or a target degree of occlusion (i.e. a preferred percentage of occlusion or pressure ratio). The balloon valve 12c may be utilized to switch between a manual pressurization of the system 10, wherein pressure is manually introduced into and
30 withdrawn from the occlusion balloon 14 by the user, such as with a syringe 101, and the above-described closed loop feedback configuration, wherein the controller 200

substantially controls the pressure within the occlusion balloon 14.

[0090] In the preferred embodiment, the atraumatic tip or p-tip 13 has a generally circular profile and is flexible for positioning in the straightened insertion configuration from the biased circular profile. The atraumatic tip 13 is preferably secured to or co-molded with the distal catheter shaft 11c. The guiding atraumatic tip 13 may be employed with any of the preferred embodiments of the occlusion catheter system 10 described herein. The guiding atraumatic tip 13 is preferably comprised of a polymeric cylindrical or tubular member that has a distal section formed into a generally flattened cylinder having two generally planar opposing surfaces and two generally curved opposing surfaces. The two generally planar opposing surfaces include an inner planar surface and an outer planar surface. The atraumatic tip 13 has a distally extending section that projects distally from the distal catheter shaft 11c and a curved section continuous with the distally extending section that curves away from the central longitudinal axis of the occlusion catheter system 10, then proximally toward the occlusion balloon 14 and subtends a generally circular arc toward the central longitudinal axis of the occlusion catheter system 10. The angle of the curvature may be between about one hundred eighty degrees (180°) and three hundred fifty-five degrees (355°), more preferably between about two hundred seventy degrees (270°) and three hundred fifty degrees (350°) and even more preferably between about three hundred degrees (300°) and three hundred fifty degrees (350°) such that a gap is provided between the terminal end of the generally cylindrical flattened distal section and the more proximal surface of the atraumatic tip 13. The distally extending section and curved section may alternatively be formed as a generally in-plane circular shape or may be formed as an out-of-plane generally helical shape, where a terminal end of the curved section is laterally displaced from the central longitudinal axis of the occlusion catheter system 10. In this manner, the generally flattened distal section is characterized by a generally circular profile

[0091] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and

scope of the present invention as defined by the present description.

CLAIMS

We claim:

1. An occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter, the occlusion catheter system comprising:
 - 5 a proximal catheter shaft having a proximal lumen;
 - a central shaft positioned partially within the proximal lumen and spaced from the proximal catheter shaft;
 - a distal catheter shaft attached to a distal end of the central shaft; and
 - an occlusion balloon having a proximal end and a distal end, the occlusion
 - 10 balloon connected at the proximal end to the proximal catheter shaft and at the distal end to the distal catheter shaft, the occlusion balloon configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces, the occlusion balloon positionable in a folded configuration around the central shaft, the proximal catheter
 - 15 shaft, the distal catheter shaft and the occlusion balloon in the folded configuration having an outer diameter less than seven French gauge.
2. The occlusion catheter system of claim 1, wherein the occlusion balloon is comprised of a non-compliant balloon.
3. The occlusion catheter system of claim 1, wherein the occlusion balloon is
- 20 comprised of a semi-compliant balloon.
4. The occlusion catheter system of claim 1, wherein the occlusion balloon is comprised of a compliant balloon.
5. The occlusion catheter system of claim 1, further comprising:
 - an inflation hub connected to a proximal end of the proximal catheter shaft and to
 - 25 a proximal end of the central shaft.
6. The occlusion catheter system of claim 4, further comprising:
 - a pressure relief valve attached to the inflation hub, the pressure relief valve in fluid communication with an inflation cavity of the occlusion balloon.

7. The occlusion catheter system of claim 1, wherein the occlusion balloon has a blown diameter greater than the vessel diameter.

8. An occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter accessed with an introducer sheath having an inner introducer diameter of seven French or less, the occlusion catheter system comprising:

- a proximal catheter shaft having a proximal lumen;
- a central shaft positioned partially within the proximal lumen;
- a distal catheter shaft attached to a distal end of the central shaft; and
- an occlusion balloon having a proximal end and a distal end, the proximal end connected to the proximal catheter shaft and the distal end connected to the distal catheter shaft, the occlusion balloon having a blown diameter of approximately twenty-five to thirty-five millimeters (25-35 mm), the occlusion balloon positionable in a folded configuration wherein the occlusion balloon is folded around the central shaft and an inflated configuration wherein the occlusion balloon is expanded to the blown diameter, the distal catheter shaft, the occlusion balloon in the folded configuration and the proximal catheter shaft movable through the introducer sheath for introduction into the vessel.

9. The occlusion catheter system of claim 8, further comprising:

- an inflation hub connected to a proximal end of the proximal catheter shaft and to a proximal end of the central shaft, the inflation hub including a balloon extension line and an arterial line extension line, the balloon extension line in fluid communication with the proximal lumen, the proximal lumen in fluid communication with an inflation cavity of the occlusion balloon.

10. The occlusion catheter system of claim 9, wherein the balloon extension line includes an inflation valve and a pressure relief valve, the inflation valve positioned closer to the occlusion balloon than the pressure relief valve.

11. The occlusion catheter system of claim 9, wherein the central shaft is comprised of a hypotube, the hypotube including a hypotube lumen, the hypotube lumen in fluid communication with the arterial line extension line.

12. The occlusion catheter system of claim 8, wherein the occlusion balloon is configured to define flow channels with inner surfaces of the vessel at folds in the occlusion balloon when the occlusion balloon is partially inflated and in engagement with the inner surfaces.

5 13. The occlusion system of claim 12, wherein the occlusion balloon is configured to fully occlude the vessel and is in facing engagement with the inner surfaces in the inflated configuration.

14. The occlusion system of claim 8, wherein the proximal catheter shaft includes depth markings.

10 15. The occlusion system of claim 14, wherein the depth markings include a zone I range and a zone III range.

16. The occlusion system of claim 8, wherein the blown diameter is approximately thirty millimeters (30 mm).

15 17. An occlusion catheter system for full or partial occlusion of a vessel having a vessel diameter, the occlusion catheter system comprising:
a proximal catheter shaft having a proximal lumen;
a central shaft positioned partially within the proximal lumen and spaced from the proximal catheter shaft;
an inflation hub connected to a proximal end of the proximal catheter shaft and to
20 a proximal end of the central shaft, the inflation hub including a balloon extension line;
a distal catheter shaft attached to a distal end of the central shaft;
an occlusion balloon having an inflation cavity, a proximal end and a distal end,
the occlusion balloon connected at the proximal end to the proximal catheter shaft and at
the distal end to the distal catheter shaft, the occlusion balloon configured to define flow
25 channels with inner surfaces of the vessel at folds in the occlusion balloon when the
occlusion balloon is partially inflated and in engagement with the inner surfaces;
an inflation valve connected to the balloon extension line; and

a pressure relief valve connected to the balloon extension line, the pressure relief valve configured to release pressure from the inflation cavity below a rupture pressure of the occlusion balloon.

18. The occlusion catheter system of claim 17, wherein the occlusion balloon
5 has a blown diameter of approximately thirty millimeters.

19. The occlusion catheter system of claim 17, further comprising:
a pressure sensor attached to the occlusion catheter system.

20. The occlusion catheter system of claim 17, wherein the occlusion balloon
is comprised of a semi-compliant balloon.

10

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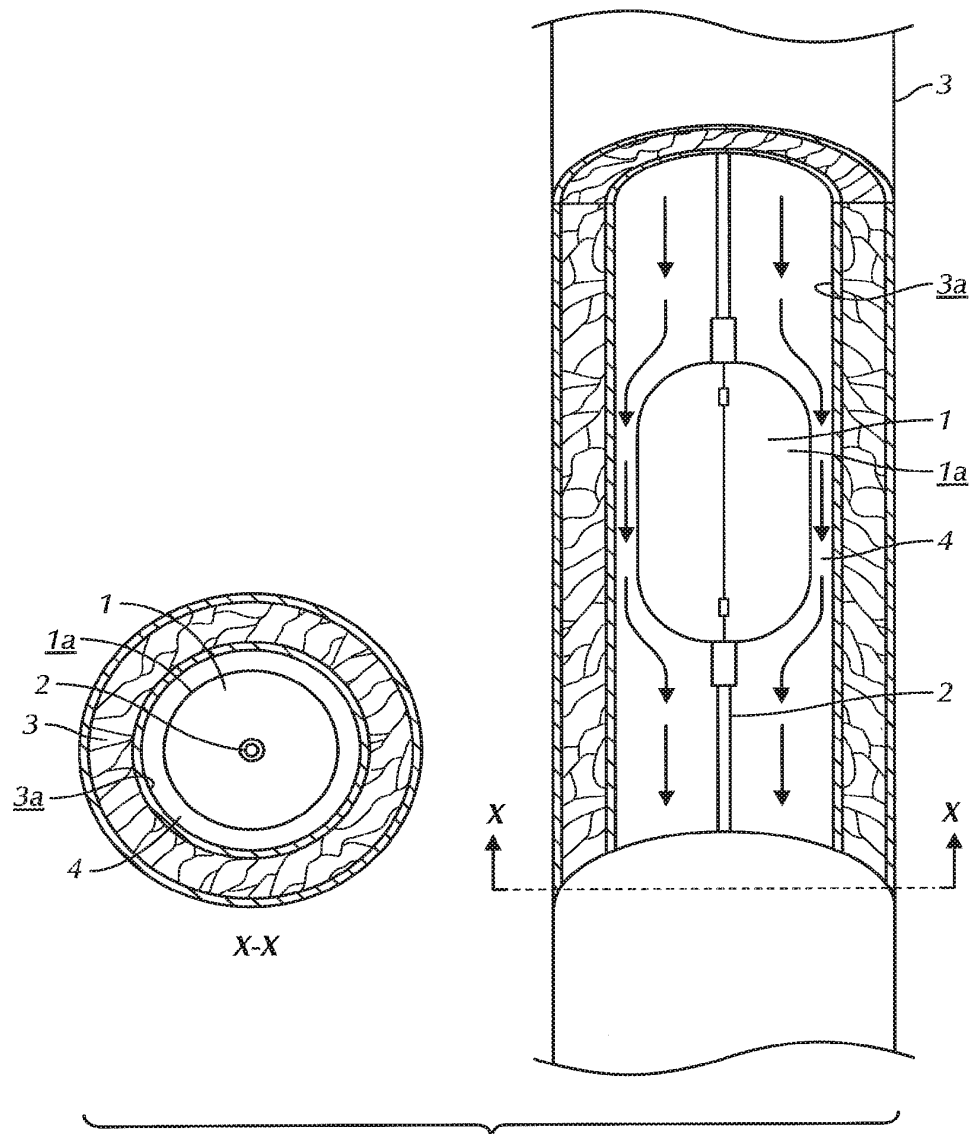


FIG. 1PA
(Prior Art)

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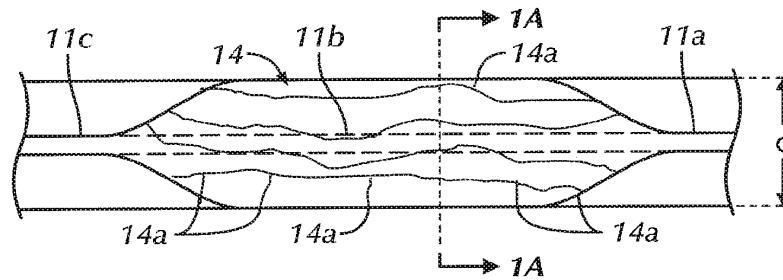


FIG. 1

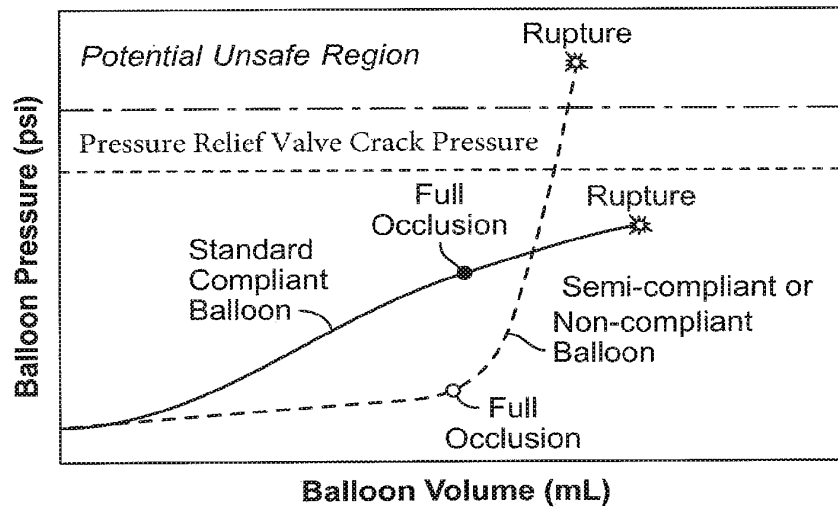


FIG. 2

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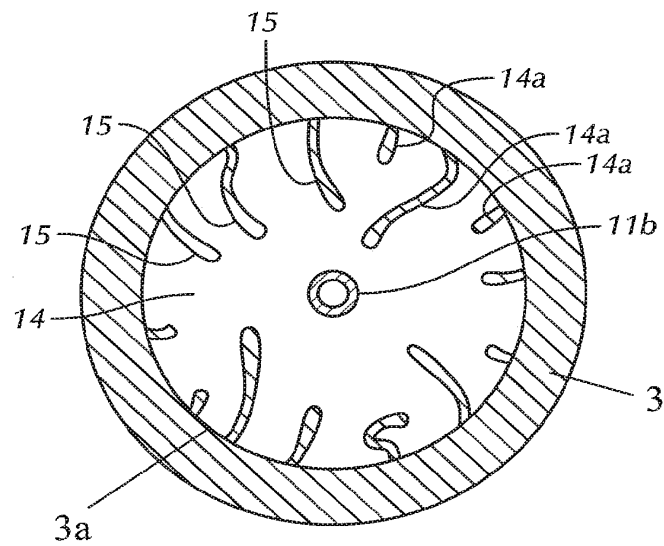


FIG. 1A

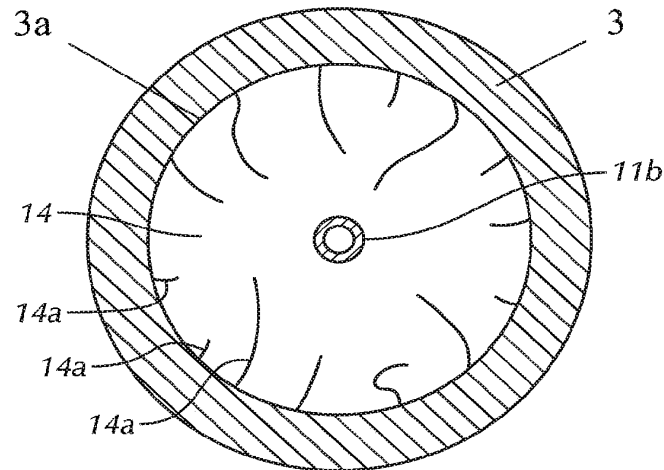
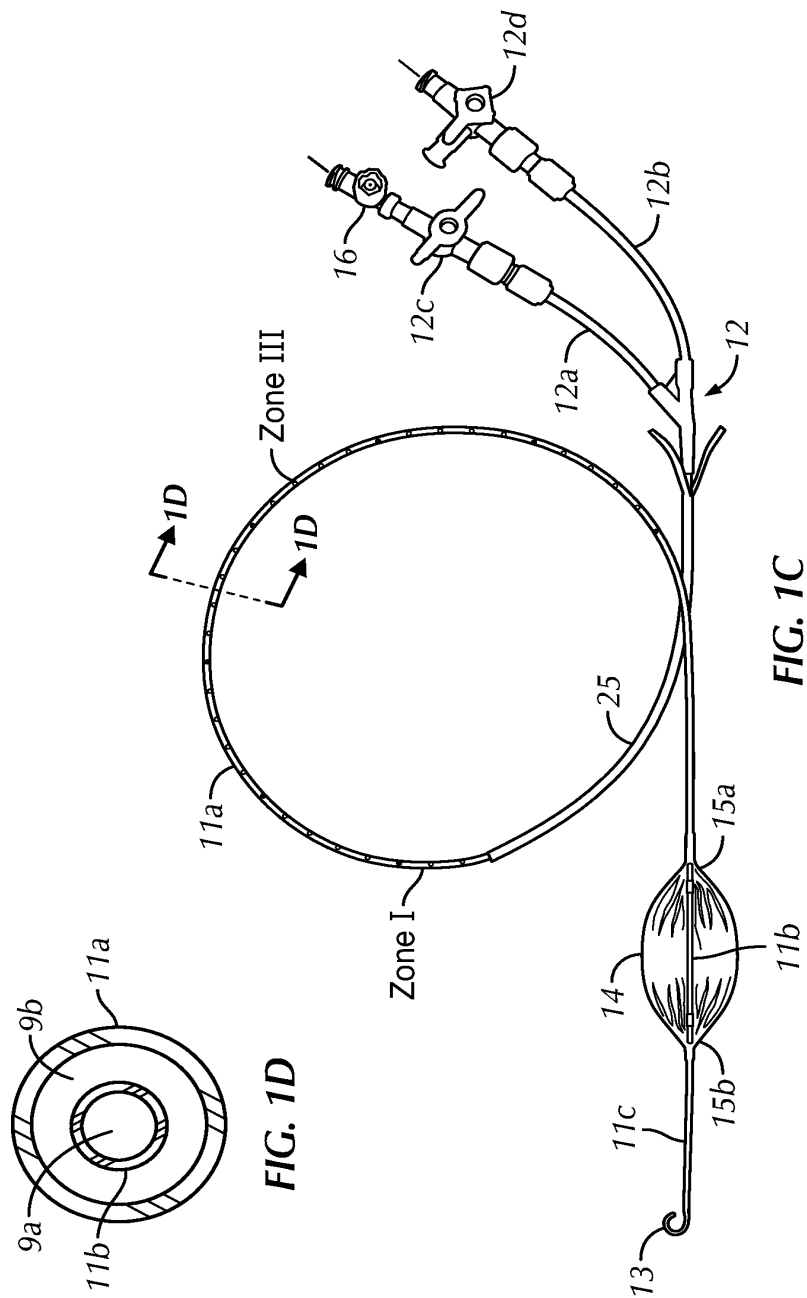


FIG. 1B



SUBSTITUTE SHEET (RULE 26)

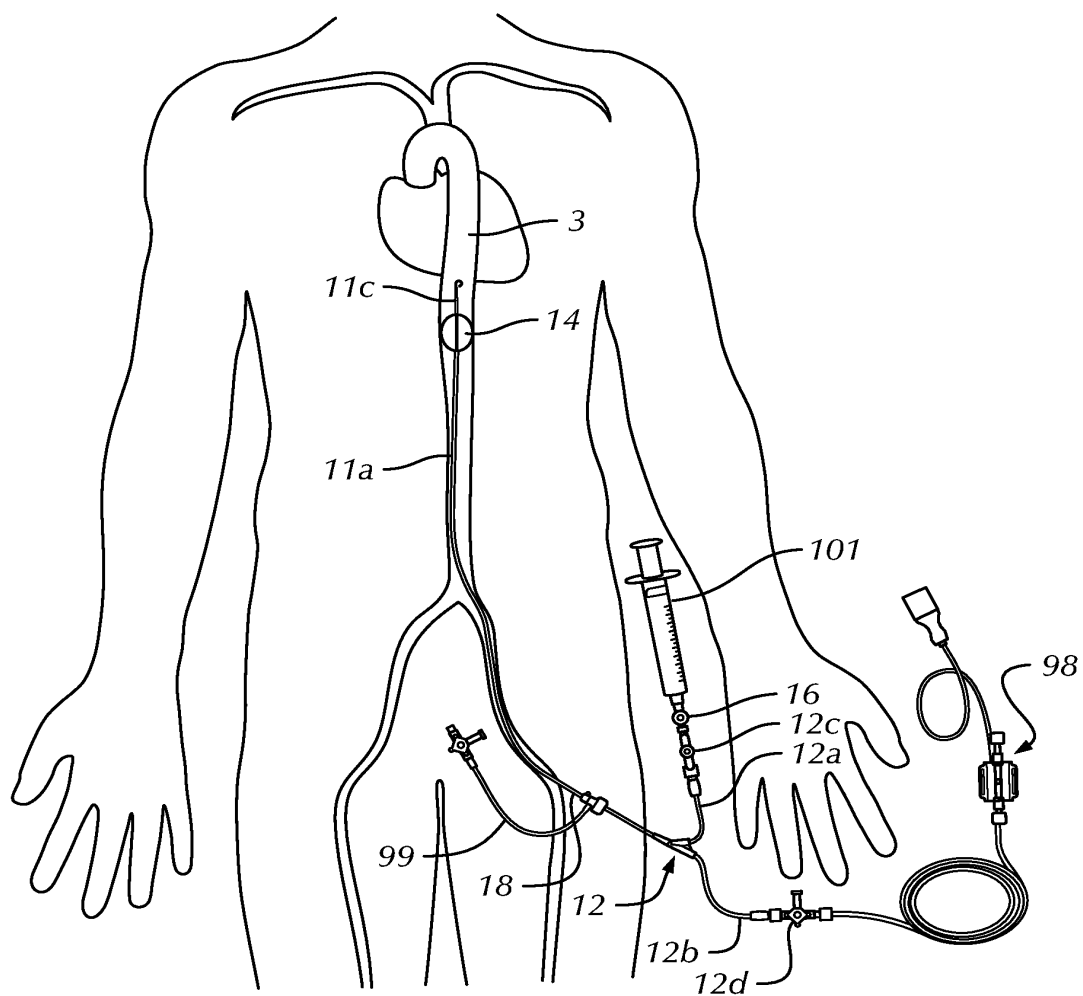
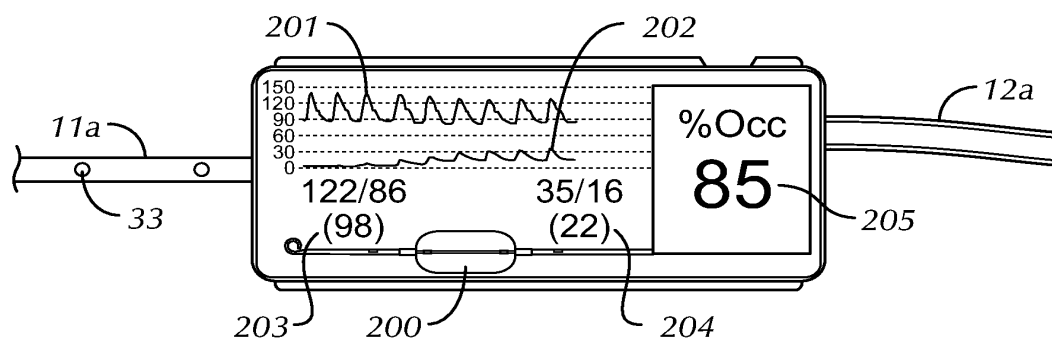
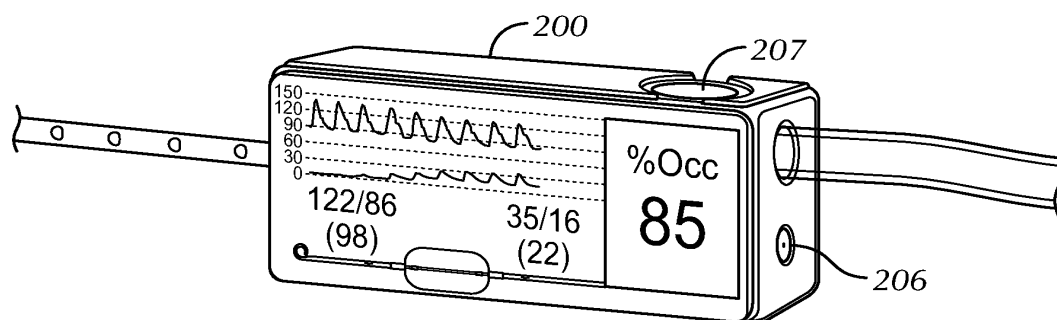


FIG. 1E

SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

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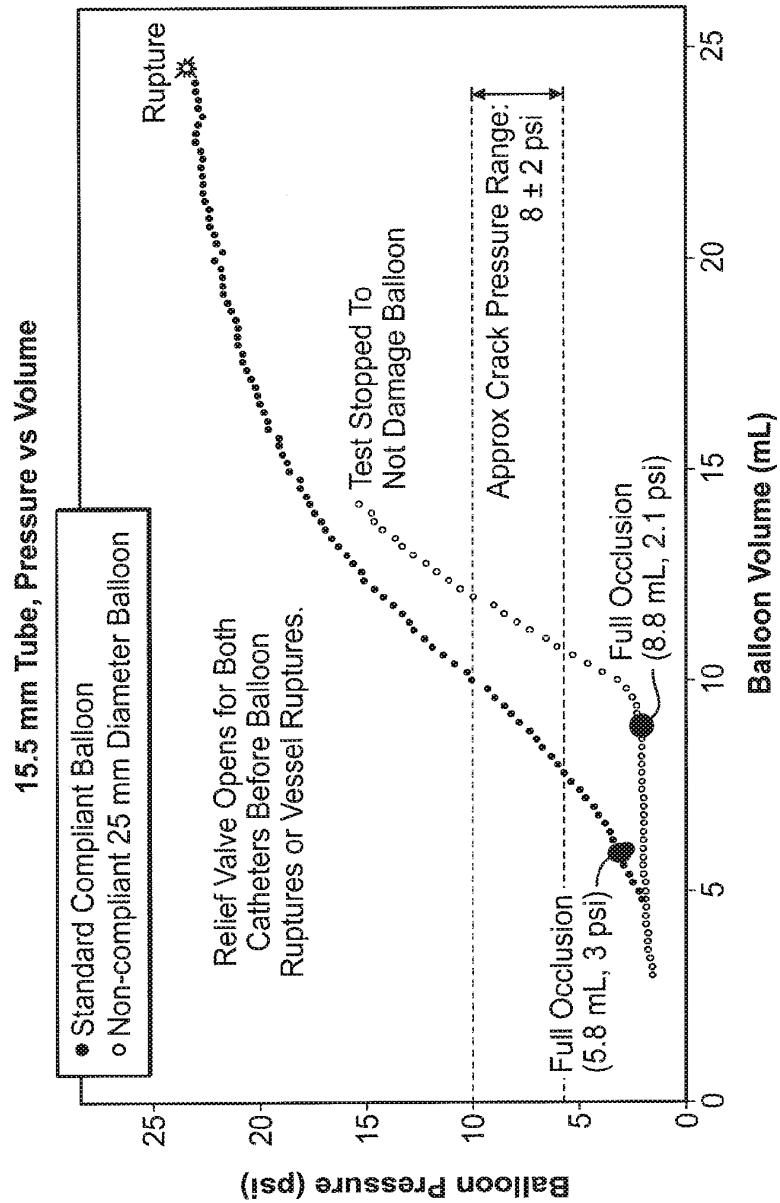


FIG. 2A

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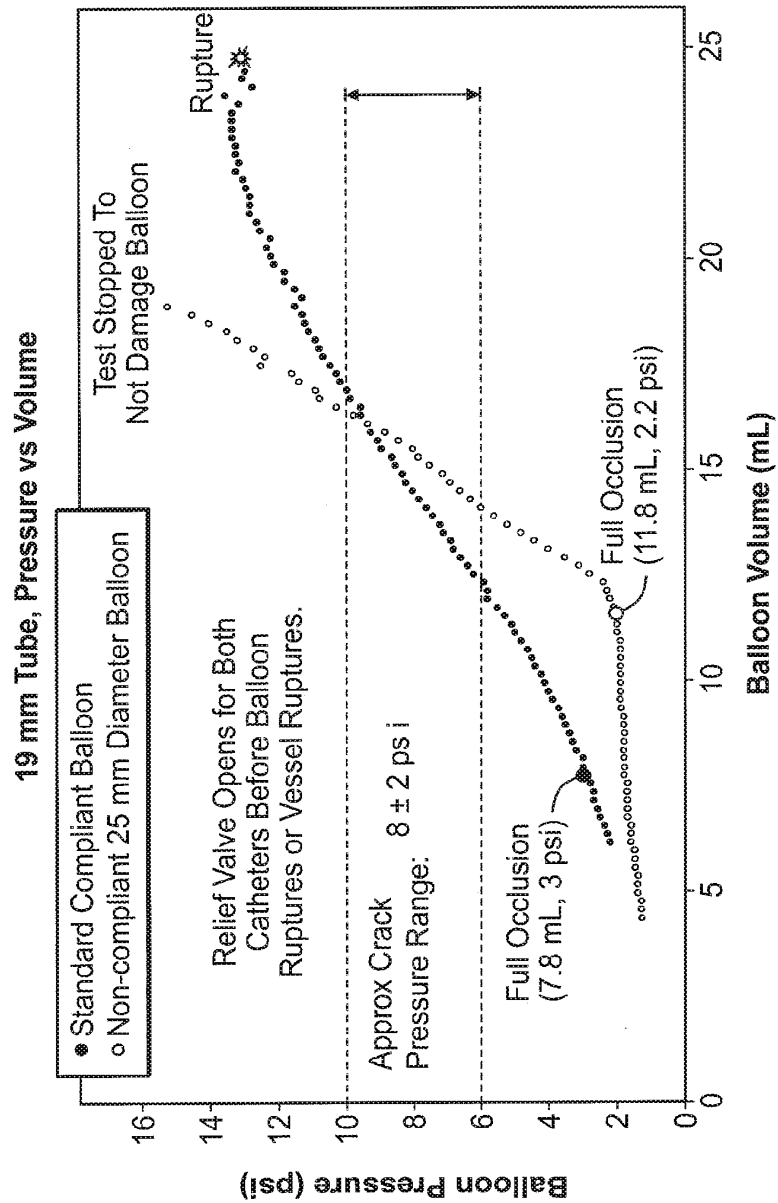


FIG. 2B

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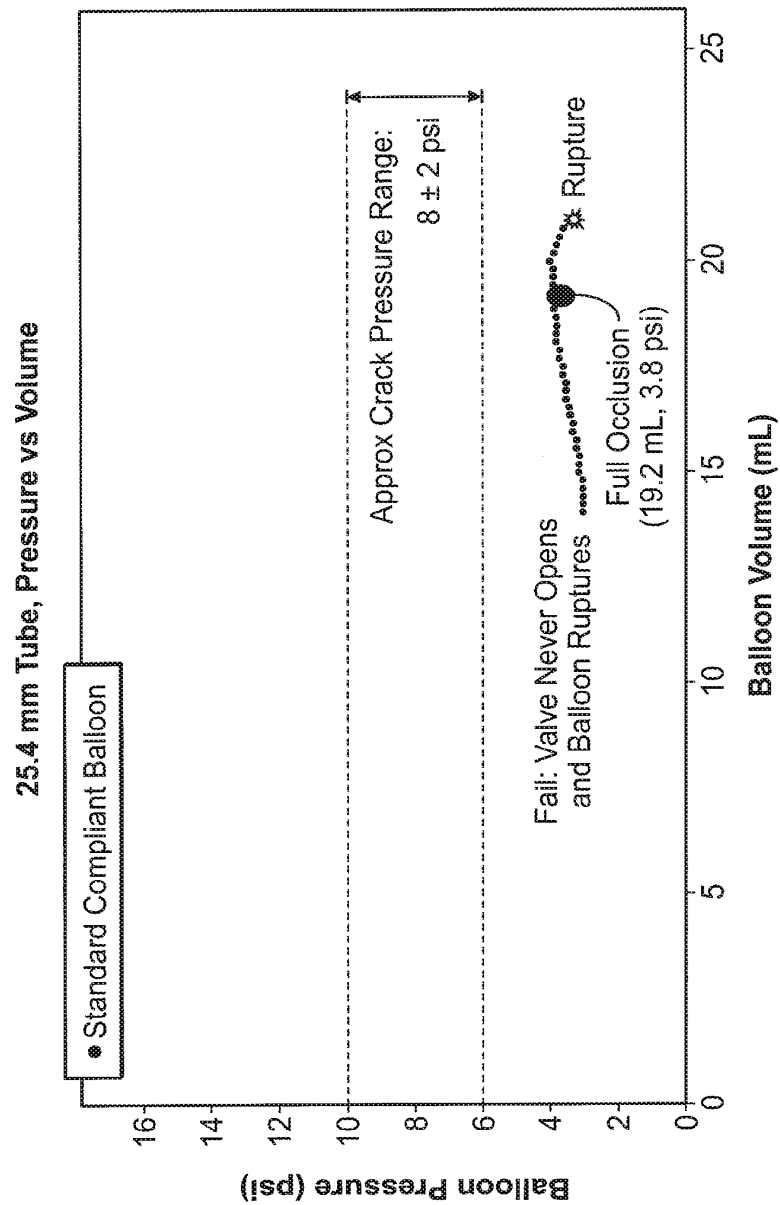


FIG. 2C

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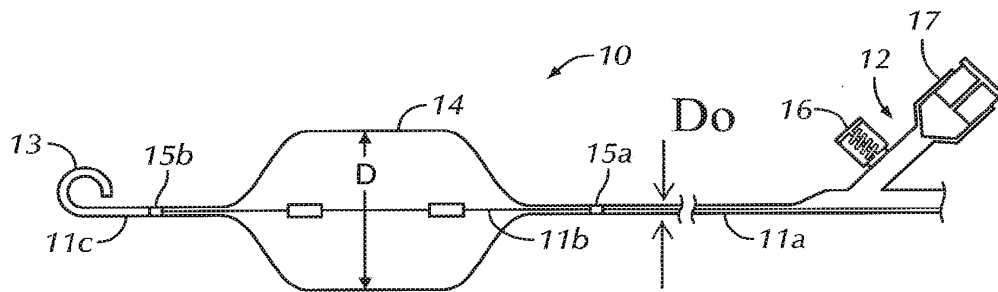


FIG. 3

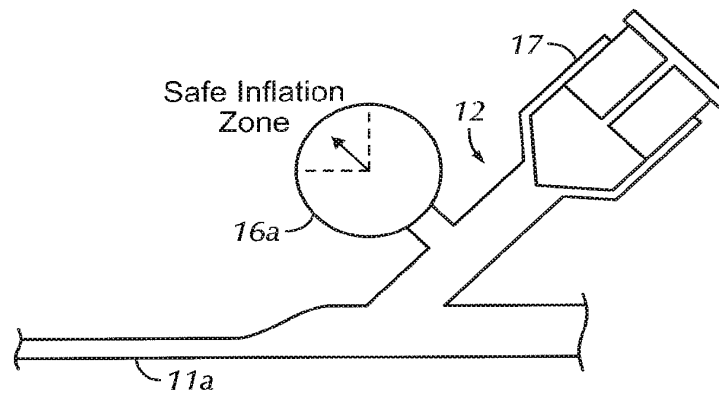


FIG. 4

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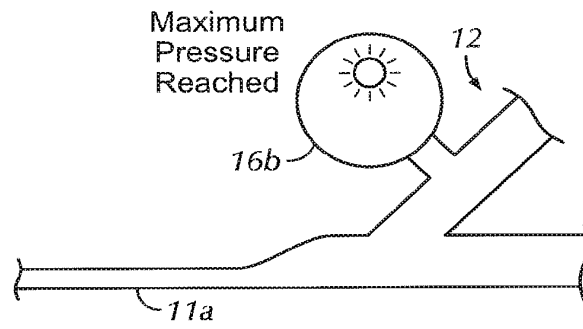


FIG. 5

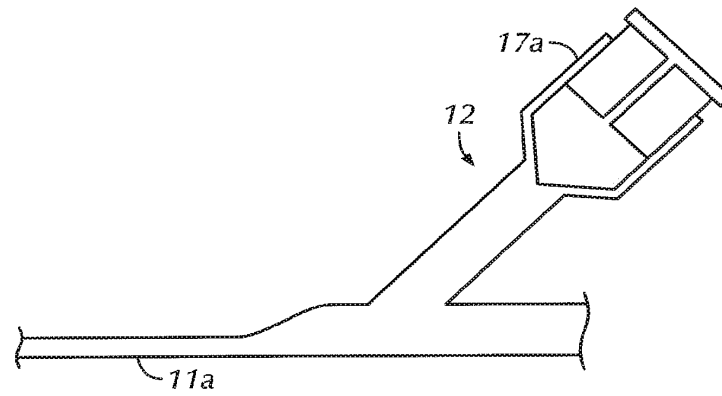


FIG. 6

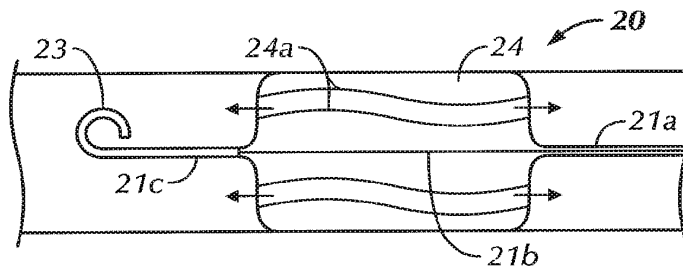


FIG. 7

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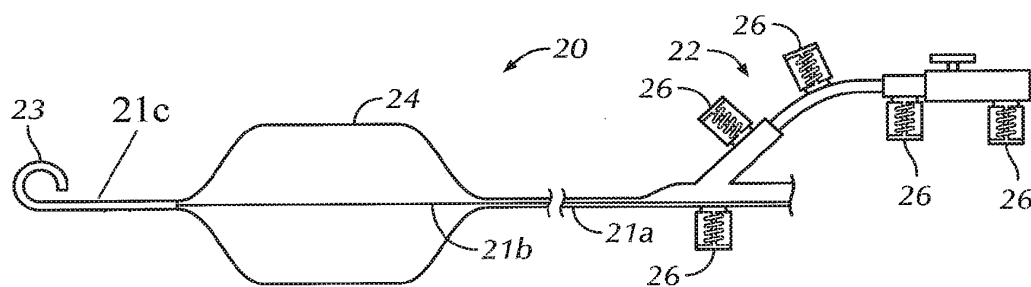


FIG. 8

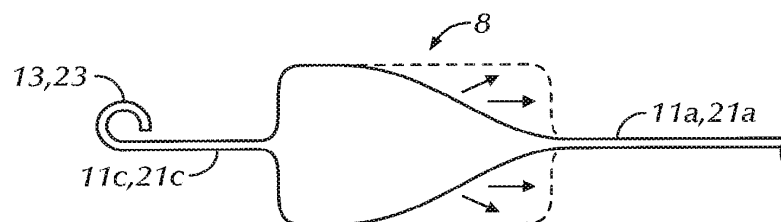


FIG. 9

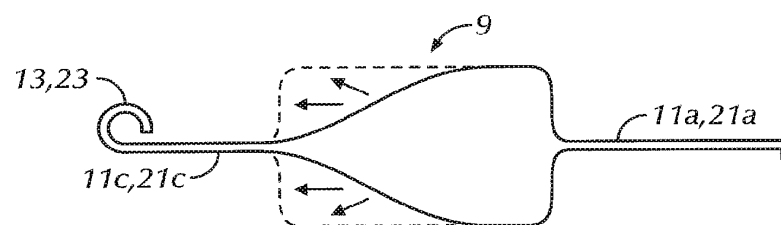


FIG. 10

13/16

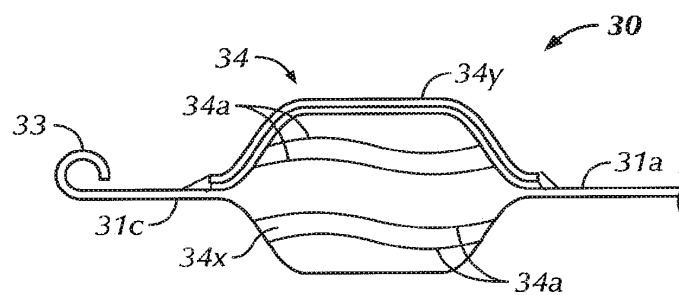


FIG. 11

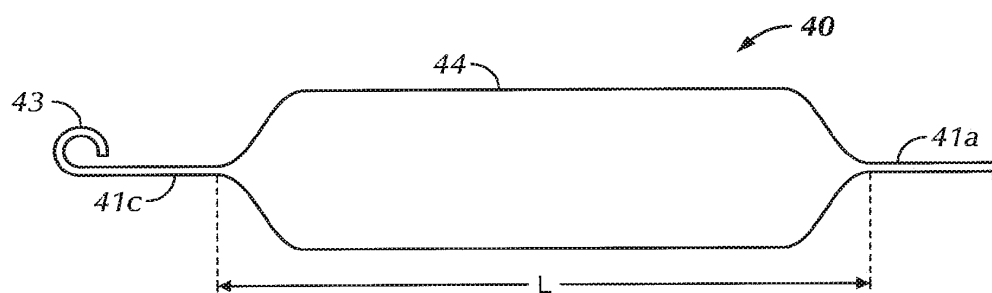


FIG. 12

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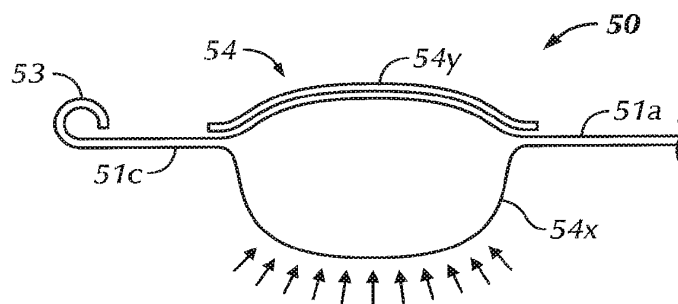


FIG. 13

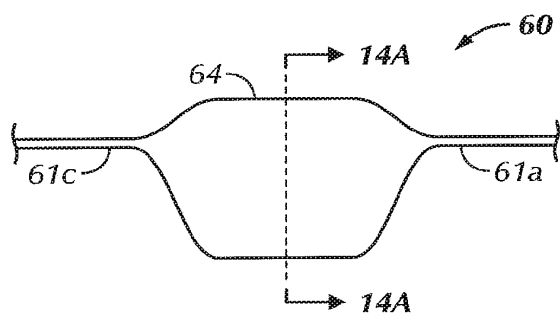


FIG. 14

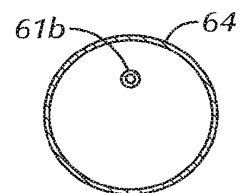


FIG. 14A

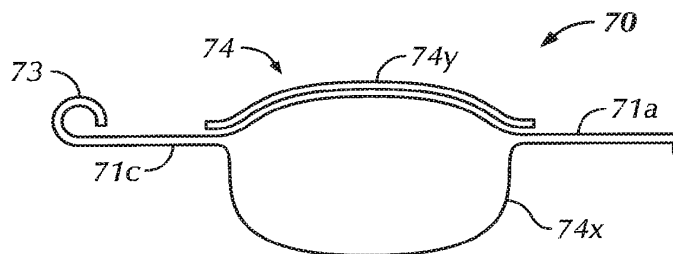


FIG. 15

15/16

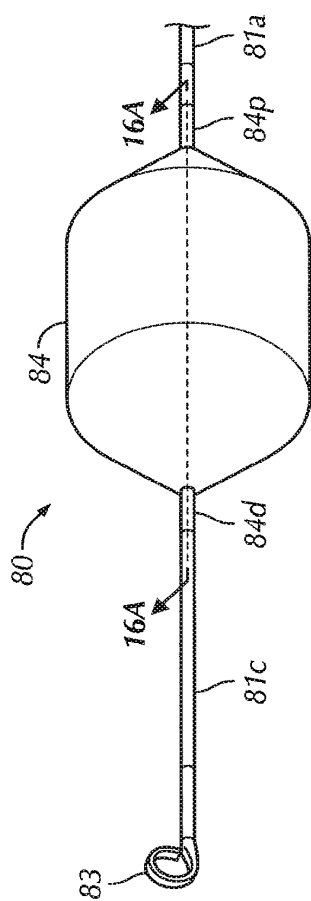


FIG. 16

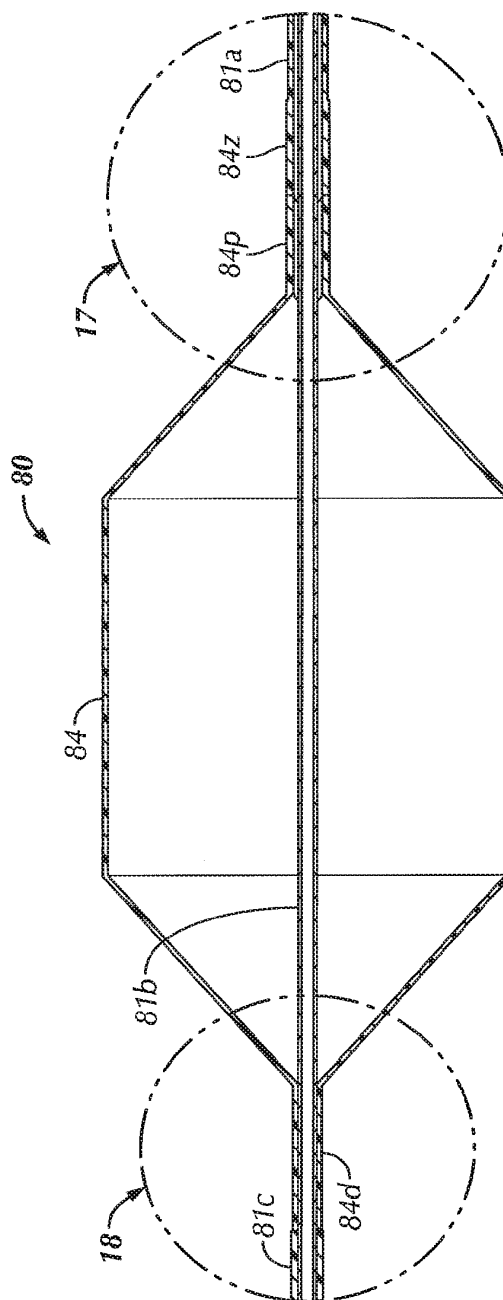


FIG. 16A

16/16

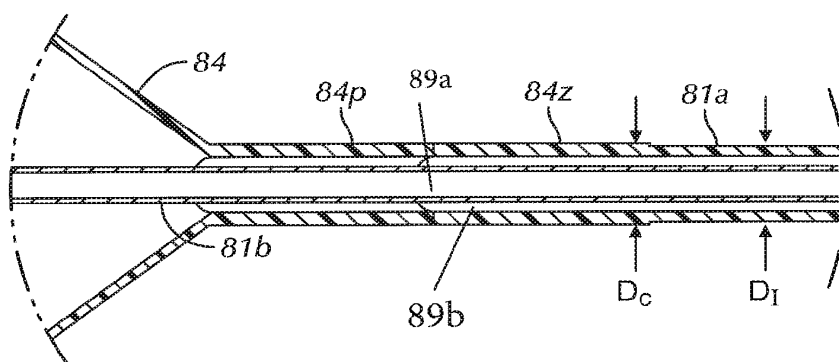


FIG. 17

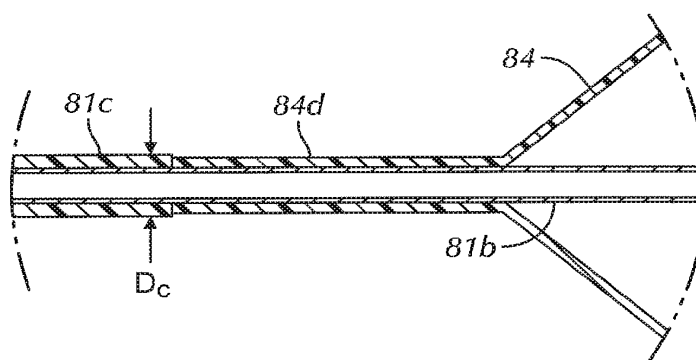


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US19/45252

A. CLASSIFICATION OF SUBJECT MATTER

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CPC - A61B 17/12036, 17/12109, 17/12136; A61M 25/1002

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/149653 A2 (PRYTIME MEDICAL DEVICES, INC.) 22 September 2016; paragraphs [0157], [0163]-[0164], [0170], [0227]; figures 1, 3-5	1-7
Y		8-20
Y	US 2014/0243873 A1 (PRYOR MEDICAL DEVICES, INC.) 28 August 2014; paragraph [0061]	8-20
A	WO 2017/210584 A1 (PRYTIME MEDICAL DEVICES, INC.) 07 December 2017; entire document	1-20
A	US 2008/0097300 A1 (ESKAROS, S et al.) 24 April 2008; entire document	1-20
A	US 2015/0272732/A1 (LOMA VISTA MEDICAL, INC.) 01 October 2015; entire document	1-20

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

30 September 2019 (30.09.2019)

Date of mailing of the international search report

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(54) Title: DUAL SENSOR SYSTEM FOR CONTINUOUS BLOOD PRESSURE MONITORING DURING TRANSCATHETER HEART VALVE THERAPIES

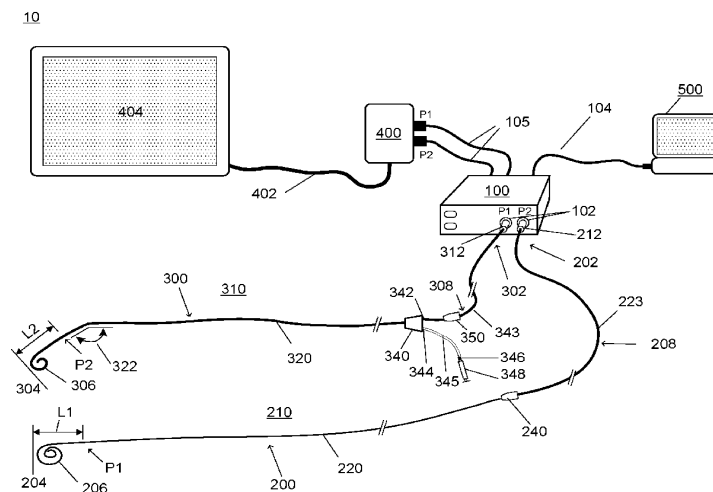


FIG. 1

(57) Abstract: Dual sensor system for continuous blood pressure monitoring during transcatheter heart valve therapies (TVT), such as transcatheter aortic valve replacement (TAVR) or transcatheter mitral valve replacement (TMVR), comprises a controller, a support guidewire for TVT containing a first Fabry-Pérot (FP) optical pressure sensor near its distal end, and a pigtail catheter for delivery of contrast medium containing a second FP optical pressure sensor near its distal end. For example, for TAVR, the support guidewire is positioned to place the first optical pressure sensor within the left ventricle (LV) for monitoring LV pressure, the pigtail catheter is positioned in the aorta to place the second optical pressure sensor in the ascending aorta for direct measurement of pressure in the aorta, downstream of the aortic valve, enabling continuous monitoring of blood pressure at both sensor locations during TAVR. The controller may be configured to interface with standard patient monitoring systems.

[Continued on next page]

HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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**DUAL SENSOR SYSTEM FOR CONTINUOUS BLOOD PRESSURE
MONITORING DURING TRANSCATHETER HEART VALVE THERAPIES**

CROSS-REFERENCE TO RELATED APPLICATIONS

5 [1] This application claims priority from United States provisional Patent Application 62/585,757, filed November 14, 2017, entitled “Dual Sensor System for Continuous Blood Pressure Monitoring During Transcatheter Heart Valve Therapies”, which is incorporated herein by reference in its entirety.

[2] This application is related to United States patent application No. 15/293,380, filed
10 October 14, 2016, entitled “System and Apparatus comprising a Multi-Sensor Catheter for Right Heart and Pulmonary Artery Catheterization”, which is a Continuation in Part of United States patent application No. 14/874,604, filed October 5, 2015 (now United States patent No. 9,504,392), which is a Continuation of United States patent application No. 14/354,624, filed April 28, 2014 (now United States patent No. 9,149,230), which is a
15 national stage entry of PCT International Application No. PCT/IB2012/055893, entitled “Apparatus, system and methods for measuring a blood pressure gradient”, filed October 26, 2012, which claims priority from United States Provisional patent application No. 61/552,778 entitled “Apparatus, system and methods for measuring a blood pressure gradient”, filed October 28, 2011 and from United States Provisional patent application No.
20 61/552,787 entitled “Fluid temperature and flow sensor apparatus and system for cardiovascular and other medical applications”, filed October 28, 2011.

[3] This application is related to United States patent application No. 15/001,347, filed January 20, 2016, entitled “System and Apparatus Comprising a Multisensor Guidewire for Use in Interventional Cardiology”, which is a Continuation-in-Part of PCT International
25 Application No. PCT/IB2015/055240, of the same title, filed July 10, 2015, designating the United States; this application is also related to United States patent application No. 15/326,134 filed January 13, 2017, which is a national stage entry of PCT International Application No. PCT/IB2015/055240; PCT/IB2015/055240 claims priority from United States Provisional patent application No. 62/023,891, entitled “System And Apparatus

Comprising a Multisensor Support Guidewire for Use in Trans-Catheter Heart Valve Therapies”, filed July 13, 2014 and from United States Provisional patent application No. 62/039,952, entitled “System and Apparatus Comprising a Multisensor Support Guidewire for Use in Trans-Catheter Heart Valve Therapies”, filed August 21, 2014.

5 TECHNICAL FIELD

[4] The present invention relates to a system and apparatus for continuous monitoring of blood pressure using optical pressure sensors contained within a guidewire or a catheter for minimally invasive interventional cardiology, including real-time blood pressure measurements during transcatheter heart therapies, such as transcatheter heart valve
10 replacement.

BACKGROUND

[5] Percutaneous procedures for minimally invasive transcatheter heart valve diagnosis, repair and replacement avoid the need for invasive open-heart surgery. These minimally invasive procedures may be referred to as Transcatheter Valve Therapies (TVT). For
15 example, when a heart valve is found to be malfunctioning because it is defective or diseased, minimally invasive methods are known for repair and replacement of the heart valve, by introduction of a guidewire and catheter intravascularly into the heart, e.g. to access a heart valve and one or more chambers of the heart. The guidewire and catheter are then used to guide components into the heart for TVT.

[6] TVT for valve repair includes, for example, procedures such as, balloon aortic valvuloplasty (BAV), to widen an aortic valve which is narrowed by stenosis, or insertion of a mitral clip to reduce regurgitation when a mitral valve fails to close properly. Alternatively, if the valve cannot be repaired, a prosthetic replacement valve may be introduced. Minimally invasive Transcatheter heart Valve Replacement (TVR) procedures,
20 including Transcatheter Aortic Valve Implantation/Replacement (TAVI or TAVR) and Transcatheter Mitral Valve Implantation/Replacement (TMVI or TMVR), have been developed over the last decade and have become more common procedures in recent years. For example, it has been reported that the TAVR market is projected to grow at 21%

Compound Annual Growth Rate (CAGR) over the next 5 years, to about 120,000 TAVR procedures per years in the United States.

[7] As experience with TVT continues to evolve, interventional cardiologists who perform TVT procedures provide feedback on existing systems and apparatus and continue to seek improved or alternative systems and apparatus to advance TVT, including diagnostic tools comprising optical pressure sensors that provide real-time direct measurements within the heart of important hemodynamic cardiovascular parameters before, during and after TVT.

[8] The above referenced related patents and patent applications disclose multi-sensor guidewires and multi-sensor micro-catheters for use in interventional cardiology; all these patents and applications are incorporated herein by reference in their entirety. For example, United States patents 9,504,392 and 9,149,230 disclose multi-sensor micro-catheters and multi-sensor guidewires in which a distal end portion contains multiple optical pressure sensors arranged for measuring blood pressure at several sensor locations, simultaneously, in real-time. The disclosed multi-sensor micro-catheters and multi-sensor guidewires can be configured for use in minimally invasive surgical procedures for measurement of intravascular pressure gradients, and more particularly, for direct measurement of a transvalvular pressure gradient within the heart, for any one of the four heart valves. For example, a transvalvular measurement of pressure across the aortic valve is made with a multi-sensor guidewire or multi-sensor catheter having optical pressure sensors positioned upstream and downstream of the aortic valve to measure pressure, in real-time, concurrently in the ascending aorta and left ventricle, allows for assessment of aortic valve regurgitation or stenosis, before and after a TAVR procedure.

[9] TAVR procedures are carried out in a specialized operating room which is equipped for therapeutic and diagnostic procedures, including fluoroscopic imaging, echocardiographic imaging, and patient monitoring. For minimally invasive transcatheter procedures, this specialized operating room is typically referred to as a cardiac catheterization laboratory, or "Cath Lab". For example, a small incision is made into a femoral artery in the groin (transfemoral approach) or a radial artery in the arm (transradial approach) to allow for introduction of guidewires and catheters, which are advanced through

the aorta and into the left ventricle (LV) of the heart. Many components used during TAVR, such as catheters, support guidewires and valve delivery devices are single-use, disposable medical supplies. For this reason, unit cost is an important consideration. For reasons of regulatory approval, and to promote user acceptance and early adoption, it is desirable that systems comprising sensor guidewires and sensor catheters are based on related predicate devices and integrate within existing procedures, e.g. they can be manufactured from materials already approved for medical use and deployed in a similar manner to existing guidewires and catheters for TAVR. Another consideration for reducing cost and ease of use is compatibility with existing operating room equipment, such as patient monitoring and display systems.

[10] The present invention seeks to provide an improved or alternative multi-sensor system and apparatus comprising optical pressure sensors for direct blood pressure measurement within the heart, e.g., for measurement of transvalvular pressure gradients during TVT, that provide for unit cost reduction, or mitigate one or more of the above-mentioned issues, or provide an alternative solution.

SUMMARY OF INVENTION

[11] Aspects of the present invention provide a system and apparatus for monitoring of blood pressure at two locations for use during transcatheter valve therapies (TVT) and for related diagnostic measurements of hemodynamic parameters to assess heart valve function.

[12] One aspect of the invention provides a dual sensor system for monitoring blood pressure at first and second locations during transcatheter valve therapy (TVT), comprising: a controller;
a sensor support guidewire for TVT comprising a tubular member having a length extending between a proximal end and a distal end, the distal end comprising an atraumatic pre-formed curved flexible distal tip, the tubular member containing a first optical fiber extending within the sensor support guidewire from an optical input/output connector at the proximal end of the sensor support guidewire to a first Fabry-Pérot (FP) optical pressure sensor, the first FP optical pressure sensor being positioned within a distal region of the tubular member, near the distal tip, and a sensor aperture in the sensor support guidewire adjacent the first FP optical pressure sensor for fluid contact therewith;

a sensor angiographic catheter comprising a length of multi-lumen catheter tubing extending between a proximal end and a distal end and comprising a first lumen and a second lumen, the distal end comprising a preformed pigtail distal tip, and the catheter tubing having at its proximal end a connection hub comprising a first port for the first lumen and a second port for the second lumen, a second optical fiber extending within the first lumen from an optical input/output connector of the first port to a second FP optical pressure sensor, the second FP optical pressure sensor being positioned within a distal region of the first lumen near the distal tip, and a sensor aperture in the sensor catheter near the second FP optical pressure sensor for fluid contact therewith; the second port comprising an injection port for injection of fluid into the second lumen and the second lumen comprising a plurality of fluid apertures for fluid ejection along a length of the distal region between the sensor aperture and the distal tip;

the controller comprising an optical control unit (signal conditioner) comprising optical input/output ports for coupling to the optical input/output connectors of the sensor support guidewire and the sensor angiographic catheter; a light source and detector for operating the first and second FP optical pressure sensors and processing optical data from the first and second optical pressure sensors to generate data indicative of blood pressure; and a processor, memory, hardware and/or software components for generating analog and/or digital data comprising first and second pressure waveforms; and a communications interface comprising analog and/or digital ports for interfacing with at least one of a patient monitoring system and other peripherals.

[13] The first and second FP optical pressure sensors are preferably two matched optical pressure sensors, i.e. a pair of similar FP Micro-Opto-Mechanical System (MOMS) sensors. These optical pressure sensors comprise, for example, standard optical fibers of 0.155mm diameter and FP MOMS pressure sensors of 0.260 mm diameter at the sensor end of the optical fiber for sensing pressure. Smaller or bigger diameter optical fibers and sensors may be used as needed.

[14] In the following description, the TVT support guidewire containing the first FP optical pressure sensor will be referred to as the 'TVT sensor support guidewire' or simply the 'sensor guidewire' and the angiographic catheter containing the second FP optical

pressure sensor will be referred to as the ‘sensor angiographic catheter’ or simply the “sensor catheter”.

[15] In one embodiment, the system comprises a dual optical pressure sensor system which is configured to enable continuous direct monitoring of blood pressure in the left ventricle and in the ascending aorta, having applicability for measurements of hemodynamic parameters during TAVR. In this embodiment, the first FP optical pressure sensor (P1) is located near the atraumatic distal tip of the sensor support guidewire for positioning of P1 within the left ventricle during TAVR. For example, the flexible distal tip comprises a preformed curved tip and the first FP optical pressure sensor is positioned in a distal region of the sensor guidewire close to the flexible distal tip, or a few centimetres from the tip, to allow for placement of the FP optical pressure sensor in a central region of the left ventricle. An atraumatic flexible tip, such as a preformed J-tip, spiral tip, or other curved tip, provides for anchoring of the distal end of the sensor guidewire firmly in the left ventricle during TAVR, while reducing risk of tissue trauma or perforation of the left ventricle.

[16] The sensor catheter takes the form of a dual lumen pigtail catheter having a plurality of apertures in the second lumen near the pigtail tip for injection of contrast medium into the LV and the aorta, and the second FP optical pressure sensor (P2) is located in a distal region of the first lumen of the sensor catheter, a small distance from the pigtail tip for positioning of P2 in the ascending aorta, downstream of the aortic valve, during TAVR. For example, the second pressure sensor is positioned adjacent a sensor aperture in the first lumen about 2 to 7 cm from the pigtail tip of the sensor catheter, and a number of apertures, e.g. 5 to 12 apertures, in the second lumen are provided closer to the tip for distributed injection of contrast medium into the LV or the aorta near the aortic valve.

[17] For example, for monitoring of an aortic transvalvular pressure gradient, the first and second FP optical pressure sensors are a pair of similar FP optical pressure sensors configured for measuring a blood pressure gradient across the aortic valve during TAVR in a range of 0mmHg to 60mmHg within ± 10 mmHg or less.

[18] In another embodiment, the dual sensor system is configured for measurements of hemodynamic parameters during TMVR, wherein: the first FP optical pressure sensor (P1) is a distance L1 from the flexible distal tip of the sensor support guidewire for positioning

of P1 within a first heart chamber on one side of the mitral valve during TMVR; the second FP optical pressure sensor (P2) is located in a distal region of the first lumen of the sensor catheter, a distance L2 from the pigtail tip for positioning of P2 in a second heart chamber, on an opposite side of the mitral valve during TMVR; and said plurality of apertures in the second lumen near the pigtail tip are provided for injection of contrast medium into the second heart chamber.

[19] For example, for monitoring of a mitral valve pressure gradient, the first and second FP optical pressure sensors are a pair of similar FP optical pressure sensors configured for measuring a blood pressure gradient across the mitral valve during TMVR in a range of 0mmHg to 20 mmHg within ± 2 mmHg or less.

[20] In some embodiments, optical input/output connector of the sensor support guidewire comprises a flexible optical coupling which is connected to the proximal end of the sensor guidewire by a separable optical connector. For over-the-guidewire mounting of components, for example a valve delivery device during a TAVR, from the proximal end of the sensor guidewire, the optical connector comprises a micro-connector, wherein the sensor guidewire comprises a male part of the optical micro-connector having a diameter no greater than the outside diameter of the sensor guidewire. The sensor guidewire has physical characteristics required of a TAVR support guidewire. For example, typically, characteristics of a TAVR support guidewire include a high stiffness, (e.g. a flexural modulus similar to that of an Amplatz™ Extra Stiff or Super Stiff guidewire, Confida™ Brecker guidewire or Safari™ guidewire), a nominal/standard outside diameter of 0.89mm (0.035 inch) and, for a transfemoral approach, a length of 260mm to 300mm to allow for over-the-guidewire mounting of a valve delivery device and valve components. The flexible optical coupling provides a low cost optical connection (e.g. a simple optical fiber cable) that extends from the female part of the optical micro-connector, that forms a connector handle, to an optical connector at the proximal end of the flexible optical coupling for connection to the controller.

[21] In some embodiments, the sensor catheter has the form of a conventional small diameter pigtail catheter used to inject a measured volume (bolus) of contrast agent into the aorta or LV through a plurality of apertures in the sensor catheter near the aortic valve, to

allow fluoroscopic imaging of blood flow in the region of the aortic valve and for imaging to check for aortic regurgitation. The sensor catheter is a multi-lumen catheter, for example a dual lumen catheter with a port for each lumen. The first lumen accommodates the second FP optical pressure sensor and its optical fiber, and a second lumen provides for fluid
5 injection of contrast agent, saline solution, or other fluids. Thus, the proximal end of the dual-lumen sensor catheter comprises a connection hub, through which each lumen of the multi-lumen sensor catheter is connected through a length of flexible tubing to the corresponding individual proximal port. One proximal port is provided for the optical input/output connector for the optical pressure sensor, and one proximal port is provided for
10 connection to a fluid delivery injector for injection of contrast agent. For example, the sensor catheter has an outside diameter of 4 to 7 French, e.g., 5 French (1.7mm /0.066 inch), and the second lumen has a diameter large enough to allow for rapid injection of a bolus of contrast medium, e.g. ~1 mm diameter. The second lumen may also be sized to allow for the introduction of a guidewire for insertion of the sensor catheter into the aorta or other
15 blood vessel over the guidewire. The first lumen can be smaller, i.e. sized to accommodate the second optical fiber and the second optical pressure sensor, e.g. ~0.3 mm diameter.

[22] Optionally, the sensor catheter may comprise one or more additional lumens, and the connection hub comprises a corresponding number of ports, for other purposes.

[23] The sensor support guidewire may comprise a marker near the FP optical pressure
20 sensor to assist in positioning the FP optical pressure sensor in use, e.g. radiopaque markers that can be visualized by conventional radio-imaging techniques. A marker is provided near the FP optical pressure sensor in the sensor catheter, and a marker may be provided at the distal tip of the sensor catheter. If required, markers may also be placed at regular intervals along the length of the sensor catheter and sensor guidewire, so that, in use, relative
25 positioning or spacing of the FP optical pressure sensors of the sensor catheter and the sensor guidewire can be determined.

[24] Embodiments of the system and apparatus of the present invention, comprising dual FP optical pressure sensors, provide for continuous direct monitoring of blood pressure at
30 two locations, e.g. within the aorta and left ventricle, or within two chambers of the heart, for diagnostic measurements during TAVT procedures, such as TAVR or TMVR, including

e.g., measurements of transvalvular pressure gradients before, during and after deployment of a prosthetic heart valve.

[25] In an embodiment, the controller comprises an optical control unit, which may be referred to as a signal conditioner, comprising a light source and detector, and an optical interface for coupling, via respective optical input/output ports, to each of the optical fibers and FP optical pressure sensors of the sensor catheter and the sensor support guidewire; data storage and processing means configured for processing optical data indicative of pressure values, and outputting digital and/or analog signals to ports of a communications interface, for coupling to a patient monitoring system and other peripherals, such as those typically found in a Cath Lab, to display pressure waveforms and associated hemodynamic data derived from the pressure data. For example, where a patient monitoring system or patient care monitor (PCM) is configured for receiving analog signals indicative of blood pressure compliant with the ANSI BP-22 Standard, the system controller comprises a BP-22 signal converter that provides ports for respective analog signal outputs from each of the two FP optical pressure sensors, together with the required control signals, i.e. the excitation signal output and sense signal input. The optical control unit comprising the signal conditioner may be integrated with, or be a separate module, from the interface/link unit which converts digital outputs from the optical control unit to provide said analog signals. Additionally, or alternatively, the optical control unit comprises ports for digital inputs and outputs, e.g. for wired or wireless coupling of the controller to a digital patient monitoring system and other peripherals, such as a network device or user device, e.g., a server, personal computer, or tablet which provides a user interface and/or data storage and analysis.

[26] For a system configured for left heart catheterization, e.g. TAVR, in addition to displaying pressure waveforms from the aorta and the left ventricle, the system may provide for display a plurality of numeric values such as peak pressures, mean pressures, peak-to-peak pressure differentials for each curve, and pressure differentials or gradients, e.g., between the aorta and the left ventricle. The system may also compute a parameter such as an aortic regurgitation index (ARi), and display the ARi value in real time. Where the controller comprises an analog interface providing blood pressure signals to a BP-22 compliant patient monitoring system, display of pressure waveforms, analysis of data and

display of related numeric data and parameters may be performed by the patient monitoring system.

[27] Another aspect of the invention provides a computer program product embodied as a non-transient computer readable medium storing instructions, for execution in a processor of a controller for a dual sensor apparatus comprising a sensor guidewire containing a first FP optical pressure sensor and a sensor catheter containing a second FP optical pressure sensor, for processing optical data received concurrently from the first and second FP optical pressure sensors, said optical data being indicative of blood pressure. Optionally, said instructions further provide for processing and displaying, on a graphical user interface, pressure waveforms and numeric data relating to selected hemodynamic parameters and indexes.

[28] Another aspect of the invention provides a sensor support guidewire for interventional cardiology comprising a tubular member having a length extending between a proximal end and a distal end, the distal end comprising a flexible distal tip, the tubular member containing an optical fiber extending within from an optical input/output connector at the proximal end of the sensor guidewire to a first FP optical pressure sensor, the first FP optical pressure sensor being positioned within a distal region of the sensor guidewire, near the distal tip, and a sensor aperture in the tubular member adjacent the first optical pressure for fluid contact therewith. In some embodiments the tubular member comprises an outer tubular member (outer tube) and an inner tubular member (inner tube or core tube), the inner tubular member being inserted within the outer tubular member. The inner and outer tubular members of this “tube-in-tube” construction are configured to provide required physical characteristics along the length of the sensor guidewire, e.g., stiffness, flexibility, and torque characteristics.

[29] For use as a support guidewire for TVT, e.g. for TAVR or TMVR, the sensor guidewire is a stiff guidewire, e.g. having a stiffness similar to that of a standard support guidewire, such as an AmplatzTM Super Stiff support guidewire. A stiff distal region of the sensor guidewire provides a rail that can support a valve delivery device and valve components mounted over the TVT sensor support guidewire, i.e. for “over-the-guidewire” delivery and deployment.

[30] For example, in the support guidewire, the first FP optical pressure sensor and its optical fiber are inserted into the inner tubular member, which may comprise a first stainless steel hypotube having physical characteristics providing a predetermined stiffness and flexibility to act as a core of the sensor guidewire, and then the inner tubular member is inserted into the outer tubular member. The outer tubular member may comprise one of: a second stainless steel hypotube which is more flexible (e.g. a laser cut hypotube); a flexible spiral wound micro-coil; and a combination thereof. In an embodiment, the inner tubular member acts as a core tube to provide a required stiffness along the length of the sensor guidewire, and the outer tubular member may be more flexible along most of its length. At the sensor position, where the inner tubular member has an aperture or is partially cut away to form an opening or cavity around the optical pressure sensor, the outer tubular layer, which itself has sensor aperture, comprises a reinforced stiffer region around the sensor aperture adjacent to the sensor.

[31] The tube-in-tube construction facilitates fabrication of the sensor guidewire. For example, where the sensor guidewire comprises an inner tube and a more flexible outer tube, the optical fiber and FP optical pressure sensor are inserted into the inner tube from an opening at the distal end or through the sensor aperture, and the fiber is adhesively secured within the inner tube near the sensor to hold the sensor in the sensor location adjacent the aperture for fluid contact. The FP optical pressure sensor and its fiber is then protected within the inner tube while the inner tube is inserted into the more flexible outer tube.

[32] The atraumatic flexible tip of the sensor guidewire may comprise an outer flexible coil wire and an inner core wire, which are configured to provide a desired flexibility and shape. The flexible tip may have a pre-formed curved shape, such as a spiral tip. If the components of the flexible tip are not formed integrally with the inner and/or outer tubular layers, the components of the flexible tip may be attached to the inner and/or outer tubular layers by suitable means, such as one or more of adhesive bonding, soldering, brazing, and welding, to provide a smooth transition between the sensor region of the sensor guidewire and the flexible tip. The flexible tip may have the same outer diameter as the sensor region of the sensor guidewire, or the tip may taper to a smaller diameter.

[33] In some embodiments, the sensor guidewire further comprises a second optical pressure sensor and second optical fiber contained within the inner tubular member, the second optical pressure sensor being positioned proximally of the first optical pressure sensor. In a dual sensor guidewire, adjacent to each FP optical pressure sensor position, the inner tubular member has an aperture or is partially cut away to form a cavity around the optical pressure sensor, and the outer tubular layer comprises a stiffer, reinforced region around the aperture adjacent to each sensor. In an embodiment, the dual sensor guidewire may be configured for TAVR or TMVR.

[34] Another aspect of the invention provides an angiographic sensor catheter comprising a length of multi-lumen catheter tubing extending between a proximal end and a distal end and comprising first and second lumens, the distal end comprising a preformed distal tip, the catheter tubing having at its proximal end a connection hub comprising corresponding a first port for the first lumen and a second port for second lumen; the first port for the first lumen providing an optical input/output connector, an optical fiber extending within the first lumen from the optical input/output connector to an FP optical pressure sensor positioned within a distal region of the sensor catheter near the distal tip, and an aperture in the first lumen near the FP optical pressure sensor for fluid contact therewith; the second port comprising an injection port for injection of fluid into the second lumen, and the second lumen comprising a plurality of apertures near the distal tip, e.g. in a distal region between the sensor aperture and the distal tip.

[35] Yet another aspect of the invention provides a kit comprising components for use with a dual sensor system for monitoring blood pressure at first and second locations during transcatheter valve therapy (TVT), comprising:

a first component comprising: a sensor support guidewire for TVT comprising a tubular member having a length extending between a proximal end and a distal end, the distal end comprising an atraumatic pre-formed curved flexible distal tip, the tubular member containing a first optical fiber extending within the support guidewire from an optical input/output connector at the proximal end of the support guidewire to a first Fabry-Pérot (FP) optical pressure sensor, the first FP optical pressure sensor being positioned within a

distal region of the tubular member, near the distal tip, and a sensor aperture in the sensor guidewire adjacent the first optical FP pressure sensor for fluid contact therewith;

- a second component comprising: a sensor angiographic catheter comprising a length of multi-lumen catheter tubing extending between a proximal end and a distal end and comprising a first lumen and a second lumen, the distal end comprising a preformed pigtail distal tip, and the catheter tubing having at its proximal end a connection hub comprising a first port for the first lumen and a second port for the second lumen, a second optical fiber extending within the first lumen from an optical/input output connector of the first port to a second FP optical pressure sensor, the second FP optical pressure sensor being positioned within a distal region of the first lumen near the distal tip, and a sensor aperture in first lumen of the catheter tubing near the FP optical pressure sensor for fluid contact therewith; the second port comprising an injection port for injection of fluid into the second lumen, and the second lumen comprising a plurality of fluid apertures along a length of the distal region between the sensor aperture and the distal tip; and
- wherein the first and second FP optical pressure sensors are pair of similar FP optical pressure sensors.

- [36] For example, the first and second FP optical pressure sensors are configured for measuring a transvalvular blood pressure gradient across an aortic valve during TAVR, in a range of 0mmHg to 60mmHg within ± 10 mmHg or less. As another example, the first and second FP optical pressure sensors are configured for measuring a transvalvular blood pressure gradient across a mitral valve during TMVR, in a range of 0mmHg to 20mmHg within ± 2 mmHg or less.

- [37] Thus, systems and apparatus comprising dual FP optical pressure sensors according to embodiments of the present invention provide for diagnostic measurements and monitoring of hemodynamic parameters, including measurement of blood pressure concurrently and continuously at two different and variable locations, e.g. within the aorta and left ventricle during TAVR. Accordingly, dual sensor systems may be provided wherein the sensor locations are configured for use during other TAVT, such as TMVR, BAV, or for diagnostic measurements during left heart catheterization.

[38] The foregoing and other objects, features, aspects and advantages of the present invention will become more apparent from the following detailed description, taken in conjunction with the accompanying drawings, of embodiments of the invention, which description is by way of example only.

5 BRIEF DESCRIPTION OF THE DRAWINGS

[39] In the drawings, identical or corresponding elements in the different Figures have the same reference numeral.

[40] **Fig. 1** illustrates schematically a system of a first embodiment, comprising a controller, a support guidewire containing a first Fabry-Perot (FP) optical pressure sensor (sensor support guidewire), a multi-lumen angiographic catheter containing a second FP optical pressure sensor (sensor catheter), wherein the sensor support guidewire and the sensor catheter are optically coupled to the controller, and the controller is connected to a patient monitoring system linked to a large screen display;

[41] **Fig. 2** shows an enlarged schematic longitudinal partial cross-sectional view of the sensor guidewire of the first embodiment, e.g., configured for measuring blood pressure in the left ventricle (LV) during TAVR;

[42] **Figs. 3A, 3B and 3C** show enlarged axial cross-sectional views of the sensor guidewire illustrated in **Fig. 2** taken, respectively, through planes **A-A, B-B** and **C-C** of **Fig. 2**;

[43] **Fig. 4** shows an enlarged schematic longitudinal cross-sectional view of the sensor catheter of the first embodiment, configured for measuring blood pressure in the ascending aorta during TAVR;

[44] **Figs. 5A and 5B** show enlarged axial cross-sectional view of the sensor catheter illustrated in **Fig. 4** taken, respectively, through planes **A-A** and **B-B** of **Fig. 4**;

[45] **Figs. 6A and 6B** show enlarged axial cross-sectional views through multi-lumen sensor catheters comprising two lumens of alternative embodiments;

[46] **Fig. 7** shows an enlarged schematic longitudinal partial cross-sectional view of a sensor guidewire of a second embodiment, comprising two FP optical pressure sensors configured for diagnostic measurements of blood pressure at two locations, e.g. in the ascending aorta and in the left ventricle (LV) during left heart catheterization;

5 [47] **Figs. 8A, 8B, 8C and 8D** show enlarged axial cross-sectional views of the sensor guidewire illustrated in **Fig. 7** taken, respectively, through planes **A-A, B-B, C-C and D-D** of **Fig. 7**;

[48] **Figs. 9A and 9B** show two schematic side views of a 3-dimensional pre-formed flexible tip of a helical form which may be used with sensor guidewires of the first and
10 second embodiments;

[49] **Figs. 10A and 10B** show two schematic side views of a 3-dimensional pre-formed flexible tip of a tapered helical form;

[50] **Fig. 11A** shows a schematic block diagram of components of a controller comprising first and second channels for a dual sensor system of an embodiment such as
15 illustrated in **Fig. 1**, comprising sensor inputs and digital and analog interfaces comprising BP-22 analog signal ports for coupling to a BP-22 compliant patient monitoring system and **Fig. 11B** shows a schematic block diagram showing details of components of one channel of the controller;

[51] **Fig. 12** shows a schematic diagram to illustrate deployment of a dual sensor system
20 of the first embodiment for measurement of pressure in the ascending aorta (Ao) and the left ventricle (LV) in which the user interface is displaying pressure waveforms and hemodynamic parameters including an aortic regurgitation index (ARi) indicative of a) a healthy heart and b) a heart with significant aortic regurgitation;

[52] **Fig. 13** shows a schematic partial cross-sectional diagram of a human heart to
25 illustrate placement of the sensor catheter and sensor support guidewire of the dual sensor system of the first embodiment for diagnostic measurements of hemodynamic parameters, wherein the sensor guidewire is positioned for continuous blood pressure measurement within the left ventricle (LV) and the sensor catheter is positioned for concurrent and continuous measurement of blood pressure within the ascending aorta;

[53] **Fig. 14** shows a schematic partial cross-sectional diagram of a human heart to illustrate placement of the dual sensor support guidewire of the second embodiment for diagnostic measurements of hemodynamic parameters, wherein the sensor support guidewire is positioned for continuous blood pressure measurement within the left ventricle (LV) and for concurrent and continuous measurement of blood pressure within the ascending aorta (e.g., transfemoral approach);

[54] **Fig. 15** shows a schematic partial cross-sectional diagram of a human heart to illustrate placement of the sensor catheter and sensor guidewire of the dual sensor system of the first embodiment for measurements of hemodynamic parameters, including concurrent measurements of blood pressure in the LV and ascending aorta during TAVR (e.g., trans-femoral approach);

[55] **Fig. 16** shows a schematic partial cross-sectional diagram of a human heart to illustrate placement of the sensor catheter and sensor guidewire of the dual sensor system of the first embodiment for measurements of hemodynamic parameters, including concurrent measurements of blood pressure in the LV and RA during TMVR, in which the sensor guidewire passes through the apex of the heart (apical approach);

[56] **Fig. 17** shows a schematic partial cross-sectional diagram of a human heart to illustrate placement of the sensor catheter and sensor guidewire of the dual sensor system of the first embodiment for measurements of hemodynamic parameters, including concurrent measurements of blood pressure in the LV and RA during TMVR (trans-septal approach);

[57] **Fig. 18** shows a schematic partial cross-sectional diagram of a human heart to illustrate placement of the sensor catheter and sensor guidewire of the dual sensor system of the first embodiment for measurements of hemodynamic parameters, including concurrent measurements of blood pressure in the LV and RA during TMVR (e.g. transfemoral approach);

[58] **Fig. 19** shows a schematic partial cross-sectional diagram of a human heart to illustrate placement of the dual sensor support guidewire for measurements of

hemodynamic parameters, including concurrent measurements of blood pressure in the LV and RA during TMVR (trans-septal approach); and

[59] **Figs. 20A, 20B, 20C, 20D and 20E** show views of a sensor support guidewire for TVT according to another embodiment, to show details of elements of a tube-in-tube construction for a single sensor support guidewire.

DETAILED DESCRIPTION

[60] Dual sensor system

[61] A schematic view of a dual sensor system 10 according to a first embodiment, configured for continuous blood pressure monitoring, e.g., during transcatheter heart valve replacement, is shown in **Fig. 1**. The dual sensor system 10 comprises a controller 100 to which is coupled to a TVT sensor support guidewire 200, a sensor angiographic catheter 300, and peripheral equipment, e.g., a patient monitoring system 400 and a user interface 500. The TVT sensor support guidewire 200 contains a first FP optical pressure sensor located at position P1, a distance L1 from the distal end 204 of the TVT sensor support guidewire, which comprises a flexible distal tip 206. The sensor angiographic catheter 300 is a multi-lumen catheter, e.g. a dual lumen catheter, containing in a first lumen a second FP optical pressure sensor, located at position P2, a distance L2 from distal end 304, and having a second lumen for fluid injection, and a pigtail tip 306. The TVT sensor support guidewire 200 is coupled to the controller 100 by an optical/input connector comprising a flexible optical coupling 208, e.g., comprising an optical fiber within flexible tubing 223 extending between optical connector 240 and optical connector 212. The sensor angiographic catheter 300 is coupled to the controller 100 by a flexible optical coupling 308, e.g., comprising an optical fiber within flexible tubing 343 extending between optical connector 350 and optical connector 312.

[62] In the following detailed description, for conciseness, the TVT sensor support guidewire 200 containing the first FP optical pressure sensor will be referred to as the “sensor support guidewire”, or simply the “sensor guidewire”, and the sensor angiographic catheter 300 containing the second FP optical sensor will be referred to as the “sensor catheter”.

[63] The controller 100 comprises first and second optical connection ports 102 (i.e. 102-P1 and 102-P2) for optical connector 212 at the proximal end 202 of the flexible optical coupling 208 of the sensor guidewire 200 and optical connector 312 at the proximal end 302 of the flexible optical coupling 308 of the sensor catheter 300. The controller 100 also comprises a communication interface having analog and digital ports comprising outputs for the patient monitoring system 400, other peripherals, network devices and user devices, e.g., the user interface 500 which may, for example, be a personal computer (PC) or tablet PC connected through link 104. As illustrated schematically in **Fig. 1**, the control unit 100 is connected through electrical connections 105 to a patient monitoring system 400, which has a link 402 to a graphical display 404, such as one of the standard large screen monitors used in the Cath Lab or operating room. The monitoring system 400 may be part of a standard patient monitoring system, which may be referred to as a Patient Care Monitor (PCM), or it may be a dedicated stand-alone monitoring unit.

[64] Referring to **Fig. 1**, the sensor guidewire 200 extends from the optical connector 240 at its proximal end to a distal end 204 comprising a soft flexible tip 206, such as a pre-formed atraumatic curved tip, e.g. a spiral tip. (That is, “proximal” and “distal” are referenced relative to the controller 100). The sensor guidewire 200 is detachably connected to the flexible optical coupling 208 by separable optical connector 240 at its proximal end. Near its distal end, the sensor guidewire 200 contains the first FP optical pressure sensor, at a location indicated by P1, and its optical fiber. The optical fiber extends from the optical sensor through the length of the sensor guidewire to the optical connector 240. A second optical fiber extends from the optical connector 240, through the flexible optical coupling 208 to the optical input/output connector 212 at the proximal end 202 of the assembly. The sensor guidewire 200 takes the form of a support guidewire for TAVR, i.e. it has suitable characteristics such as, stiffness, flexibility, torque characteristics, length and outside diameter to act as a support guidewire over which heart valve components may be delivered, as will be explained below in more detail with reference to Figs. 2, 3A, 3B and 3C. The flexible optical coupling 208 does not need to have the same stiffness characteristics and provides a more flexible optical coupling (e.g. a simple optical cable) between the control unit 100 and the optical connector 240 for connection to the sensor guidewire 200. In use, for activation of the FP optical pressure sensor, the sensor guidewire

200 is optically coupled through the flexible optical coupling 208 to the corresponding optical input/output port 102-P2 of the optical control unit 100. The optical connector 240 is a separable optical connector so that the sensor guidewire 200 can be detachably connected to the flexible optical coupling 208, for activation as needed.

5 [65] The sensor catheter 300 comprises a length of dual lumen catheter tubing extending from a connection hub 340 near its proximal end to a distal end 304 comprising a distal tip in the form of a preformed pigtail tip 306. The connection hub 340 comprises dual ports 342 and 344. The sensor catheter 300 has a form similar to a conventional multi-lumen catheter, in this case a dual lumen catheter, which will be described in more detail below
10 with reference to Figs. 4, 5A and 5B. The FP optical pressure sensor, indicated by position P2 is contained within the distal region of a first lumen and its optical fiber extends through the lumen, through the connection hub 340, and through a length of flexible tubing from the first port 342 to an optical input/output connector 350. A second lumen of the sensor catheter has a plurality of apertures in the distal region near the pigtail tip 306 and the second
15 lumen coupled through connection hub 340 to a second port 344 comprising a length of flexible tubing 345 to a fluid port or connector 346 for coupling to a fluid injector 348, e.g. a syringe or pump. The flexible optical coupling 308 comprises a flexible optical cable 343 containing an optical fiber extending between the optical connector 350 and the control unit 100, i.e. proximal end 302 of the flexible optical coupling 308 is optically coupled via
20 optical input/output connector 312 to port 102-P1 of the optical control unit 100. The separable optical connector 350 allows for the flexible optical coupling 308 to be disconnected while the pigtail catheter is inserted and used in the normal manner. Then, optical connector 350 is connected to the sensor catheter to activate the second FP optical pressure sensor when pressure measurements, e.g. in the aorta (Ao) are required. The port
25 344 at the proximal end which is coupled to the injector 348 provides for injection of contrast medium, or other fluid, through the second lumen of the sensor catheter 300 to a plurality of apertures distributed radially along a length of the distal region near the pigtail tip 306. The second lumen may also provide for passing of a guidewire for introduction of the sensor catheter over the guidewire into the aorta or other vessel. The pigtail sensor
30 catheter 300 may be a straight catheter, or it may be a preformed angled pigtail catheter, e.g. having a 145° or 155° angle, as indicated by 322.

[66] The TVT sensor support guidewire 200 and its input/output optical connector comprising the flexible optical coupling 208 may be referred to as the sensor guidewire assembly 210. The sensor angiographic catheter 300 and its input/output optical connector comprising the flexible optical coupling 308 may be referred to as the sensor catheter assembly 310.

[67] The TVT sensor support guidewire assembly 210 is illustrated in more detail in the schematic longitudinal cross-sectional view shown in **Fig. 2**, and in schematic cross-sectional views shown in **Figs. 3A, 3B and 3C**. The sensor angiographic catheter assembly 310 is illustrated in more detail in the schematic longitudinal cross-sectional view shown in **Fig. 4**, and schematic cross-sectional views shown in **Figs. 5A and 5B**.

[68] **TVT Sensor Support Guidewire**

[69] An enlarged schematic longitudinal partial cross-sectional view of the assembly 210 comprising a sensor guidewire 200 and a flexible optical coupling 208, of the first embodiment, is shown in **Fig. 2**. The sensor guidewire 200 is configured for measuring blood pressure, e.g. in the left ventricle (LV) during TAVR. The length of the sensor guidewire 200 extends from the separable optical connector 240 at its proximal end to the atraumatic flexible tip 206 at the distal end 204. The sensor guidewire 200 and the flexible optical coupling 208 are detachably connected by the separable optical connector 240. The sensor guidewire 200 comprises a flexible tubular member comprising an outer tubular layer 220 and an inner tubular layer 234. The structure and materials of the outer tubular covering 220 and the inner tubular layer 234 are selected to provide stiffness and other required physical characteristics of a support guidewire along its length. This tube-in-tube construction allows for the stiffness and other characteristics of the sensor guidewire 200 to be varied along its length between the optical connector 240 and the distal end 204 comprising the distal tip 206. For example, the inner tubular layer or core tube 234 comprises a stainless-steel hypotube which is relatively stiff and acts as a core for the outer tubular layer 220, which may be a more flexible stainless-steel hypotube or micro-coil. The first FP optical pressure sensor 230, at position P1, is optically and physically connected to the distal end (i.e. the sensor end) of the optical fiber 232, and the optical fiber 232 terminates at the proximal end (i.e. connector end) within the optical connector 240. At the

sensor end of the fiber, a short length of protective tubing may be bonded around the sensor 230. The tubular layer 234 extends around the optical fiber 232 and extends beyond the sensor end of the fiber to toward the tip 206. In the region of the sensor 230, there is an aperture 226 in the outer tubular layer 220, and the inner tubular layer 234 is shaped to leave space around the sensor 230, e.g., has an aperture or is cut away to form a cavity 225, to accommodate the sensor 230 and to allow for fluid contact with the sensor 230. In this embodiment, the distal end portion of the tube-in-tube construction providing the tubular member comprises more flexible portions 227 of the outer tube 220, e.g. comprising a length of flexible stainless-steel micro-coil, and a reinforced stiffer section 224 of hypotube in between. As illustrated, the reinforced region 224 of the external tubular layer 220 extends a short length each side of the sensor position P1, to provide a required stiffness in the region of the sensor, i.e., where the stiffer inner tubular layer 234 is cut away to provide for fluid contact with the sensor. If required, a radiopaque marker 236 is provided near the sensor, to assist in positioning the sensor 230 in use, e.g., by fluoroscopic imaging. The inner tubular layer 234 extends a short distance past the sensor 230 and is bonded to the tip of core wire 239 of the flexible tip 206. For example, the flexible tip 206 comprises an outer flexible coil wire, and the tip core wire 239 has a ground profile along its length, i.e. is tapered to a smaller diameter, to progressively reduce stiffness of the flexible tip 206. To secure the sensor 230 in the sensor position P1 next to the aperture 226, the inner core tube 234 and outer tubular layer 220 may be secured to each other, e.g. by adhesive, filler or solder, at points 237 at each end of the reinforced region 224. The atraumatic flexible tip 206 may be a preformed J-tip, a preformed flat spiral tip, or a preformed 3-dimensional spiral or coiled tip, as will be described in more detail in subsequent paragraphs. A coating, such as a hydrophilic coating, may be provided along the length of the sensor guidewire.

[70] The sensor guidewire 200 has physical characteristics along its length, e.g. stiffness, as required of a TAVR support guidewire. For example, typically, a support guidewire for use in TAVR has a high stiffness to act as a support wire for over-the-guidewire delivery and deployment of valve components. An example of a guidewire used for TAVR is the Amplatz™ Super Stiff guidewire (Boston Scientific), which has been reported to have a flexural modulus of ~60GPa (G. Harrison *et al.*, J. Endovasc. Ther. 2011: 18, pp 797-801). Other guidewires used for TAVR include the Confida™ Brecker guidewire (Medtronic Inc.)

and Safari™ pre-shaped guidewire (Boston Scientific). The latter are both reported to be stiffer than the Amplatz Super Stiff guidewire, but less stiff than the Lunderquist® Extra-Stiff Wire Guide (Cook Medical) (~158GPa).

[71] TAVR guidewires are typically available with a standard outer diameter of 0.89mm (0.035 inch). The sensor guidewire 200 of the first embodiment comprising the tube-in-tube construction as illustrated in **Fig. 2**, e.g., having an outside diameter of 0.89 mm, can readily accommodate a single FP optical pressure sensor 230 in an inner tube 234 comprising a stainless steel hypotube having an inside diameter of e.g., 0.285mm to accommodate the optical fiber and optical sensor. The inner tube has an outside diameter (OD) which, together with the outer tubular layer, provides required stiffness characteristics along the length of the sensor guidewire. For example, the inner tubular layer may be a hypotube having an OD in the range from 0.26 to 0.40 mm OD (0.014 to 0.016 inch OD). The flexible tip 206 may have the same diameter as the outer tube 220 of the sensor guidewire or may be tapered to a smaller diameter. For the transfemoral approach, the sensor support guidewire 200 typically has a length in the range of about 260 mm to 300 mm. This length enables over-the-guidewire mounting of a valve delivery device and valve components. For an apical approach, i.e. through a small incision between the ribs, directly into the apex of the left ventricle of the heart, a shorter guidewire and delivery device is typically used. For paediatric use, a sensor support guidewire of smaller dimensions may be used, e.g. a smaller outer diameter, tip size, and smaller spacing of the sensor from the tip. The micro-coil and/or hypotube forming the outer tubular layer is sized to allow for an external coating which provides the sensor guidewire with an appropriate lubricity, e.g. a hydrophilic coating.

[72] The optical fiber 232 extending from the optical sensor along the length of the sensor guidewire 200 is optical coupled through the optical connector 240 to a second length of optical fiber 238 in the flexible optical coupling 208 of the sensor guidewire. The flexible optical coupling 208 provides a flexible optical connection to the input/output connector 212 which connects to the optical input/output port 102-P2 of the controller 100, and it does not require the same stiffness characteristics as the sensor support guidewire 200. For example, the flexible optical connection 208 of the sensor guidewire may simply comprise a length of low cost flexible tubing 222 and a protective outer jacket 223 containing the

optical fiber 238. Flexible optical connection 208 has at its proximal end 202 a standard type of optical input/output connector 212, comprising a strain boot 219, for connection of the first optical pressure sensor to a corresponding port 102-P2 of the optical control system. This input/output connector 212 may be a smart connector which has a memory chip or
5 readable tag that stores a sensor ID and calibration data, e.g. a SCAI connector comprising an EEPROM.

[73] Preferably, the optical connector 240 connecting the sensor guidewire 200 to the flexible optical coupling 208 is a separable optical coupler in which the male part of the connector is carried by the proximal end of the sensor guidewire 200, and which has a
10 diameter no greater than a maximum outside diameter D_g (e.g., 0.89mm) of the external covering of the sensor guidewire 200. Separation of the two parts of the connector 240 enables over-the-wire mounting of a valve delivery system and valve components on the proximal end of the sensor guidewire 200. The female part of the optical connector 240 forms the distal end of the flexible optical connection 208. The body 241 of the female part
15 of the connector 240 may be of sufficient external size to form a handle for manipulating the sensor guidewire 200 to assist with pushing, pulling and twisting the sensor guidewire 200 as the sensor guidewire is inserted and withdrawn. The optical fiber connector 240 comprises alignment means for the optical alignment of ends of the two optical fibers 232 and 238, for example, as illustrated schematically, using a pair of ferrules 243 and an
20 alignment sleeve 242.

[74] **Figs. 3A, 3B and 3C** show enlarged axial cross-sectional views of the sensor guidewire assembly illustrated in **Fig. 2** taken, respectively, through planes **A-A**, **B-B** and **C-C** of **Fig. 2**. The cross-section in Fig. 3A through cross-section A-A of the flexible optical connection 208 shows the flexible tubing layer 222 surrounding optical fiber 238, and the
25 outer protective jacket 223. The cross-section in Fig. 3B through cross-section B-B of the TVT sensor support guidewire 200 shows the optical fiber 232 surrounded by protective inner core tube 234 within the outer tube 220. The optical fiber 232 fits slideably within the inner core tube 234. For example, the core tube has an inner diameter of 0.285mm to accommodate an optical sensor of 0.260 mm diameter, and the optical fiber is a standard
30 optical fiber having an outside diameter in the range from about 0.100mm to 0.200mm. The cross-section shown in Fig. 3C taken through cross-section C-C of the distal region of the

sensor support guidewire near the sensor shows the sensor 230, the protective inner tube 234 cut away in the sensor region to form a cavity 225 and the surrounding reinforced region 224 of the outer tube 220. An aperture 226 is provided in reinforced region 224 near the sensor 230 to allow for fluid contact with the sensor 230. The outer diameter of the sensor
5 guidewire D_g is indicated in Figs. 3B and 3C, and, for example, is typically 0.035 inch (0.89mm) for a guidewire for left heart catheterization. The flexible tubing layers of flexible optical connection 208 shown in Fig. 3A may have any suitable diameter.

[75] **Angiographic Sensor Catheter**

[76] An enlarged schematic longitudinal partial cross-sectional view of the assembly 310
10 comprising a sensor catheter 300 and a flexible optical coupling 308, of the first embodiment, is shown in **Fig. 4**. The sensor catheter 300 comprises a dual lumen pigtail catheter configured for measuring blood pressure, e.g., in the aorta during TAVR, and for injecting contrast medium, saline or other fluid, e.g., into the LV and the aorta during TAVR. That is, the sensor catheter 300 has the form of a small diameter, angiographic
15 pigtail catheter of the type used to deliver a fluid injection of contrast agent into the aorta near the aortic valve, to allow fluoroscopic imaging of blood flow in the region downstream of the aortic valve and for imaging to look for aortic regurgitation. This type of catheter may be referred to as an angiographic catheter or a diagnostic catheter. However, unlike a conventional pigtail catheter used for injecting contrast medium, the sensor catheter has a
20 first lumen 314-1 containing the optical pressure sensor 330 and optical fiber 332. As illustrated in the longitudinal cross-sectional view shown in Fig. 4, the sensor catheter 300 comprises a length of dual lumen catheter tubing 320, extending from the connection hub 340 to a distal end 304 comprising a pre-formed pigtail tip 306. The first lumen 314-1 accommodates the second optical pressure sensor 330 and its optical fiber 332. The optical
25 pressure sensor 330 is located an appropriate distance L_2 from the pigtail tip 306, so that the sensor can be positioned in the ascending aorta when the pigtail tip 306 is positioned close to the cusps of the aortic valve. A sensor aperture 326 for fluid contact is provided in the wall of the first lumen 314-1 near the sensor 330, and the first lumen 314-1 is plugged distally of the sensor position by plug 336. The optical fiber 332 may also be secured in the
30 lumen 314-1 near the sensor 330, e.g. by adhesive 315. A radiopaque marker band 311 is provided near the optical pressure sensor 330, and another radiopaque marker band 311 is

also provided at the distal end 304, to assist with positioning the pigtail tip near the aortic valve. The spacing L2 between the sensor 330 and the distal end 304 is selected to place the sensor 330 in the ascending aorta a few centimeters downstream of the aortic valve. The second lumen 314-2 provides for fluid injection and has a plurality of apertures 335 which

5 are spaced around the circumference of the sensor catheter, along a length of the distal region of the sensor catheter near the pigtail distal tip 306, to allow for distributed injection of contrast medium or other fluids. In the distal region beyond the sensor position and the plug 336 in the first lumen, the first and second lumens may be connected to allow for more distributed ejection of fluid through apertures 335. The end 316 of the second lumen 314-

10 2 is open to allow the sensor catheter to be inserted over a guidewire. The connection hub 340 at the proximal end of the sensor catheter has a port for each lumen of the catheter tubing. The port 344 for the second lumen 314-2 for fluid injection comprises a length of flexible tubing 345 extending from the connection hub 340 to a standard type of fluid injection port 346 for coupling to, as example, a syringe. This port also allows for insertion

15 of the sensor catheter into the body over a guidewire. (A conventional port of this type may be referred to as a “tail” of the catheter). The port 342 for the first lumen comprises another length of flexible tubing through which the optical fiber 332 extends to a separable optical connector 350 for detachably connecting the flexible optical coupling 308, which comprises a length of flexible tubing 343 containing an optical fiber 338 and an optical input/output

20 connector 312 for connection to the controller. The separable optical connector 350 is provided near the connection hub 340 to facilitate connection and disconnection of the flexible optical coupling 308, as needed. By way of example, along its length from the connection hub 340 to the pigtail tip 306, the sensor catheter 300 has an outside diameter in the range of about 4 French to 7 French, e.g., 5 French (1.7mm /0.066 inch).

25 [77] **Figs. 5A and 5B** show enlarged axial cross-sectional views of the sensor catheter illustrated in **Fig. 4** taken, respectively, through planes **A-A** and **B-B** of **Fig. 4**. The cross-section of Fig. 5A shows lumens 314-1 and 314-2, with optical fiber 332 within the first lumen 314-1. The cross-section of Fig 5B shows the sensor 330 in lumen 314-1 and aperture 326 adjacent the sensor 330 for fluid contact with the sensor 330. If, for example, the

30 sensor catheter 300 has an outer diameter D_o of 5 French (1.7mm/0.066 inch), the inner diameter of second lumen 314-2 is sized to be large enough to allow rapid injection of a

bolus of contrast medium into the aorta downstream of the aortic valve, e.g. 25 ml to 60ml of contrast medium over 1 or 2 seconds which requires a larger lumen, e.g. ~1mm diameter. The inner diameter of the second lumen is also sized to accommodate a conventional guidewire, i.e., for introduction of the sensor catheter into the aorta or other vessel, by passing it over the guidewire. The inner diameter of the first lumen 314-1 is large enough to accommodate the optical fiber 332 and the optical pressure sensor 330, and need not be as large as the fluid injection lumen 314-2. For example, if the sensor 330 has a diameter of 0.260 mm, the first lumen may have a diameter which provides some clearance around the sensor for insertion of the sensor into the lumen, e.g. a lumen of 0.325 mm diameter.

[78] In variants of the dual lumen sensor catheter of the first embodiment illustrated schematically in Figs. 4, 5A and 5B, the cross-section of the catheter tubing has other geometries or configurations that provide first and second lumens of appropriate sizes. By way of example, cross-sectional views of examples of dual lumen catheters of two alternative embodiments are shown in Figs. 6A and 6B. Corresponding elements are numbered with the same reference numerals as those shown in Figs. 4, 5A and 5B. Catheter tubing 320 having a cross-section as shown in Fig. 6A, with first lumen 314-1 for the optical fiber 332 and second lumen 314-2, provides a more uniform wall thickness than the cross-section shown in Fig. 5A, to provide a sensor catheter with more radially symmetric physical characteristics, such as flexibility and torque steering characteristics. Catheter tubing having a cross-section as shown in Fig. 6B provides a similar sized lumen 314-1 for the optical pressure sensor 330 and optical fiber 332 as the sensor catheter cross-section shown in Figs. 5A, and provides a fluid lumen 314-2 with a larger cross-sectional area. Dual lumen sensor catheters having other cross-sections may be used. Also, if required, multi-lumen sensor catheters having one or more additional lumens for other purposes may be used, such as a central lumen for insertion of a guidewire, or additional fluid lumens.

[79] **Dual Sensor Support Guidewire for Left Heart Catheterization**

[80] An enlarged schematic longitudinal partial cross-sectional view of a sensor guidewire assembly 1210 comprising a sensor guidewire 1200 and a flexible optical coupling 1208 of a second embodiment is shown in **Fig. 7**. The sensor guidewire 1200 of this embodiment comprises two FP optical pressure sensors 1230-1 and 1230-2 and is

configured for diagnostic measurements of blood pressure concurrently in two locations, e.g., in the left ventricle (LV) and in the aorta during left heart catheterization. Many parts of this dual sensor guidewire are similar to those of the sensor guidewire 200 of the first embodiment and are labelled with the same reference numerals incremented by 1000. The

5 dual sensor guidewire 1200 extends from the optical coupler 1240 at its proximal end to the atraumatic flexible tip 1206 at the distal end 1204. The dual sensor guidewire is coupled through the separable optical connector 1240 to the flexible optical coupling 1208 for connection by input/output connector 1212 to the controller. The sensor guidewire 1200 comprises a flexible tubular member comprising an outer tubular layer 1220 and an inner

10 tubular layer 1234. Like the sensor guidewire 200 of the first embodiment, the structure and materials of the outer tubular covering 1220 and the inner tubular layer 1234 of the sensor guidewire 1200 are selected to provide stiffness and other required physical characteristics of a support guidewire along its length. For example, most of the length of the flexible tubular covering 1220 of the distal portion of the sensor guidewire 1200

15 comprises a stainless-steel metal hypotube having an appropriate stiffness/flexibility, while the distal end portion comprises more flexible regions 1227, which comprises a length of flexible stainless-steel micro-coil, and a reinforced, e.g. stiffer, section of hypotube 1224 in between. A first FP optical pressure sensor 1230-1, at position P1, is optically and physically connected to the distal end (i.e. the sensor end) of a first optical fiber 1232-1

20 which terminates at the proximal end (i.e. connector end) of the sensor guidewire within the optical connector 1240. A second FP optical pressure sensor 1230-2, at position P2, is optically and physically connected to the distal end (i.e. the sensor end) of the optical fiber 1232-2 which terminates at the proximal end of the sensor guidewire within the optical connector 1240. The inner tube 1234 extends around the fibers and extends beyond the

25 sensor end of the fiber 1232-1 towards the tip 1206. In the region of each sensor 1230-1 and 1230-2, there is an aperture 1226 in the outer tubular layer 1220, and the inner tubular layer 1234 is shaped to leave space around the sensor, e.g. cut away to form a cavity 1225, to accommodate the sensor 1230 and to allow for fluid contact with the sensors 1230. As illustrated, the reinforced region 1224 of the outer tube 1220 extends a short length each

30 side of the sensor position P1 and sensor position P2 to provide a required stiffness in the region of the sensors, i.e. where the inner tubular layer 1234 is cut away. A radiopaque marker 1236 may be provided near each sensor, to assist in locating the sensors 1230-1 and

1230-2 in use, e.g. by fluoroscopic imaging. The inner tubular layer 1234 extends a short distance past the first sensor 1230-1 and the tip core wire 1239 forms the core of the flexible tip 1206. To position each sensor 1230 next to its aperture 1226 within the reinforced region 1224 of the outer tubular layer 1220, the inner and outer tubular layers 1220 and 1234 may
5 be secured to each other, e.g. by bonding with adhesive or filler, soldering or welding, at points 1237 at each end of the reinforced region 1224. The atraumatic flexible tip 1206 may be a preformed J-tip, a preformed flat spiral tip, or a preformed 3-dimensional spiral or coiled tip.

[81] Similar to the sensor guidewire 200 of the first embodiment, if the sensor guidewire
10 1200 is to be used for TVT, e.g. TAVR or TMVR, the sensor guidewire 1200 has physical characteristics along its length, e.g. stiffness, required of a support guidewire to provide a rail for the delivery device and valve components. The optical fibers 1232-1 and 1232-2 in the sensor guidewire 1200 are optically coupled through the dual fiber optical connector 1240 to corresponding optical fibers 1238-1 and 1238-2 in the flexible optical coupling 1208
15 of the sensor guidewire 1200 to the controller. The dual optical fiber connector 1240 comprises alignment means for optical alignment of the pair of optical fibers 1232-1 and 1232-2 with the pair of optical fibers 1238-1 and 1238-2 using a pair of ferrules 1243 and an alignment sleeve 1242 comprising an alignment facet, e.g., using D-shaped ferrules and a correspondingly shaped alignment sleeve. In use, the sensor guidewire 1200 is connected
20 to a flexible optical connection 1208 to the input/output connectors 1212-1 and 1212-2 which connect to the optical input/output ports 102-P1 and 102-P2 of the controller. For example, the flexible optical connection 1208 for the sensor guidewire 1200 may simply comprise a length of flexible tubing 1222, and protective outer jacket 1223 containing the optical fibers 1238-1 and 1238-2. The flexible optical coupling 1208 of sensor guidewire
25 1200 differs from that of the sensor guidewire of the first embodiment because it has a connection hub 1216 at its proximal end 1202, which separates the two optical fibers 1238-1 and 1238-2 and provides two separate ports, each comprising a length of flexible tubing 1218 and a standard optical input/output coupler 1212-1, 1212-2, such as a SCAI connector, each comprising a strain boot 1219, for connection of the first optical pressure sensor to a
30 corresponding optical ports 102-P1 and 102-P2 of the controller 100. If required, the optical coupler 1240 connecting the sensor guidewire 1200 and the flexible optical coupling 1208

is a separable optical coupler 1240 in which the male part of the connector is provided by the sensor guidewire 1200 and has a diameter no greater than a maximum outside diameter D_g of the external covering the sensor guidewire 1200. Separation of the two parts of the connector 1240 enables over-the-wire mounting of a valve delivery system and valve components on the sensor guidewire 1200. The female part of the coupler forms the distal end of the flexible optical coupling 1208 to the sensor guidewire 1200. The female part 1241 of the optical connector 1240 may be of sufficient external size to form a handle for manipulating the sensor guidewire, e.g. to assist with pushing and pulling the sensor guidewire 1200 as it is inserted and withdrawn. The flexible optical coupling 1208 of the sensor guidewire may be of a larger diameter, more flexible and fabricated from lower cost components to facilitate fabrication and reduce costs.

[82] **Figs. 8A, 8B, 8C and 8D** show enlarged axial cross-sectional views of the sensor guidewire illustrated in **Fig. 7** taken, respectively, through planes **A-A, B-B, C-C and D-D** of **Fig. 7**. The cross-section in Fig. 8A through the flexible optical coupling 1208 shows the flexible tubing layer 1222 surrounding optical fibers 1238-1 and 1238-2, and the outer protective jacket 1223. The cross-section in Fig. 8B through the sensor guidewire 1200 shows the optical fibers 1232-1 and 1232-2 surrounded by protective inner tubular layer 1234 within the outer tubular layer 1220. The inner diameter of the inner tubular layer is sized so that the two optical fibers 1232-1 and 1232-2 fit slideably within the inner tubular layer 1234. The cross-section shown in Fig. 8C taken through the distal end of the sensor guidewire 1200 near the first FP optical pressure sensor 1230-1 shows the sensor 1230-1, the protective inner layer 1234 cut away in the sensor region to form a cavity 1225 and the surrounding reinforced region 1224 of the outer tubular layer 1220. An aperture 1226 is provided in reinforced region 1224 near the sensor to allow for fluid contact with the sensor. The cross-section shown in Fig. 8D is taken through the distal end near the second FP optical pressure sensor 1230-2 shows the second FP optical pressure sensor 1230-2 lying beside the first optical fiber 1232-1, where the protective inner layer 1234 is cut away in the sensor region to form a cavity 1225 for the second FP optical pressure sensor 1230-2 and the surrounding reinforced region 1224 of the outer tubular layer 1220. As for the first FP optical pressure sensor 1232-1, an aperture 1226 is provided in a reinforced region 1224 near the second sensor 1230-2 to allow for fluid contact with the second sensor 1230-2. The

outer diameter of the sensor guidewire Dg is indicated in Figs. 3B, 3C, and 3D, and is e.g., typically 0.035 inch (0.89mm) or less for left heart catheterization. The diameter of the flexible optical coupling 1208 shown in Fig. 8A may have any suitable diameter.

[83] The tip 206 and 1206 of the sensor guidewires 200 and 1200 of the first and second
5 embodiments is preferably an atraumatic pre-formed curved tip such as a pre-formed spiral tip. For example, for firmly anchoring of the tip of the sensor guidewires 200 and 1200 in the left ventricle during TAVR, a 3-dimensional curved spiral tip may be preferred. For example, **Figs. 9A and 9B** show two schematic side views of a 3-dimensional pre-formed flexible spiral tip 206-1 having a helical form and comprising an aperture 226 for the FP
10 optical pressure sensor spaced a distance L1 from the apex of the curved tip. Another example of a 3-dimensional pre-formed curved flexible tip 206-2 of a tapered helical form is shown schematically in **Figs. 10A and 10B**. The radii, number of turns and other dimensions of the spiral or helix may be selected based on dimensions of the left ventricle. For other TVT procedures, e.g. insertion of a sensor guidewire into other chambers of the
15 heart, e.g. the left atrium, or for an apical approach to the aorta, a flexible preformed curved tip of another form may be used.

[84] Schematic views showing details of components of a TVT sensor support guidewire 2200 of another embodiment are shown in **Figs. 20A to 20E**. Fig. 20A shows a schematic partially cut-away view a TVT sensor support guidewire 2200 comprising a main body 2201
20 having a length L extending between a proximal end 2202 comprising a fiber optic termination 2243 and a sensor region 2203 near the distal end 2204. The distal end comprises a flexible pre-formed curved distal tip 2206. Fig. 20A shows the tapered inner core wire 2239 of the spiral distal tip, with its outer coil removed. The main body 2201 of the TVT sensor support guidewire comprises an inner tubular layer, which may be referred
25 to as a core tube, 2234, extending within an outer tubular layer 2220, e.g., as shown schematically in Figs. 20D and 20E. In this embodiment the core tube 2234 comprise a stainless steel hypotube. The outer tubular layer 2220 comprises a flexible coilwire 2220-1 covering the core tube 2234 between the fiber optic termination 2243 and the sensor region 2203 of the sensor guidewire, and a length of stainless steel hypotube 2220-2 in the sensor
30 region 2203 (Fig. 20B). As shown in more detail in the enlarged view in Fig. 20B, the hypotube 2220-2 provides reinforcement and stiffness to the outer tubular layer in the sensor

region 2203 around the sensor aperture 2226. An enlarged view of the proximal end 2202 of the sensor guidewire is shown in Fig. 20C, showing the fiber optic termination comprising an optical input/output micro-connector 2212, e.g. a ceramic ferrule 2243 surrounding the connector end of the optical fiber 2232, and an outer sleeve 2245. The outer sleeve 2245, e.g. a length of stainless steel hypotube, extends a short distance between the ferrule 2243 and the flexible coil wire 2220-1 to reinforce and stiffen the proximal end of the sensor guidewire near the ferrule 2243. The ferrule 2243 is configured to insert into a corresponding female part of an optical connector carried by a flexible optical coupling, such as a length of optical cable, for connecting the sensor guidewire 1200 to the optical controller 100, as illustrated for example in Fig. 1, for sensor guidewire 200 of the first embodiment. Preferably, the ferrule 2243 and the outer sleeve 2245 have a maximum outer diameter similar to the maximum diameter of the main body 2201 of the sensor guidewire, e.g., 0.035 inch, to allow for over-the-wire mounting of the components for TVT, such as a catheter carrying a valve delivery device. An enlarged view of part of the sensor guidewire in the sensor region 2203 is shown in Fig. 20D, with the outer tubular layer comprising the hypotube 2220-2 removed to show the inner core tube 2234 comprising aperture 2226 near the FP optical pressure sensor 2230, and the core wire 2239 which forms the core of the spiral tip 2206 (Fig. 20A). A cross-sectional view of the sensor region is shown in Fig. 20E to show details of the inner core tube 2234 and the outer sensor hypotube 2220-1 near the sensor 2230. In this embodiment, inner core tube 2234 is cut away to form an aperture 2228 in the region where the sensor 2230 is placed and the sensor aperture or “pressure window” 2226 in the outer hypotube 2220-2 is formed by a through hole which is drilled right through the sensor hypotube 2220-2 in the sensor region, to provide an aperture on each side of the sensor position.

25 [85] **Control system**

[86] Referring to the controller 100 shown schematically in Fig. 1, the controller of the dual sensor system may be used with a sensor guidewire and a sensor catheter for concurrent blood pressure measurements at two locations. Alternatively, the same controller may be used with a dual sensor guidewire such as described with reference to Fig. 7.

[87] For dual optical pressure sensors, the controller 100 has a corresponding number of signal processing channels with optical ports 102-P1 and 102-P2 for optical connectors each of the optical pressure sensors as illustrated schematically in **Fig. 11A**. Each channel comprises an optical control unit, which may be referred to as a signal conditioner, comprising an optical light source and detector for operating a FP optical pressure sensor, associated signal processing electronics and communications interfaces providing digital ports 132, and analog ports 134 for input/output signals to connectors for an ANSI BP-22 compliant PCM. For example, as illustrated schematically in the block diagram in **Fig. 11B**, each channel of the control system comprises a signal conditioner 110, that comprises the light source and detector and an optical interface 112 for coupling, via respective input/output ports, to an optical fiber and FP optical pressure sensor of a sensor catheter or a sensor guidewire. Calibration data from the sensor EEPROM is input at interface 114 to digital interface 116 which provides calibration data to the signal conditioner 110. The control system also comprises processing means and data storage, e.g. a microprocessor 120, and associated firmware 122, RAM 124, display and indicators 126. The signal conditioner 110 comprises hardware and software configured for processing optical data indicative of pressure values to output calibrated digital sensor data to the microprocessor 120. Digital outputs from the microprocessor 120 are provided to the digital interface 128 comprising standard digital ports 132 and to BP-22 signal converter 130 which provides analog ports 134 for input/output signals for a BP-22 compliant patient care monitor (PCM). The system also comprises AC/DC power electronics 125 for these components.

[88] Where the controller is to be interfaced to a BP-22 compliant PCM for monitoring blood pressure data, and the PCM is configured for displaying blood pressure waveforms, i.e. a pressure waveform from each optical pressure sensor, on a graphical user interface, the concurrent blood pressure waveforms for each of the FP optical pressure sensors may be displayed for one or more time intervals, and during one or more cardiac cycles. The PCM may be further configured to derive hemodynamic parameters from the blood pressure data and display numeric values of the parameters, such as aortic regurgitation index, as well as display the pressure waveforms from each sensor.

[89] If the controller is not connected to a BP-22 compliant patient monitor, digital outputs may be provided to a digital patient monitoring system or to a general-purpose

computer 500, such as a tablet PC, running software configured to display of the pressure waveforms and associated hemodynamic parameters. Alternatively, the microprocessor 120 of the controller 100 may be configured to generate digital outputs for displaying of blood pressure waveforms and other hemodynamic parameters on a monitor linked directly to the controller 100.

[90] The user interface of the PC or PCM may allow the operator to input user data such as patient identification, and data interfaces may be provided to output data to other devices or systems, or receive data from other sources, such as from other sensors or monitoring systems, which are typically used in an ICU or OR. For example, in a cardiac catheterization laboratory, the control system 100 for a sensor catheter and sensor guidewire may be coupled to, or part of, a computing system controlling other equipment, and which is equipped with one or more large screen displays close to the operating table, and other remote displays in a monitoring area. The latter are used to display various forms of data, sequentially, concurrently, or on demand. Such data may include, e.g. fluoroscopic imaging, with or without contrast media, and transoesophageal echo-cardiography (TEE) images, as well as sensor data comprising pressure waveforms from the sensor catheter and sensor guidewire and associated hemodynamic parameters calculated or derived from the received FP optical pressure sensor data.

[91] In practice, pressure waveforms and pressure values vary from patient to patient and may be dependent on a number of factors, such as, whether or not the patient has a healthy or diseased heart, or other conditions that may affect functioning of the heart. Skilled medical practitioners will recognize characteristic variations in each pressure waveform and associated pressure values, indicative of e.g. valvular stenosis or other patient physiology. For example, in use of dual sensor system comprising a sensor catheter and a sensor guidewire, concurrent pressure measurements from two FP optical pressure sensors enable the cardiologist to directly compare pressure waveforms and hemodynamic parameters, in real-time, to assess functioning of the heart valve. For example, the aortic regurgitation index (ARi) is an important parameter for assessing functioning of the aortic valve. The ARi is computed from measured values of the left ventricular end-diastolic pressure (LVEDP), diastolic blood pressure (DBP), and systolic blood pressure (SBP), which is defined as:

$$ARi = ((DBP-LVEDP)/SBP) \times 100$$

[92] **Examples: Use of dual sensor system for TAVR and TMVR**

[93] **Fig. 12** shows a schematic diagram to illustrate deployment of a dual sensor system of the first embodiment comprising a sensor catheter 300 for measurement of pressure in the ascending aorta (Ao) and a sensor guidewire 200 for concurrent measurement of pressure in the left ventricle (LV), and in which the controller 100 is connected to a dedicated user interface, e.g. a tablet PC 500, for displaying pressure waveforms and associated hemodynamic parameters including an aortic regurgitation index (ARi). Fig. 12 includes schematic examples of screen shots indicative of a) a healthy heart, as represented by screenshot 500-1 and b) a heart with significant aortic regurgitation, as represented by screenshot 500-2. In this example, the calibrated pressure data is also output via analog ports of controller 100 to a BP-22 PCM 400, e.g. for further processing or display of data by other equipment, such as the large screen monitors, as typically used in a Cath Lab.

[94] A schematic partial cross-sectional diagram of a human heart 600-1 is shown in **Fig. 13** to illustrate placement of the sensor catheter 300 and sensor support guidewire 200 of the dual sensor system of the first embodiment for diagnostic measurements of hemodynamic parameters. The distal region of sensor support guidewire 200 is positioned for continuous blood pressure measurement by FP optical pressure sensor 230 (P1) within the left ventricle (LV) 601. The sensor catheter 300 is positioned for concurrent and continuous measurement of blood pressure by sensor 330 (P2) positioned within the ascending aorta 602, downstream of the aortic valve 604, i.e. with the pigtail of the sensor catheter 300 positioned close to the cusps of the aortic valve 604, and apertures 335 arranged for injection of contrast medium into the ascending aorta 602 downstream of the aortic valve 604. The sensor catheter 300 replaces a conventional pigtail catheter that is in place for contrast medium injection during TAVR and preferably has the same outer diameter, and other physical characteristics, of a conventional pigtail catheter of this type, so it may be used interchangeably without change of procedure, other than connecting the optical connector directly or indirectly to the control unit (e.g. control unit 100 shown in Fig. 1) when activation of the FP optical pressure sensor 330 P2 for pressure measurements is required. The tip 206 of the sensor support guidewire 200 is introduced through the

descending aorta 603, the ascending aorta 602 and through aortic valve 604 in the manner of a conventional support guidewire for TAVR. The preformed curved tip 206 anchors the sensor guidewire in the left ventricle 601 and positions the sensor 230 within the left ventricle, upstream of the aortic valve 604, as illustrated schematically. Thus, the FP optical pressure sensors 230 (P1) and 330 (P2) are positioned so that one sensor is located upstream of the aortic valve and one sensor located downstream of the aortic valve. This arrangement enables concurrent blood pressure measurements in the ascending aorta and in the left ventricle, e.g., for measurement of a transvalvular pressure gradient across the aortic valve and other hemodynamic parameters. In use of a dual sensor system comprising a sensor guidewire and a sensor catheter as illustrated schematically in Fig. 13, which are independently movable, the relative positions of the two sensors 230 and 330 may be adjusted to some extent, depending on a patient's size and individual anatomy.

[95] A schematic partial cross-sectional diagram of a human heart 600-2 is shown in **Fig. 14** to illustrate placement of the dual sensor guidewire 1200 of the second embodiment for diagnostic measurements of hemodynamic parameters within the left heart. The tip 1206 of the sensor support guidewire 1200 is introduced through the descending aorta 603, the ascending aorta 602 and through aortic valve 604 in the manner of a conventional support guidewire for TAVR. As illustrated schematically the helical spiral tip 1206 anchors the sensor guidewire in the left ventricle 601, with the first optical pressure sensor 1230-1 (P1) located within the left ventricle 601. The second optical pressure sensor 1230-2 (P2) is positioned in the ascending aorta 602. For example, a sensor spacing of about 20mm to 50mm would be sufficient to place one sensor upstream and one downstream of a heart valve. However, blood pressure measurements may be affected by significant turbulence in the blood flow through the cardiac cycle. For this reason, a larger spacing, e.g. 70mm to 100mm, between the two sensor locations may be preferred to enable one sensor to be located further into the left ventricle 601 and another sensor to be located further upstream of the aortic valve 604 in the aorta 602, so that both sensors are located in regions of less turbulent flow, i.e. spaced some distance each side of the aortic valve 604. For example, based on review of CT scans to assess dimensions of the heart of a number of subjects, an 80 mm spacing of two pressure sensors may typically be required, e.g., to enable

measurement of a transvalvular pressure gradient. For paediatric use, a smaller gauge sensor guidewire and closer spacing of the sensors may be appropriate.

[96] A schematic partial cross-sectional diagram of a human heart 600-3 is shown in **Fig. 15** to illustrate placement of the sensor catheter 300 and sensor guidewire 200 of the dual system, for measurements of hemodynamic parameters, including concurrent measurements of blood pressure in the ascending aorta and LV during TAVR. The tip 206 of the sensor support guidewire 200 is introduced through the descending aorta 603, the ascending aorta 602 and through aortic valve 604. In this example, the distal region of the sensor catheter 300 is positioned with sensor 330 (P2) in the aorta 602 and the distal region of the sensor guidewire 200 is positioned with the sensor 230 (P1) in the left ventricle 601, similar to the arrangement shown in **Fig. 13**. Apertures 335 in the sensor catheter provide for injection of contrast medium into the ascending aorta. A catheter 700 carrying a valve delivery device 702 is mounted over the sensor guidewire 200, and is shown with the nose cone 701 of the valve delivery device 702 positioned through the aortic valve 604 ready for deployment of a prosthetic aortic valve. Even when the valve delivery device is this position during valve deployment, the first optical pressure sensor 230 (P1) of the sensor support guidewire is positioned to enable continuous measurement of the LV pressure and the second optical pressure sensor 330 (P2) of the sensor catheter is positioned to enable continuous measurement of the Aortic pressure. Since the catheter 700 of the valve delivery device 702 is mounted over the sensor guidewire 200 in the aorta, if the sensor guidewire 200 is provided with an optional second sensor as shown in **Fig. 14**, the second sensor in the aorta would be covered by the catheter 700 at this stage in valve deployment. During this time, the optional second sensor of the sensor guidewire would be blocked or disabled from measuring blood pressure in the aorta. This application of the dual sensor system comprising a sensor guidewire 200 and a sensor catheter 300 enables pressure measurements in the left ventricle and in the ascending aorta be monitored on demand during TAVR, and potentially continuously, before, during and after valve deployment.

[97] In this disclosure, enabling “continuous” measurements of blood pressure refers to enabling “on demand” sampling of blood pressure measurements at any time during a TAVR procedure. A typical heart rate is e.g., 60 to 120 beats per minute. Typically, the digital signal conditioner for the first and second FP optical pressure sensors use a much faster

sampling rate, e.g., 250Hz, to generate digital pressure waveforms for blood pressures for LV and Ao. These digital pressure waveforms, and derived parameters, may be output to a digital monitor for display and further analysis. To enable interfacing to a BP-22 compliant PCM, the control unit comprises a signal converter that converts the digital waveforms and
5 generates analog input and output signals for interfacing to a BP-22 compliant PCM.

[98] **Figs. 13 to 15** show examples of an aortic approach to the left ventricle 601, which is the most commonly used approach for TAVR e.g. using either transfemoral or transradial percutaneous entry for left heart catheterization. Alternatively, in some patients, an apical approach for TAVR may be used (not shown in the drawings), where a small incision is
10 made between the ribs to allow the sensor guidewire and valve delivery device to be inserted into the heart through the apex of the left ventricle. Since the latter is a more direct approach, a shorter sensor guidewire and valve delivery device may be used; the length, diameter, stiffness and other characteristics of the sensor guidewire are therefore selected accordingly.

[99] An example of an apical approach to the left ventricle 601, i.e. through apex 607 of
15 the left ventricle 601, to access the mitral valve 606 for TMVR is shown in **Fig. 16**, which shows a schematic partial cross-sectional diagram 600-4 of a human heart to illustrate placement of the sensor catheter 300 and sensor guidewire 200 of dual sensor system, for measurements of hemodynamic parameters, including concurrent measurements of blood pressure in the LV 601 and left atrium (LA) 614 during TMVR. As illustrated schematically
20 in Fig. 16, in this example, the tip 206 of sensor guidewire 200 is introduced through the apex 607 of the LV 601 and passed through the mitral valve 606 into the LA 614, for measurement of LA pressure by pressure sensor 230 (P1) positioned in the LA. The sensor catheter 300 is inserted through the descending aorta into the ascending aorta 602, and the tip of the catheter is advanced through the aortic valve 604 into the LV 601 for injection of
25 contrast medium into the LV 601 through apertures 335, and for measurement of LV pressure by pressure sensor 330 (P2). A catheter 700 carrying mitral valve delivery device 702 is delivered over the sensor support guidewire 200 and positioned through the mitral valve 606. This arrangement allows for blood pressure monitoring in the LV and LA during TMVR.

- [100] For comparison, a schematic partial cross-sectional diagram 600-5 is shown in **Fig. 17** to illustrate placement of the sensor catheter 300 and sensor guidewire 200 using a trans-septal approach, via the inferior vena cava 620 and the right atrium 621, via a trans-septal puncture to enter the LA 614 and LV 601 for TMVR. In this example, the tip of the sensor catheter 300 is positioned in the LA 614 for measurement of LA pressure by pressure sensor 330 (P2). The tip 206 of the sensor guidewire 200 is positioned in the LV 601 for measurement of LV pressure by pressure sensor 230 (P1). Catheter 700 carrying valve delivery device 702 is delivered over the sensor support guidewire 200 to position the valve delivery device through the mitral valve 606.
- 10 [101] A schematic partial cross-sectional diagram 600-6 is shown in **Fig. 18** to illustrate placement of the sensor catheter 300 and sensor guidewire 200 of the dual sensor system using an aortic approach to the LV and LA for TMVR. The tip 206 of the sensor guidewire 200 is inserted through the aorta, through the aortic valve into the LV 601 and then advanced through the mitral valve 606 into the LA to position pressure sensor 230 (PA) in the LA for measurement of LA pressure. The sensor catheter 300 is introduced through the aorta, and through the aortic valve for measurement of LV pressure by pressure sensor 330 (P2), and injection of contrast medium through apertures 335. The catheter 700 carrying the valve delivery device 702 is inserted over the sensor support guidewire 200 to position the valve delivery device through the mitral valve 606.
- 15 [102] **Fig. 19** shows a schematic partial cross-sectional diagram 600-7 showing placement of a dual sensor support guidewire 1200 through the inferior vena cava 620 and the RA 621 for a trans-septal approach to the LA 614 and LV 601 for TMVR. In this example, the tip 1206 of the sensor support guidewire 1200 is positioned in the LV 601 for measurement of the LV pressure by pressure sensor 1230-1 (P1). Catheter 700 and valve delivery device 702 are mounted over the sensor support guidewire 1200 to position the valve delivery device through the mitral valve 606. The pressure in the left atrium 614 may be obtained by a second optical sensor 1230-2 (P2) in the sensor support guidewire 1200 positioned in the LA 614, i.e., measurements made before introducing or after withdrawing the valve delivery device 702. Alternatively, the LA pressure may be obtained indirectly from a pulmonary wedge pressure measurement made with a pulmonary artery (PA) catheter.
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[103] Regarding pressure ranges to be measured within the aorta and chambers of the heart, the peak pressure in the LV may be around 150mmHg or more, so for absolute pressure measurements, pressure sensors capable of directly measuring blood pressure in the range of 0 to ~300mmHg are suitable. For assessing heart valve function, accurate measurement of smaller differences in blood pressure is required to assess a transvalvular pressure gradient. For example, considering a transvalvular pressure gradient across the aortic valve, in a healthy heart, this pressure difference would be close to zero, or e.g., <5mmHg. A pressure difference measured in the LV and ascending aorta (Ao) in the range of e.g., >40mmHg to 60mmHg, would be indicative of severe aortic valve stenosis. During TAVR to deploy a prosthetic aortic valve, if a measurement of the aortic transvalvular pressure gradient is made before and after deployment and positioning of a prosthetic aortic valve, if the valve deployment is successful, it would be expected to see a significant decrease in the transvalvular pressure gradient, e.g. from >40mmHg to <10mmHg if valve placement is optimal. For repositionable prosthetic valves, measurements of the transvalvular pressure gradient when the prosthetic valve is first positioned, and then repositioned to achieve a lower pressure gradient, may provide additional data to assist in optimal placement of the prosthetic valve. Thus, for TAVR, while measurement of transvalvular pressure gradients in the range of 0 to 60mmHg within ± 2 mmHg is desirable, measurement within ± 10 mmHg may be adequate to assess aortic valve function before and after TAVR, e.g., to show a significant reduction in transvalvular pressure gradient from >40mmHg before TAVR to <20mmHg or <10mmHg after deployment of prosthetic valve. To improve the accuracy of transvalvular pressure measurements with the pair of FP optical pressure sensors, it is beneficial if the first and second FP pressure sensors are “zeroed” relative to each other by taking simultaneous pressure measurements with both first and second FP optical pressure sensors placed within one chamber of the heart, e.g. with both sensors placed within the LV measuring the same pressure concurrently.

[104] In comparison, for the mitral valve, it is required to measure a pressure gradient with greater accuracy. For example, a transvalvular pressure gradient of 20mmHg would be indicative of severe mitral valve stenosis or other severe mitral valve malfunctioning. Thus, a mitral valve transvalvular pressure gradient of >5mmHg may be indicative of mitral valve stenosis. For this reason, assessment of mitral valve function requires measurement of a

transvalvular pressure gradient within $\pm 2\text{mmHg}$, and preferably within $\pm 1\text{mmHg}$ is desirable. As mentioned above, to improve the accuracy of transvalvular pressure measurements, it is beneficial if the first and second FP pressure sensors are “zeroed” relative to each other by taking simultaneous baseline pressure measurements with both first
5 and second FP sensors positioned within one chamber of the heart, if possible in the LA, or alternatively in the LV.

[105] The optical pressure sensors 230 and 330 (P1 and P2) are preferably Fabry-Pérot (FP) Micro-Opto-Mechanical System (MOMS) sensors, such as those described by FISO Technologies (E. Pinet, “Pressure measurement with fiber-optic sensors: Commercial
10 technologies and applications” 21st International Conference on Optical Fiber Sensors, edited by Wojtek J. Bock, Jacques Albert, Xiaoyi Bao, Proc. of SPIE Vol. 7753, (2011)). These optical pressure sensors comprise an optical fiber having a FP MOMS sensor at the sensor end of the fiber for sensing pressure. By way of example, for standard diameter optical fibers, each fiber has a diameter of 0.155mm (0.006 inch) and each optical pressure
15 sensor has a diameter of 0.260mm (0.010 inch). FP optical pressure sensors capable of pressure measurements in a range suitable for medical applications and blood pressure measurements are also available from Opsens Inc.

[106] For smaller fibers, e.g. 0.100mm fibers, and smaller diameter sensors, the dimensions of the sensor lumen of the sensor catheter and the inside diameter of inner
20 tubular layer of the sensor guidewire may be reduced in size accordingly.

[107] Since the sensor guidewires and sensor catheters of the embodiments are intended for single-use only, preferably the optical connectors for connection to the control unit are standard low cost optical connectors. Similarly, the flexible tubing, and other connectors for the other ports are preferably standard materials and components, such as luer fittings or
25 other medical standard fluid ports, as appropriate, which can be sterilized, and so that the sensor catheter and sensor guidewire can be provided in single-use sterile packaging, using conventional processes for packaging and sterilization of medical devices.

[108] As mentioned above, it is desirable that the sensor guidewire has mechanical characteristics, such diameter, stiffness and torque characteristics, similar to a conventional
30 support guidewire for TVT. The optical fiber and optical pressure sensor do not add

significant stiffness to the sensor guidewire, and thus these characteristics are primarily determined by structure and materials of the sensor guidewire, e.g. the inner tubular layer which may be a stainless steel hypotube or polymer layer and the outer tubular layer which may be an outer stainless steel hypotube or stainless steel micro-coil or a combination thereof. The inner tubular layer may comprise a multilayer structure. Similarly, the outer tubular layer may also comprise a multilayer structure.

[109] As mentioned above, it is desirable that the sensor catheter has mechanical characteristics, such diameter, stiffness and flexibility, similar to a conventional pig-tail catheter used for injection of contrast agent and other fluids. The optical fiber and optical pressure sensor do not add significant stiffness to the sensor catheter, and thus these characteristics are primarily determined by the type of material and wall thickness used for the multi-lumen catheter tubing.

[110] Other factors for consideration are: regulatory requirements for medical devices, ease of use and safety. For these reasons, it is desirable that the materials for fabrication of sensor guidewire and sensor catheter are based on a conventional tried and tested medical devices, i.e. based on a predicate device structure which has regulatory approval and which is fabricated with materials and components which already have FDA and/or CE mark regulatory approval.

[111] It will be appreciated that in alternative embodiments or variants of the dual sensor system of the embodiments described in detail above, different combinations of one or more features disclosed herein, and features disclosed in the related patent applications referenced herein, may provide further alternative embodiments.

[112] As disclosed herein, in one embodiment, the cardiologist is offered dual sensor system comprising a TVT support guidewire containing a first optical pressure sensor (sensor support guidewire) and an angiographic pigtail catheter containing a second optical pressure sensor (sensor catheter), which has particular application for continuous blood pressure measurements during TVT, e.g. TAVR or TMVR, wherein the pair of optical pressure sensors are configured for monitoring and diagnostic measurements of hemodynamic parameters, including concurrent measurement of blood pressure at two different and variable locations within the heart and aorta during left heart catheterization.

The interventional cardiologist may adjust the relative positioning of the sensor catheter and the sensor guidewire so that the first and second optical pressure sensors are positioned to suit the dimensions of an individual's heart, and are appropriately positioned for relative to the heart valve. Radiopaque markers on the sensor guidewire and sensor catheter may be
5 provided to assist in positioning of the first and second FP optical sensors. A dual sensor system comprising single sensor guidewire used in conjunction with a single sensor catheter may offer a more cost-effective solution, which is more readily fabricated than multisensor guidewires and multisensor catheters.

[113] If required a second sensor may be provided in a sensor guidewire. Thus, in another
10 embodiment, a dual sensor system comprises a dual sensor guidewire for diagnostic measurements during left heart catheterization. The dual sensor guidewire may be used with the same two channel controller as described above.

[114] In other applications of a TAVT support guidewire containing a first FP optical pressure sensor, the TAVT support guidewire is positioned for continuous direct measurement
15 of LV pressure in the left ventricle during TAVT, e.g. during TAVR or BAV. A second pressure measurement may be obtained using another type of pressure sensor placed in the ascending aorta, e.g. a fluid filled catheter with an external pressure sensor, or a catheter with an electrical pressure sensor. For TMVR, the pressure in the left atrium may be obtained indirectly by using a pulmonary artery (PA) catheter to obtain a pulmonary wedge
20 pressure.

[115] Systems and apparatus according to embodiments of the present invention described herein offer real-time hemodynamic valve function data to the cardiologist during TAVR. The first and second optical pressure sensors provide accurate measurements of blood pressure concurrently at two positions, i.e. in the left ventricle and in the ascending aorta.
25 If required, the pressure measurements can be provided continuously, i.e. at any time throughout the TAVR procedure. In practice, pressure measurements may be made continually, e.g. periodically or at intervals before, during or after a TAVT procedure. For example, the system enables uninterrupted monitoring of the LV pressure by the first sensor in the sensor support guidewire and the second pressure sensor in the sensor catheter can
30 provide uninterrupted pressure measurements in the ascending aorta even during balloon

valvuloplasty and valve deployment, when the part of the sensor guidewire downstream of the aortic valve is surrounded by a guide catheter, balloon catheter, valve delivery device or other components.

[116] With the introduction of prosthetic valves that are repositionable during TVT, pressure measurements during TVT could potentially provide data on valve function at the point of deployment to assist in optimizing valve placement, to mitigate issues of sub-optimal valve placement, such as regurgitation or paravalvular leakage.

[117] Advantageously, the sensor catheter has the external form and dimensions of a conventional pigtail catheter which is typically already in place in the aorta during TAVR, i.e. for delivery of contrast medium into the aorta and LV near the aortic valve. Externally, the sensor guidewire resembles a conventional support guidewire, having appropriate dimensions, stiffness and torque characteristics, and functionality to enable the sensor guidewire to be used in a conventional manner as a support guidewire for TAVR. Thus, apart from the need to make the optical connections for the sensor catheter and sensor guidewire to the control unit for activation of the optical pressure sensors, the sensor pigtail catheter can be introduced and used in same manner as a conventional angiographic pigtail catheter, and the sensor guidewire can be introduced and deployed in the same manner as a conventional support guidewire. Each of the sensors can provide pressure data continuously, or at intervals as needed during TAVR, without disrupting the standard TAVR procedure. With a suitably configured interface, the controller provides compatibility with standard PCM systems, and thus can be integrated more readily into the Cath Lab, with less equipment clutter, and avoiding additional cabling.

[118] For some applications, such as diagnostic measurements to assess heart valve function, it may be desirable to provide a dual sensor guidewire, such as sensor guidewire 1200 described above. However, providing two or more optical pressure sensors within a support guidewire adds to cost and manufacturing complexity. Since a pigtail catheter is typically in place during TVT for delivery of contrast medium, providing one sensor in the pigtail catheter and one sensor in the support guidewire potentially offers a lower cost system. Further cost reductions are offered when the controller is configured to interface

directly with standard operating room and Cath Lab monitoring systems, thereby avoiding the need for a dedicated stand-alone monitoring unit.

[119] Table 2: Abbreviations or acronyms

ARi or AR Index	Aortic Regurgitation Index
BAV	Balloon Aortic Valvuloplasty
Cath Lab	Cardiac Catheterization Laboratory
CE Mark	‘Conformité Européenne’, a European certification mark
DBP	Diastolic Blood Pressure
FP MOMS Sensor	Fabry-Pérot Micro-Opto-Mechanical-System Sensor
ICU	Intensive Care Unit
LVEDP	Left Ventricular End-Diastolic Pressure
OR	Operating Room
RA	Right Atrium
RV	Right Ventricle
SBP	Systolic Blood Pressure
TAVI or TAVR	Transcatheter Aortic Valve Implantation or Replacement
TMVI or TMVR	Transcatheter Mitral Valve Implantation or Replacement
TVR	Transcatheter heart Valve Replacement
TVT	Transcatheter Valve Therapies
LV	Left Ventricle
LA	Left Atrium
FDA	Food and Drug Administration
EEPROM	Electrically Erasable Programmable Read-Only Memory
AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ANSI BP-22	Standards document ANSI/AAMI BP22:1994/(R)2016 relating to performance and safety requirements for transducers, including cables, designed for blood pressure measurements through an indwelling catheter or direct puncture.

5 [120] **Industrial Applicability**

[121] Dual sensor systems comprising sensor catheters and sensor guidewires according to embodiments disclosed herein are configured to provide real-time, concurrent, pressure measurements at two locations during TAVR, other TVT procedures and for diagnostic measurements of hemodynamic parameters to assess heart function. A pair of optical pressure sensors enables two pressure measurements to be taken concurrently, i.e. using similar FP optical pressure sensors in the both a sensor catheter and a sensor support guidewire. For example, the sensor guidewire has the same physical characteristics, such as stiffness, of a support guidewire for TAVR, and the sensor catheter has the form of an angiographic catheter which is conventionally placed in the aorta for injection of contrast medium. Blood pressure measurements can be obtained continually during TAVR by placement of the sensor guidewire to position the first optical pressure sensor in the LV for LV pressure monitoring, and placement of the sensor catheter to position the second optical pressure sensor within the aorta downstream of the aortic valve for Aortic pressure monitoring. Pressure measurements may be made continuously or at intervals on demand during TAVR. The controller may be configured to interface directly with ANSI BP-22 compliant patient monitoring systems. For some applications, a dual sensor support guidewire is provided.

[122] Although embodiments of the invention have been described and illustrated in detail, it is to be clearly understood that the same is by way of illustration and example only and not to be taken by way of limitation, the scope of the present invention being limited only by the appended claims.

CLAIMS

1. A dual sensor system for monitoring blood pressure at first and second locations during transcatheter valve therapy (TVT), comprising:
- a controller;
- 5 a sensor support guidewire for TVT comprising a tubular member having a length extending between a proximal end and a distal end, the distal end comprising an atraumatic pre-formed curved flexible distal tip, the tubular member containing a first optical fiber extending within the sensor support guidewire from an optical input/output connector at the proximal end of the sensor support guidewire to a first Fabry-Pérot (FP) optical pressure sensor, the
- 10 first FP optical pressure sensor being positioned within a distal region of the tubular member, near the distal tip, and a sensor aperture in the sensor support guidewire adjacent the first optical FP pressure sensor for fluid contact therewith;
- a sensor angiographic catheter comprising a length of multi-lumen catheter tubing extending between a proximal end and a distal end and comprising a first lumen and a second lumen,
- 15 the distal end comprising a preformed pigtail distal tip, and the catheter tubing having at its proximal end a connection hub comprising a first port for the first lumen and a second port for the second lumen, a second optical fiber extending within the first lumen from an optical/input output connector of the first port to a second FP optical pressure sensor, the
- 20 second FP optical pressure sensor being positioned within a distal region of the first lumen near the distal tip, and a sensor aperture in first lumen of the catheter tubing near the FP optical pressure sensor for fluid contact therewith; the second port comprising an injection port for injection of fluid into the second lumen, and the second lumen comprising a plurality of apertures for fluid ejection along a length of the distal region between the sensor aperture and the distal tip;
- 25 the controller comprising an optical control unit comprising optical input/output ports for coupling to the optical input/output connectors of the sensor support guidewire and the sensor angiographic catheter and a light source and detector for operating the first and second FP optical pressure sensors and processing optical data from the first and second FP optical pressure sensors to generate data indicative of blood pressure; a processor, memory,

hardware and/or software components for generating at least one of analog and digital data comprising first and second pressure waveforms; and a communications interface comprising ports for interfacing with at least one of a patient monitoring system and other peripherals.

- 5 2. The dual sensor system of claim 1, configured for measurements of hemodynamic parameters during TAVR, wherein:

the flexible distal tip of the sensor support guidewire comprises a preformed curved tip configured for positioning within the left ventricle and the first FP optical pressure sensor (P1) is a distance L1 from the flexible distal tip of the sensor support guidewire for
10 positioning of P1 within the left ventricle during TAVR; and

the sensor angiographic catheter comprises a dual lumen pigtail catheter wherein said plurality of apertures in the second lumen near the pigtail distal tip are arranged for injection of contrast medium into the aorta, and the second FP optical pressure sensor (P2) is located in a distal region of the first lumen of the sensor angiographic catheter a distance L2 from
15 the pigtail tip for positioning of P2 in the ascending aorta, downstream of the aortic valve, during TAVR.

3. The dual sensor system of claim 1, configured for measurements of hemodynamic parameters during TMVR, wherein:

the first FP optical pressure sensor (P1) is located a distance L1 from the flexible distal tip
20 of the sensor support guidewire for positioning of P1 within a first heart chamber on one side of the mitral valve during TMVR;

the second FP optical pressure sensor (P2) is located in the first lumen of the sensor catheter a distance L2 from the pigtail tip for positioning of P2 in a second heart chamber, on an opposite side of the mitral valve during TMVR; and said plurality of apertures in the second
25 lumen near the pigtail tip are arranged for injection of contrast medium into the second heart chamber.

4. The dual sensor system of claim 1 or claim 2, wherein the first and second FP optical pressure sensors are a pair of similar FP optical pressure sensors configured for measuring

a blood pressure gradient across the aortic valve during TAVR in a range of 0mmHg to 60mmHg within ± 10 mmHg or less.

5. The dual sensor system of claim 1 or claim 3 wherein first and second FP optical
5 pressure sensors are a pair of similar FP optical pressure sensors configured for measuring
a blood pressure gradient across the mitral valve during TMVR in a range of 0 to 20 mmHg
within ± 2 mmHg or less.
6. The dual sensor system of any one of claims 1 to 5, wherein the TVT sensor support
10 guidewire has stiffness characteristics along its length configured for over-the-guidewire
mounting of a prosthetic valve delivery device, said stiffness characteristics of a distal
region for use during valve deployment being in a range of stiffness characteristics of
support guidewires of a group comprising a Safari™ guidewire, a Confida™ guidewire and
an Amplatz™ Super Stiff Guidewire.
7. The dual sensor system of any one of claims 1 to 5, wherein the TVT sensor support
15 guidewire has stiffness characteristics along its length configured for over-the-guidewire
mounting of a prosthetic valve delivery device, said stiffness characteristics of a distal
region for use during prosthetic valve deployment being defined by a flexural modulus in a
range of 17GPa to 158GPa.
8. The dual sensor system of any one of claims 1 to 7, wherein the TVT sensor support
20 guidewire has a maximum outside diameter of ≤ 0.89 mm (0.035 inch) and a length in a
range from 1m to 3m.
9. The dual sensor system of any one of claims 1 to 8, wherein the optical input/output
connector of the first port of the sensor angiographic catheter comprises a separable optical
connector and a flexible optical coupling comprising a length of optical cable, the separable
25 optical connector detachably connecting the sensor angiographic catheter to one end of the
optical cable, and the optical cable having at its other end an optical connector for
connection to the control system.
10. The dual sensor system of any one of claims 1 to 8, wherein the optical input/output
connector at the proximal end of the TVT sensor support guidewire comprises a separable

optical connector and a flexible optical coupling comprising a length of optical cable, the separable optical connector detachably connecting the TVT sensor support guidewire to one end of the optical cable, and the optical cable having at its other end an optical connector for connection to the control system.

5 11. The dual sensor system of claim 10, wherein for over-the-guidewire mounting of components from the proximal end of the TVT sensor support guidewire, the separable optical connector comprises an optical micro-connector having male and female parts, wherein the sensor support guidewire comprises the male part of the optical micro-connector, which has a diameter no greater than a maximum outside diameter the TVT
10 sensor support guidewire.

12. The dual sensor system of claim 11, wherein the flexible optical coupling comprises the female part of the optical micro-connector, which forms a connector handle for manipulating the TVT sensor support guidewire.

13. The dual sensor system of any one of claims 1 to 12 wherein the sensor support
15 guidewire comprise a radiopaque marker near the first FP optical pressure sensor, and the sensor catheter comprises a radiopaque marker near the second FP optical sensor and at the distal tip, and optionally, radiopaque markers are placed at regular intervals along the length of the sensor catheter and sensor support guidewire, so that, in use, relative positioning or spacing of the first and second FP optical pressure sensors of the sensor catheter and the
20 sensor support guidewire can be determined.

14. A TVT sensor support guidewire for the dual sensor system of claim 1, comprising a tubular member having a length extending between a proximal end and a distal end, the distal end comprising a flexible distal tip, the tubular member comprising an outer tubular member (outer tube) and an inner tubular member (inner tube or core tube), the inner tubular
25 member inserted within the outer tubular member, and an optical fiber extending within the inner tubular member from an optical input/output connector at the proximal end of the sensor support guidewire to a FP optical pressure sensor, the FP optical pressure sensor being positioned within a distal region of the sensor support guidewire, near the flexible distal tip, a sensor aperture in the tubular member adjacent the first FP optical pressure

sensor for fluid contact therewith, and the flexible distal tip comprising a pre-formed curved tip.

15. The TVT sensor support guidewire of claim 14, wherein the inner tubular member comprises a first stainless steel hypotube having physical characteristics providing a predetermined stiffness and flexibility to act as a core of the TVT sensor support guidewire and the outer tubular member comprises one of a second stainless steel hypotube, a flexible spiral wound micro-coil, and a combination thereof.

16. The TVT sensor support guidewire of claim 15, wherein the inner tubular member acts as a core tube to provide a required stiffness along the length of the sensor support guidewire, and the outer tubular member is generally more flexible along most of its length.

17. The TVT sensor support guidewire of any one of claims 14 to 16, wherein at the sensor position, the sensor aperture comprises a first sensor aperture in the outer tubular member and a second sensor aperture in the inner tubular member, the outer tubular member comprising a reinforced stiffer region around the sensor aperture.

18. The TVT sensor support guidewire of any one of claims 14 to 16, wherein at the sensor position, the sensor aperture comprises a first sensor aperture in the outer tubular member, and a region of the inner tubular member which is partially cut away to form a cavity around the optical pressure sensor, the outer tubular layer comprising a reinforced stiffer region extending around the sensor aperture.

19. The TVT sensor support guidewire of any one of claims 14 to 18, further comprising a second FP optical pressure sensor and second optical fiber contained within the inner tubular member, the second FP optical pressure sensor being positioned proximally of the first optical pressure sensor, and wherein the inner tubular member has an aperture adjacent the second optical pressure sensor, or is partially cut away to form a cavity around the second optical pressure sensor, and the outer tubular layer comprises a second sensor aperture adjacent the second optical pressure sensor and a reinforced region around the second sensor aperture adjacent each sensor.

20. The TVT sensor support guidewire of claim 19, wherein the first and second FP optical pressure sensors are spaced apart by a distance L in the range from about 20 mm to 100mm.
21. The TVT sensor support guidewire of any one of claims 14 to 18, having stiffness characteristics along its length similar to stiffness characteristics of a TVT support guidewire comprising one of a Safari™ guidewire, a Confida™ guidewire and an Amplatz™ Super Stiff guidewire.
22. A sensor angiographic catheter for the dual sensor system of claim 1, comprising a length of multi-lumen catheter tubing extending between a proximal end and a distal end and comprising a first lumen and a second lumen, the distal end comprising a preformed pigtail distal tip, and the catheter tubing having at its proximal end a connection hub comprising a first port for the first lumen and a second port for the second lumen, an optical fiber extending within the first lumen from an optical/input output connector of the first port to a FP optical pressure sensor, the FP optical pressure sensor being positioned within a distal region of the first lumen near the distal tip, and a sensor aperture in the sensor catheter near the FP optical pressure sensor for fluid contact therewith; and the second port comprising an injection port for injection of fluid and the second lumen comprising a plurality of apertures for fluid ejection along a length of the the distal region near the distal tip between the sensor aperture and the distal tip.
23. The sensor angiographic catheter of claim 22 wherein the multi-lumen catheter tubing comprises dual lumen tubing having an outside diameter in the range from about 4 French to 7 French, wherein the first lumen is sized to accommodate the optical fiber and the FP optical pressure sensor and the second lumen is sized for rapid injection of contrast medium.
24. The sensor angiographic catheter of claim 23, wherein the second lumen is sized to act as a guidewire lumen for insertion of the sensor angiographic catheter over a guidewire.
25. The sensor angiographic catheter of claim 22, wherein the catheter tubing further comprises one or more additional lumens, and the connection hub further comprises a corresponding number of additional ports.

26. The sensor angiographic catheter of any one of claims 22 to 25, further comprising a radiopaque marker near the FP optical pressure sensor and a radiopaque marker at the distal tip of the sensor catheter.

27. A controller for the dual sensor system of claim 1, comprising: an optical control
5 unit comprising a light source and detector, and an optical interface for coupling, via
respective optical input/output ports, to each of the optical input/output connectors of the
TVT sensor support guidewire containing the first FP optical pressure sensor and the
angiographic catheter containing the second FP optical pressure sensor; data storage and
processing means configured for processing optical data indicative of pressure values, and
10 outputting digital and/or analog signals to ports of a communications interface, for coupling
to a patient monitoring system and other peripherals.

28. The controller of claim 27, for connection to a patient care monitor (PCM)
configured for receiving analog signals indicative of blood pressure compliant with the
ANSI BP-22 Standard, the controller comprises a BP-22 signal converter, and wherein the
15 communications interface comprises ports for respective analog signal outputs from each of
the optical pressure sensors and analog control signal inputs.

29. A kit comprising components for use with a dual sensor system for monitoring
blood pressure at first and second locations during transcatheter valve therapy (TVT),
comprising:

20 a first component comprising: a sensor support guidewire for TVT comprising a tubular
member having a length extending between a proximal end and a distal end, the distal end
comprising an atraumatic pre-formed curved flexible distal tip, the tubular member
containing a first optical fiber extending within the sensor support guidewire from an optical
input/output connector at the proximal end of the sensor support guidewire to a first Fabry-
25 Pérot (FP) optical pressure sensor, the first FP optical pressure sensor being positioned
within a distal region of the tubular member, near the distal tip, and a sensor aperture in the
sensor support guidewire adjacent the first optical FP pressure sensor for fluid contact
therewith;

a second component comprising: a sensor angiographic catheter comprising a length of multi-lumen catheter tubing extending between a proximal end and a distal end and comprising a first lumen and a second lumen, the distal end comprising a preformed pigtail distal tip, and the catheter tubing having at its proximal end a connection hub comprising a first port for the first lumen and a second port for the second lumen, a second optical fiber
5 extending within the first lumen from an optical/input output connector of the first port to a second FP optical pressure sensor, the second FP optical pressure sensor being positioned within a distal region of the first lumen near the distal tip, and a sensor aperture in first lumen of the catheter tubing near the FP optical pressure sensor for fluid contact therewith;
10 the second port comprising an injection port for injection of fluid into the second lumen, and the second lumen comprising a plurality of fluid apertures along a length of the distal region between the sensor aperture and the distal tip; and

wherein the first and second FP optical pressure sensors are pair of similar FP optical pressure sensors.

15 30. The kit of claim 29, wherein
the optical input/output connector of the first port of the sensor angiographic catheter comprises a separable optical connector and a flexible optical coupling comprising a length of optical cable, the separable optical connector detachably connecting the sensor angiographic catheter to one end of the optical cable, and the optical cable having at its other
20 end an optical connector for connection to controller; and
the optical input/output connector at the proximal end of the TVT sensor support guidewire comprises a separable optical connector and a flexible optical coupling comprising a length of optical cable, the separable optical connector detachably connecting the TVT sensor support guidewire to one end of the optical cable, and the optical cable having at its other
25 end an optical connector for connection to the controller; and wherein for over-the-guidewire mounting of components from the proximal end of the TVT sensor support guidewire, the separable optical connector comprises an optical micro-connector having male and female parts, wherein the sensor support guidewire comprises the male part of the optical micro-connector, which has a diameter no greater than a maximum outside diameter
30 the TVT sensor support guidewire, and the flexible optical coupling comprises the female

part of the optical micro-connector, which forms a connector handle for manipulating the TVT sensor support guidewire.

31. The kit of claim 29 wherein the first and second FP optical pressure sensors are
5 configured for measuring a transvalvular blood pressure gradient across an aortic valve during TAVR in a range of 0mmHg to 60mmHg within ± 10 mmHg or less.

32. The kit of claim 29 wherein first and second FP optical pressure sensors are
configured for measuring a transvalvular blood pressure gradient across a mitral valve
10 during TMVR in a range of 0mmHg to 20mmHg within ± 2 mmHg or less.

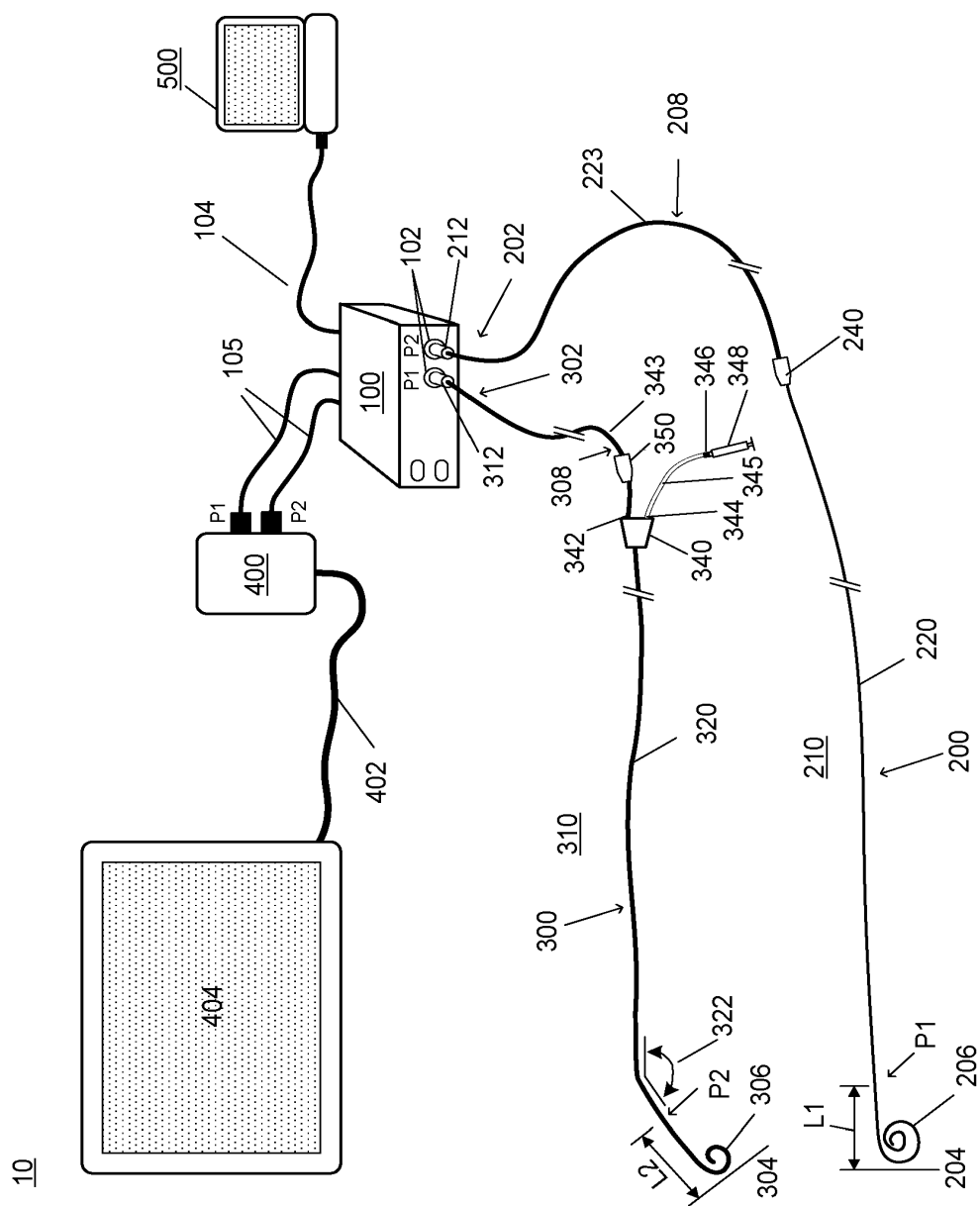
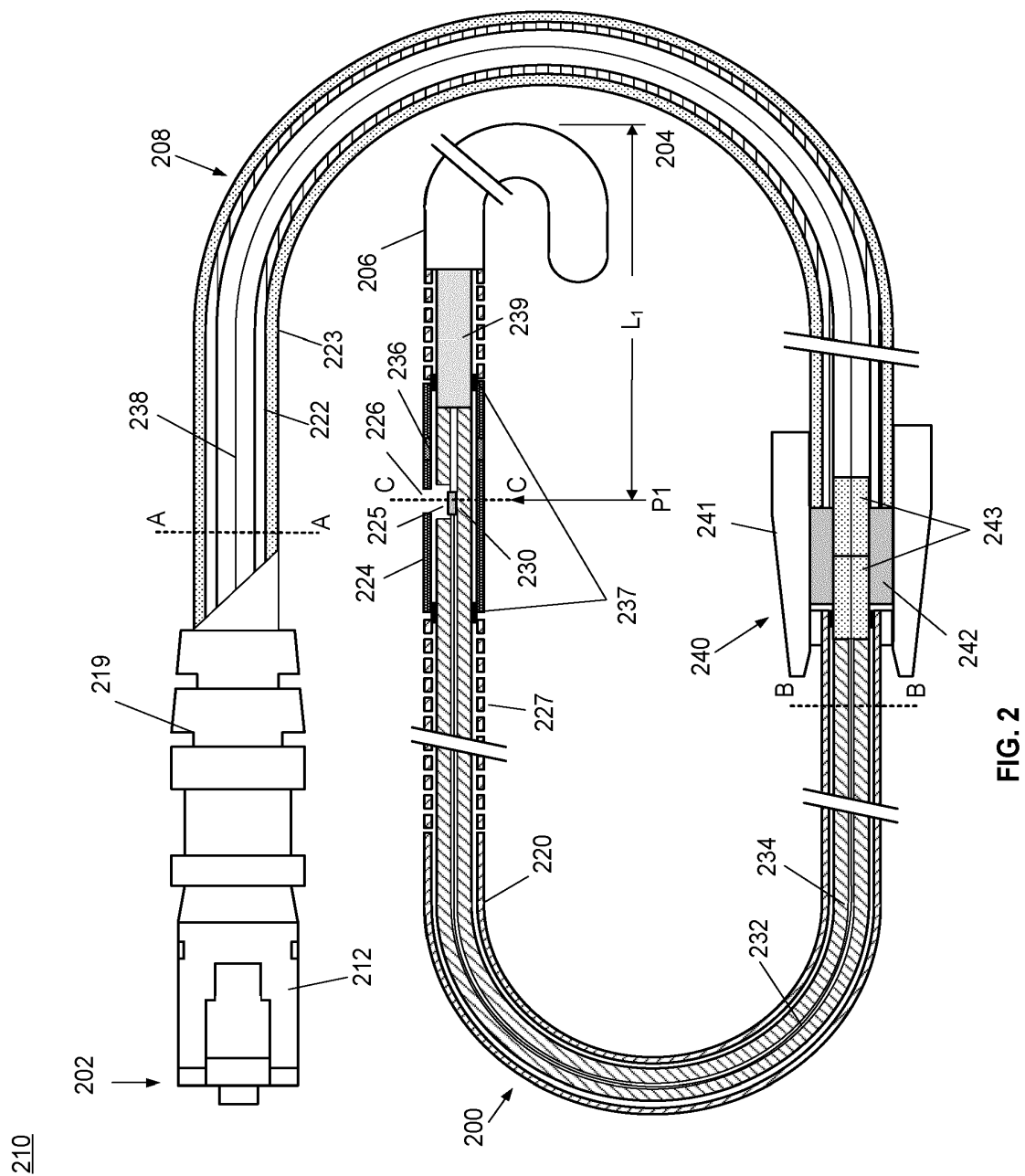


FIG. 1



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A-A CROSS-SECTION VIEW OF FIG. 2

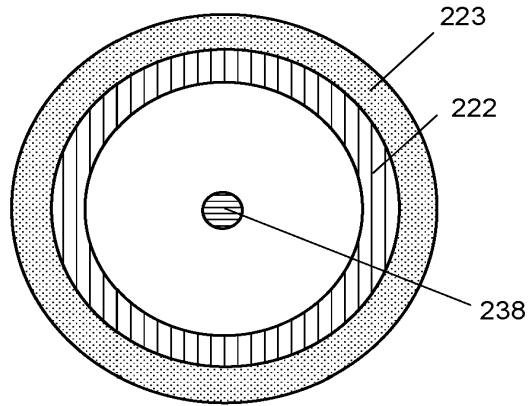


FIG. 3A

B-B CROSS-SECTION VIEW OF FIG. 2

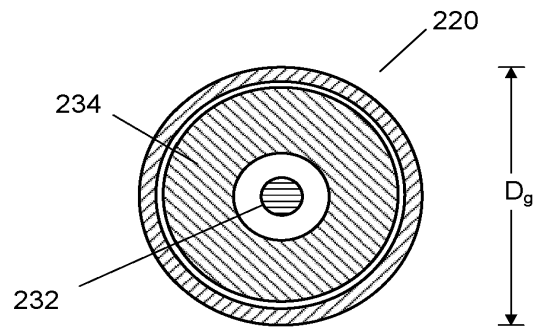


FIG. 3B

C-C CROSS-SECTION VIEW OF FIG. 2

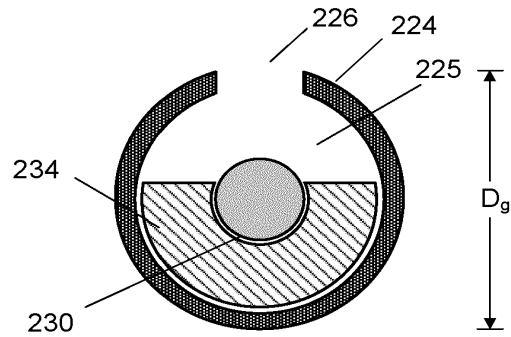
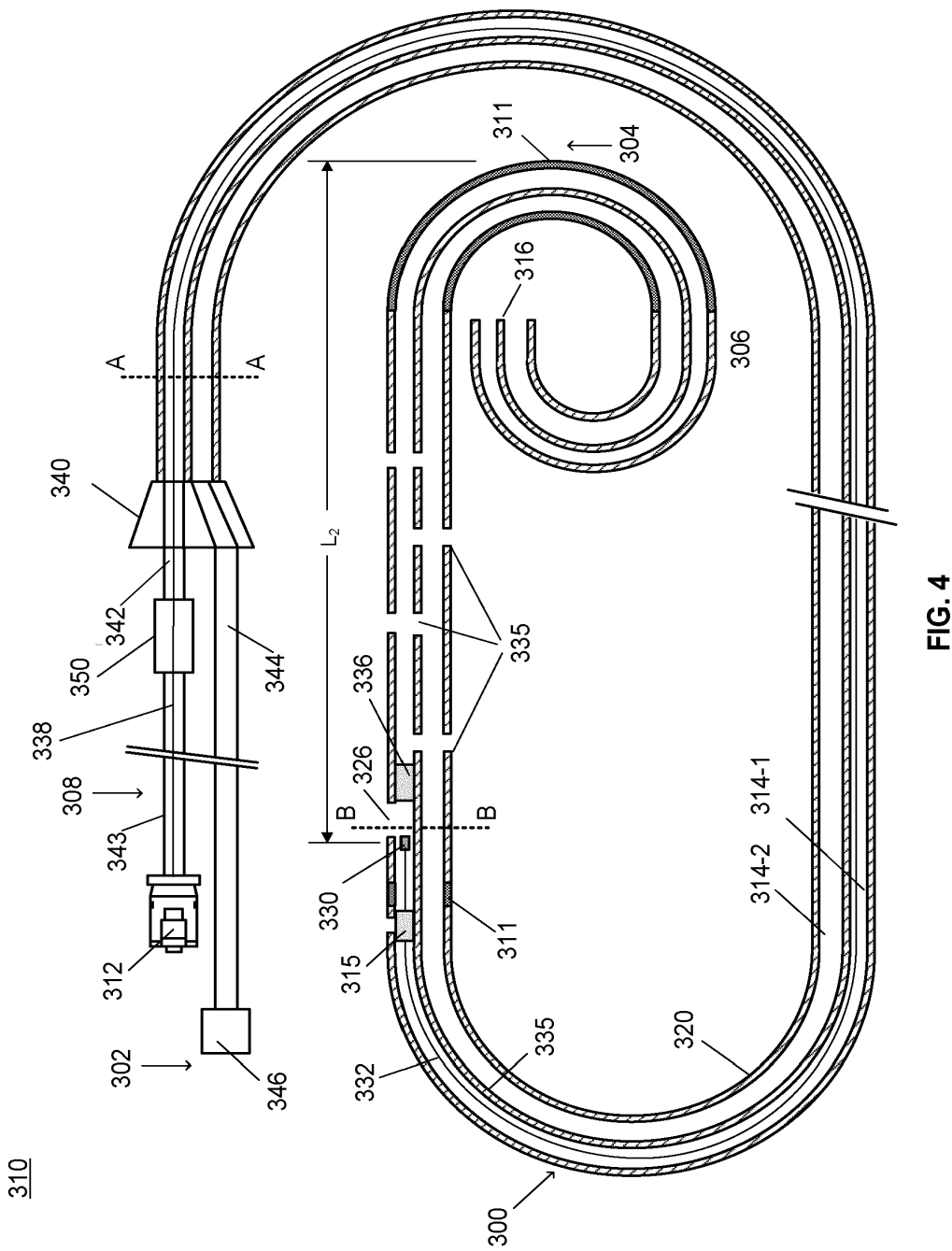


FIG. 3C



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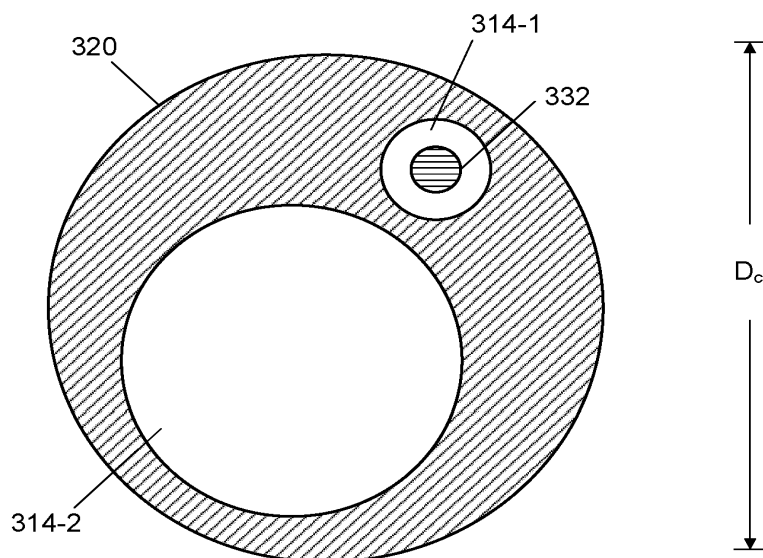


FIG. 5A

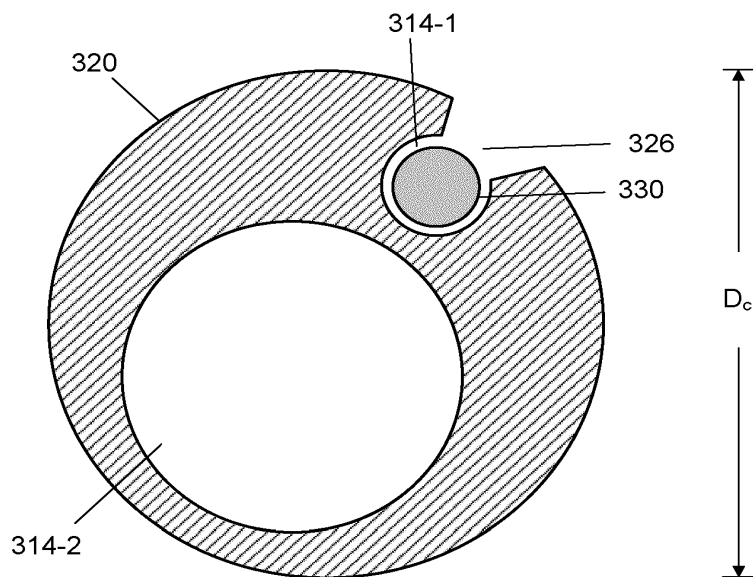


FIG. 5B

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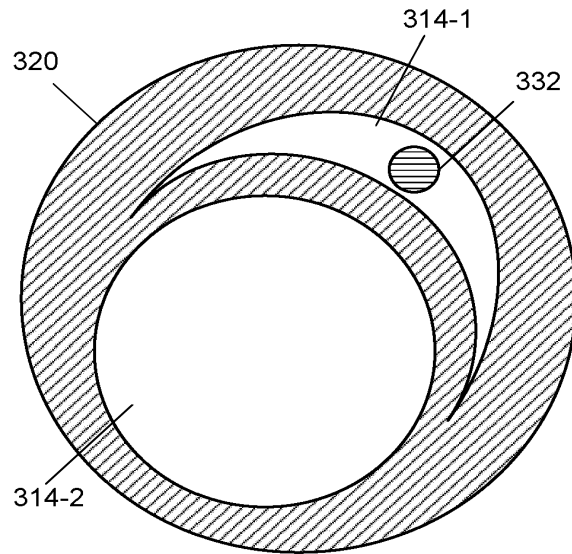


FIG. 6A

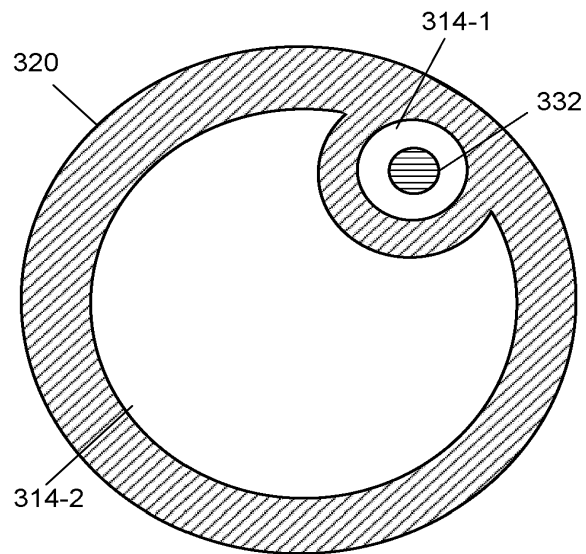
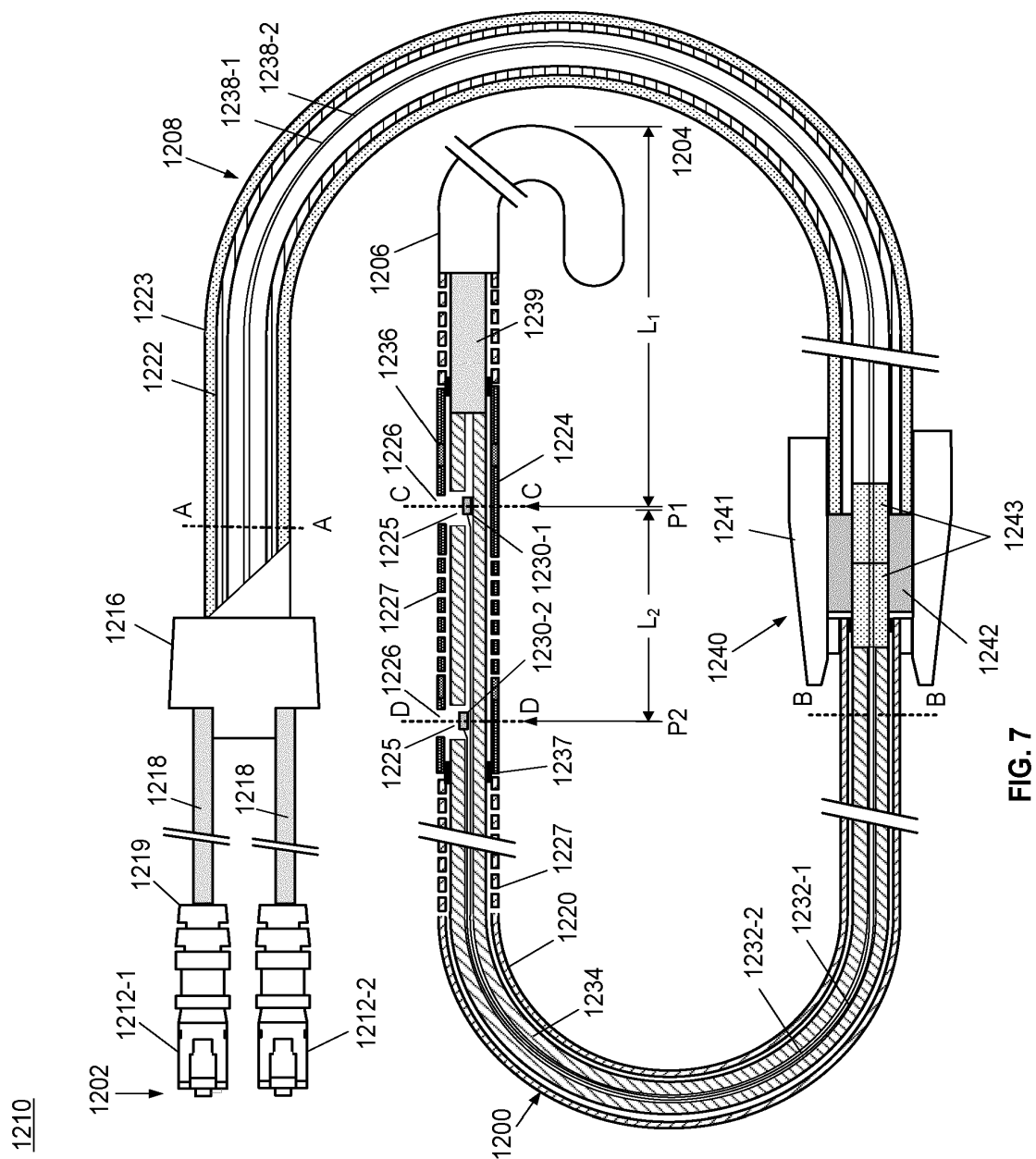


FIG. 6B



B-B CROSS-SECTION VIEW OF FIG. 2

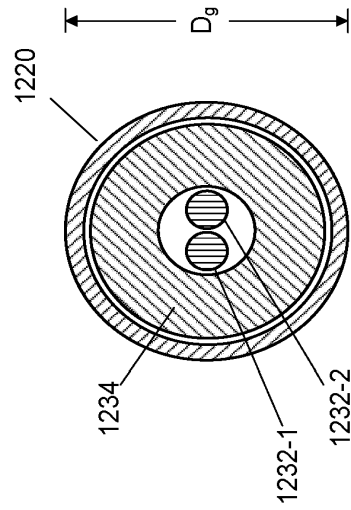


FIG. 8B

A-A CROSS-SECTION VIEW OF FIG. 2

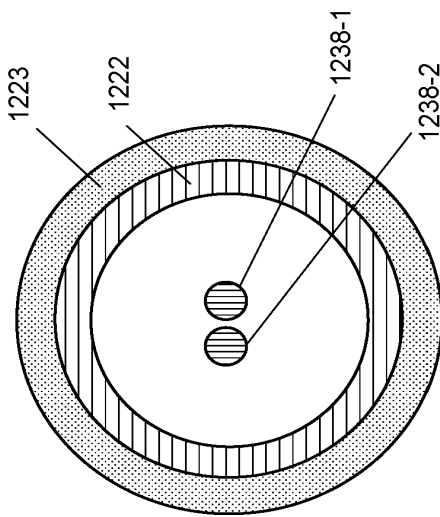


FIG. 8A

D-D CROSS-SECTION VIEW OF FIG. 2

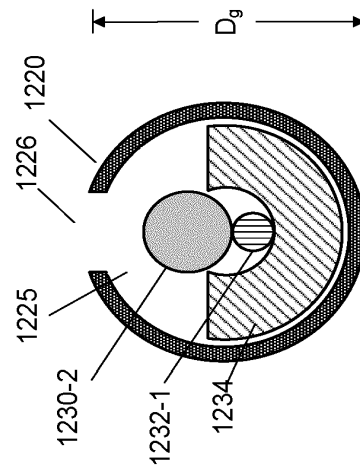


FIG. 8D

C-C CROSS-SECTION VIEW OF FIG. 2

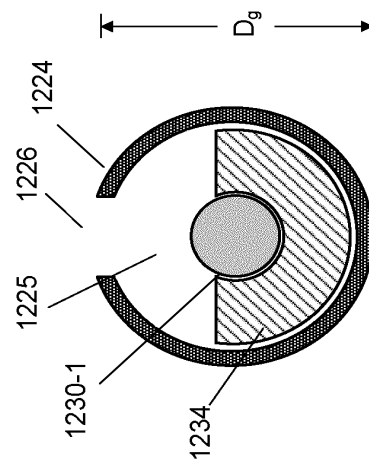


FIG. 8C

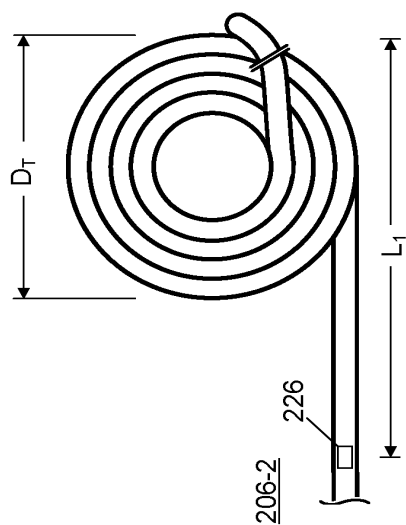


FIG. 10A

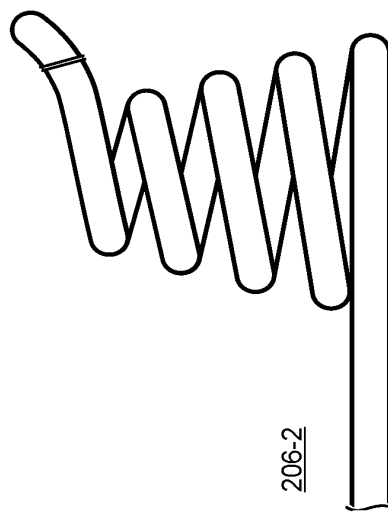


FIG. 10B

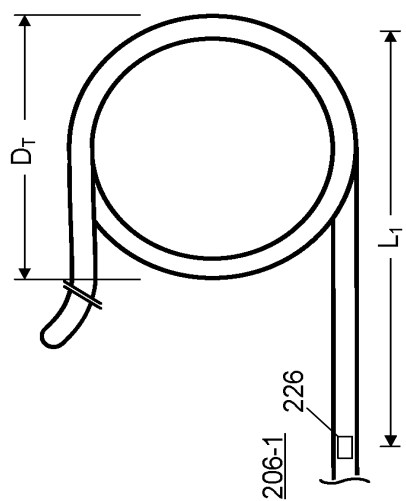


FIG. 9A

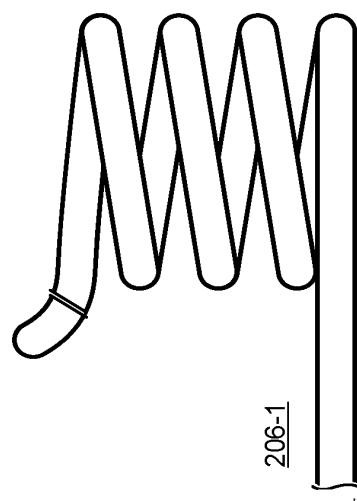
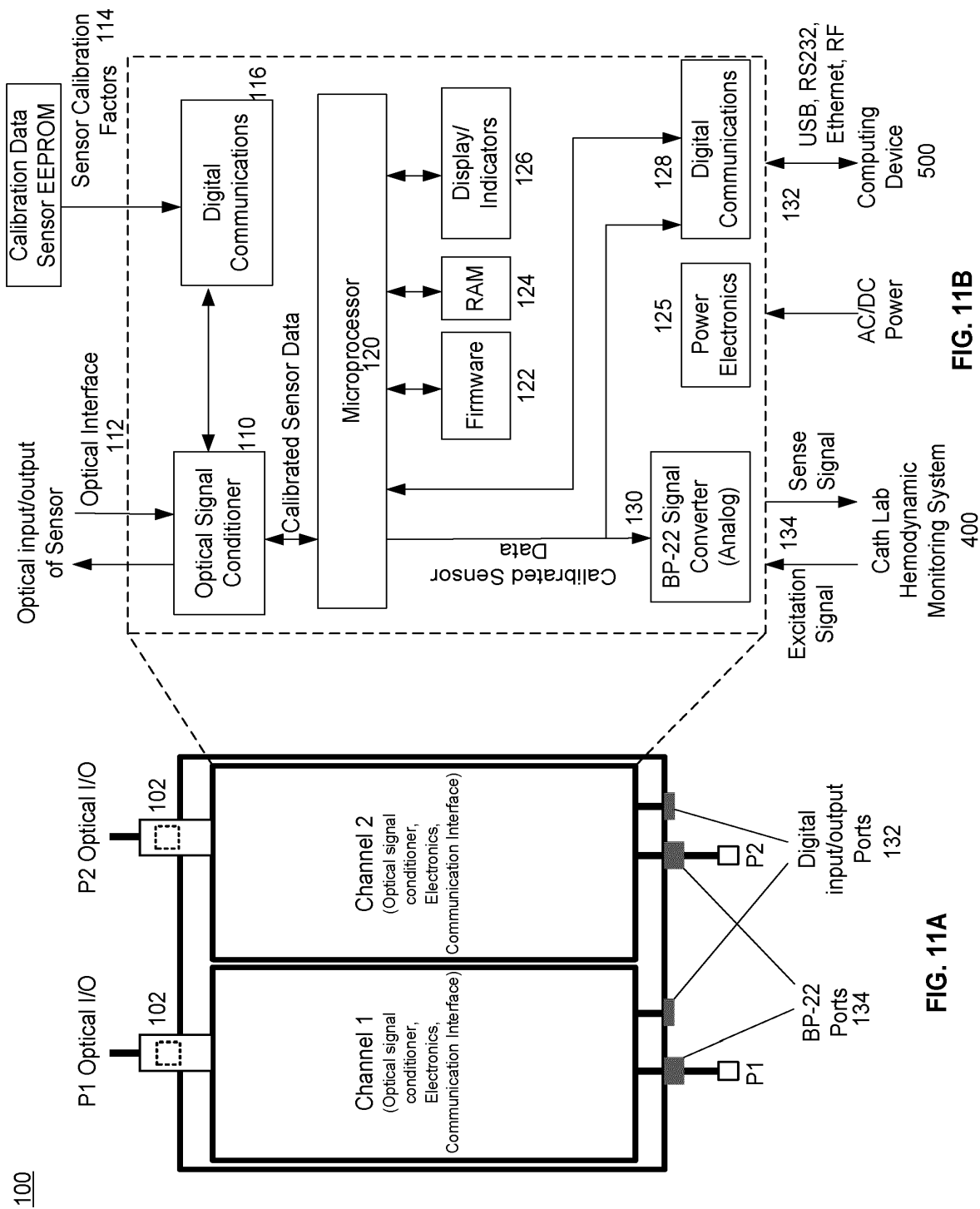


FIG. 9B

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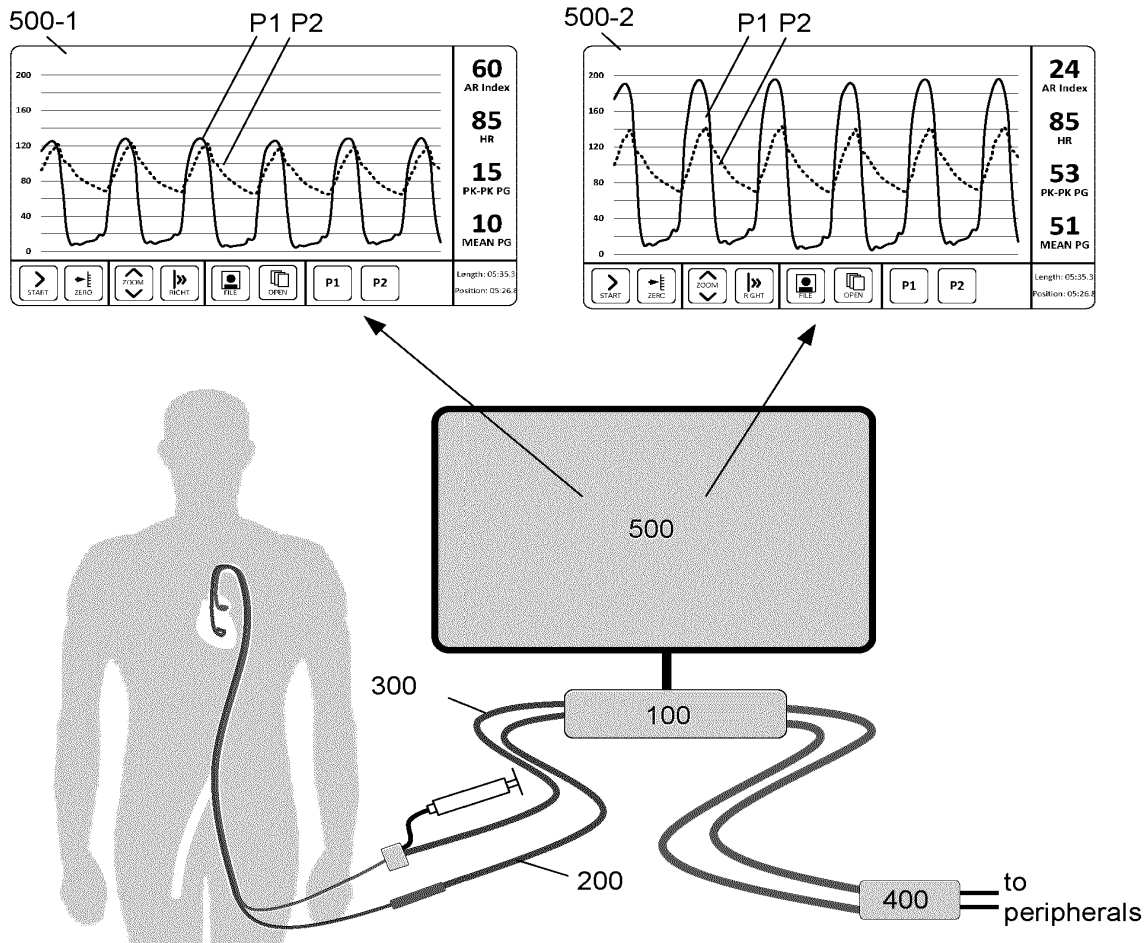


FIG. 12

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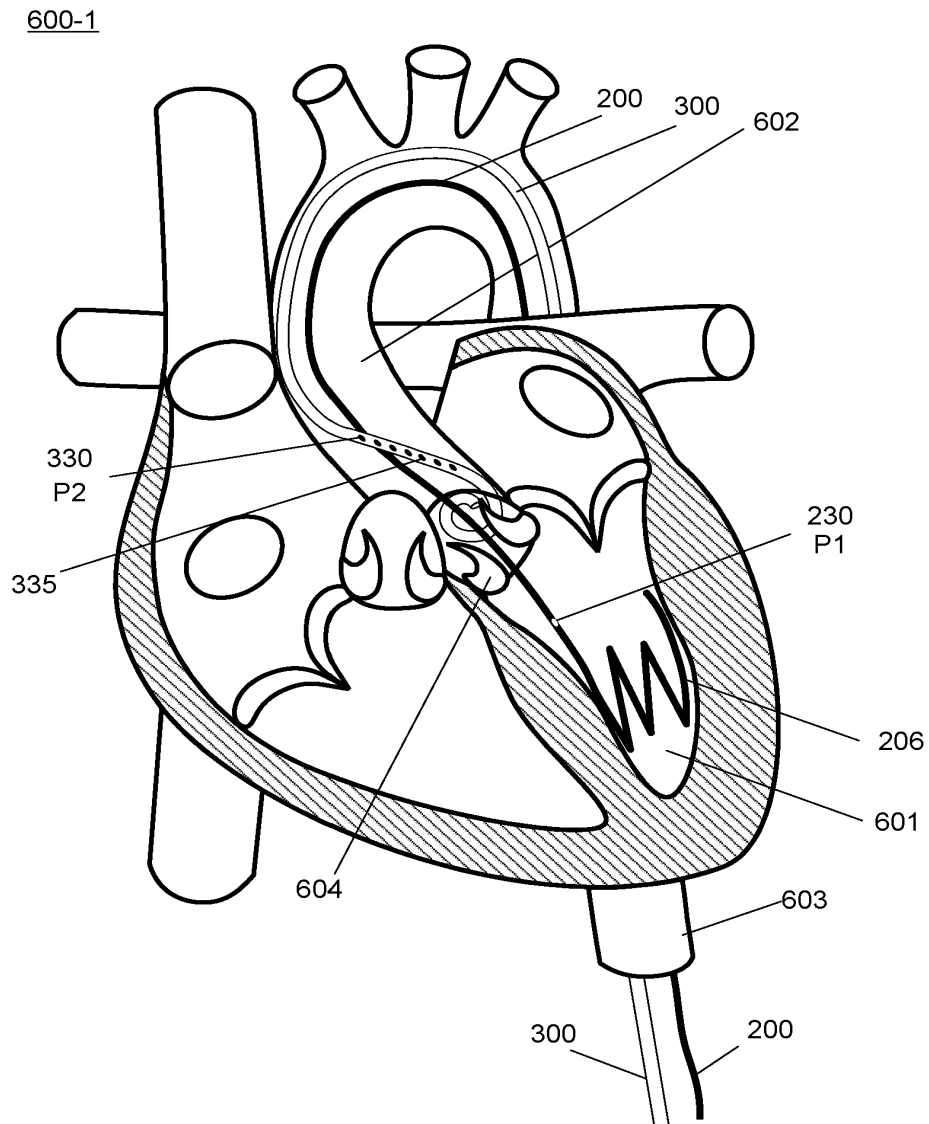


FIG. 13

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600-2

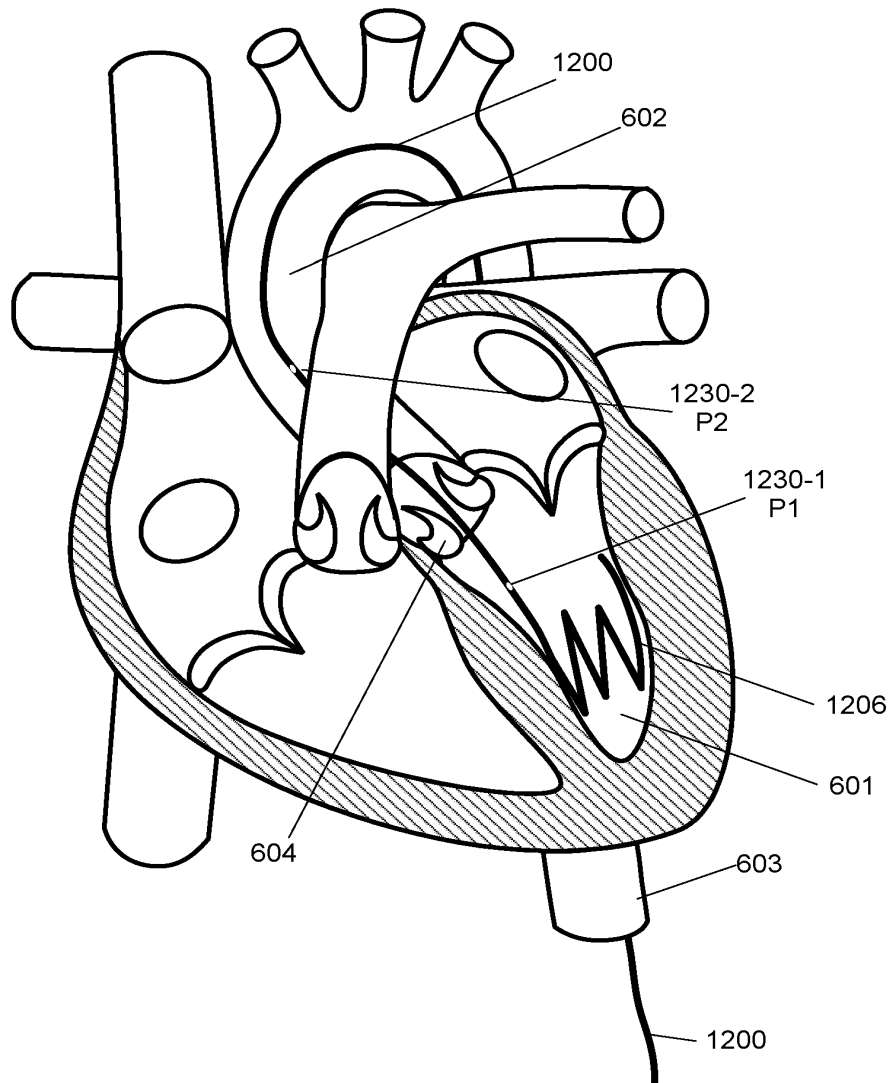


FIG. 14

600-3

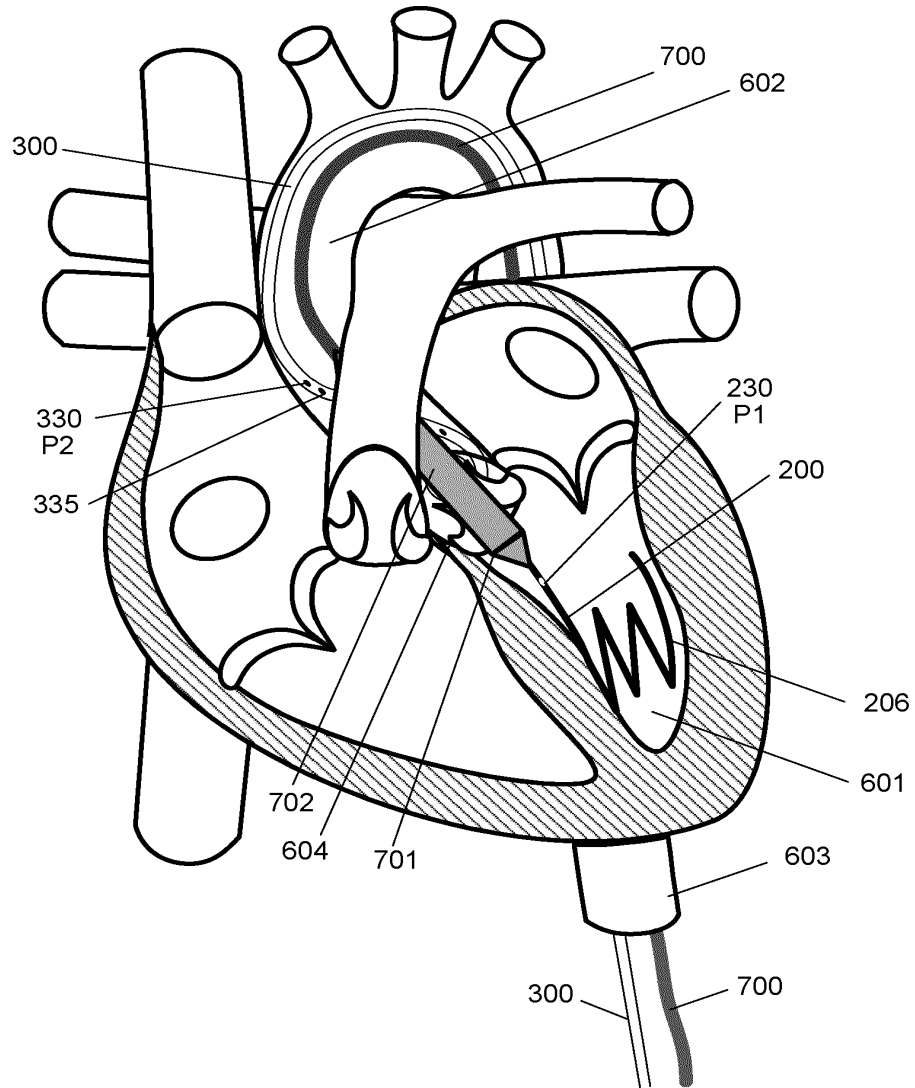


FIG. 15

600-4

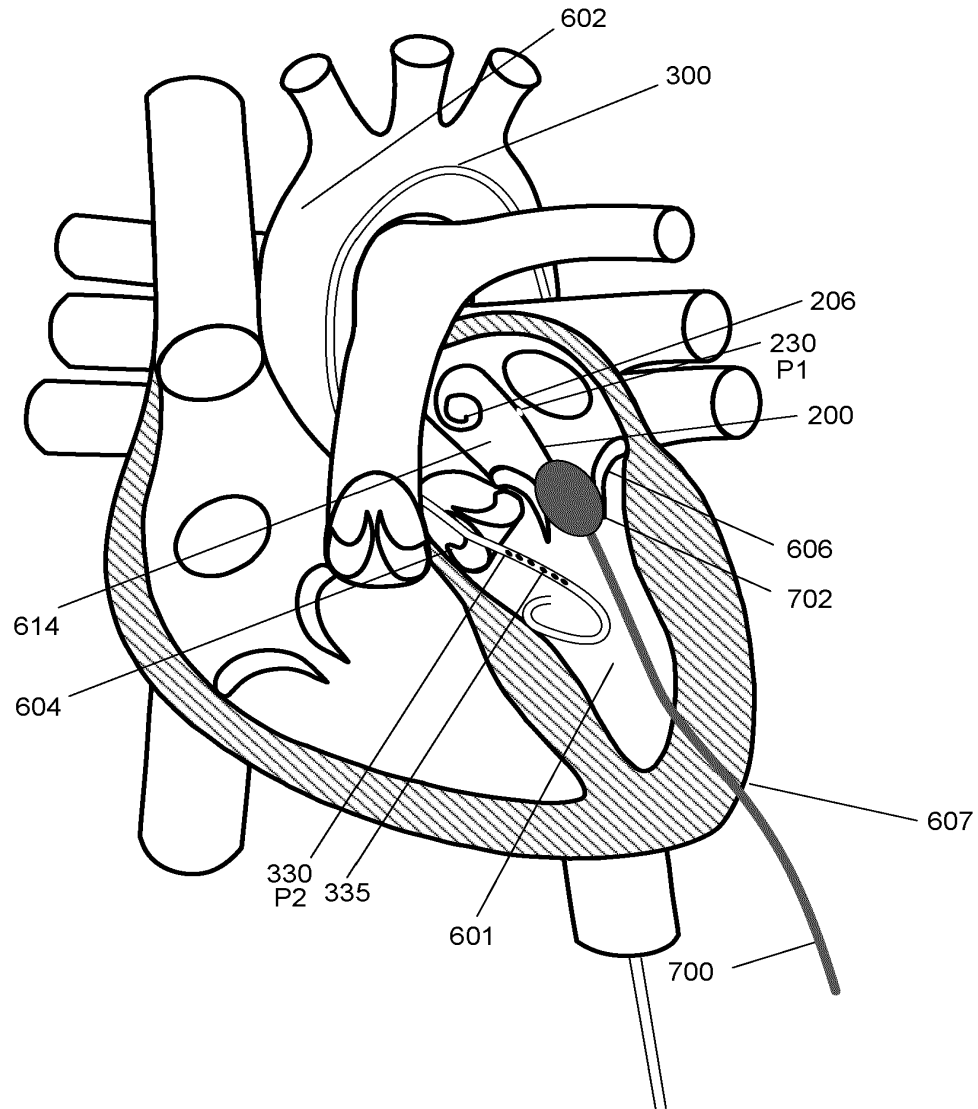
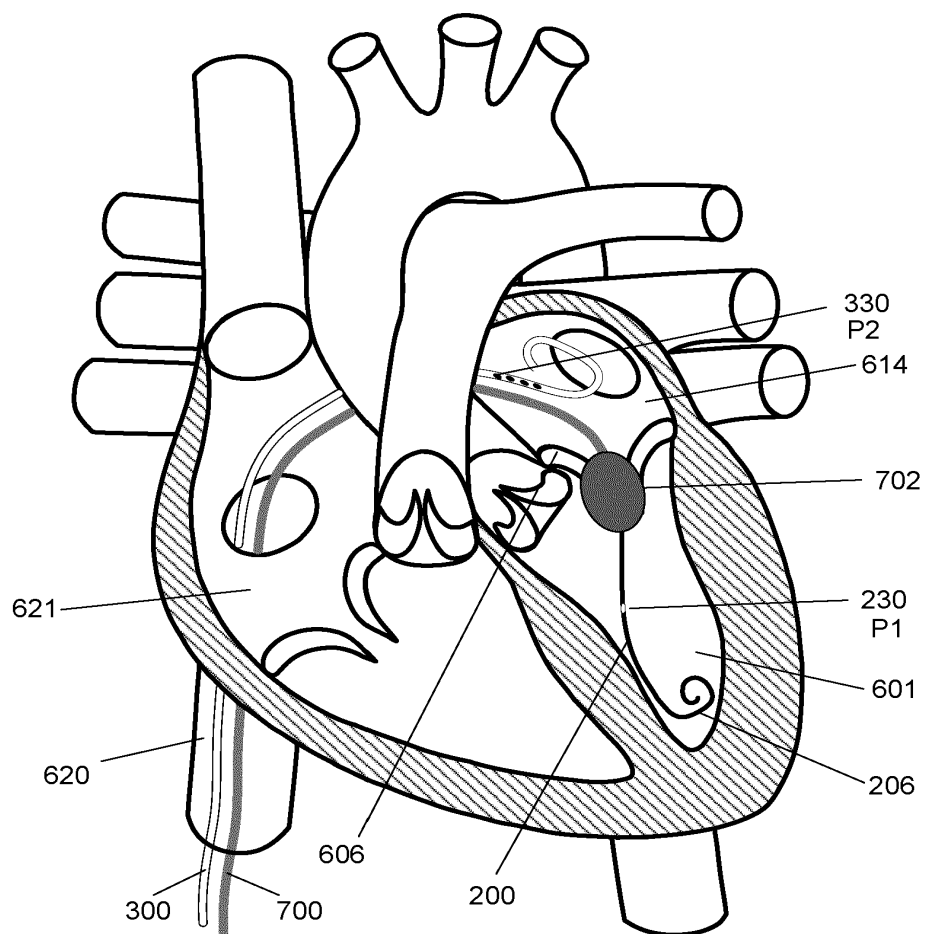


FIG. 16

600-5



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600-6

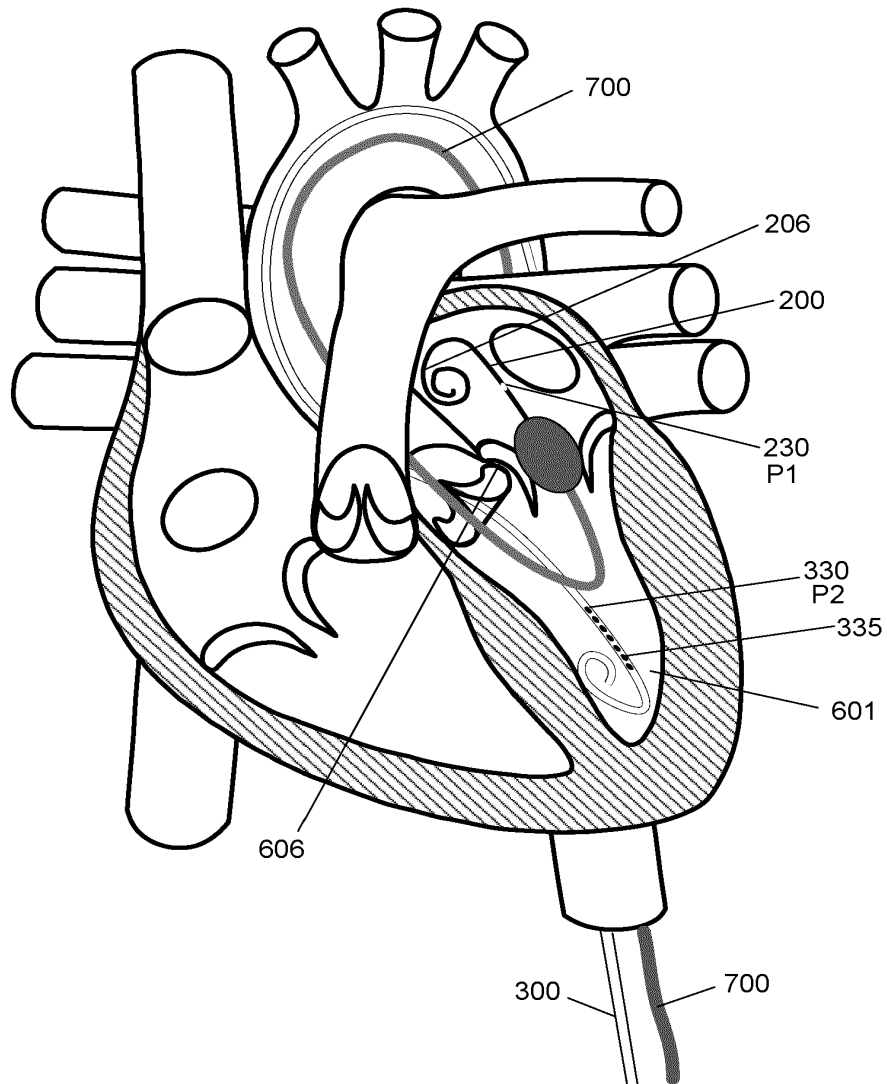


FIG. 18

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600-7

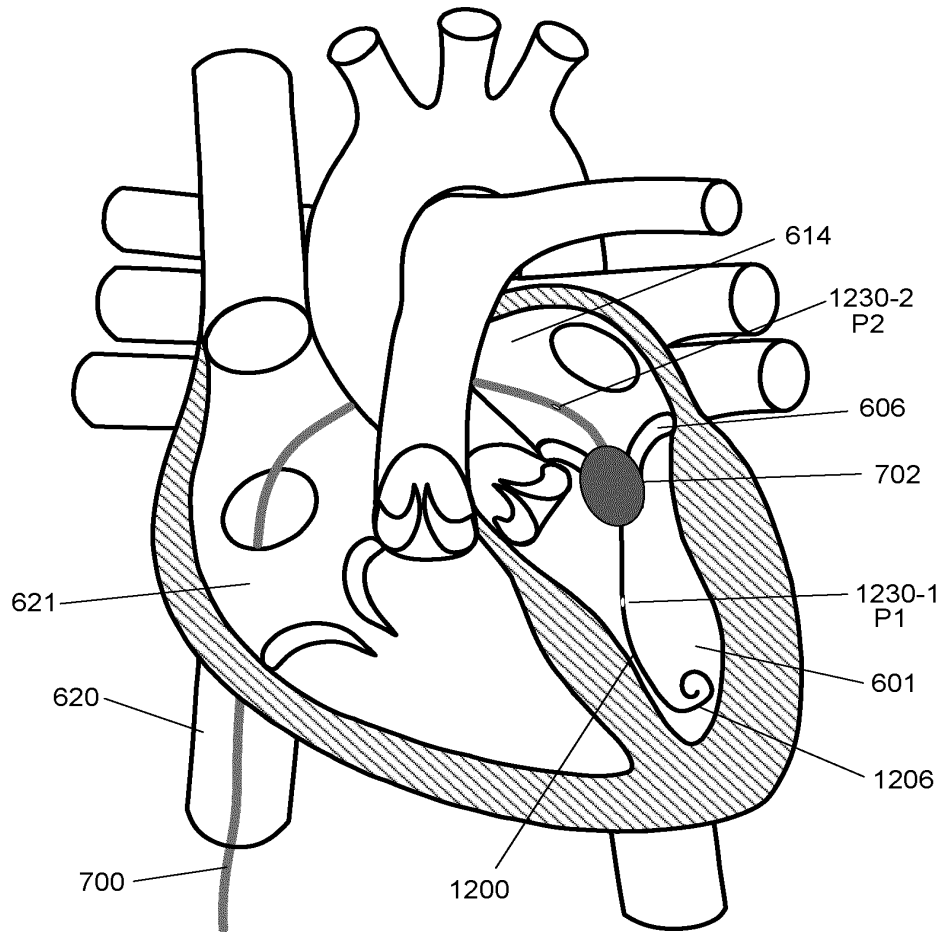
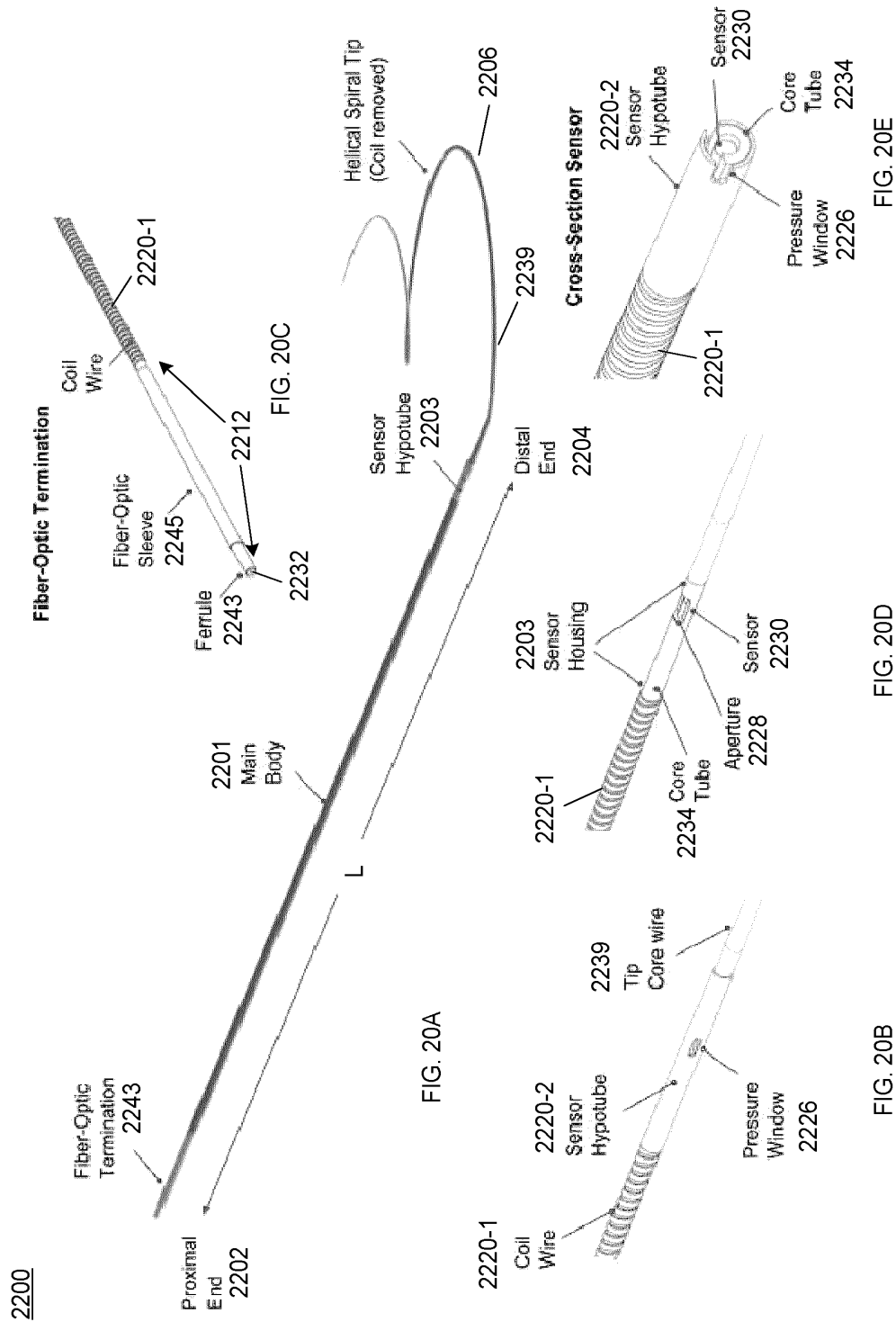


FIG. 19

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INTERNATIONAL SEARCH REPORT

 International application No.
PCT/CA2018/051430

A. CLASSIFICATION OF SUBJECT MATTER

 IPC: *A61B 5/0215* (2006.01), *A61M 25/14* (2006.01), *A61M 25/18* (2006.01), *A61F 2/24* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

 IPC: *A61B 5/0215* (2006.01), *A61M 25/14* (2006.01), *A61M 25/18* (2006.01), *A61F 2/24* (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Canadian database, Questel Orbit, and Internet search engine – Keywords: dual, sensor, transcatheter, valve, therapy, blood pressure, controller, fabry, lumen, guidewire, angiographic, aperture, reinforced, hypotube, tubular member, radiopaque, marker, catheter, optical, connector, female, part, input, flexural modulus, measur+, safari, confida, amplatz, stiffness, mitral, replacement, hemodynamic, aortic, fluid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CA2,954,959 (THREE RIVERS CARDIOVASCULAR SYSTEMS INC.) 21 January 2016 (21-01-2016) Abstract, page 12, paragraph 37	1 to 32
A	CA2,849,717 (THREE RIVERS CARDIOVASCULAR SYSTEMS INC) 02 May 2013 (02-05-2013) Abstract, page 8, lines 30 to 34	1 to 32
A	Melamud, R., et al. "Development of an SU-8 Fabry-Perot blood pressure sensor." Micro Electro Mechanical Systems, 2005. MEMS 2005. 18th IEEE International Conference on. IEEE, 2005. Abstract, see whole document	1 to 32

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier application or patent but published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
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Date of the actual completion of the international search

 Date of mailing of the international search report
 22 January 2019 (22-01-2019)

 Name and mailing address of the ISA/CA
 Canadian Intellectual Property Office
 Place du Portage I, C114 - 1st Floor, Box PCT
 50 Victoria Street
 Gatineau, Quebec K1A 0C9
 Facsimile No.: 819-953-2476

Authorized officer

Gilbert Jean (819) 639-5546

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2018/051430

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication date
CA2954959A1	21 January 2016 (21-01-2016)	CA2954959A1	21 January 2016 (21-01-2016)
		CA2954959C	20 March 2018 (20-03-2018)
		AU2012327930B2	28 July 2016 (28-07-2016)
		CA2849717A1	02 May 2013 (02-05-2013)
		CA2849717C	21 October 2014 (21-10-2014)
		CN103997954A	20 August 2014 (20-08-2014)
		CN103997954B	15 August 2017 (15-08-2017)
		CN106659394A	10 May 2017 (10-05-2017)
		EP2770904A1	03 September 2014 (03-09-2014)
		EP2770904A4	03 September 2014 (03-09-2014)
		EP3166478A1	17 May 2017 (17-05-2017)
		EP3166478A4	14 February 2018 (14-02-2018)
		HK1200300A1	07 August 2015 (07-08-2015)
		JP2015501184A	15 January 2015 (15-01-2015)
		JP6143764B2	07 June 2017 (07-06-2017)
		RU2014121062A	10 December 2015 (10-12-2015)
		US2014249386A1	04 September 2014 (04-09-2014)
		US9149230B2	06 October 2015 (06-10-2015)
		US2016022159A1	28 January 2016 (28-01-2016)
		US9504392B2	29 November 2016 (29-11-2016)
		US2014243688A1	28 August 2014 (28-08-2014)
		US2016128583A1	12 May 2016 (12-05-2016)
		US2017027458A1	02 February 2017 (02-02-2017)
		US2017281025A9	05 October 2017 (05-10-2017)
		US2017209099A1	27 July 2017 (27-07-2017)
		WO2013061280A1	02 May 2013 (02-05-2013)
		WO2013061281A1	02 May 2013 (02-05-2013)
		WO2016009317A1	21 January 2016 (21-01-2016)
		WO2016009317A4	10 March 2016 (10-03-2016)
CA2849717A1	02 May 2013 (02-05-2013)	CA2849717A1	02 May 2013 (02-05-2013)
		CA2849717C	21 October 2014 (21-10-2014)
		AU2012327930B2	28 July 2016 (28-07-2016)
		CA2954959A1	21 January 2016 (21-01-2016)
		CA2954959C	20 March 2018 (20-03-2018)
		CN103997954A	20 August 2014 (20-08-2014)
		CN103997954B	15 August 2017 (15-08-2017)
		CN106659394A	10 May 2017 (10-05-2017)
		EP2770904A1	03 September 2014 (03-09-2014)
		EP2770904A4	03 September 2014 (03-09-2014)
		EP3166478A1	17 May 2017 (17-05-2017)
		EP3166478A4	14 February 2018 (14-02-2018)
		HK1200300A1	07 August 2015 (07-08-2015)
		JP2015501184A	15 January 2015 (15-01-2015)
		JP6143764B2	07 June 2017 (07-06-2017)
		RU2014121062A	10 December 2015 (10-12-2015)
		US2014249386A1	04 September 2014 (04-09-2014)
		US9149230B2	06 October 2015 (06-10-2015)
		US2016022159A1	28 January 2016 (28-01-2016)
		US9504392B2	29 November 2016 (29-11-2016)
		US2014243688A1	28 August 2014 (28-08-2014)
		US2016128583A1	12 May 2016 (12-05-2016)
		US2017027458A1	02 February 2017 (02-02-2017)
		US2017281025A9	05 October 2017 (05-10-2017)
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		WO2013061281A1	02 May 2013 (02-05-2013)
		WO2016009317A1	21 January 2016 (21-01-2016)
		WO2016009317A4	10 March 2016 (10-03-2016)

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 17/563,669		Filing Date 12/28/2021		☐ To be Mailed		
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO										
APPLICATION AS FILED - PART I										
		(Column 1)			(Column 2)					
FOR		NUMBER FILED			NUMBER EXTRA			RATE (\$)	FEE (\$)	
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A			N/A			N/A		
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A			N/A			N/A		
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A			N/A			N/A		
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 =		*			x \$50 =			
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =		*			x \$240 =			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL				
APPLICATION AS AMENDED - PART II										
		(Column 1)			(Column 2)			(Column 3)		
AMENDMENT	07/31/2023	CLAIMS REMAINING AFTER AMENDMENT			HIGHEST NUMBER PREVIOUSLY PAID FOR			PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(j))	* 10	Minus	** 20	= 0			x \$40 =	0	
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0			x \$192 =	0	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
								TOTAL ADD'L FEE	0	
		(Column 1)			(Column 2)			(Column 3)		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT			HIGHEST NUMBER PREVIOUSLY PAID FOR			PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(j))	*	Minus	**	=			x \$0 =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$0 =		
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
								TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE		
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/ROZENIA HARMON/		
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Docket No.: 688961-25U7
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Curtis J. FRANKLIN et al.

Application No.: 17/563,669

Confirmation No.: 4495

Filed: December 28, 2021

Art Unit: 3783

For: SYSTEM AND METHOD FOR LOW-PROFILE Examiner: J. A. Doubrava
OCCLUSION BALLOON CATHETER

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

UNDER 37 C.F.R. 1.111

The following Amendment and Remarks are being submitted in response to the Office Action dated June 20, 2023 (Paper No. 20230612) and are being timely filed within the three-month period set for reply, namely by September 20, 2023.

Kindly amend the above-identified U.S. patent application, without prejudice, as follows:

Amendment to the Claims is reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Amendment to and Listing of the Claims:

In accordance with 37 C.F.R. § 1.121(c), this listing of claims will replace all prior versions and listings of claims in the application. Please amend claims 1 and 9, wherein underlining indicates additions and strikethrough indicates deletions, and cancel claim 6, so that the claims read as follows:

1. (Currently Amended) An occlusion catheter system comprising:
 - a proximal hub;
 - a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device;
 - a proximal catheter section in fluid communication with the proximal hub;
 - a distal catheter section distally terminating with an atraumatic tip;
 - an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being constructed of a compliant biocompatible material;
 - at least one length marking on an exterior of the proximal catheter shaft to indicate an insertion depth of the occlusion catheter system;
 - a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon;~~and~~
 - a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and the distal catheter section[.]; and
~~the occlusion balloon,~~ the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.
2. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.
3. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

4. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.

5. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

6. (Canceled).

7. (Original) The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.

8. (Original) The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.

9. (Currently Amended) The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon.[:]

10. (Original) An inflation control system kit comprising:
the occlusion catheter system of claim 1; and
a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.

11. (Previously Presented) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.

REMARKS

With entry of the foregoing amendment, claims 1-5 and 7-11, as amended, are pending in this application. Claims 1-11 stand rejected. Claim 6 is canceled herein.

Independent claim 1 is amended to clarify that the solid wire is secured at a proximal-most end thereof within the proximal hub. Support for this amendment can be found at least in paragraph [0163] of the specification, as well as in original claim 6 (now-canceled).

No new matter has been added to the present application as a result of the amendments, and entry is respectfully requested.

Examiner Interview Summary

Applicant and Applicant's undersigned attorney wish to thank Examiner John Doubrava and Primary Examiner Laura Bouchelle for the courtesies extended during the telephonic interview conducted on July 28, 2023. During the July 28, 2023, interview, Examiners Doubrava and Bouchelle agreed to a claim amendment to independent claim 1 that would overcome the 35 U.S.C. § 103 rejection of record, as discussed further below. In response, Applicant is amending the claims as agreed upon during the interview.

Objection to the Drawings

The Examiner objects to the drawings, contending that the features of claims 2 and 3 are not shown in the drawings. Applicant respectfully disagrees.

Claim 2 recites that the balloon is asymmetrical. Applicant submits that this feature is shown at least in Figs. 19 and 44.

Claim 3 recites that the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion. Applicant submits that this feature is shown in Fig. 34 and taught in para. [0226].

Accordingly, Applicant respectfully requests withdrawal of the objections to the drawings.

Claim Objections

The Examiner objects to the claims for typographical errors in claims 1 and 9, which are addressed herein. Accordingly, Applicant respectfully requests withdrawal of the claim objections.

Claim Rejections – 35 U.S.C. § 103

1. The Examiner rejects claims 1, 4-6 and 9-11 under 35 U.S.C. § 103 as being unpatentable over US 2004/0039332 (Kantor), in view of US 2010/0204712 (Mallaby), US 2011/0172696 (Jeffrey) and US 2019/0366046 (Klocke).

Namely, with respect to independent claim 1, the Examiner contends that Kantor discloses an occlusion catheter system (300) comprising: a proximal hub (310); a proximal catheter section (304); a distal catheter section (606), an intervening occlusion balloon (312); a lumen (inflation lumens, Para. [0071]) extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon; and a solid wire (guidewire 302) extending within the proximal catheter section, the occlusion balloon and the distal catheter section (Fig. 3), the occlusion balloon, the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration (para. [0070]). The Examiner acknowledges that Kantor does not teach a flow valve, but contends that Mallaby teaches a microcatheter comprising a flow valve (32) configured to selectively fluidly communicate the proximal hub with an inflation device, and takes the position that it would have been obvious to modify the hub of Kantor with the valve and syringe of Mallaby for the purpose of controlling fluid flow. The Examiner also acknowledges that Kantor does not teach a distal catheter section distally terminating with an atraumatic tip. Nevertheless, the Examiner contends that Jeffrey teaches a catheter having a soft distal tip wherein the distal catheter section is distally terminating with an atraumatic tip (Fig. 2A), and takes the position that it would have been obvious to combine the catheter of Kantor with the sleeve of Jeffrey for the purpose of minimizing the risks to vessel injury or rupture. Lastly, the Examiner acknowledges that Kantor does not teach at least one length marking on an exterior of the proximal catheter shaft, but contends that Klocke teaches a catheter with markings having at least one length marking (marks 32, P0023) on an exterior of the catheter shaft (Fig. 7A) to indicate an insertion depth of the occlusion catheter system

(P0024). The Examiner takes the position that it would have been obvious to combine the catheter of Kantor with the marks of Klocke. Applicant respectfully traverses the rejection in view of the following remarks and accompanying claim amendments.

As a first matter, the Examiner acknowledges that Kantor does not teach a distal catheter section distally terminating with an atraumatic tip. Applicant notes, however, that Kantor teaches that the guidewire is introduced into a coronary artery and is steered by manipulation of its proximal end, while being observed under a fluoroscope (para. [0013]). Kantor also teaches that the guidewire 302 is rounded at a tip of distal end 314, and that it is a steerable guidewire that can be easily manipulated through a tortuous blood vessel (para. [0035]). Accordingly, Applicant submits that one of ordinary skill in the art would not modify Kantor with Jeffrey for the purpose of minimizing the risks to vessel injury or rupture, as the Examiner contends, because Kantor already addresses this risk via the rounded tip of the guidewire 302.

Nevertheless, to advance examination, independent claim 1 is amended to recite that the solid wire is secured at a proximal-most end thereof within the proximal hub. As agreed upon with the Examiners during the July 28, 2023, Interview, this is not the case in Kantor.

The Examiner equates the guidewire 302 of Kantor with the claimed solid wire. The guidewire 302 is not secured to the luer hub 310 (which the Examiner equates with the claimed proximal hub). Moreover, Kantor cannot be modified to include such a feature for several reasons. Firstly, and with respect to previously presented claim 6, the Examiner contends that Mallaby teaches a guide wire lock 72 for locking the guidewire to the hub thereof, and contends that it would have been obvious to modify Kantor accordingly. The guidewire 16 of Mallaby, however, is not secured to the multi-access hub 70 at a proximal-most end of the guidewire, as claimed. As clearly seen in Fig. 1, the guidewire 16 extends proximally to the hub.

As for Kantor, and as clearly shown in Fig. 3, the guidewire 302 is a separate component that is fed through the luer hub 310 and also has a manipulating proximal end 316 and a guidewire manipulator 320. Accordingly, Kantor cannot be modified such that the proximal-most end of the guidewire 302 is secured to the luer hub 310 as such a modification would render Kantor inoperable for its intended purpose. That is, the manipulating proximal end 316 and the guidewire manipulator would be removed and the guidewire 302 would no longer be rotatable and

manipulatable. As previously explained, the guidewire 302 of Kantor is configured to be steered and manipulated through the blood vessel, and subsequently removed, and, therefore, cannot be secured at a proximal end thereof to the luer hub 310. Neither Jeffrey nor Klocke address the deficiencies of Kantor or Mallaby.

Applicant, therefore, respectfully submits that the cited art, Kantor, Mallaby, Jeffrey and Klocke, alone or in combination, fails to disclose, teach or suggest each and every feature of amended independent claim 1. Applicant, accordingly, respectfully submits that the cited art cannot render amended independent claim 22, anticipated or otherwise unpatentable. Applicant also submits that claims 4, 5 and 9-11, which are dependent upon claim 1, are also patentable over Kantor, Mallaby, Jeffrey and Klocke for at least the same reasons presented above with respect to amended independent claims 21. *See* MPEP § 2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) (claims depending from a patentable claim are also patentable over the prior art).

For at least the above reasons, the rejections under 35 U.S.C. § 103 should be withdrawn and claims 1, 4, 5 and 9-11, as amended, allowed. Claim 6 is canceled herein, rendering moot the rejection thereof.

2. The Examiner rejects claim 2 under 35 U.S.C. § 103 as being unpatentable over Kantor, Mallaby, Jeffrey and Klocke, and further in view of US 6,129,737 (Hamilton). Claim 3 is rejected under 35 U.S.C. § 103 as being unpatentable over Kantor, Mallaby, Jeffrey and Klocke, and further in view of US 2010/0113939 (Mashimo). Claims 7 and 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Kantor, Mallaby, Jeffrey and Klocke, and further in view of US 2008/0287786 (Lentz).

However, as amended independent claim 1 is patentable over Kantor, Mallaby, Jeffrey and Klocke, for at least the reasons discussed above, claims 2, 3, 7 and 8, dependent upon claim 1, are also patentable for at least the same reasons, since the additional cited art does not disclose or add any teaching or suggestion which overcomes the deficiencies of Kantor, Mallaby, Jeffrey and Klocke with respect to claim 1. *See* MPEP § 2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) (claims depending from a patentable claim are also patentable over the prior art).

For at least the above reasons, the rejection under 35 U.S.C. § 103 should be withdrawn and claims 2, 3, 7 and 8, as amended, allowed.

CONCLUSION

It is respectfully submitted that, in view of the above remarks, all issues raised by the Examiner have been addressed, and the application, including claims 1-5 and 7-11, as amended, is in condition for allowance. A timely notice of allowance is earnestly solicited.

Dated: July 31, 2023

Respectfully submitted,

Electronic signature: /Ragi A.I. Elias/
Ragi A. I. Elias
Registration No.: 67,772
PANITCH SCHWARZE BELISARIO & NADEL LLP
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Electronic Acknowledgement Receipt	
EFS ID:	48369364
Application Number:	17563669
International Application Number:	
Confirmation Number:	4495
Title of Invention:	SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER
First Named Inventor/Applicant Name:	Curtis J. FRANKLIN
Customer Number:	570
Filer:	Ragi A.I. Elias/Angela Kryszczak
Filer Authorized By:	Ragi A.I. Elias
Attorney Docket Number:	688961-25U7
Receipt Date:	31-JUL-2023
Filing Date:	28-DEC-2021
Time Stamp:	08:30:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response_to_6-20-23_NFOA. PDF	91380	yes	8
			93854405fc452433b488a9a0fce5dea33a84 ea49		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Request for Reconsideration-After Non-Final Rejection	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	8
Warnings:			
Information:			
Total Files Size (in bytes):		91380	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>			



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495
570 7590 08/03/2023 PANITCH SCHWARZE BELISARIO & NADEL LLP TWO COMMERCE SQUARE 2001 MARKET STREET, SUITE 2800 PHILADELPHIA, PA 19103			EXAMINER DOUBRAVA, JOHN A	
			ART UNIT 3783	PAPER NUMBER
			NOTIFICATION DATE 08/03/2023	DELIVERY MODE ELECTRONIC

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

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

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

usptomail@panitchlaw.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/563,669	Applicant(s) FRANKLIN et al.		
	Examiner JOHN A DOUBRAVA	Art Unit 3783	AIA (First Inventor to File) Status Yes	Page 1 of 2

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
JOHN A DOUBRAVA	Examiner	Telephonic
Laura Bouchelle	Primary Examiner	
Ragi A.I. Elias	Attorney of Record	

Date of Interview: 28 July 2023

Issues Discussed:

Objections

Indicated the drawing objections would be withdrawn.

Proposed Amendment(s)

Indicated that proposed amendment would overcome the cited art if the proposed claim was further amended to recite in lines 13-14 "...a solid wire, secured at a proximal most end thereof within the hub, and extending...and the distal catheter section; and...".

Other

Indicated that the argument made on page 2 of 5 regarding the modification to Kantor with an atraumatic tip was not persuasive. No agreement was reached.

☒ Attachment

/J.A.D./ Examiner, Art Unit 3783	/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/563,669	Applicant(s) FRANKLIN et al.		
	Examiner JOHN A DOUBRAVA	Art Unit 3783	AIA (First Inventor to File) Status Yes	Page 2 of 2

indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

PANITCH SCHWARZE BELISARIO & NADEL LLP
Two Commerce Square - 2001 Market Street - Suite 2800 - Philadelphia, PA 19103
TELEPHONE: (215) 965-1221 - FACSIMILE: (215) 965-1331
E-MAIL: relias@panitchlaw.com

VIA FAX

ATTN: Examiner John A. Doubrava

App. No.: 17/563,669

From: Ragi A.I. Elias

Fax: 571-483-7203

Group Art Unit: 3783

Date: July 27, 2023

Re: Interview Agenda

Panitch File No: 688961-25U7

Pages: 5

Examiner Doubrava,

In accordance with our telephone call, the following is an Agenda for our telephone interview, scheduled for **Friday, July 28, 2023**, at 2:30 P.M.

Examiner objects to claims 2 and 3, claiming that the features thereof are not shown in the drawings.

- Claim 2 recites that the balloon is asymmetrical. Applicant submits that this feature is shown at least in Figs. 19 and 44.
- Claim 3 recites that the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion. Applicant submits that this feature is shown in Fig. 34 and taught in para. [0226].

Examiner rejects claims 1, 4-6 and 9-11 under 35 U.S.C. § 103 as being unpatentable over US 2004/0039332 (Kantor), in view of US 2010/0204712 (Mallaby), US 2011/0172696 (Jeffrey) and US 2019/0366046 (Klocke).

- Namely, with respect to independent claim 1, the Examiner contends that Kantor discloses an occlusion catheter system (300) comprising: a proximal hub (310); a proximal catheter section (304); a distal catheter section (606), an intervening occlusion balloon (312); a lumen (inflation lumens, Para. [0071]) extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon; and a solid wire (guidewire 302) extending within the proximal catheter section, the occlusion balloon and the distal catheter section (Fig. 3), the occlusion balloon, the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration (para. [0070]). The Examiner acknowledges that Kantor does not teach a flow valve, but contends that Mallaby teaches a microcatheter comprising a flow valve (32) configured to selectively fluidly communicate the proximal hub with an inflation device, and takes the position that it would have been obvious to modify the hub of Kantor with the valve and syringe of Mallaby for the purpose of controlling fluid flow. The Examiner also acknowledges that Kantor does not teach a distal catheter section distally terminating with an atraumatic tip. Nevertheless, the Examiner contends that Jeffrey teaches

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PAGE 1/5 * RCVD AT 7/27/2023 10:56:17 AM [Eastern Daylight Time] * SVR:W-PTOFAX-DTS-E4/20 * DNIS:4837203 * CSID:Fax Services * ANI:2064520140 * DURATION (mm-ss):02-02

Front Line Med. Techs., Inc. Ex-1002-586

a catheter having a soft distal tip wherein the distal catheter section is distally terminating with an atraumatic tip (Fig. 2A), and takes the position that it would have been obvious to combine the catheter of Kantor with the sleeve of Jeffrey for the purpose of minimizing the risks to vessel injury or rupture. Lastly, the Examiner acknowledges that Kantor does not teach at least one length marking on an exterior of the proximal catheter shaft, but contends that Klocke teaches a catheter with markings having at least one length marking (marks 32, P0023) on an exterior of the catheter shaft (Fig. 7A) to indicate an insertion depth of the occlusion catheter system (P0024). The Examiner takes the position that it would have been obvious to combine the catheter of Kantor with the marks of Klocke. Applicant respectfully traverses.

- The Examiner acknowledges that Kantor does not teach a distal catheter section distally terminating with an atraumatic tip. Applicant notes, however, that Kantor teaches that the guidewire is introduced into a coronary artery and is steered by manipulation of its proximal end, while being observed under a fluoroscope (para. [0013]). Kantor also teaches that the guidewire 302 is rounded at a tip of distal end 314, and that it is a steerable guidewire that can be easily manipulated through a tortuous blood vessel (para. [0035]). Accordingly, one of ordinary skill in the art would not modify Kantor with Jeffrey for the purpose of minimizing the risks to vessel injury or rupture, as the Examiner contends, because Kantor already addresses this risk via the rounded tip of the guidewire 302.
- **Nevertheless, to advance examination, Applicant proposes amending independent claim 1 to recite that the solid wire is secured at a proximal end thereof to the proximal hub.** Support for this amendment can be found from claim 6, as well as at paragraph [0163] of the specification, as well as in Fig. 6 of the application.
 - The Examiner equates the guidewire 302 of Kantor with the claimed solid wire.
 - The guidewire 302 is not secured to the luer hub 310 (which the Examiner equates with the claimed proximal hub).
 - Moreover, Kantor cannot be modified to include such a feature for several reasons.
 - Firstly, and with respect to claim 6, the Examiner contends that Mallaby teaches a guide wire lock 72 for locking the guidewire to the hub thereof, and contends that it would have been obvious to modify Kantor accordingly. The guidewire 16 of Mallaby, however, is not secured to the multi-access hub 70 at a proximal end of the guidewire, as claimed.
 - As clearly seen in Fig. 1, the guidewire 16 extends proximal to the hub. As for Kantor, and as clearly shown in Fig. 3, the guidewire 302 is a separate component that is fed through the luer hub 310 and also has a manipulating proximal end 316 and a guidewire manipulator 320. Accordingly, Kantor cannot be modified such that the proximal end of the guidewire 302 is secured to the luer hub 310 as such a modification would render Kantor inoperable for its intended purpose. That is, the manipulating proximal end 316 and the guidewire manipulator would be removed and the guidewire 302 would no longer be rotatable and manipulatable. As previously explained, the guidewire 302 of Kantor is configured to be steered and manipulated through

the blood vessel, and subsequently removed, and, therefore, cannot be secured at a proximal end thereof to the luer hub 310.

/Ragi A.I. Elias/
(Reg. 67,772)

Proposed Claim Amendment***NOT TO BE ENTERED, SUBMITTED OR PLACED INTO THE RECORD******THIS PAPER IS BEING SUBMITTED SOLELY TO FACILITATE DISCUSSION***

Strikethrough and double brackets indicate a deletion and underlining indicates an addition, as follows:

1. (Proposed Amendment) An occlusion catheter system comprising:
 - a proximal hub;
 - a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device;
 - a proximal catheter section in fluid communication with the proximal hub;
 - a distal catheter section distally terminating with an atraumatic tip;
 - an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being constructed of a compliant biocompatible material;
 - at least one length marking on an exterior of the proximal catheter shaft to indicate an insertion depth of the occlusion catheter system;
 - a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon; and
 - a solid wire, secured at a proximal end thereof to the proximal hub, and extending within the proximal catheter section, the occlusion balloon and the distal catheter section,
 - ~~the occlusion balloon,~~ the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.
2. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.
3. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.
4. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.
5. (Original) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

6. ~~(Canceled) The occlusion catheter system of claim 1, wherein the solid wire is secured to the proximal hub.~~

7. (Original) The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.

8. (Original) The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.

9. (Proposed Amendment) The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon.[];

10. (Original) An inflation control system kit comprising:
the occlusion catheter system of claim 1; and
a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.

11. (Previously Presented) The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

570 7590 11/08/2023
PANITCH SCHWARZE BELISARIO & NADEL LLP
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 2800
PHILADELPHIA, PA 19103

EXAMINER

DOUBRAVA, JOHN A

ART UNIT

PAPER NUMBER

3783

DATE MAILED: 11/08/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495

TITLE OF INVENTION: SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	02/08/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

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Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495

TITLE OF INVENTION: SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	02/08/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
DOUBRAVA, JOHN A	3783	604-096010

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495
570	7590	11/08/2023	EXAMINER	
PANITCH SCHWARZE BELISARIO & NADEL LLP			DOUBRAVA, JOHN A	
TWO COMMERCE SQUARE			ART UNIT	PAPER NUMBER
2001 MARKET STREET, SUITE 2800			3783	
PHILADELPHIA, PA 19103			DATE MAILED: 11/08/2023	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 17/563,669	Applicant(s) FRANKLIN et al.	
	Examiner JOHN A DOUBRAVA	Art Unit 3783	AIA (FITF) Status Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 31 July 2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☒ The allowed claim(s) is/are 1-5 and 7-11. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. <u>20231027</u> .	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/J.A.D./ Examiner, Art Unit 3783	/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783
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DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on July 31, 2023. As directed by the amendment: claim 1 has been amended, claim 6 has been cancelled, and no claims have been added. Thus, claims 1-5 and 7-11 are presently pending in this application. Applicant's amendments are sufficient to overcome the claim objections of the previous action.

Drawings

2. Applicant's arguments, see Remarks, filed July 31, 2023, with respect to the drawing objections of the previous action have been fully considered and are persuasive. The drawing objections have been withdrawn.

Response to Arguments

3. Applicant's arguments, see Remarks, filed July 31, 2023, with respect to newly amended claim 1 have been fully considered and are persuasive. The rejection of newly amended claim 1 and claims depending from newly amended claim 1 have been withdrawn.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Ragi A.I. Elias on October 27, 2023.

5. The application has been amended as follows:

Claim 1, line 8 "...the occlusion balloon being constructed of a compliant biocompatible material;..." should be "...the occlusion balloon being compliant;...".

Claim 1, line 14 "...the occlusion balloon and the distal catheter..." should be "...the occlusion balloon and into the distal catheter ...".

Allowable Subject Matter

6. **Claims 1-5 and 7-11** are allowed.

Reasons for Allowance

7. The following is an Examiner's statement of reasons for allowance: the claims in this application are allowed because the prior art of record fails to disclose either singularly or in combination the claimed occlusion catheter system.

8. The closest prior art is Smith US 5,087,246.

9. **Regarding claim 1**, Smith fails to teach among all the limitations or render obvious an occlusion catheter system as claimed, which includes a flow valve, the occlusion balloon being compliant, at least one length marking on an exterior of the proximal shaft, and the catheter distal to the hub having a greatest outer diameter of less than 6 French in an uninflated configuration, in combination with the total structure and function of the occlusion catheter system as claimed. Although compliant balloons are known in the art, one of ordinary skill in the art would not modify Smith with a

compliant balloon as this modification would render the modified device unsuitable for dilatation.

10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN A DOUBRAVA whose telephone number is (408)918-7561. The examiner can normally be reached M-F 9-5 Pacific Time.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nathan Price can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For

Application/Control Number: 17/563,669
Art Unit: 3783

Page 5

additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.A.D./
Examiner, Art Unit 3783

/LAURA A BOUCHELLE/
Primary Examiner, Art Unit 3783

<i>Examiner-Initiated Interview Summary</i>	Application No. 17/563,669	Applicant(s) FRANKLIN et al.		
	Examiner JOHN A DOUBRAVA	Art Unit 3783	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
JOHN A DOUBRAVA	Examiner	Telephonic
Ragi A.I. Elias	Attorney of Record	

Date of Interview: 27 October 2023

Issues Discussed:

Proposed Amendment(s)

Examiner's Amendment.

Claim 1, line 8 "...the occlusion balloon being constructed of a compliant biocompatible material;..." should be "...the occlusion balloon being compliant;...".

Claim 1, line 14 "...the occlusion balloon and the distal catheter..." should be "...the occlusion balloon and into the distal catheter ...".

Agreed to by Ragi A.I. Elias on October 27, 2023.

/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783	/JOHN A DOUBRAVA/ Examiner, Art Unit 3783
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Notice of References Cited	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.	
	Examiner JOHN A DOUBRAVA	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20090018500-A1	01-2009	Carter; Matthew P.	A61M25/10	604/99.01
*	B	US-5087246-A	02-1992	Smith; Charles E.	A61M25/1002	604/103
*	C	US-20020081406-A1	06-2002	Wang, Lixiao	B32B27/08	428/35.2
	D					
	E					
	F					
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	I					
	J					
	K					
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	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

<i>Search Notes</i> 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

CPC - Searched*		
Symbol	Date	Examiner
A61M25/ 0068, 0074, 1002, 1006	06/12/2023	JAD
A61B17/12036	06/12/2023	JAD
A61M2025/1052	06/12/2023	JAD

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Searched Search, NPL, Inventors and Assignee.	06/12/2023	JAD
Additional Search.	10/27/2023	JAD

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61M\$.cpc.	all of A61M	10/27/2023	JAD
A61B\$.cpc.	all of A61B	10/27/2023	JAD

/J.A.D./ Examiner, Art Unit 3783	
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Issue Classification 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

CPC						
Symbol					Type	Version
A61M	/	25	/	0068	F	2013-01-01
A61M	/	25	/	1002	I	2013-01-01
A61M	/	25	/	1006	I	2013-01-01
A61M	/	25	/	10182	I	2013-11-05
A61M	/	25	/	008	I	2013-01-01
A61M	/	25	/	104	I	2013-01-01
A61B	/	17	/	12036	I	2013-01-01
A61M	/	25	/	0074	I	2013-01-01
A61M	/	2025	/	0002	A	2013-01-01
A61M	/	2025	/	1052	A	2013-01-01
A61M	/	2025	/	1086	A	2013-01-01
A61M	/	25	/	007	A	2013-01-01
A61B	/	2017	/	00017	A	2013-01-01
A61M	/	2025	/	1093	A	2013-01-01
A61B	/	17	/	12045	A	2013-01-01
A61M	/	2025	/	1084	A	2013-01-01
A61B	/	17	/	12109	A	2013-01-01
A61M	/	2025	/	1059	A	2013-01-01
A61M	/	2025	/	1081	A	2013-01-01

CPC Combination Sets					
Symbol	Type	Set	Ranking	Version	
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/JOHN A DOUBRAVA/ Examiner, Art Unit 3783 (Assistant Examiner)	27 October 2023 (Date)	Total Claims Allowed: 10	
/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783 (Primary Examiner)	30 October 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 12

Issue Classification 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61M		25	00

NON-CLAIMED			

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

JOHN A DOUBRAVA/ Examiner, Art Unit 3783 (Assistant Examiner)	27 October 2023 (Date)	Total Claims Allowed: 10	
/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783 (Primary Examiner)	30 October 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 12

Issue Classification 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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5	5														
-	6														
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7	8														
8	9														

JOHN A DOUBRAVA/ Examiner, Art Unit 3783 (Assistant Examiner)	27 October 2023 (Date)	Total Claims Allowed: 10	
/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783 (Primary Examiner)	30 October 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 12

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	130	("20070043409" "20070129466" "20070135830" "20090171293" "20090312807" "20100268017" "8419648" "9474882" "20040254528" "20050059931" "5505702" "6190356" "7763043" "20020193735" "20030167038" "20040073162" "20050148812" "20070043307" "20080027356" "20080082046" "20080082119" "20080243067" "20080262477" "20090026595" "20090062666" "20090265951" "20090287079" "20100016735" "20100041984" "20100234915" "20100262076" "20100280451" "20110196412" "20110295301" "20110295302" "201110301630" "20120101413" "20120108979" "20120116352" "2012012911" "20120215166" "20120271231" "20120302994" "20130102926" "20130102929" "20130190619" "20130281869" "20130289607" "20140243873" "20140249504" "20140316012" "20140378869" "20150012031" "20150039012" "20150367098" "20160000446" "2156289" "4464172" "4713888" "4777951" "4823469" "4865549" "4926885" "4983166" "5135494" "5282479" "5320605" "5383856" "5447503" "5522400" "5718678" "5738652" "5911702" "6011988" "6013019" "6102930" "6146370" "6161547" "6165199" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669	(US-PGPUB; USPAT)	OR	ON	ON	2018/05/31 10:50 AM

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L4	563	((("FRANKLIN") near3 ("Curtis")) OR ((("SPENCER") near3 ("David")) OR ((("KRUMMENACHER") near3 ("Todd")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:51 AM
L5	688	L1 or L2 or L3	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:51 AM
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L7	0	604/096	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:52 AM
L8	12594	A61M25/0068.cpc. or A61M25/0074.cpc. or A61M25/1002.cpc. or A61M25/1006.cpc. or A61M2025/0002.cpc. or A61M2025/1052.cpc. or A61M2025/1059.cpc. or A61M2025/1081.cpc. or A61M2025/1086.cpc.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:54 AM

L9	58	L5 and L8	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:54 AM
L10	12536	L8 not L9	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 10:55 AM
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L25	2081	L19 and (catheter tip designs stent).ti.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:08 AM
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		stent).ti.	USOCR; EPO; JPO; DERWENT)				11:08 AM
L27	176	L19 and (tip designs).ti.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:08 AM
L28	2	"6517515".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/05/31 11:14 AM
L29	229	("3631848" "3766915" "3788326" "3911927" "3915171" "4085185" "4195637" "4249536" "4251305" "4307722" "4323071" "4385635" "4413989" "4425919" "4530698" "4531512" "4531943" "4540404" "4551292" "4581019" "4582181" "4588399" "4596563" "4610662" "4616653" "4636272" "4636346" "4676229" "4699611" "4706670" "4739768" "4748982" "4753765" "4759748" "4764324" "4777951" "4782834" "4790331" "4798586" "4808164" "4817613" "4819751" "4820349" "4846174" "4848344" "4863442" "4884573" "4886506" "4898896" "4906244" "4917666" "4921483" "4943278" "4946466" "4950227" "4955377" "4960410" "4964409" "4964853" "4976720" "4983168" "4990139" "4994018" "5002559" "5007434" "5047045" "5050606" "5054501" "5055101" "5078702" "5078727" "5093546" "5100381" "5104377" "5108416" "5120308" "5122125" "5139496" "5143093" "5147377" "5154725" "5156594" "5156612" "5158548" "5159937" "5163906" "5171221" "5171230" "5176637" "5180585" "5209728" "5213574" "5221270" "5226888" "5226889" "5234416" "5240537" "5254091"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:15 AM

		"5256144" "5258160" "5259839" "5261878" "5270086" "5279559" "5279561" "5279562" "5290295" "5304134" "5304198" "5316706" "5318032" "5318527" "5318529" "5318532" "5320604" "5324257" "5324259" "5324263" "5327885" "5328468" "5334148" "5334168" "5335410" "5338296" "5342389").PN. OR ("5344400" "5346505" "5370615" "5370655" "5387193" "5389087" "5397306" "5399164" "5403292" "5405338" "5405380" "5407432" "5411477" "5415664" "5423754" "5423771" "5425709" "5425712" "5445646" "5449373" "5454788" "5454795" "5458573" "5458613" "5470322" "5480383" "5496271" "5496294" "5503263" "5509910" "5520644" "5531685" "5531715" "5538513" "5540236" "5542924" "5542937" "5549552" "5549556" "5554121" "5554139" "5569218" "5588965" "5591129" "5605543" "5624449" "5643209" "5645528" "5647857" "5674198" "5716373" "5718686" "5725513" "5728063" "5776100" "5891110" "5971955" "6048338" "6102891" "6113579" "6287320" "RE33166").PN. OR ("6517515").URPN.					
L30	141	L29 and catheter.ti.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:16 AM
L31	877	A6125/0071.cpc. or A61M25/0026.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:37 AM
L32	0	A6125/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:47 AM
L33	2138	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 11:47 AM
L34	2018	A61M25/0068.cpc. not	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31

L35	28	L31 ("4795446" "4842585" "5100390" "5167645" "5183470" "5295980" "6186987" "6254578").PN. OR ("6979318").URPN.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	11:47 AM 2018/05/31 11:56 AM
L36	261	("3631848" "3766915" "3788326" "3911927" "4085185" "4195637" "4249536" "4251305" "4307722" "4323071" "4385635" "4413989" "4425919" "4530698" "4531512" "4531943" "4540404" "4551292" "4581019" "4582181" "4588399" "4596563" "4616653" "4636272" "4636346" "4676229" "4699611" "4706670" "4739768" "4748982" "4753765" "4759748" "4764324" "4777951" "4782834" "4790331" "4798586" "4808164" "4817613" "4819751" "4820349" "4846174" "4848344" "4863442" "4884573" "4886506" "4898896" "4906244" "4917666" "4921483" "4943278" "4946466" "4950227" "4955377" "4960410" "4964409" "4964853" "4976720" "4983168" "4994018" "5002559" "5007434" "5047045" "5050606" "5054501" "5055101" "5078702" "5078727" "5093546" "5100381" "5108416" "5120308" "5122125" "5139496" "5143093" "5147377" "5154725" "5156594" "5156612" "5158548" "5159937" "5163906" "5171221" "5171230" "5176637" "5180585" "5209728" "5213574" "5221270" "5226888" "5226889" "5234416" "5240537" "5254091" "5256144" "5258160" "5259839" "5261878" "5270086" "5279559"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 12:03 PM

		"5279561" "5279562" "5290295" "5304134" "5304198" "5316706" "5318032" "5318527" "5318529" "5318532" "5324257" "5324259" "5324263" "5327885" "5328468" "5334148" "5334168" "5335410" "5338296" "5342386" "5344400" "5346505" "5370615" "5370655" "5387193").PN. OR ("5389087" "5397306" "5399164" "5403292" "5405338" "5405380" "5407432" "5411477" "5415664" "5423754" "5423771" "5425709" "5425712" "5445646" "5449373" "5454788" "5454795" "5458573" "5458613" "5470322" "5480383" "5496271" "5496294" "5503263" "5509910" "5520644" "5531685" "5531715" "5538513" "5540236" "5542924" "5542937" "5549552" "5549556" "5554121" "5554139" "5569218" "5591129" "5605543" "5624449" "5643209" "5645528" "5647857" "5716373" "5725513" "5728063" "5776100" "5931829" "B14323071" "Re33166").PN. OR ("6113579").URPN.					
L37	1	(11/619979).APP.	(USPAT; USOCR)	OR	ON	ON	2018/05/31 12:48 PM
L38	20	("20010021840" "20020055771" "20030149467" "20050045183" "20050209676" "20060276808" "2862498" "3710777" "3754554" "3884242" "4819619" "5207232" "5273527" "5685824" "5720275" "5791341" "5873362" "6096052" "6432116").PN. OR ("8961532").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/05/31 12:48 PM
L39	886	A61M2025/1093.cpc.	(US-PGPUB; USPAT;	OR	ON	ON	2018/06/01

L40	130	("20070043409" "20070135830" "20090171293" "20090312807" "20100268017" "8419648" "9474882" "20040254528" "2005059931" "5505702" "6190356" "7763043" "20020193735" "20030167038" "20040073162" "20050148812" "20070043307" "20080027356" "20080082046" "20080082119" "20080243067" "20080262477" "20090026595" "20090062666" "20090265951" "20090287079" "20100016735" "20100041984" "20100234915" "20100262076" "20100280451" "20110196412" "20110295301" "20110295302" "201110301630" "2012010413" "20120108979" "20120116352" "2012012911" "20120215166" "20120271231" "20120302994" "20130102926" "20130102929" "20130190619" "20130281869" "20130289607" "20140243873" "20140249504" "20140316012" "20140378869" "20150012031" "20150039012" "20150367098" "20160000446" "2156289" "4464172" "4713888" "4777951" "4823469" "4865549" "4926885" "4983166" "5135494" "5282479" "5320605" "5383856" "5447503" "5522400" "5718678" "5738652" "5911702" "6011988" "6013019" "6102930" "6146370" "6161547" "6165199" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669679" "6679860" "6695811" "6719270" "6719720" "6733513" "6735532" "6736790" "6746462" "	USOCR) (US-PGPUB; USPAT)	OR	OFF	OFF	09:03 AM 2018/06/05 04:01 PM
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		6796959 "6936056 "7341571 "7434326 "7503904 "7503909 "7892469 "7909810 "7951186 "7951819 "7959644 "8088103 "8162879 "8241241 "8262611 "8430899 "8499681 "8545382 "8655798 "8672868 "8747358 "8814900 "8900214 "8948848 "8951565 "9131874 "9414843 "D748257 "20030032974 "20050261725 "20070219488 "20120109057").P N.					
L48	1	((("PRYOR") near3 ("MEDICAL") near3 ("DEVICES") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2018/06/06 03:25 PM
L49	72	("FRANKLIN") near3 ("Curtis").INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/06/06 03:27 PM
L50	14	("FRANKLIN") near3 ("Curtis").INV. and catheter	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/06/06 03:27 PM
L51	2	"9687333".pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2018/07/09 10:49 AM
L52	153	("20080097300 "20150272732 "20080243221 "20110144742 "20140364835 "20160375230 "2015158529 "20020007146 "20020062119 "20120209176 "20130172786 "20130338637 "5047045 "20020193735 "20030032974 "20030167038 "20040073162 "20040082935 "20040254528 "20050059931 "20050148812 "20050261725 "20070043307 "20070043409 "20070129466 "20070135830 "20070219466 "20070219488 "20080027356 "20080082046 "20080082119 "20080243067 "20080262477 "20090026595 "20090062666 "20090171272 "20090171293 "20090265951 "2009028	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/14 03:09 PM

		7079" "20090312807" "20100016735" "20100041984" "20100234915" "20100262076" "20100268017" "20100280451" "20110196412" "20110295301" "20110295302" "20110301630" "20120101413" "20120108979" "20120109057" "20120116352" "20120130359" "20120172911" "20120215166" "20120271231" "20120302994" "20130102926" "20130102929" "20130190619" "20130281869" "20130289607" "20140221898" "20140243873" "20140249504" "20140316012" "20140378869" "20150012031" "20150039012" "20150367098" "20160000446" "2156289" "4464172" "4713888" "4777951" "4823469" "4865549" "4926885" "4983166" "5135494" "5169386" "5282479" "5320605" "5383856" "5447503" "5505702" "5522400" "5571093" "5718678" "5738652" "5911702" "6011988" "6013019" "6102930" "6113579" "6146370" "6161547" "6165199" "6190356" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669679" "6679860" "6695811" "6719270" "6719720" "6733513" "6735532" "6736790" "6746462" "6796959" "6936056" "6979318" "7341571" "7434326" "7503904" "7503909" "763043" "7892469" "7909810" "7951186" "7951819" "7959644" "8088103" "8162879" "8241241" "8262611" "8419648" "8430899" "8499681" "8545382" "8655798" "8672868" "8747358" "8814900" "8900214" "89				
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L53	5	48848" "8951565" "9131874" "9414843" "9474882" "9687333" "D748257").PN. (("20120302994") or ("6579221") or ("6013019") or ("20110251497") or ("7341571")).PN.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/14 04:32 PM
L54	1	(13/481532).APP.	(USPAT; USOCR)	OR	ON	ON	2021/07/14 04:35 PM
L55	287	("20010001812" "20010029362" "20010037085" "20020018866" "20020082549" "20020165523" "20030009151" "20030032920" "20030055447" "20030055448" "20030105426" "20030139762" "20040059291" "20040059292" "20040064130" "20040068240" "20040097892" "20040116956" "20040131808" "20040167441" "20040170782" "20040173935" "20040181206" "20040191443" "20040215141" "20040267195" "20040267280" "20050015048" "20050043679" "20050124976" "20050131445" "20050148997" "20050154414" "20050186370" "20050228429" "20050238833" "20050261725" "20050277878" "20060008606" "20060136032" "20060165926" "20060175739" "20060282041" "20070016165" "20070021772" "20070060863"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/14 04:35 PM

		"20070142771" "20070167973" "20070191813" "20070240817" "20080015499" "20080045895" "20080045928" "20080065188" "20080262470" "20090005754" "20090036829" "20090156998" "20090223624" "20090247946" "20090264822" "20100010439" "20100130925" "20100189876" "20100285085" "20110022150" "20110070355" "20110172696" "20110315301" "20120065586" "20120143129" "4425919" "4563181" "4596563" "4721117" "4775371" "4782834" "4820349" "4877031" "4886506" "4892519" "4952357" "4976690" "4976720" "5047045" "5061273" "5078702" "5085649" "5112304" "5156594" "5176661" "5195969" "5205822" "5207700" "5217434" "5217482" "5250059" "5256144" "5270086" "5277199" "5290232").PN. OR ("5290306" "5300025" "5304134" "5312430" "5318032" "5318526" "5342386" "5358486" "5364357" "5370655" "5378238" "5395336" "5423754" "5425712" "5447497" "5451233" "5454789" "5458615" "5470315" "5476477" "5478320" "5484409" "5490837" "5496275" "5499980" "5507768" "5512051" "5526823" "5538513" "5545134" "5549552" "5554121" "5556383" "5569195"				
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		"5587125"	"5599326"				
		"5613979"	"5620649"				
		"5622665"	"5632760"				
		"5643209"	"5649909"				
		"5658264"	"5690613"				
		"5728063"	"5743874"				
		"5743875"	"5749849"				
		"5755690"	"5759173"				
		"5766151"	"5769817"				
		"5769819"	"5775327"				
		"5779731"	"5782811"				
		"5791036"	"5792124"				
		"5792144"	"5795325"				
		"5795341"	"5797887"				
		"5814016"	"5820594"				
		"5833657"	"5879369"				
		"5879499"	"5902290"				
		"5908406"	"5911715"				
		"5916193"	"5947939"				
		"5964778"	"6004289"				
		"6004339"	"6010521"				
		"6021340"	"6024693"				
		"6024722"	"6027510"				
		"6036670"	"6056719"				
		"6059751"	"6059770"				
		"6071266"	"6086556"				
		"6102890"	"6124007"				
		"6132824"	"6136258"				
		"6146356"	"6165166"				
		"6165195"	"6168588"				
		"6171275"	"6171278"				
		"6179810"	"6179856"				
		"6193686"	"6197015"				
		"6210396"	"6217565"				
		"6242063"	"6245053"				
		"6251093"	"6264063"				
		"6265016"	"6306097"				
		"6306124"	"6308342"				
		"6358227"	"6364894"				
		"6416494"	"6482348"				
		"6495090"	"6495127"				
		"6500148"	"6508784"				
		"6575934"	"6575958"				
		"6579259"	"6585687"				
		"6585688"	"6589207"				
		"6589226")	PN. OR				
		("6620127"	"6620128"				
		"6626889"	"6629961"				
		"6645422"	"6663614"				
		"6673291"	"6673302"				
		"6695809"	"6702802"				
		"6718211"	"6733487"				
		"6756094"	"6777644"				
		"6793647"	"6796958"				
		"6796960"	"6835189"				
		"6837890"	"6863678"				
		"6875197"	"6887219"				
		"6890395"	"6893456"				

		"6911038" "6913600" "6918920" "6923822" "6946092" "6951555" "6951675" "6964750" "6979342" "7026026" "7029732" "7037291" "7037295" "7074206" "7108877" "7112357" "7141059" "7147817" "7163523" "7195638" "7273485" "7303798" "7322959" "7335185" "7341571" "7549975" "7556634" "7662130" "7828766" "7833193" "7833597" "7862541" "7906066" "7967836" "8048058" "8052638" "8070719").PN. OR ("10406329").URPN.					
L56	8	((("Prytime") near3 ("Medical") near3 ("Devices") near3 ("Inc"))).AS,AANM.	(USPAT)	OR	ON	ON	2021/11/23 11:01 AM
L57	673	((("FRANKLIN") near3 ("Curtis")) OR (("SPENCER") near3 ("David")) OR (("KRUMMENACHER") near3 ("Todd"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/11/23 11:01 AM
L58	153	("20080097300" "20150 272732" "20080243221 " "20110144742" "2014 0364835" "2016037523 0" "5158529" "2002000 7146" "20020062119" " 20120209176" "201301 72786" "20130338637" " "5047045" "200201937 35" "20030032974" "20 030167038" "20040073 162" "20040082935" "2 0040254528" "2005005 9931" "20050148812" " 20050261725" "200700 43307" "20070043409" " "20070129466" "20070 135830" "20070219466 " "20070219488" "2008 0027356" "2008008204 6" "20080082119" "200 80243067" "200802624 77" "20090026595" "20 090062666" "20090171 272" "20090171293" "2 0090265951" "2009028 7079" "20090312807" "	(US-PGPUB; USPAT)	OR	ON	ON	2021/11/23 11:02 AM

		20100016735 "201000 41984 "20100234915" "20100262076 "20100 268017 "20100280451 "20110196412 "2011 0295301 "2011029530 2 "20110301630 "201 20101413 "201201089 79 "20120109057 "20 120116352 "20120130 359 "20120172911 "2 0120215166 "2012027 1231 "20120302994 " 20130102926 "201301 02929 "20130190619" "20130281869 "20130 289607 "20140221898 "20140243873 "2014 0249504 "2014031601 2 "20140378869 "201 50012031 "201500390 12 "20150367098 "20 160000446 "2156289" "4464172 "4713888 "4 777951 "4823469 "48 65549 "4926885 "498 3166 "5135494 "5169 386 "5282479 "53206 05 "5383856 "544750 3 "5505702 "5522400" "5571093 "5718678 " 5738652 "5911702 "6 011988 "6013019 "61 02930 "6113579 "614 6370 "6161547 "6165 199 "6190356 "62315 72 "6248121 "628043 4 "6423031 "6453572" "6575932 "6579221 " 6602270 "6656153 "6 666814 "6669679 "66 79860 "6695811 "671 9270 "6719720 "6733 513 "6735532 "67367 90 "6746462 "679695 9 "6936056 "6979318" "7341571 "7434326 " 7503904 "7503909 "7 763043 "7892469 "79 09810 "7951186 "795 1819 "7959644 "8088 103 "8162879 "82412 41 "8262611 "841964 8 "8430899 "8499681" "8545382 "8655798 " 8672868 "8747358 "8 814900 "8900214 "89 48848 "8951565 "913				
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		1874" "9414843" "9474882" "9687333" "D748257").PN.					
L59	2818	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L60	1655	A61M25/0074.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L61	3455	A61M25/1002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L62	644	A61M25/1006.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L63	944	A61M2025/0002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L64	2670	A61M2025/1052.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L65	386	A61M2025/1059.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L66	953	A61M2025/1081.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:03 AM
L67	762	A61M2025/1084.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:04 AM
L68	1676	A61M2025/1086.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/11/23 11:04 AM
L69	6	((("20160213893") or ("20030032974") or ("20120109057") or ("20070219488") or ("20050261725") or ("5830181"))).PN.	(US-PGPUB; USPAT)	OR	ON	ON	2021/11/23 04:30 PM
L70	1	("20070135830").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:35 PM
L71	2	((("6113579") or ("5047045"))).PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:38 PM
L72	6	((("20040082935") or ("5169386") or ("20120330359") or ("9687333") or ("8419648") or ("20090312807"))).PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:42 PM
L73	1	("6579221").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:47 PM
L74	0	("60130019").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:50 PM
L75	1	("6013019").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:50 PM
L76	1	("8419648").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:50 PM
L77	1	("9687333").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/11/23 04:52 PM
L78	0	("(US-20180117279-\$orUS-20020169457-	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/03 10:27 AM

		\$orUS-20060167421-\$orUS-20070060911-\$orUS-20140221898-\$orUS-20070219466-\$orUS-20180140806-\$orUS-20170043123-\$orUS-20160213893-\$).did.or(US-6517515-\$orUS-5645528-\$orUS-5425709-\$orUS-4777951-\$orUS-5571093-\$orUS-9211389-\$orUS-6979318-\$orUS-6254578-\$orUS-6113579-\$orUS-D748257-\$).did.or(WO-9944666-\$).did.).PN.					
L79	19	(US-20180117279-\$ or US-20020169457-\$ or US-20060167421-\$ or US-20070060911-\$ or US-20140221898-\$ or US-20070219466-\$ or US-20180140806-\$ or US-20170043123-\$ or US-20160213893-\$).did. or (US-6517515-\$ or US-5645528-\$ or US-5425709-\$ or US-4777951-\$ or US-5571093-\$ or US-9211389-\$ or US-6979318-\$ or US-6254578-\$ or US-6113579-\$ or US-D748257-\$).did. or (WO-9944666-\$).did.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/03 10:28 AM
L80	1	(14/917286).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/07 09:47 AM
L81	1	(14/917286).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/07 09:48 AM
L82	142	("20020193735" "20030032974" "20030167038" "20040073162" "20040082935" "20040254528" "20050059931" "20050148812" "20050261725" "20070043307" "20070043409" "20070129466" "20070135830" "20070219466" "20070219488"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 09:48 AM

		"20080027356"					
		"20080082046"					
		"20080082119"					
		"20080243067"					
		"20080262477"					
		"20090026595"					
		"20090062666"					
		"20090171272"					
		"20090171293"					
		"20090265951"					
		"20090287079"					
		"20090312807"					
		"20100016735"					
		"20100041984"					
		"20100234915"					
		"20100262076"					
		"20100268017"					
		"20100280451"					
		"20110196412"					
		"20110295301"					
		"20110295302"					
		"20110301630"					
		"20120101413"					
		"20120108979"					
		"20120109057"					
		"20120116352"					
		"20120130359"					
		"20120172911"					
		"20120215166"					
		"20120271231"					
		"20120302994"					
		"20130102926"					
		"20130102929"					
		"20130190619"					
		"20130281869"					
		"20130289607"					
		"20140221898"					
		"20140243873"					
		"20140249504"					
		"20140316012"					
		"20140378869"					
		"20150012031"					
		"20150039012"					
		"20150367098"					
		"20160000446"					
		"2156289" "4464172"					
		"4713888" "4777951"					
		"4823469" "4865549"					
		"4926885" "4983166"					
		"5047045" "5135494"					
		"5169386" "5282479"					
		"5320605" "5383856"					
		"5447503" "5505702"					
		"5522400" "5571093"					
		"5718678" "5738652"					
		"5911702" "6011988"					
		"6013019" "6102930"					
		"6113579" "6146370"					

		"6161547" "6165199" "6190356" "6231572" "6248121" "6280434" "6423031" "6453572" "6575932" "6579221" "6602270" "6656153" "6666814" "6669679" "6679860" "6695811" "6719270" "6719720" "6733513").PN. OR ("6735532" "6736790" "6746462" "6796959" "6936056" "6979318" "7341571" "7434326" "7503904" "7503909" "7763043" "7892469" "7909810" "7951186" "7951819" "7959644" "8088103" "8162879" "8241241" "8262611" "8419648" "8430899" "8499681" "8545382" "8655798" "8672868" "8747358" "8814900" "8900214" "8948848" "8951565" "9131874" "9414843" "9474882" "9687333" "D748257").PN. OR ("10569062").URPN.					
L83	0	L82 and rboa	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 10:02 AM
L84	1	L82 and reboa	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 10:03 AM
L85	28	A61M\$.cpc. and (catheter same reboa)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 10:07 AM
L86	1	(14/990465).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/07 10:15 AM
L87	23	("20020188344" "20030083617" "20030195382" "20030212361" "20040010282" "20040172055" "20060282115" "20090082800" "20120078343" "20130102926" "20140243873" "20140350523" "20150104331" "4456011" "5320604" "6135981" "6743196" "6743208" "7198632"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 10:15 AM

		"7220269" "7771448" "7927346" "8257421").PN. OR ("10279094").URPN.					
L88	2823	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 12:54 PM
L89	1206	A61B17/12036.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 12:55 PM
L90	38	L88 and L89	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:18 PM
L91	1662	A61M25/0074.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:23 PM
L92	0	A61M25/1084.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:24 PM
L93	839	A61M25/10184.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:24 PM
L94	36	L89 and L93	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:25 PM
L95	1679	A61M2025/1086.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:33 PM
L96	238	L95 and grooves	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:33 PM
L97	34	A61B\$.cpc. and (catheter same reboa)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:34 PM
L98	28	A61M\$.cpc. and (catheter same reboa)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:34 PM
L99	8	L97 not L98	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 01:34 PM
L100	77	L95 and flute	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 02:58 PM
L101	69	L100 not L96	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 02:59 PM
L102	228	("2330399" "2486056" "3409016" "3557794" "3822593" "4018231" "4141364" "4178939" "4248246" "4275591" "4276874" "4292974" "4346698" "4416267" "4444186" "4449532" "4572186" "4573470" "4576142" "4592744" "4601713" "4636201" "4681092" "4711181" "4738666" "4743258" "4762125" "4762130" "4771776" "4796629" "4820349" "4846174" "4846344" "4846801" "4881547" "4896669" "4906244" "4921483" "4930341" "4935190" "4938676" "4941877"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 03:09 PM

L103	2	"4994072" "5015230" "5015231" "5017325" "5037392" "5041125" "5087246" "5147302" "5192296" "5195970" "5196024" "5209799" "5226887" "5250070" "5254091" "5295995" "5306246" "5308356" "5318587" "5320634" "5336178" "5336472" "5342301" "5342307" "5350361" "5370614" "5411477" "5423745" "5456666" "5458572" "5470313" "5478319" "5490839" "5658311" "5718684" "5853389").PN. OR ("6013055").URPN. "4195637".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 03:17 PM
L104	307	("3086525" "3498286" "3635223" "3831588" "3837347" "3924632" "3941119" "3978863" "4033331" "4057065" "4072146" "4088135" "4114603").PN. OR ("4195637").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 03:23 PM
L105	1	(13/777667).APP.	(US-PGPUB; USOCR)	OR	ON	ON	2021/12/07 04:54 PM
L106	404	(perfusion with dilatation) same catheter	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 04:56 PM
L107	0	L106 and reboa	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/07 04:56 PM
L108	328	(perfusion with dilatation) same catheter	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:56 PM
L109	252	(perfusion with dilatation) and catheter.ab.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:57 PM
L110	706	(perfusion with occlusion) and catheter.ab.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:59 PM
L111	486	(perfusion with occlusion) with balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:59 PM
L112	275	L111 and catheter.ab.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 04:59 PM
L113	12	L112 and (balloon with (flute or groove))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/07 05:00 PM

L114	947	A61M2025/0002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:29 PM
L115	2674	A61M2025/1052.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:30 PM
L116	0	A61M2025/1025.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:30 PM
L117	387	A61M2025/1059.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:31 PM
L118	3778	L114 or L115 or L117	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:32 PM
L119	111	L118 and (pressure near1 relief near1 valve)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/08 12:33 PM
L120	4	(US-20070135830-\$ or US-20120302994-\$).did. or (US-6013055-\$ or US-5558644-\$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/08 01:13 PM
L121	0	L120 and sensor	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:13 PM
L122	53	(US-20180117279-\$ or US-20020169457-\$ or US-20060167421-\$ or US-20070060911-\$ or US-20140221898-\$ or US-20070219466-\$ or US-20180140806-\$ or US-20170043123-\$ or US-20160213893-\$ or US-20120302994-\$ or US-20110251497-\$ or US-20120109057-\$ or US-20070219488-\$ or US-20050261725-\$ or US-20030032974-\$ or US-20070135830-\$ or US-20090312807-\$ or US-20040082935-\$ or US-20120330359-\$ or US-20160206798-\$ or US-20140243873-\$ or US-20150142045-\$).did. or (US-6517515-\$ or US-5645528-\$ or US-5425709-\$ or US-4777951-\$ or US-5571093-\$ or US-9211389-\$ or US-6979318-\$ or US-6254578-\$ or US-6113579-\$ or US-D748257-\$ or US-7341571-\$ or US-6579221-\$ or US-6013019-\$ or US-	(US-PGPUB; USPAT; DERWENT)	OR	ON	ON	2021/12/08 01:13 PM

		5830181-\$ or US- 5047045-\$ or US- 9687333-\$ or US- 8419648-\$ or US- 5169386-\$ or US- 9474882-\$ or US- 5250070-\$ or US- 6013055-\$ or US- 5295995-\$ or US- 4195637-\$ or US- 5423745-\$ or US- 5516336-\$ or US- 5087246-\$).did. or (US- 4944745-\$ or US- 7195612-\$ or US- 5308356-\$ or US- 5558644-\$).did. or (WO-9944666-\$).did.					
L123	10	L122 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:14 PM
L124	2	"20190015630".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:18 PM
L125	1	L124 and (back adj flow)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:19 PM
L126	0	L122 and (back adj flow)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:21 PM
L127	2	L122 and (check adj valve)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 01:21 PM
L128	1	L124 and (distal adj pressure adj sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 02:18 PM
L129	1	L124 and (pressure adj sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/08 02:20 PM
L130	153	("20080097300" "20150 272732" "20080243221 " "20110144742" "2014 0364835" "2016037523 0" "5158529" "2002000 7146" "20020062119" " 20120209176" "201301 72786" "20130338637" " 5047045" "200201937 35" "20030032974" "20 030167038" "20040073 162" "20040082935" "2 0040254528" "2005005 9931" "20050148812" " 20050261725" "200700 43307" "20070043409"	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/09 04:25 PM

		"20070129466" "20070 135830" "20070219466 " "20070219488" "2008 0027356" "2008008204 6" "20080082119" "200 80243067" "200802624 77" "20090026595" "20 090062666" "20090171 272" "20090171293" "2 0090265951" "2009028 7079" "20090312807" " 20100016735" "201000 41984" "20100234915" " "20100262076" "20100 268017" "20100280451 " "20110196412" "2011 0295301" "2011029530 2" "20110301630" "201 20101413" "201201089 79" "20120109057" "20 120116352" "20120130 359" "20120172911" "2 0120215166" "2012027 1231" "20120302994" " 20130102926" "201301 02929" "20130190619" " "20130281869" "20130 289607" "20140221898 " "20140243873" "2014 0249504" "2014031601 2" "20140378869" "201 50012031" "201500390 12" "20150367098" "20 160000446" "2156289" " "4464172" "4713888" "4 777951" "4823469" "48 65549" "4926885" "498 3166" "5135494" "5169 386" "5282479" "53206 05" "5383856" "544750 3" "5505702" "5522400" "5571093" "5718678" " 5738652" "5911702" "6 011988" "6013019" "61 02930" "6113579" "614 6370" "6161547" "6165 199" "6190356" "62315 72" "6248121" "628043 4" "6423031" "6453572" "6575932" "6579221" " 6602270" "6656153" "6 666814" "6669679" "66 79860" "6695811" "671 9270" "6719720" "6733 513" "6735532" "67367 90" "6746462" "679695 9" "6936056" "6979318" "7341571" "7434326" "				
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		7503904 "7503909 "7 763043 "7892469 "79 09810 "7951186 "795 1819 "7959644 "8088 103 "8162879 "82412 41 "8262611 "841964 8 "8430899 "8499681" "8545382 "8655798 "8 8672868 "8747358 "8 814900 "8900214 "89 48848 "8951565 "913 1874 "9414843 "9474 882 "9687333 "D7482 57").PN.					
L131	37	L130 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 04:39 PM
L132	9	L131 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 04:56 PM
L133	2	"20080015404".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:03 PM
L134	0	L133 and (pressure near1 sensor) and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:04 PM
L135	0	L133 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:04 PM
L136	0	L133 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:04 PM
L137	1	"20110196297".pn.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L138	0	L137 and (pressure near1 sensor) and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L139	0	L137 and (pressure near1 sensor)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L140	0	L137 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/09 05:05 PM
L141	1	(12/855473).APP.	(USPAT; USOCR)	OR	ON	ON	2021/12/09 05:09 PM
L142	5	("4934996").PN. OR ("8262580").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09 05:09 PM
L143	6	L137 or L142	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09 05:10 PM
L144	5	L143 and (blood near1 pressure)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09 05:10 PM
L145	1	L144 and sensor	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/12/09

L146	10	(US-20140364835-\$ or US-20120215166-\$ or US-20110295301-\$ or US-20080015404-\$ or US-20110295302-\$ or US-20030032974-\$ or US-20120172911-\$).did. or (US-8419648-\$ or US-4934996-\$ or US-6656153-\$).did.	USOCR) (US-PGPUB; USPAT)	OR	ON	ON	05:10 PM 2021/12/10 09:17 AM
L147	3	L146 and feedback	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 09:18 AM
L148	8	L146 and (blood near1 pressure)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 09:21 AM
L149	3	L147 and L148	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 09:21 AM
L150	6	(US-20070135830-\$ or US-20120302994-\$ or US-20190015630-\$).did. or (US-6013055-\$ or US-5558644-\$ or US-8419648-\$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/10 03:24 PM
L151	243	engel near1 matthew	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 03:50 PM
L152	135	doubrava near1 john	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/10 03:52 PM
L153	0	(08/969904).APP.	(US-PGPUB; USOCR)	OR	ON	ON	2021/12/14 09:30 AM
L154	0	(08/372741).APP.	(US-PGPUB; USOCR)	OR	ON	ON	2021/12/14 09:31 AM
L155	7	(US-20070135830-\$ or US-20120302994-\$ or US-20190015630-\$ or US-20110295302-\$).did. or (US-6013055-\$ or US-5558644-\$ or US-8419648-\$).did.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 01:26 PM
L156	3	L155 and (proximal same (pressure near1 sensor))	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 01:27 PM
L157	1	L155 and (compliant near1 balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:27 PM
L158	60	(US-20180117279-\$ or US-20020169457-\$ or US-20060167421-\$ or US-20070060911-\$ or US-20140221898-\$ or US-20070219466-\$ or	(US-PGPUB; USPAT; DERWENT)	OR	ON	ON	2021/12/14 02:28 PM

L159	7	US-20180140806-\$ or US-20170043123-\$ or US-20160213893-\$ or US-20120302994-\$ or US-20110251497-\$ or US-20120109057-\$ or US-20070219488-\$ or US-20050261725-\$ or US-20030032974-\$ or US-20070135830-\$ or US-20090312807-\$ or US-20040082935-\$ or US-20120330359-\$ or US-20160206798-\$ or US-20140243873-\$ or US-20150142045-\$ or US-20190015630-\$ or US-20140364835-\$ or US-20080015404-\$ or US-20110196297-\$).did. or (US-20110295302-\$).did. or (US-6517515-\$ or US-5645528-\$ or US-5425709-\$ or US-4777951-\$ or US-5571093-\$ or US-9211389-\$ or US-6979318-\$ or US-6254578-\$ or US-6113579-\$ or US-D748257-\$ or US-7341571-\$ or US-6579221-\$ or US-6013019-\$ or US-5830181-\$ or US-5047045-\$ or US-9687333-\$ or US-8419648-\$ or US-5169386-\$ or US-9474882-\$ or US-5250070-\$ or US-6013055-\$ or US-5295995-\$ or US-4195637-\$ or US-5423745-\$ or US-5516336-\$ or US-5087246-\$).did. or (US-4944745-\$ or US-7195612-\$ or US-5308356-\$ or US-5558644-\$ or US-4934996-\$ or US-6248121-\$).did. or (WO-9944666-\$).did. L158 and (compliant near1 balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:28 PM
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L160	546	A61M\$.cpc. and (PET same (semi near1 compliant))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:33 PM
L161	511	A61M\$.cpc. and (PET same (semi near1 compliant) same balloon)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:34 PM
L162	508	A61M\$.cpc. and (PET same (semi near1 compliant) same balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:34 PM
L163	336	L162 and catheter.ab.	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:35 PM
L164	215	L163 and angioplasty	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 02:35 PM
L165	3	L158 and wireless	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:40 PM
L166	14	L158 and (proximal same (pressure near1 sensor))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 02:53 PM
L167	324	A61M\$.cpc. and (proximal same (pressure near1 sensor)) and catheter.ab. and balloon.ab.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO)	OR	ON	ON	2021/12/14 03:12 PM
L168	99	L167 and angioplasty	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 03:13 PM
L169	53	L168 and (blood near1 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/14 03:45 PM
L170	1	(13/481532).APP.	(USPAT; USOCR)	OR	OFF	OFF	2022/07/12 01:31 PM
L171	288	("20010001812" "20010029362" "20010037085" "20020018866" "20020082549" "20020165523" "20030009151" "20030032920" "20030055447" "20030055448" "20030105426" "20030139762" "20040059291" "20040059292" "20040064130" "20040068240" "20040097892" "20040116956" "20040131808" "20040167441" "20040170782")	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/07/12 01:31 PM

		"20040173935"					
		"20040181206"					
		"20040191443"					
		"20040215141"					
		"20040267195"					
		"20040267280"					
		"20050015048"					
		"20050043679"					
		"20050124976"					
		"20050131445"					
		"20050148997"					
		"20050154414"					
		"20050186370"					
		"20050228429"					
		"20050238833"					
		"20050261725"					
		"20050277878"					
		"20060008606"					
		"20060136032"					
		"20060165926"					
		"20060175739"					
		"20060282041"					
		"20070016165"					
		"20070021772"					
		"20070060863"					
		"20070142771"					
		"20070167973"					
		"20070191813"					
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		"20080015499"					
		"20080045895"					
		"20080045928"					
		"20080065188"					
		"20080262470"					
		"20090005754"					
		"20090036829"					
		"20090156998"					
		"20090223624"					
		"20090247946"					
		"20090264822"					
		"20100010439"					
		"20100130925"					
		"20100189876"					
		"20100285085"					
		"20110022150"					
		"20110070355"					
		"20110172696"					
		"20110315301"					
		"20120065586"					
		"20120143129"					
		"4425919" "4563181"					
		"4596563" "4721117"					
		"4775371" "4782834"					
		"4820349" "4877031"					
		"4886506" "4892519"					
		"4952357" "4976690"					
		"4976720" "5047045"					
		"5061273" "5078702"					

		"5085649" "5112304"					
		"5156594" "5176661"					
		"5195969" "5205822"					
		"5207700" "5217434"					
		"5217482" "5250059"					
		"5256144" "5270086"					
		"5277199"					
		"5290232").PN. OR					
		("5290306" "5300025"					
		"5304134" "5312430"					
		"5318032" "5318526"					
		"5342386" "5358486"					
		"5364357" "5370655"					
		"5378238" "5395336"					
		"5423754" "5425712"					
		"5447497" "5451233"					
		"5454789" "5458615"					
		"5470315" "5476477"					
		"5478320" "5484409"					
		"5490837" "5496275"					
		"5499980" "5507768"					
		"5512051" "5526823"					
		"5538513" "5545134"					
		"5549552" "5554121"					
		"5556383" "5569195"					
		"5587125" "5599326"					
		"5613979" "5620649"					
		"5622665" "5632760"					
		"5643209" "5649909"					
		"5658264" "5690613"					
		"5728063" "5743874"					
		"5743875" "5749849"					
		"5755690" "5759173"					
		"5766151" "5769817"					
		"5769819" "5775327"					
		"5779731" "5782811"					
		"5791036" "5792124"					
		"5792144" "5795325"					
		"5795341" "5797887"					
		"5814016" "5820594"					
		"5833657" "5879369"					
		"5879499" "5902290"					
		"5908406" "5911715"					
		"5916193" "5947939"					
		"5964778" "6004289"					
		"6004339" "6010521"					
		"6021340" "6024693"					
		"6024722" "6027510"					
		"6036670" "6056719"					
		"6059751" "6059770"					
		"6071266" "6086556"					
		"6102890" "6124007"					
		"6132824" "6136258"					
		"6146356" "6165166"					
		"6165195" "6168588"					
		"6171275" "6171278"					
		"6179810" "6179856"					
		"6193686" "6197015"					

L172	2	"6210396" "6217565" "6242063" "6245053" "6251093" "6264063" "6265016" "6306097" "6306124" "6308342" "6358227" "6364894" "6416494" "6482348" "6495090" "6495127" "6500148" "6508784" "6575934" "6575958" "6579259" "6585687" "6585688" "6589207" "6589226").PN. OR ("6620127" "6620128" "6626889" "6629961" "6645422" "6663614" "6673291" "6673302" "6695809" "6702802" "6718211" "6733487" "6756094" "6777644" "6793647" "6796958" "6796960" "6835189" "6837890" "6863678" "6875197" "6887219" "6890395" "6893456" "6911038" "6913600" "6918920" "6923822" "6946092" "6951555" "6951675" "6964750" "6979342" "7026026" "7029732" "7037291" "7037295" "7074206" "7108877" "7112357" "7141059" "7147817" "7163523" "7195638" "7273485" "7303798" "7322959" "7335185" "7341571" "7549975" "7556634" "7662130" "7828766" "7833193" "7833597" "7862541" "7906066" "7967836" "8048058" "8052638" "8070719").PN. OR ("10406329").URPN. ((US-6013055-A).did. AND USPT.dbnm.) OR ((US-20110172696- A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA,	OR	ON	ON	2022/12/21 05:45 PM
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L173	3	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1).did. AND PGPB.dbnm.)	VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/21 05:48 PM
L174	40	(Artificial Intelligence) More like doc: US-6013055-A Text: (EP-1030708-B1 OR EP-1030708-A1 OR WO-9925417-A1 OR DE-69832811-T2 OR DE-69731561-T2 OR US-5954740-A OR EP-1007134-A1 OR WO-9811933-A1 OR US-4941877-A OR US-20030236495-A1 OR EP-1007134-B1 OR US-5041125-A OR US-6110192-A OR EP-1620160-B1 OR EP-1620160-A1 OR US-6355013-B1 OR US-7306616-B2 OR US-20060015134-A1 OR WO-9725093-A1 OR CA-2568727-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/21 06:02 PM
L175	156	("20210290243" OR "8021330" OR "9211396" OR "20080097300" OR "20150272732" OR "20080243221" OR "20110144742" OR "20140364835" OR "20160375230" OR "5158529" OR "20020007146" OR "20020062119" OR "20120209176" OR "20130172786" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/21 07:04 PM

		"20130338637" OR "5047045" OR "20020193735" OR "20030032974" OR "20030167038" OR "20040073162" OR "20040082935" OR "20040254528" OR "20050059931" OR "20050148812" OR "20050261725" OR "20070043307" OR "20070043409" OR "20070129466" OR "20070135830" OR "20070219466" OR "20070219488" OR "20080027356" OR "20080082046" OR "20080082119" OR "20080243067" OR "20080262477" OR "20090026595" OR "20090062666" OR "20090171272" OR "20090171293" OR "20090265951" OR "20090287079" OR "20090312807" OR "20100016735" OR "20100041984" OR "20100234915" OR "20100262076" OR "20100268017" OR "20100280451" OR "20110196412" OR "20110295301" OR "20110295302" OR "20110301630" OR "20120101413" OR "20120108979" OR "20120109057" OR "20120116352" OR "20120130359" OR "20120172911" OR "20120215166" OR "20120271231" OR "20120302994" OR "20130102926" OR "20130102929" OR "20130190619" OR "20130281869" OR "20130289607" OR "20140221898" OR "20140243873" OR "20140249504" OR "20140316012" OR "20140378869" OR				
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		"20150012031" OR "20150039012" OR "20150367098" OR "20160000446" OR "2156289" OR "4464172" OR "4713888" OR "4777951" OR "4823469" OR "4865549" OR "4926885" OR "4983166" OR "5135494" OR "5169386" OR "5282479" OR "5320605" OR "5383856" OR "5447503" OR "5505702" OR "5522400" OR "5571093" OR "5718678" OR "5738652" OR "5911702" OR "6011988" OR "6013019" OR "6102930" OR "6113579" OR "6146370" OR "6161547" OR "6165199" OR "6190356" OR "6231572" OR "6248121" OR "6280434" OR "6423031" OR "6453572" OR "6575932" OR "6579221" OR "6602270" OR "6656153" OR "6666814" OR "6669679" OR "6679860" OR "6695811" OR "6719270" OR "6719720" OR "6733513" OR "6735532" OR "6736790" OR "6746462" OR "6796959" OR "6936056" OR "6979318" OR "7341571" OR "7434326" OR "7503904" OR "7503909" OR					
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		"7763043" OR "7892469" OR "7909810" OR "7951186" OR "7951819" OR "7959644" OR "8088103" OR "8162879" OR "8241241" OR "8262611" OR "8419648" OR "8430899" OR "8499681" OR "8545382" OR "8655798" OR "8672868" OR "8747358" OR "8814900" OR "8900214" OR "8948848" OR "8951565" OR "9131874" OR "9414843" OR "9474882" OR "9687333" OR "D748257").pn.					
L176	3	("9211396" "8021330" "20210290243").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/12/21 07:04 PM
L177	4	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/22 01:39 PM
L178	5	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA,	OR	ON	ON	2022/12/22 01:39 PM

L179	5	((US-6013055-A OR US-5558644-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/23 12:26 PM
L180	69	((US-5250070-A OR US-7195612-B2 OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-5169386-A OR US-8419648-B2 OR US-9687333-B2 OR US-5308356-A OR US-5558644-A OR US-4934996-A OR US-6248121-B1 OR US-7862541-B2 OR US-5047045-A OR US-6517515-B1 OR US-5645528-A OR US-5425709-A OR US-4777951-A OR US-5571093-A OR US-9211389-B2 OR US-6979318-B1 OR US-6254578-B1 OR US-6113579-A OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-8021330-B2 OR US-9211396-B2).did. AND USPT.dbnm.) OR ((US-20140243873-A1 OR US-20160206798-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:18 PM

L181	7	OR US-20120330359-A1 OR US-20040082935-A1 OR US-20150142045-A1 OR US-20190015630-A1 OR US-20140364835-A1 OR US-20080015404-A1 OR US-20110196297-A1 OR US-20110295302-A1 OR US-20030083579-A1 OR US-20100113939-A1 OR US-20110224606-A1 OR US-20110172696-A1 OR US-20180117279-A1 OR US-20020169457-A1 OR US-20060167421-A1 OR US-20070060911-A1 OR US-20140221898-A1 OR US-20070219466-A1 OR US-20180140806-A1 OR US-20090312807-A1 OR US-20070135830-A1 OR US-20030032974-A1 OR US-20050261725-A1 OR US-20070219488-A1 OR US-20120109057-A1 OR US-20110251497-A1 OR US-20120302994-A1 OR US-20160213893-A1 OR US-20170043123-A1 OR US-20210290243-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) ((US-6013055-A OR US-5558644-A OR US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK,	OR	ON	ON	2023/04/10 07:31 PM
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L182	6	L181 AND angioplasty	TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:31 PM
L183	6	L182	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:31 PM
L184	4	L182 AND (polyethylene OR polyurathane OR polyester)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:36 PM
L185	2	((US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA,	OR	ON	ON	2023/04/10 07:39 PM

L186	2	L185	EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:39 PM
L187	295	("1115224" "2701559" "4018231" "4141364" "4471776" "4878495" "4881939" "4927412" "5002531" "5041125" "5090958").pn. OR ("5250070").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:39 PM
L188	113	("2930377" "3889686" "4040413" "4183102" "4233983" "4329993" "4423725" "4581017" "4601713" "4661094" "4710181" "4738666" "4787388" "4790315" "4795427" "4877031" "4878495" "4892519" "4909252" "5102416" "5167628").pn. OR ("5295995").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:39 PM
L189	36	(Artificial Intelligence) More like doc: US-5295995-A Text: (WO-9405365-A1 OR US-6007517-A OR EP-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2023/04/10 07:39 PM

L190	38	<p>0688233-A4 OR EP-0688233-A1 OR WO-9501200-A1 OR US-5571089-A OR US-5344402-A OR JP-2001513374-A OR US-5522800-A OR JP-H08504652-A OR US-5542926-A OR JP-2865426-B2 OR JP-H06233822-A OR JP-2607896-Y2 OR EP-0526102-A1 OR US-5716340-A OR WO-9516487-A1 OR CA-2074304-C OR US-5558642-A OR EP-0526102-B1).did.</p> <p>(Artificial Intelligence) More like doc: US-5250070-A</p> <p>Text: (EP-0735906-A1 OR WO-9517223-A1 OR EP-0735906-B1 OR US-5545132-A OR US-5273536-A OR US-20040098018-A1 OR FR-2753907-A1 OR EP-1009469-A1 OR WO-9814233-A1 OR JP-H09506805-A OR JP-2001501115-A OR US-5718684-A OR EP-0746362-A1 OR EP-0746362-A4 OR DE-102012001188-A1 OR EP-0746362-B1 OR US-5951514-A OR WO-9834670-A2 OR JP-2005224635-A OR JP-3694524-B2).did.</p>	<p>IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)</p> <p>(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)</p>	OR	ON	ON	2023/04/10 07:39 PM
L191	676	L187 L188 L189 L190	<p>(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT;</p>	OR	ON	ON	2023/04/10 07:40 PM

L192	222	L191 AND angioplasty	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:40 PM
L193	4	L191 AND (partial near1 inflation)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:40 PM
L194	180	L192	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:41 PM
L195	13	L194 AND (flow near1 channel)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:42 PM
L196	266	("4581017" "4601713" "4762129" "4771777" "4790315" "4819751" "4850969" "4909252" "4909781" "4944745" "4983167" "4988356" "4994033" "5040548" "5046503" "5049131" "5061273" "5078685" "5102403" "5108370" "5116318" "5135535" "5147377" "5154725" "5156594" "5158540" "5171222" "5180367" "5205822" "5232445" "5267958" "5284473" "5295959" "5295995" "5308356" "5318535" "5324269" "5336184" "5342297" "5346505" "5370617" "5378237" "5383856" "5383890" "5395333" "5395353" "5403274" "5409458" "5411478" "5425709" "5425714" "5433706" "5470314" "5472425" "5484411" "5484412" "5489271" "B14581017").pn. OR ("6007517").urpn. AND (PGPB USPT USOC).dbnm.	OR	ON	ON	2023/04/10 07:46 PM	

L197	36	(Artificial Intelligence) More like doc: US-6007517-A Text: (EP-0362268-A1 OR AU-614976-B2 OR US-5462530-A OR US-4958634-A OR JP-2007512931-A OR EP-0362268-B1 OR EP-1708779-A4 OR WO-9320882-A1 OR EP-1708779-A2 OR US-20050124939-A1 OR EP-0590140-A1 OR US-20060259062-A1 OR US-5295995-A OR EP-0853956-A2 OR US-5522800-A OR EP-0688233-A4 OR WO-9501200-A1 OR EP-0688233-A1 OR US-5571089-A OR US-5324259-A).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:46 PM
L198	536	L196 L197	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:46 PM
L199	336	L198	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN))	OR	ON	ON	2023/04/10 07:46 PM
L200	233	L199 AND angioplasty	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:46 PM

L201	2	L200 AND (partial near1 inflation)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L202	6	L200 AND (flow near1 channel)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L203	8	L201 L202	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L204	8	L203	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 07:47 PM
L205	3	((US-5250070-A OR US-5295995-A OR US-6007517-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:48 PM
L206	3	L205	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 07:49 PM
L207	1974	(angioplasty near1 balloon) AND apposition	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:01 PM
L208	72	L207 AND (flow near1 channel)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:01 PM
L209	9	L207 AND (partial near1 inflation)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:02 PM
L210	7	((US-6013055-A OR US-5558644-A OR US-5250070-A OR US-5295995-A).did. AND USPT.dbnm.) OR ((US-20110172696-A1 OR US-20030083579-A1).did. AND	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV,	OR	ON	ON	2023/04/10 08:14 PM

		PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L211	201	(thermoplastic near1 polymer) AND balloon AND angioplasty AND (semi near1 compliant)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:18 PM
L212	25	L211 AND (thermoplastic near1 polymer) SAME (semi near1 compliant)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:25 PM
L213	25	L211 AND ((thermoplastic near1 polymer) SAME (semi near1 compliant))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/04/10 08:26 PM
L214	7	((US-6013055-A OR US-5558644-A OR US- 5250070-A OR US- 5295995-A).did. AND USPT.dbnm.) OR ((US- 20110172696-A1 OR US-20030083579- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/04/10 08:39 PM
L215	1	("10149962" "116772951").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:41 PM
L216	0	("11677951").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:41 PM
L217	0	L215 AND marking	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:42 PM
L218	1	L215 AND marker	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/09 07:47 PM
L219	8	((US-5250070-A OR US-5295995-A OR US- 6007517-A OR US- 6013055-A OR US- 5558644-A).did. AND USPT.dbnm.) OR ((US- 20030083579-A1 OR US-20110172696- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2023/06/10 02:23 PM

		AND EPAB.dbnm.)	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L220	1	("20190366046").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:26 PM
L221	0	("2015015046").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:29 PM
L222	1	("20150015046").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:29 PM
L223	1	("20150150436").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:29 PM
L224	3	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/10 02:30 PM
L225	2	L224 AND atraumatic	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/10 02:35 PM
L226	1	L224 AND compliant	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2023/06/10 02:36 PM

L227	0	L224 AND french	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/10 02:39 PM
L228	0	(balloon AND catheter) AND (6 near1 (french OR fr))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L229	114824	(balloon AND catheter)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L230	0	6 near1 (french OR fr)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L231	0	6 near1 french	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:40 PM
L232	0	6 near1 fr	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:41 PM
L233	15101	L229 AND french	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:41 PM
L234	0	L233 AND 6	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:41 PM
L235	15047	L233 AND "6"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L236	8811	("6" near1 (french OR fr))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L237	3312	L229 AND L236	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L238	1348	L237 AND hub	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:42 PM
L239	642	L238 AND stiff	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:48 PM
L240	1025	L238 AND stiff\$4	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:48 PM
L241	21	L238 AND stiffener	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:48 PM
L242	1025	L240	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:53 PM

L243	1348	L238	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:53 PM
L244	295	L238 AND (hub WITH (wire OR stiffener))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 02:57 PM
L245	83	L244 NOT (guide near1 wire)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 03:00 PM
L246	295	L244	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/10 04:13 PM
L247	5	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 01:00 PM
L248	1	L247 AND french	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 01:00 PM
L249	5	L247	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:17 PM

L250	32	(Artificial Intelligence) More like doc: US-20170296798-A1 Text: (WO-2019010077-A1 OR EP-3648828-A1 OR CA-3068925-A1 OR EP-4183440-A1 OR EP-3648828-B1 OR US-11027104-B2 OR US-20210322738-A1 OR JP-2020527964-A OR JP-2023072042-A OR US-20210228847- A1 OR US- 20190175885-A1 OR US-10864357-B2 OR US-20170354803-A1 OR US-10039906-B2 OR US-20160158502- A1 OR US-9126018-B1 OR US-9399118-B2 OR US-9241699-B1 OR US-20170043141-A1 OR US-9662480- B2).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:18 PM
L251	15	((US-5250070-A OR US-5295995-A OR US- 6007517-A OR US- 6013055-A OR US- 5558644-A OR US- 4369790-A).did. AND USPT.dbnm.) OR ((US- 20030083579-A1 OR US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:20 PM
L252	79	((US-9211389-B2 OR US-6113579-A OR US- 6254578-B1 OR US- 6979318-B1 OR US- 5571093-A OR US- 4777951-A OR US- 5425709-A OR US- 5645528-A OR US- 6517515-B1 OR US- 5047045-A OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2023/06/12 02:21 PM

		7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US- 5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US- 6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20110172696- A1 OR US-	NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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L253	18	20110224606-A1 OR US-20100113939-A1 OR US-20030083579- A1 OR US- 20110295302-A1 OR US-20080015404-A1 OR US-20140364835- A1 OR US- 20190015630-A1 OR US-20150142045-A1 OR US-20040082935- A1 OR US- 20110196297-A1 OR US-20210290243-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) L252 AND french	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 02:21 PM
L254	9	L253 AND "6" near1 french	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO;	OR	ON	ON	2023/06/12 02:21 PM

L255	3312	(balloon AND catheter) AND ("6" near1 (french OR fr))	JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:27 PM
L256	260	L255 AND (core near1 wire)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:27 PM
L257	2	("5549557" "5549556").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:37 PM
L258	260	L256	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 02:37 PM
L259	96942	guide near1 wire	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:24 PM
L260	52052	L259 AND catheter	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:24 PM
L261	975	L260 AND ((guide near1 wire) WITH lock)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:25 PM
L262	662	L261 AND balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:25 PM
L263	260	L262 AND radiopaque	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:26 PM
L264	19	L263 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:27 PM
L265	5245	L260 AND (radio near1 (paque OR opaque))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:39 PM
L266	318	(L265 AND ("6" near1 (fr OR french)))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 03:39 PM
L267	10	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 04:41 PM
L268	10	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2023/06/12 04:42 PM

L269	10	A1 OR US-20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.) (((US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20140243873-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A).did. AND USPT.dbnm.))	NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 04:51 PM
L270	169	("5250070" OR "5295995" OR "6007517" OR "5087246" OR "5425711" OR "5554121" OR "5609606" OR "20110172696" OR "10368872" OR "20210290243" OR "8021330" OR "9211396" OR "20020007146" OR "20020062119" OR "20020193735" OR "20030032974" OR "20030083579" OR "20030167038" OR "20040073162" OR "20040082935" OR "20040254528" OR "20050059931" OR "20050148812" OR "20050261725" OR "20070043307" OR "20070043409" OR "20070129466" OR "20070135830" OR "20070219466" OR "20070219488" OR "20080027356" OR "20080082046" OR "20080082119" OR "20080097300" OR "20080243067" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/12 06:55 PM

		"20080243221" OR "20080262477" OR "20090026595" OR "20090062666" OR "20090171272" OR "20090171293" OR "20090265951" OR "20090287079" OR "20090312807" OR "20100016735" OR "20100041984" OR "20100113939" OR "20100234915" OR "20100262076" OR "20100268017" OR "20100280451" OR "20110144742" OR "20110196412" OR "20110295301" OR "20110295302" OR "20110301630" OR "20120101413" OR "20120108979" OR "20120109057" OR "20120116352" OR "20120130359" OR "20120172911" OR "20120209176" OR "20120215166" OR "20120271231" OR "20120302994" OR "20130102926" OR "20130102929" OR "20130172786" OR "20130190619" OR "20130281869" OR "20130289607" OR "20130338637" OR "20140221898" OR "20140243873" OR "20140249504" OR "20140316012" OR "20140364835" OR "20140378869" OR "20150012031" OR "20150039012" OR "20150272732" OR "20150367098" OR "20160000446" OR "20160375230" OR "2156289" OR "4464172" OR "4713888" OR "4777951" OR "4823469" OR "4865549" OR "4926885" OR "4983166" OR				
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		"5047045" OR "5135494" OR "5158529" OR "5169386" OR "5282479" OR "5320605" OR "5383856" OR "5447503" OR "5505702" OR "5522400" OR "5558644" OR "5571093" OR "5718678" OR "5738652" OR "5911702" OR "6011988" OR "6013019" OR "6013055" OR "6102930" OR "6113579" OR "6146370" OR "6161547" OR "6165199" OR "6190356" OR "6231572" OR "6248121" OR "6280434" OR "6423031" OR "6453572" OR "6575932" OR "6579221" OR "6602270" OR "6656153" OR "6666814" OR "6669679" OR "6679860" OR "6695811" OR "6719270" OR "6719720" OR "6733513" OR "6735532" OR "6736790" OR "6746462" OR "6796959" OR "6936056" OR "6979318" OR "7341571" OR "7434326" OR "7503904" OR "7503909" OR "7763043" OR "7892469" OR "7909810" OR "7951186" OR "7951819" OR "7959644" OR "8088103" OR "8162879" OR				
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		"8241241" OR "8262611" OR "8419648" OR "8430899" OR "8499681" OR "8545382" OR "8655798" OR "8672868" OR "8747358" OR "8814900" OR "8900214" OR "8948848" OR "8951565" OR "9131874" OR "9414843" OR "9474882" OR "9687333" OR "D748257").pn.					
L271	9	((("Prytime") near3 ("Medical") near3 ("Devices") near3 ("Inc"))).AS,AANM.	(USPAT)	OR	ON	ON	2023/06/12 07:02 PM
L272	716	((("FRANKLIN") near3 ("Curtis")) OR (("SPENCER") near3 ("David")) OR (("KRUMMENACHER") near3 ("Todd"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/06/12 07:02 PM
L273	3106	A61M25/0068.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L274	1873	A61M25/0074.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L275	3727	A61M25/1002.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L276	697	A61M25/1006.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:07 PM
L277	2921	A61M2025/1052.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:08 PM
L278	1355	A61B17/12036.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:08 PM
L279	6044	L275 OR L277	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:09 PM
L280	3727	L279 AND L275	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:10 PM
L284	50	L280 AND (asymmetric\$2 near1 balloon)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:12 PM
L285	2	L284 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:12 PM
L286	50	L284	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:13 PM
L287	727	L272 L271 L270	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:18 PM

L288	634	L287 NOT (guide near1 wire)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:18 PM
L289	139	L288 AND wire	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:18 PM
L290	55	L289 AND balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:19 PM
L291	213	L273 AND L277	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/12 07:36 PM
L292	16	((US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20140243873-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1 OR US-20130338637-A1).did. AND PGPB.dbnm.) OR ((US-5464394-A OR US-5087246-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 07:48 PM
L293	4	L292 AND compliant	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:33 PM
L294	90	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO,	OR	ON	ON	2023/06/12 11:35 PM

	5047045-A OR US- 7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US- 5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US- 6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 5690613-A OR US- 5464394-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR	MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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L295	24	US-20120330359-A1 OR US-20110172696-A1 OR US-20110224606-A1 OR US-20100113939-A1 OR US-20030083579-A1 OR US-20110295302-A1 OR US-20080015404-A1 OR US-20140364835-A1 OR US-20190015630-A1 OR US-20150142045-A1 OR US-20040082935-A1 OR US-20110196297-A1 OR US-20210290243-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)	L294 AND compliant	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:37 PM
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L296	5547	balloon SAME (compliant WITH (pet OR polyethylene OR pvc OR polypropylene OR nylon OR pebax))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:53 PM
L297	1182	balloon SAME (compliant WITH pebax)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:54 PM
L298	219	L296 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/12 11:54 PM
L299	111	L296 AND ("6" near1 (fr OR french))	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/12 11:54 PM
L300	18	((US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2023/06/13 12:00 AM

L301	1	20140243873-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20120302994-A1 OR US-20090018500-A1 OR US-20130338637- A1 OR US- 20110224606-A1 OR US-20160051386- A1).did. AND PGPB.dbnm.) OR ((US- 5464394-A OR US- 5087246-A).did. AND USPT.dbnm.) L300 AND (insertion near1 depth)	IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:02 AM
L302	18	((US-20110172696-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20140243873-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20120302994-A1 OR US-20090018500-A1 OR US-20130338637- A1 OR US- 20110224606-A1 OR US-20160051386- A1).did. AND	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:01 AM

L303	4	PGPB.dbnm.) OR ((US-5464394-A OR US-5087246-A).did. AND USPT.dbnm.) ((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM
L304	0	L303 AND asymmetric\$2	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM
L305	29	((US-5250070-A OR US-5295995-A OR US-6007517-A OR US-6013055-A OR US-5558644-A OR US-4369790-A OR US-5690613-A OR US-5464394-A OR US-5087246-A).did. AND USPT.dbnm.) OR ((US-20030083579-A1 OR US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM

L306	2	A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-A1 OR US-20140243873-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) (L305 AND asymmetric\$2)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:13 AM
L307	4	L303	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:15 AM
L308	61	(angioplasty WITH catheter) AND (asymmetric\$2 near1 balloon)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/13 11:17 AM
L309	5	((US-20040039332-A1 OR US-20190366046-A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/06/13 11:26 AM

L310	30	20100204712-A1 OR US-20110172696-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:32 AM
		((US-5250070-A OR US-5295995-A OR US-6007517-A OR US-6013055-A OR US-5558644-A OR US-4369790-A OR US-5690613-A OR US-5464394-A OR US-5087246-A OR US-6129737-A).did. AND USPT.dbnm.) OR ((US-20030083579-A1 OR US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-A1 OR US-20140243873-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L311	20	L310 AND angioplasty	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2023/06/13 11:34 AM

L312	92	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-5047045-A OR US-7195612-B2 OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-7862541-B2 OR US-5250070-A OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-5169386-A OR US-8419648-B2 OR US-9687333-B2 OR US-6248121-B1 OR US-4934996-A OR US-5558644-A OR US-5308356-A OR US-8021330-B2 OR US-9211396-B2 OR US-10149962-B2 OR US-4369790-A OR US-5476450-A OR US-5690613-A OR US-5464394-A OR US-6129737-A OR US-6007517-A).did. AND USPT.dbnm.) OR ((US-20070219466-A1 OR US-20140221898-A1 OR US-20070060911-	CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:35 AM
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		A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20110295302- A1 OR US- 20040082935-A1 OR US-20110172696-A1 OR US-20110224606- A1 OR US- 20100113939-A1 OR US-20030083579-A1 OR US-20110196297- A1 OR US- 20080015404-A1 OR US-20140364835-A1 OR US-20190015630- A1 OR US- 20150142045-A1 OR US-20210290243-A1 OR US-20190366046- A1 OR US- 20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20150342581-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20090018500-A1 OR US-20130338637-A1 OR US-20160051386- A1 OR US- 20190076152-A1).did.					
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L313	59	AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.)					
		L312 AND angioplasty	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:35 AM
L314	7	((US-20040039332-A1 OR US-20190366046- A1 OR US- 20100204712-A1 OR US-20110172696-A1 OR US-20100113939- A1 OR US- 20120109057-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:43 AM
L315	6	((US-20040039332-A1 OR US-20190366046- A1 OR US- 20100204712-A1 OR US-20110172696-A1 OR US-20100113939- A1).did. AND PGPB.dbnm.) OR ((US- 6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 11:59 AM
L316	1	L315 AND metal	(US-PGPUB; USPAT; USOCR; FIT (AU, AP,	OR	ON	ON	2023/06/13 12:05 PM

L317	92	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-5047045-A OR US-7195612-B2 OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-7862541-B2 OR US-5250070-A OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-5169386-A OR US-8419648-B2 OR US-9687333-B2 OR US-6248121-B1 OR US-4934996-A OR US-5558644-A OR US-5308356-A OR US-8021330-B2 OR US-9211396-B2 OR US-10149962-B2 OR US-4369790-A OR US-5476450-A OR US-5690613-A OR US-5464394-A OR US-6129737-A OR US-6007517-A).did. AND USPT.dbnm.) OR ((US-20070219466-A1 OR	AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:06 PM
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		US-20140221898-A1 OR US-20070060911-A1 OR US-20060167421-A1 OR US-20020169457-A1 OR US-20180140806-A1 OR US-20180117279-A1 OR US-20090312807-A1 OR US-20070135830-A1 OR US-20030032974-A1 OR US-20050261725-A1 OR US-20070219488-A1 OR US-20120109057-A1 OR US-20110251497-A1 OR US-20120302994-A1 OR US-20160213893-A1 OR US-20170043123-A1 OR US-20140243873-A1 OR US-20160206798-A1 OR US-20120330359-A1 OR US-20110295302-A1 OR US-20040082935-A1 OR US-20110172696-A1 OR US-20110224606-A1 OR US-20100113939-A1 OR US-20030083579-A1 OR US-20110196297-A1 OR US-20080015404-A1 OR US-20140364835-A1 OR US-20190015630-A1 OR US-20150142045-A1 OR US-20210290243-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-					
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L318	1	A1 OR US-20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) L317 AND (metal WITH (guide near1 wire))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:07 PM
L319	2	(L317 AND (stainless WITH (guide near1 wire)))	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/13 12:07 PM
L320	92	((US-9211389-B2 OR US-6113579-A OR US- 6254578-B1 OR US- 6979318-B1 OR US- 5571093-A OR US- 4777951-A OR US- 5425709-A OR US- 5645528-A OR US- 6517515-B1 OR US- 5047045-A OR US- 7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US- 5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:17 PM

		6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 5690613-A OR US- 5464394-A OR US- 6129737-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20110295302- A1 OR US- 20040082935-A1 OR US-20110172696-A1 OR US-20110224606- A1 OR US- 20100113939-A1 OR US-20030083579-A1 OR US-20110196297- A1 OR US- 20080015404-A1 OR US-20140364835-A1 OR US-20190015630- A1 OR US- 20150142045-A1 OR US-20210290243-A1 OR US-20190366046- A1 OR US-				
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L321	39	20150150436-A1 OR US-20140358123-A1 OR US-20170296798- A1 OR US- 20150342581-A1 OR US-20040039332-A1 OR US-20100204712- A1 OR US- 20020156469-A1 OR US-20020007146-A1 OR US-20120209176- A1 OR US- 20090018500-A1 OR US-20130338637-A1 OR US-20160051386- A1 OR US- 20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) L320 AND stainless	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:17 PM
L322	9	L321 AND radio	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:17 PM
L323	1117	(radio SAME stainless)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13

L324	726	AND (guide near1 wire) L323 AND balloon AND catheter	USOCR) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	12:19 PM 2023/06/13 12:19 PM
L325	7	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:27 PM
L326	7	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:52 PM
L327	8	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1 OR US-20160051386-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/06/13 12:59 PM
L328	8	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA,	OR	ON	ON	2023/07/28 12:58 PM

L329	8	OR US-20100113939-A1 OR US-20080287786-A1 OR US-20160051386-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/24 01:47 PM
L330	177	((US-20040039332-A1 OR US-20190366046-A1 OR US-20100204712-A1 OR US-20110172696-A1 OR US-20100113939-A1 OR US-20080287786-A1 OR US-20160051386-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/24 05:54 PM
		("10111669" OR "10143789" OR "10279094" OR "10449337" OR "20030083617" OR "20170296779" OR "20200022587" OR "20220000486" OR "3585983" OR "5250070" OR "5295995" OR "6007517" OR "5087246" OR "5425711" OR "5554121" OR "5609606" OR "20110172696" OR "10368872" OR "20210290243" OR "8021330" OR "9211396" OR "20020007146" OR "20020062119" OR "20020193735" OR "20030032974" OR "20030083579" OR "20030167038" OR "20040073162" OR "20040082935" OR "20040254528" OR	(US-PGPUB; USPAT)	OR	ON	ON	

		"20050059931" OR "20050148812" OR "20050261725" OR "20070043307" OR "20070043409" OR "20070129466" OR "20070135830" OR "20070219466" OR "20070219488" OR "20080027356" OR "20080082046" OR "20080082119" OR "20080097300" OR "20080243067" OR "20080243221" OR "20080262477" OR "20090026595" OR "20090062666" OR "20090171272" OR "20090171293" OR "20090265951" OR "20090287079" OR "20090312807" OR "20100016735" OR "20100041984" OR "20100113939" OR "20100234915" OR "20100262076" OR "20100268017" OR "20100280451" OR "20110144742" OR "20110196412" OR "20110295301" OR "20110295302" OR "20110301630" OR "20120101413" OR "20120108979" OR "20120109057" OR "20120116352" OR "20120130359" OR "20120172911" OR "20120209176" OR "20120215166" OR "20120271231" OR "20120302994" OR "20130102926" OR "20130102929" OR "20130172786" OR "20130190619" OR "20130281869" OR "20130289607" OR "20130338637" OR "20140221898" OR "20140243873" OR "20140249504" OR "20140316012" OR "20140364835" OR "20140378869" OR				
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		"20150012031" OR "20150039012" OR "20150272732" OR "20150367098" OR "20160000446" OR "20160375230" OR "2156289" OR "4464172" OR "4713888" OR "4777951" OR "4823469" OR "4865549" OR "4926885" OR "4983166" OR "5047045" OR "5135494" OR "5158529" OR "5169386" OR "5282479" OR "5320605" OR "5383856" OR "5447503" OR "5505702" OR "5522400" OR "5558644" OR "5571093" OR "5718678" OR "5738652" OR "5911702" OR "6011988" OR "6013019" OR "6013055" OR "6102930" OR "6113579" OR "6146370" OR "6161547" OR "6165199" OR "6190356" OR "6231572" OR "6248121" OR "6280434" OR "6423031" OR "6453572" OR "6575932" OR "6579221" OR "6602270" OR "6656153" OR "6666814" OR "6669679" OR "6679860" OR "6695811" OR "6719270" OR "6719720" OR "6733513" OR "6735532" OR "6736790" OR "6746462" OR "6796959" OR					
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L331	93	"6936056" OR "6979318" OR "7341571" OR "7434326" OR "7503904" OR "7503909" OR "7763043" OR "7892469" OR "7909810" OR "7951186" OR "7951819" OR "7959644" OR "8088103" OR "8162879" OR "8241241" OR "8262611" OR "8419648" OR "8430899" OR "8499681" OR "8545382" OR "8655798" OR "8672868" OR "8747358" OR "8814900" OR "8900214" OR "8948848" OR "8951565" OR "9131874" OR "9414843" OR "9474882" OR "9687333" OR "D0748257").pn. ((US-9211389-B2 OR US-6113579-A OR US- 6254578-B1 OR US- 6979318-B1 OR US- 5571093-A OR US- 4777951-A OR US- 5425709-A OR US- 5645528-A OR US- 6517515-B1 OR US- 5047045-A OR US- 7195612-B2 OR US- 5830181-A OR US- 6013019-A OR US- 6579221-B1 OR US- 7341571-B1 OR US- D748257-S OR US- 7862541-B2 OR US- 5250070-A OR US- 4944745-A OR US- 5087246-A OR US- 5516336-A OR US- 5423745-A OR US- 4195637-A OR US- 5295995-A OR US- 6013055-A OR US- 9474882-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 12:29 PM
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		5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US- 6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 5690613-A OR US- 5464394-A OR US- 6129737-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20040082935- A1 OR US- 20110172696-A1 OR US-20110224606-A1 OR US-20100113939- A1 OR US- 20030083579-A1 OR US-20110295302-A1 OR US-20110196297- A1 OR US- 20080015404-A1 OR US-20140364835-A1 OR US-20190015630- A1 OR US- 20150142045-A1 OR				
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L332	33	US-20210290243-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-A1 OR US-20080287786-A1 OR US-20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) ((US-5250070-A OR US-5295995-A OR US-6007517-A OR US-6013055-A OR US-5558644-A OR US-4369790-A OR US-5690613-A OR US-5464394-A OR US-5087246-A OR US-6129737-A).did. AND USPT.dbnm.) OR ((US-20030083579-A1 OR US-20110172696-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20120302994-A1 OR US-20090018500-A1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 12:53 PM
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L333	93	OR US-20130338637-A1 OR US-20160051386-A1 OR US-20140243873-A1 OR US-20100113939-A1 OR US-20120109057-A1 OR US-20080287786-A1).did. AND PGPB.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) OR ((US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 12:54 PM
L334	93	((US-9211389-B2 OR US-6113579-A OR US-6254578-B1 OR US-6979318-B1 OR US-5571093-A OR US-4777951-A OR US-5425709-A OR US-5645528-A OR US-6517515-B1 OR US-5047045-A OR US-7195612-B2 OR US-5830181-A OR US-6013019-A OR US-6579221-B1 OR US-7341571-B1 OR US-D748257-S OR US-7862541-B2 OR US-5250070-A OR US-4944745-A OR US-5087246-A OR US-5516336-A OR US-5423745-A OR US-4195637-A OR US-5295995-A OR US-6013055-A OR US-9474882-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 12:56 PM

		5169386-A OR US- 8419648-B2 OR US- 9687333-B2 OR US- 6248121-B1 OR US- 4934996-A OR US- 5558644-A OR US- 5308356-A OR US- 8021330-B2 OR US- 9211396-B2 OR US- 10149962-B2 OR US- 4369790-A OR US- 5476450-A OR US- 5690613-A OR US- 5464394-A OR US- 6129737-A OR US- 6007517-A).did. AND USPT.dbnm.) OR ((US- 20070219466-A1 OR US-20140221898-A1 OR US-20070060911- A1 OR US- 20060167421-A1 OR US-20020169457-A1 OR US-20180140806- A1 OR US- 20180117279-A1 OR US-20090312807-A1 OR US-20070135830- A1 OR US- 20030032974-A1 OR US-20050261725-A1 OR US-20070219488- A1 OR US- 20120109057-A1 OR US-20110251497-A1 OR US-20120302994- A1 OR US- 20160213893-A1 OR US-20170043123-A1 OR US-20140243873- A1 OR US- 20160206798-A1 OR US-20120330359-A1 OR US-20040082935- A1 OR US- 20110172696-A1 OR US-20110224606-A1 OR US-20100113939- A1 OR US- 20030083579-A1 OR US-20110295302-A1 OR US-20110196297- A1 OR US- 20080015404-A1 OR US-20140364835-A1 OR US-20190015630- A1 OR US- 20150142045-A1 OR				
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L335	4	US-20210290243-A1 OR US-20190366046-A1 OR US-20150150436-A1 OR US-20140358123-A1 OR US-20170296798-A1 OR US-20150342581-A1 OR US-20040039332-A1 OR US-20100204712-A1 OR US-20020156469-A1 OR US-20020007146-A1 OR US-20120209176-A1 OR US-20090018500-A1 OR US-20130338637-A1 OR US-20160051386-A1 OR US-20080287786-A1 OR US-20190076152-A1).did. AND PGPB.dbnm.) OR ((WO-9944666-A2 OR US-9126018-B1 OR US-9241699-B1).did. AND DWPI.dbnm.) OR ((WO-9725093-A1).did. AND EPAB.dbnm.) ((US-20090018500-A1 OR US-20120209176-A1 OR US-20080287786-A1).did. AND PGPB.dbnm.) OR ((US-5087246-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 02:44 PM
L336	2	((US-20090018500-A1).did. AND PGPB.dbnm.) OR ((US-5087246-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK,	OR	ON	ON	2023/10/25 03:08 PM

L337	298	("3960143" "4018231" "4195637" "4276874" "4292974" "4323071" "4327709" "4346698" "4490421" "4552127" "4846174" "4848344" "4968300").pn. OR ("5087246").urpn. AND (PGPB USPT USOC).dbnm.	TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 03:10 PM
L338	115	L337 AND compliant	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 03:11 PM
L340	167	L337 AND (french OR fr)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 03:16 PM
L342	7415	angioplasty AND compliant AND balloon	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 05:01 PM
L343	2709	L342 AND (compliant near1 balloon)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 05:01 PM
L345	149	L343 AND ("6" near1 french)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 05:07 PM
L346	149	L345	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 05:43 PM
L347	8	((US-20100113939-A1 OR US-20040039332- A1 OR US- 20110172696-A1 OR US-20190366046-A1 OR US-20160051386- A1 OR US- 20100204712-A1 OR US-20080287786- A1).did. AND PGPB.dbnm.) OR ((US- 6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 06:10 PM
L348	242	L345	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA,	OR	ON	ON	2023/10/25 07:01 PM

L349	16043	(occlusion AND compliant AND balloon)	VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 07:03 PM
L350	4644	(L349 AND (compliant near1 balloon))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 07:03 PM
L351	187	(L350 AND ("6" near1 french))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 07:03 PM
L352	99	L351	(US-PGPUB; USPAT)	OR	ON	ON	2023/10/25 07:11 PM
L353	1193	angioplasty SAME (compliant WITH balloon)	(US-PGPUB; USPAT)	OR	ON	ON	2023/10/25 07:15 PM

L354	1	("20070142771").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:21 PM
L355	1	("20100130926").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:30 PM
L356	1	("20100057001").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:31 PM
L357	1	("20070142772").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:33 PM
L358	7	((US-20090018500-A1 OR US-20120089047-A1 OR US-20070142771-A1 OR US-20100130926-A1 OR US-20100057001-A1 OR US-20070142772-A1).did. AND PGPB.dbnm.) OR ((US-5087246-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 07:35 PM
L359	4	L358 AND compliant	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 07:36 PM
L360	1	("20100130970").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:42 PM
L361	7	((US-20090018500-A1 OR US-20120089047-A1 OR US-20070142771-A1 OR US-20100130926-A1 OR US-20100057001-A1 OR US-20070142772-A1).did. AND PGPB.dbnm.) OR ((US-5087246-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO;	OR	ON	ON	2023/10/25 07:46 PM

L362	1	("5447497").pn.	JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:51 PM
L363	1	("20020081406").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/10/25 07:55 PM
L364	8	((US-20100113939-A1 OR US-20040039332- A1 OR US- 20110172696-A1 OR US-20190366046-A1 OR US-20160051386- A1 OR US- 20100204712-A1 OR US-20080287786- A1).did. AND PGPB.dbnm.) OR ((US- 6129737-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/25 07:59 PM
L365	9	((US-20090018500-A1 OR US-20120089047- A1 OR US- 20070142771-A1 OR US-20100130926-A1 OR US-20100057001- A1 OR US- 20070142772-A1 OR US-20020081406- A1).did. AND PGPB.dbnm.) OR ((US- 5087246-A OR US- 5447497-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/27 12:33 PM
L366	9	((US-20090018500-A1 OR US-20120089047- A1 OR US- 20070142771-A1 OR US-20100130926-A1 OR US-20100057001- A1 OR US- 20070142772-A1 OR US-20020081406- A1).did. AND PGPB.dbnm.) OR ((US- 5087246-A OR US- 5447497-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/27 06:14 PM
L367	9	((US-20100113939-A1 OR US-20040039332-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP,	OR	ON	ON	2023/10/27 06:14 PM

L368	9	A1 OR US-20110172696-A1 OR US-20190366046-A1 OR US-20160051386-A1 OR US-20100204712-A1 OR US-20080287786-A1 OR US-20020081406-A1).did. AND PGPB.dbnm.) OR ((US-6129737-A).did. AND USPT.dbnm.)	AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/27 06:15 PM
		((US-20090018500-A1 OR US-20120089047-A1 OR US-20070142771-A1 OR US-20100130926-A1 OR US-20100057001-A1 OR US-20070142772-A1 OR US-20020081406-A1).did. AND PGPB.dbnm.) OR ((US-5087246-A OR US-5447497-A).did. AND USPT.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N41	4666	A61M2025/1093.cpc. or A61M25/0068.cpc. or A61M25/0071.cpc. or A61M25/0026.cpc. or A61M2025/0002.cpc. or A61M2025/1052.cpc. or A61M2025/1059.cpc. or A61M2025/1081.cpc. or A61M2025/1086.cpc. or A61M25/0074.cpc. or A61M25/1002.cpc. or A61M25/1006.cpc.	(USPAT)	OR	OFF	OFF	2018/06/06 09:41 AM
N42	0	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and occlusion and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and	(USPAT)	OR	OFF	OFF	2018/06/06 09:43 AM

N43	0	flattened and solid and beyond N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and occlusion and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and flattened and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:43 AM
N44	2	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and occlusion and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:43 AM
N45	10	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and distal and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:45 AM
N46	0	N41 and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid	(USPAT)	OR	OFF	OFF	2018/06/06 09:52 AM
N47	5	A61M\$.cpc. and catheter and hub and inflation and port and lumen and longitudinal and axis and balloon and atraumatic and tip and circular and proximate and profile and guide and wire and shaft and solid not N45	(USPAT)	OR	OFF	OFF	2018/06/06 09:53 AM
N48	0	A61M\$.cpc. AND (occlusion AND	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:05 PM

N49	0	catheter AND hub AND balloon AND radially AND projecting AND landing AND inflation AND partial AND apposition AND curvilinear AND valve AND pressure).clm. A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND radially AND projecting AND landing AND inflation AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:05 PM
N50	0	A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND landing AND inflation AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:05 PM
N51	4	A61M\$.cpc. AND (occlusion AND catheter AND hub AND balloon AND inflation AND valve AND pressure).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 06:06 PM
N52	1	(A61M\$.cpc. OR A61B\$.cpc.) AND (hub AND valve AND balloon AND compliant AND marking AND lumen AND wire AND solid).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/10/27 06:05 PM

Bibliographic Data

Application No: 17/563,669

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged:

Examiner's Signature

Initials

Title:

SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION
BALLOON CATHETER

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/28/2021	604	3783	688961-25U7
RULE			

APPLICANTS

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INVENTORS

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David SPENCER, Boerne, TX, UNITED STATES

Todd J. KRUMMENACHER, Lakewood, CO, UNITED STATES

CONTINUING DATA

This application is a CON of 16133193 09/17/2018 PAT 11672951

16133193 is a CON of 15551504 08/16/2017 PAT 10149962

15551504 is a 371 of PCT/US16/23223 03/18/2016

PCT/US16/23223 has PRO of 62204804 08/13/2015

PCT/US16/23223 has PRO of 62136571 03/22/2015

PCT/US16/23223 has PRO of 62136180 03/20/2015

PCT/US16/23223 has PRO of 62136370 03/20/2015

PCT/US16/23223 has PRO of 62136152 03/20/2015

PCT/US16/23223 has PRO of 62136123 03/20/2015

PCT/US16/23223 has PRO of 62136326 03/20/2015

PCT/US16/23223 has PRO of 62136390 03/20/2015

PCT/US16/23223 has PRO of 62136230 03/20/2015

PCT/US16/23223 has PRO of 62135576 03/19/2015

PCT/US16/23223 has PRO of 62135552 03/19/2015

PCT/US16/23223 has PRO of 62135609 03/19/2015

PCT/US16/23223 has PRO of 62135528 03/19/2015

PCT/US16/23223 has PRO of 62135603 03/19/2015

FOREIGN APPLICATIONS

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UNITED STATES

FILING FEE RECEIVED

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Doc code: IDS

PTO/SB/08a (02-18)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 11/30/2020. OMB 0651-0031

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17563669
	Filing Date	2021-12-28
	First Named Inventor	Curtis J. FRANKLIN
	Art Unit	3783
	Examiner Name	J. A. Doubrava
	Attorney Docket Number	688961-25U7

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10449337		2019-10-22	Kassab et al.	
	2	10279094		2019-05-07	Williams et al.	
	3	10143789		2018-12-04	Frost, Habib	
	4	10111669		2018-10-30	Eliason et al.	
	5	3585983		1971-06-22	Kantrowitz et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220000486	A1	2022-01-06	Williams et al.	

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

Application Number	17563669
Filing Date	2021-12-28
First Named Inventor	Curtis J. FRANKLIN
Art Unit	3783
Examiner Name	J. A. Doubrava
Attorney Docket Number	688961-25U7

2	20170296779	A1	2017-10-19	Purdy et al.
3	20030083617	A1	2003-05-01	St. Germain et al.
4	20200022587	A1	2020-01-23	GLOVER et al.

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	1	2020033372	WO	A1	2020-02-13	Prytime Medical Devices, Inc		
	2	2019095049	WO	A1	2019-05-23	Three Rivers Cardiovascular Systems Inc		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	M. Austin Johnson et al. (published on May 27, 2016). Partial Resuscitative Balloon Occlusion of the Aorta (P-REBOA): Clinical Technique and Rationale, J Trauma Acute Care Surg, 81(5) Suppl 1:S133-S137	
	2	Rachel M. Russo et al. (presented at the Military Surgical Symposium, Nashville, TN in April 2015, published on April 29, 2016). Partial Resuscitative Endovascular Balloon Occlusion of the Aorta in Swine Model of Hemorrhagic Shock, J Am Coll Surg, 223:359-368	

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Application Number	17563669
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Art Unit	3783
Examiner Name	J. A. Doubrava
Attorney Docket Number	688961-25U7

3	Rachel M. Russo et al. (published on December 14, 2015. Extending the Golden Hour: Partial Resuscitative Endovascular Balloon Occlusion of the Aorta in a Highly Lethal Swine Liver Injury Model, J Trauma Acute Care Surg (80)3:372-380
4	Extended Search Report issued May 10, 2023 in European Application No. 22743436.2

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/JOHN A DOUBRAVA/	Date Considered	10/24/2023
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

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

Application Number	17563669
Filing Date	2021-12-28
First Named Inventor	Curtis J. FRANKLIN
Art Unit	3783
Examiner Name	J. A. Doubrava
Attorney Docket Number	688961-25U7

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Ragi A.I. Elias/	Date (YYYY-MM-DD)	2023-07-10
Name/Print	Ragi A. I. Elias	Registration Number	67,772

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

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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.



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495
570 7590 11/15/2023 PANITCH SCHWARZE BELISARIO & NADEL LLP TWO COMMERCE SQUARE 2001 MARKET STREET, SUITE 2800 PHILADELPHIA, PA 19103			EXAMINER DOUBRAVA, JOHN A	
			ART UNIT 3783	PAPER NUMBER
			NOTIFICATION DATE 11/15/2023	DELIVERY MODE ELECTRONIC

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

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

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

usptomail@panitchlaw.com

Corrected Notice of Allowability	Application No. 17/563,669	Applicant(s) FRANKLIN et al.	
	Examiner JOHN A DOUBRAVA	Art Unit 3783	AIA (FITF) Status Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to an Examiner's Amendment.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3. ☒ The allowed claim(s) is/are 1-5 and 7-11. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
 a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. <u>20231109</u> .	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
---	---

/J.A.D./ Examiner, Art Unit 3783	/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783
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DETAILED ACTION

Response to Amendment

1. The purpose of this office action is correct an antecedent basis issue in claim 1, line 9, as described below as well as in the attached interview summary.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Ragi A.I. Elias on October 27, 2023.

3. The application has been amended as follows:

Claim 1, line 8 "...the occlusion balloon being constructed of a compliant biocompatible material;..." should be "...the occlusion balloon being compliant;...".

Claim 1, line 14 "...the occlusion balloon and the distal catheter..." should be "...the occlusion balloon and into the distal catheter ...".

Authorization for this examiner's amendment was given in an interview with Ragi A.I. Elias on November 9, 2023.

4. The application has been amended as follows:

Claim 1, line 9 "...the proximal catheter shaft..." should be "...the proximal catheter section...".

Allowable Subject Matter

5. **Claims 1-5 and 7-11** are allowed.

Reasons for Allowance

6. The following is an Examiner's statement of reasons for allowance: the claims in this application are allowed because the prior art of record fails to disclose either singularly or in combination the claimed occlusion catheter system.

7. The closest prior art is Smith US 5,087,246.

8. **Regarding claim 1**, Smith fails to teach among all the limitations or render obvious an occlusion catheter system as claimed, which includes a flow valve, the occlusion balloon being compliant, at least one length marking on an exterior of the proximal shaft, and the catheter distal to the hub having a greatest outer diameter of less than 6 French in an uninflated configuration, in combination with the total structure and function of the occlusion catheter system as claimed. Although compliant balloons are known in the art, one of ordinary skill in the art would not modify Smith with a compliant balloon as this modification would render the modified device unsuitable for dilatation.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN A DOUBRAVA whose telephone number is (408)918-7561. The examiner can normally be reached M-F 9-5 Pacific Time.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nathan Price can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

Application/Control Number: 17/563,669
Art Unit: 3783

Page 5

(toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.A.D./
Examiner, Art Unit 3783

/LAURA A BOUCHELLE/
Primary Examiner, Art Unit 3783

<i>Examiner-Initiated Interview Summary</i>	Application No. 17/563,669	Applicant(s) FRANKLIN et al.		
	Examiner JOHN A DOUBRAVA	Art Unit 3783	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
JOHN A DOUBRAVA	Examiner	Telephonic
Ragi A.I. Elias	Attorney of Record	

Date of Interview: 09 November 2023

Issues Discussed:

Proposed Amendment(s)

Examiner's Amendment.

Claim 1, line 9 "...the proximal catheter shaft..." should be "...the proximal catheter section...".

Approved by Ragi A.I. Elias on November 9, 2023.

/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783	/JOHN A DOUBRAVA/ Examiner, Art Unit 3783
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Issue Classification 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

CPC						
Symbol					Type	Version
A61M	/	25	/	0068	F	2013-01-01
A61M	/	25	/	1002	I	2013-01-01
A61M	/	25	/	1006	I	2013-01-01
A61M	/	25	/	10182	I	2013-11-05
A61M	/	25	/	008	I	2013-01-01
A61M	/	25	/	104	I	2013-01-01
A61B	/	17	/	12036	I	2013-01-01
A61M	/	25	/	0074	I	2013-01-01
A61M	/	2025	/	0002	A	2013-01-01
A61M	/	2025	/	1052	A	2013-01-01
A61M	/	2025	/	1086	A	2013-01-01
A61M	/	25	/	007	A	2013-01-01
A61B	/	2017	/	00017	A	2013-01-01
A61M	/	2025	/	1093	A	2013-01-01
A61B	/	17	/	12045	A	2013-01-01
A61M	/	2025	/	1084	A	2013-01-01
A61B	/	17	/	12109	A	2013-01-01
A61M	/	2025	/	1059	A	2013-01-01
A61M	/	2025	/	1081	A	2013-01-01

CPC Combination Sets					
Symbol	Type	Set	Ranking	Version	
/					

JOHN A DOUBRAVA/ Examiner, Art Unit 3783 (Assistant Examiner)	09 November 2023 (Date)	Total Claims Allowed: 10	
/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783 (Primary Examiner)	10 November 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 12

U.S. Patent and Trademark Office

Part of Paper No.: 20231109

<i>Issue Classification</i> 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61M		25	00

NON-CLAIMED			

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

JOHN A DOUBRAVA/ Examiner, Art Unit 3783 (Assistant Examiner)	09 November 2023 (Date)	Total Claims Allowed: 10	
/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783 (Primary Examiner)	10 November 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 12

Issue Classification 	Application/Control No. 17/563,669	Applicant(s)/Patent Under Reexamination FRANKLIN et al.
	Examiner JOHN A DOUBRAVA	Art Unit 3783

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10												
2	2	9	11												
3	3														
4	4														
5	5														
-	6														
6	7														
7	8														
8	9														

JOHN A DOUBRAVA/ Examiner, Art Unit 3783 (Assistant Examiner)	09 November 2023 (Date)	Total Claims Allowed: 10	
/LAURA A BOUCHELLE/ Primary Examiner, Art Unit 3783 (Primary Examiner)	10 November 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 12

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

570 7590 11/09/2023
PANITCH SCHWARZE BELISARIO & NADEL LLP
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 2800
PHILADELPHIA, PA 19103

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495

TITLE OF INVENTION: SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	02/08/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
DOUBRAVA, JOHN A	3783	604-096010

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). ☐ Change of correspondence address (for Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached. ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 1 <u>Panitch Schwarze Belisario & Nadel LLP</u> 2 _____ 3 _____
---	--

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

Prytime Medical Devices, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Boerne, TX

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 50-1017

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Ragi A.I. Elias/

Date 11-16-23

Typed or printed name Ragi A.I. Elias

Registration No. 67,772



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/563,669

RECEIPT DATE / TIME
11/16/2023 08:11:25 AM Z ET

ATTORNEY DOCKET #
688961-25U7

Title of Invention

SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 4495

FILED BY SONIA KING

PATENT CENTER # 63272620

FILING DATE 12/28/2021

CUSTOMER # 570

FIRST NAMED INVENTOR Curtis J. FRANKLIN

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Ragi Elias

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
Issue Fee Transmittal.pdf	1	Issue Fee Payment (PTO-85B)	1907 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Issue Fee Transmittal.pdf	2F61EE242EE1DB04E9F43044705F2FC6AB8BB7907787D32BB 17E69EF5AFDBCE122298BDADF71608CE8E496C39EE65521B 415B81FF16204091CA24B75F00D2B39

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
17/563,669

RECEIPT DATE / TIME
11/16/2023 08:11:25 AM Z ET

ATTORNEY DOCKET #
688961-25U7

Title of Invention

SYSTEM AND METHOD FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 4495

FILED BY SONIA KING

PATENT CENTER # 63272620

AUTHORIZED BY Ragi Elias

CUSTOMER # 570

FILING DATE 12/28/2021

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Curtis J. FRANKLIN

Payment Information

PAYMENT METHOD
CARD / 1085

PAYMENT TRANSACTION ID
E2023AF912167602

PAYMENT AUTHORIZED BY
SONIA KING

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2501	UTILITY ISSUE FEE	480.00	1	480.00
TOTAL AMOUNT:				\$480.00

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.

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submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	01/02/2024	11857737	688961-25U7	4495

570 7590 12/13/2023
PANITCH SCHWARZE BELISARIO & NADEL LLP
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 2800
PHILADELPHIA, PA 19103

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at <https://certifiedcopycenter.uspto.gov/index.html>. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 112 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (<https://patentcenter.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional inventors):

Curtis J. FRANKLIN, Lakewood, CO;
David SPENCER, Boerne, TX;
Todd J. KRUMMENACHER, Lakewood, CO;

APPLICANT(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional applicants):

Prytime Medical Devices, Inc., Boerne, TX;

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/563,669	12/28/2021	Curtis J. FRANKLIN	688961-25U7	4495
570 7590 01/02/2024 PANITCH SCHWARZE BELISARIO & NADEL LLP TWO COMMERCE SQUARE 2001 MARKET STREET, SUITE 2800 PHILADELPHIA, PA 19103			EXAMINER DOUBRAVA, JOHN A	
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