



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

August 26, 2019

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE UNDER 35 USC 111.**

APPLICATION NUMBER: 16/140,836

FILING DATE: September 25, 2018

**THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY
APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS
CONVENTION, IS US16/140,836**

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**



**P. R. GRANT
Certifying Officer**

Electronic Acknowledgement Receipt	
EFS ID:	33818027
Application Number:	16140836
International Application Number:	
Confirmation Number:	3660
Title of Invention:	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM
First Named Inventor/Applicant Name:	Juan LORENZO
Customer Number:	6980
Filer:	Louis J. DelJuidice/Wendy Higgins
Filer Authorized By:	Louis J. DelJuidice
Attorney Docket Number:	243382.000119
Receipt Date:	25-SEP-2018
Filing Date:	
Time Stamp:	12:40:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$1720
RAM confirmation Number	092518INTEFSW00011524201507
Deposit Account	201507
Authorized User	Wendy Higgins

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:
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	Transmittal of New Application	TRANSMITTAL.pdf	279825	no	1
			b6e0b4f8126c5680a20a39b022d05d6672916978		
Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1276584	no	9
			94799625264f9a34a7f433bda70e3ef9d765cce		
Warnings:					
Information:					
3	Oath or Declaration filed	DECLARATIONS.pdf	264186	no	3
			728600396b04b3ebc1a01ccd734a8c16c89f3383		
Warnings:					
Information:					
4	Power of Attorney	POA.pdf	733747	no	5
			bb58c4c69116f4da5aac3bdd50f7bf757a0023d		
Warnings:					
Information:					
5		APPLICATION.pdf	165897	yes	23
			3465c4664ff55179d488ec6dae2046e40c5350e4		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Abstract		23	23	
	Claims		18	22	
	Specification		1	17	

Warnings:					
Information:					
6	Drawings-only black and white line drawings	DRAWINGS.pdf	2650280	no	9
			442f0328356e85ba18a8de5b2f09f690708da1b1		
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	34996	no	2
			63987551f0a5a640953dd092aee280c2cf9e5b15		
Warnings:					
Information:					
Total Files Size (in bytes):			5405515		
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. <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. <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. <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.					

UTILITY
PATENT APPLICATION
TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	243382.000119
First Named Inventor	Juan LORENZO
Title	INTRASACULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM
Priority Mail Express® Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

- ☐ Fee Transmittal Form (PTO/SB/17 or equivalent)
- ☐ Applicant asserts small entity status. See 37 CFR 1.27
- ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
- ☒ Specification [Total Pages 23]
Both the claims and abstract must start on a new page.
(See MPEP § 608.01(a) for information on the preferred arrangement)
- ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 9]
- ☒ Inventor's Oath or Declaration [Total Pages 3]
(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))
 - ☒ Newly executed (original or copy)
 - ☐ A copy from a prior application (37 CFR 1.63(d))
- ☒ Application Data Sheet * See note below.
See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
- ☐ CD-ROM or CD-R
in duplicate, large table, or Computer Program (Appendix)
☐ Landscape Table on CD
- ☐ Nucleotide and/or Amino Acid Sequence Submission
(if applicable, items a. – c. are required)
 - ☐ Computer Readable Form (CRF)
 - ☐ Specification Sequence Listing on:
 - ☐ CD-ROM or CD-R (2 copies); or
 - ☐ Paper
 - ☐ Statements verifying identity of above copies

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

ACCOMPANYING APPLICATION PAPERS

- ☐ Assignment Papers
(cover sheet & document(s))
Name of Assignee _____
- ☒ 37 CFR 3.73(c) Statement (when there is an assignee) ☒ Power of Attorney
- ☐ English Translation Document (if applicable)
- ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449)
☐ Copies of citations attached
- ☐ Preliminary Amendment
- ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized)
- ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
- ☐ Nonpublication Request
Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
- ☐ Other: _____

*Note: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 must be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

☒ The address associated with Customer Number: 06980 OR ☐ Correspondence address below

Name			
Address			
City	State	Zip Code	
Country	Telephone	Email	
Signature	/Louis J. DelJuidice - 47,522/		Date
Name (Print/Type)	Louis John DelJuidice		2018-09-25
	Registration No. (Attorney/Agent)		47522

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM

Field of Invention

The present invention generally relates to medical instruments, and more particularly, delivery systems for a device for aneurysm therapy.

Background

Cranial aneurysms can be complicated and difficult to treat due to their proximity to critical brain tissues. Prior solutions have included endovascular treatment whereby an internal volume of the aneurysm sac is removed or excluded from arterial blood pressure and flow. Current alternatives to endovascular or other surgical approaches can include occlusion devices that either fill the sac of the aneurysm with embolic material or treating the entrance or neck of the aneurysm. Both approaches attempt to prevent blood flow into the aneurysm. When filling an aneurysm sac, the embolic material clots the blood, creating a thrombotic mass within the aneurysm. When treating the aneurysm neck, blood flow into the entrance of the aneurysm is inhibited, inducing venous stasis in the aneurysm and facilitating a natural formation of a thrombotic mass within the aneurysm.

Current occlusion devices typically utilize multiple embolic coils to either fill the sac or treat the entrance. In either treatment, obtaining an embolic coil packing density sufficient to either occlude the aneurysm neck or fill the aneurysm sac is difficult and time consuming. Further, aneurysm morphology (e.g. wide neck, bifurcation, etc.) can required ancillary devices such as stents or balloons to support the coil mass and obtain the desired packing density.

Naturally formed thrombotic masses formed by treating the entrance of the aneurysm with embolic coils can improve healing compared to aneurysm masses packed with embolic coils by reducing possible distention from arterial walls and permitting reintegration into the original parent

The expansion ring can be mechanically connected to a portion of the outer fold segment such that the outer fold segment covers at least a portion of the notch and at least a portion of the expansion ring.

In the deployed configuration, the expansion ring can include an attached segment and an extending portion. The attached segment can be attached to the braided implant and can open a first region of the occlusive sack to a first circumference, and the extending portion can be attached to the attaching segment and can open a second region of the occlusive sack to a second circumference greater than the first circumference.

The expansion ring can have leaf shaped elements that extend radially as the expansion ring moves from the collapsed configuration to the deployed configuration.

The expansion ring can have segments joined to form a substantially tubular zig-zag structure when in the collapsed configuration.

The inner elongated member can be pushed distally to implant at least a portion of the braided implant.

An example device for treating an aneurysm can include a tubular delivery member, an inner elongated member, a braided tubular implant, and an expansion component. The braided tubular implant can be movable from a delivery configuration to an implanted configuration. In the delivery configuration, the braided tubular implant can have a first end extending proximally within an interior of the tubular delivery member that is detachably attached to a distal end of the inner elongated member and a second end extending distally from the distal end of the tubular delivery member and folding proximally over at least a portion of a notch positioned on an exterior of the tubular delivery member near a distal end of the tubular delivery member. The expansion component can be positioned within the notch on the tubular delivery member and attached to the

braided tubular implant near the second end of the braided tubular implant. The expansion component can be movable from a collapsed configuration engaging the notch to a deployed configuration disengaging the notch.

The notch on the exterior of the tubular delivery member can be a circumferential indentation. The expansion component can be positioned in the circumferential indentation when in the collapsed configuration.

When in the implanted configuration, the braided tubular implant can have an occlusive sack and the expansion component can be positioned within the occlusive sack. The expansion component can have extending members that appose the occlusive sack when the expansion component is in the deployed configuration. When in the collapsed configuration, the expansion component can have an opening through which the braided tubular implant passes through upon movement from the delivery configuration to the implanted configuration.

An example method for treating an aneurysm can include the steps of providing a braided implantation delivery system having a braided implant, a delivery tube, and an expansion component, attaching the braided implant to the expansion component, engaging the expansion component with a notch on the delivery tube, implanting the braided implant in the aneurysm, expanding the expansion component to disengage the expansion component from the notch, and releasing the expansion component from the delivery tube which releases the braided implant from the delivery tube.

The method can further include the step of expanding the expansion component to occlude at least a portion of the neck of the aneurysm.

The step of implanting the braided implant in the aneurysm can include the step of forming an occlusive sack, and the step of expanding the expansion component can include the step of extending the occlusive sack across the neck of the aneurysm.

The provided braided implantation delivery system can further include an inner elongated member, and the method can further include the step of attaching the braided implant to the inner elongated member. The step of implanting the braided implant can further include the steps of pushing the inner elongated member distally, thereby pushing a portion of the braided implant into the aneurysm and detaching the braided implant from the inner elongated member.

Brief Description of the Drawings

The above and further aspects of this invention are further discussed with reference to the following description in conjunction with the accompanying drawings, in which like numerals indicate like structural elements and features in various figures. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating principles of the invention. The figures depict one or more implementations of the inventive devices, by way of example only, not by way of limitation.

FIG. 1 is a cross-sectional drawing of an implantation device or system according to the present invention;

FIG. 2A is a drawing depicting braided implant in a delivery configuration according to the present invention;

FIG. 2B is a drawing depicting an expansion ring in a collapsed configuration according to the present invention;

FIG. 2C is a drawing depicting a distal end of a delivery tube according to the present invention;

FIG. 3 is a drawing depicting a distal end of an implantation system according to the present invention;

FIG. 4 is a cross-sectional drawing of an implantation system within a microcatheter according to the present invention;

FIGS. 5A to 5G are drawings illustrating a method of use of an implantation system according to the present invention;

FIG. 6 is a drawing depicting a braided implant in an implanted configuration with an expansion ring in a deployed configuration according to the present invention;

FIG. 7A is a cut-away drawing of an aneurysm with a partially implanted braided implant.

FIG. 7B is a cut-away drawing of an aneurysm with a completely implanted braided implant.

FIGs. 8A to 8C is drawing depicting a braided implant in an implanted configuration and an expansion ring in a deployed configuration according to the present invention;

FIGs. 9A to 9B is a drawing depicting a braided implant in an implanted configuration and an expansion ring in a deployed configuration according to the present invention;

FIGs. 10A, and 10B are drawings depicting expansion rings in a collapsed configuration according to the present invention; and

FIGs. 11 and 12 are flow diagrams outlining method steps according to the present invention.

Detailed Description

Previous approaches utilizing embolic coils can be improved upon by treating the aneurysm entrance and/or packing the aneurysm with an embolic braided implant. For example, see U.S. Patent Application Number 15/903,860, incorporated herein, in its entirety, by reference. Treating the aneurysm with the braided implant can have potential advantages over treatments utilizing embolic coils such as an ability to achieve higher packing density, ability to retract and reposition the implant during the implantation procedure, ability to perform implantation without ancillary devices such as stents or balloons, reduced risk of reanalyzing or compacting, and improved coverage across the aneurysm neck, for example.

In braided implant delivery systems, it can be advantageous to maintain an attachment between an implant and a delivery device until the implant is in place at the treatment site, then detach the implant so that portions of the delivery device and system can be extracted. When implanted in an aneurysm, for example, the delivery system can also serve to at least partially occlude the neck of the aneurysm. The present disclosure describes various example systems, devices, and methods that can be utilized for at least such purposes.

The system for positioning and deployment of an intrasaccular device (e.g. braided implant) into an aneurysm can include an outer hollow braid pusher, an inner braid pusher, a braided implant, and a microcatheter. The outer pusher (delivery tube) be coaxially mounted over the inner pusher (inner elongated member). A first (proximal) end of the braided implant (braided intrasaccular component) can be mounted to a distal end of the outer pusher, while a second (distal) end of the braided implant can be attached to a distal end of the inner pusher. The first end of the braided implant can have a self-expanding ring mounted to the braid. The self-expanding ring can be made of Nitinol or other similar self-expanding material. The self-expanding ring can be

crimped in place within a notch located at a distal end of the outer pusher to attach the braided implant to the outer pusher, and the first, proximal end of the braided implant can fit within a notch at the distal end of the inner pusher. The inner pusher can include a release mechanism of known design. For example, see U.S. Patent Number 7,377,932 and U.S. Patent Number 8,062,325, each incorporated herein, in their entirety, by reference.

FIG. 1 depicts a cross-sectional view of an implantation device 100 having a braided implant 300, a delivery tube 500, and an inner elongated member 400. The braided implant 300 can have an outer fold segment 302 near a distal end 314 of the braided implant 300. The outer fold segment 302 can be attached to an expansion ring 200, and the expansion ring 200 can be positioned within a notch 510 on an outer surface 508 of the delivery tube 500 near a distal end 514 of the delivery tube 500. The braided implant can have a fold 303 positioned distal the distal end 514 of the delivery tube 500 such that the outer fold segment 302 extends proximally from the fold 303 over the delivery tube 500 and an inner fold segment 304 extends proximally from the fold 303 within the delivery tube 500. The inner fold segment 304 can extend to a proximal end 312 of the braided implant 300, and a distal end 414 of the inner elongated member 400 can be detachably attached to the proximal end 312 of the braided implant 300. The delivery tube 500 and the inner elongated member 400 can each have proximal ends 512, 412 that can be accessible by a user for manipulation of the device 100 during treatment.

FIGs. 2A to 2C depict a braided implant 300, an expansion ring 200, and a delivery tube 500 that can be assembled to form at least part of an implantation device, such as the device 100 depicted in FIG. 1. FIG. 2A depicts the braided implant 300 in a delivery configuration having an outer fold segment 302 separated from an inner fold segment 304 by a fold 303. The inner fold 304 can be sized to fit within a lumen 504 of the delivery tube 504 such as the delivery tube 500

depicted in FIG. 2C. The inner fold 304 can extend to a first end 312 that can attach to an inner elongated member (not shown). The outer fold segment 302 can be positioned at a second end 314 of the braided implant and can be sized to fit over an expansion ring 200, such as the expansion ring 200 depicted in FIG. 2B. The outer fold segment 302 can also be sized to fit over a distal end 514 of a delivery tube 500 such as the delivery tube depicted in FIG. 2C.

FIG. 2B depicts the expansion ring 200 in a collapsed configuration. In the collapsed configuration, the expansion ring 200 can be sized to fit within a notch 510 on an outer surface 508 of a delivery tube 500 such as the delivery tube 500 depicted in FIG. 2C. The expansion ring 200 can include extending portions 210 that are attached by attaching segments 220 to form a ring having an opening 240 sized to fit within the delivery tube notch 510. Each extending portion 210 can have a petal or oval shape such as shown in FIG. 2B, and the shape can be characterized by a first width 216 at a base of the extending portion 210 and a second width 218 near a middle of the extending portion that is wider than the first width 216.

FIG. 2C depicts a portion of a delivery tube 500 near a distal end 514 of the delivery tube 500. As discussed in reference to FIGs. 2A and 2B, the delivery tube 500 can have notch 510 near its distal end 514 on its outer surface 508, and the delivery tube 500 can have a lumen 504 therethrough.

FIG. 3 depicts a braided implant 300, expansion ring 200, and delivery tube 500 such as those depicted in FIGs. 2A to 2C assembled together to form an implantation device. As shown, an outer fold segment 302 of the braided implant 300 can be folded over and attached to an expansion ring 200, and the expansion ring 200 can be sized to fit within a notch 510 on an outer surface 508 of the delivery tube 500. An inner fold segment 304 of the braided implant 300 can

extend into a lumen 504 of the delivery tube. Configured thusly, the depicted device can be inserted into a microcatheter for delivery to a treatment site.

FIG. 4 depicts a cross-sectional view of an implantation system including a device 100 positioned within a microcatheter 600 for delivery to a treatment site. The microcatheter can be any catheter suitable for insertion into a patient and navigation to a treatment site. Once in place, the implantation device 100 can be fed through the catheter 600 to the treatment site. The catheter 600 can have a distal end 614 that can be positioned at a treatment site and a proximal end 612 that can be accessible to a user during a treatment procedure.

FIGs. 5A to 5G are cross-sectional drawings illustrating a method of use of an implantation system for treatment of an aneurysm. FIG. 5A depicts an implantation system configured to begin implantation of the braided implant. As shown, the device can be approximately aligned with a distal end 614 of the microcatheter 600. The braided implant 300 can be attached to an expansion ring 200 within a delivery tube notch 510 and can extend within the delivery tube 500 to attach to an inner elongated member 400 at a braid release 400.

FIG. 5B depicts a partially implanted braided implant 300. As shown, the inner elongated member 400 can be pushed distally, pushing the braided implant 300 out of the delivery tube 500 and microcatheter 600. As the braided implant 300 exits the delivery tube 500, the implant 300 can invert and begin to form an occlusive sack 308.

As shown in FIG. 5C, the inner elongated member 400 can be continued to be pushed distally, pushing more of the braided implant 300 out of the delivery tube 500. As the braided implant 300 further exits the delivery tube 500, the implant 300 can continue to invert and the occlusive sack 308 can expand.

As shown in FIG. 5D, the inner elongated member 400 can be pushed until the braided implant 300 fully exits the delivery tube. As shown, the occlusive sack 308 can be fully expanded, and the portion of the braided implant 300 that does not invert to form the occlusive sack 308 can be pushed into the occlusive sack 308 forming an embolic filler braid 310. As shown, the embolic filler braid 310 can remain attached to the inner elongated member 400 by a braid release mechanism 404. While the embolic filler braid 310 is attached to the inner elongated member 400, the braided implant 300 can be partially or fully retracted by pulling the inner elongated member 400 proximally. Once retracted, the implantation system can be repositioned and the inner elongated member 400 can be pushed distally to re-implant the braided implant 300.

As shown in FIG. 5E, the braided implant 300 can be released from the inner elongated member 400 by detaching the braid release mechanism 404.

As shown in FIG. 5F, the delivery tube 500 can be pushed distally from the microcatheter 600, or the microcatheter 600 can be pulled proximally, and the expansion ring 200 can begin to expand from a delivery configuration as shown in FIGs. 5A to 5E to an expanded configuration. As the expansion ring 200 expands, it can begin to disengage the notch 510 in the delivery tube 500. The expansion ring 200 can be made of a memory shape material that has a deformed shape in the delivery configuration that is crimped to fit within the notch 510 in the delivery tube and a predetermined shape that the expansion ring 200 expands to in the expanded or deployed configuration. When the delivery tube 500 exits the microcatheter 600, the expansion ring 200 can make contact with bodily fluids, and the temperature of the bodily fluids can cause the expansion ring 200 to expand to the predetermined shape.

As shown in FIG. 5G, the expansion ring 200 can continue to expand and disengage from the notch 510 in the delivery tube 500. Once the expansion ring 200 is fully expanded in the deployed configuration, the delivery tube can be extracted.

FIG. 6 depicts a braided implant in an implanted configuration with an expansion ring in a deployed configuration. The delivery tube 500 and microcatheter 600 can be extracted from the patent.

FIG. 7A depicts a cut-away of an aneurysm 10 with a partially implanted braided implant 300. A delivery catheter 600 can be delivered through a blood vessel 20 to a neck 16 of the aneurysm, and the braided implant 300 can be pushed through the neck 16 into the aneurysm 10 to form an occlusive sack 308 that extends to walls of the aneurysm 10. The partially implanted braided implant 300 can be retracted and repositioned.

FIG. 7B depicts a cut-away of an aneurysm 10 with a completely implanted braided implant 300. An occlusive sack 308 extends the walls 14 of the aneurysm 10, and an embolic braid 310 can fill the occlusive sack 308. Together, the occlusive sack 308 and embolic braid 310 can fill the aneurysm sac 12. The expansion ring 200 can reside near the aneurysm neck 16 and can have extending portions 210 that extend to appose the occlusive sack 308. The expansion ring 200 can have attaching segments 220 that connect the extending portions 210, and the attaching segments 220 can form a ring or other shape that defines an opening 240 of the expansion ring 200 and occlusive sack 308.

FIGs. 8A to 8C depict a braided implant 300 in an implanted configuration and an expansion ring 200 in a deployed configuration. As shown in FIGs. 8A to 8C, the expansion ring 200 can have leaf or petal shaped extending portions 210 connected by attaching segments 220. The expansion ring 200 can have a collapsed configuration as shown in FIG. 2B and expand to a

deployed configuration as shown in FIGs. 8A to 8C. FIG. 8A depicts a side view of an occlusive sack 308 having an embolic filler braid 310 and the expansion ring 200. FIGs. 8B and 8C illustrate a cross-sectional view of the occlusive sack 308 as indicated in FIG. 8A. Referring to FIG. 8B, the expansion ring can be constructed with multiple independent sections that are connected together with segment connectors 232. As shown, each extending portion 210 can have a connector 232 positioned to connect two halves of each extending portion 210. The occlusive sack 308 can be connected to the expansion ring at the attaching segments 220, and the extending portions can be free to slide against the occlusive sack 308 as the expansion ring 200 opens to the deployed configuration. As illustrated in FIG. 8C, the attaching segments 220 can define a first circumference 324 of the occlusive sack 308 near an opening in the occlusive sack 308, and the extending portions 210 can open the occlusive sack to a larger, second circumference 326.

FIGs. 9A and 9B depict a braided implant 300 in an implanted configuration and an expansion ring 300 in a deployed configuration. FIG. 9A is a side view, and FIG. 9B is a cross-sectional view as indicated in FIG. 9A. As shown in FIGs. 9A and 9B, the expansion ring 200 can have four segments 230 connected by connectors 232 to form four corners.

FIGs. 10A and 10B depict an expansion ring 200 in a collapsed configuration. The expansion ring 200 can be shaped as shown in FIGs. 10A and 10B in the collapsed configuration and expand to a deployed configuration. FIG. 10A depicts the expansion ring 200 within a notch 510 of a delivery tube, and FIG. 10B depicts the expansion ring of FIG. 10A absent the delivery tube. As shown, the segments 230 can be substantially straight, and bends 234 or connectors (not shown) can join the segments 230 to form a zig zag structure. The expansion ring can include attachment tabs 236 for attaching to a braided implant 300.

As will be appreciated and understood, an expansion ring can have any number of segments, bends, and connectors to form a zig-zag shape. In a collapsed configuration, the zig-zag shape can have a tubular shape, having a substantially uniform circumference along its length. In an expanded or deployed configuration, the expansion ring can have a tubular shape having a substantially uniform circumference larger than the collapsed circumference or a tapered shape having a first circumference near the occlusive sack opening and a second circumference at a region within an occlusive sack that is larger than the first circumference.

Expansion rings disclosed herein are preferably formed of a shape memory material such as nickel-titanium alloy, or a shape memory polymer, for example, having a shape memory position in an expanded configuration. The expansion rings can be appropriately heat treated so that the expansion ring forms in the desired shape of the expanded shape memory position. Each expansion ring can be formed by cutting a tube or a sheet formed of a shape memory material such as nickel-titanium alloy, or shape memory polymer, by a laser

FIGs. 11 and 12 are flow diagrams outlining example method steps for use of a device or system for treating an aneurysm. The method steps can be implemented by any of the example means described herein or by any means that would be known to one of ordinary skill in the art.

Referring to method 700 outlined in FIG. 11, in step 710, a braided implantation delivery system having a braided implant, a delivery tube, and an expansion component can be provided. In step 720, the braided implant can be attached to the expansion component. In step 730, the expansion component can be engaged with a notch on the delivery tube. In step 740, the braided implant can be implanted into the aneurysm. In step 750, the expansion component can be expanded to disengage the expansion component from the notch. In step 760, the expansion

component can be released from the delivery tube, thereby releasing the braided implant from the delivery tube.

Referring to method 800 outlined in FIG. 12, in step 810, a braided implantation delivery system having a braided implant, a delivery tube, an inner elongated member, and an expansion component can be provided. In step 820, the braided implant can be attached to the expansion component. In step 825, the braided implant can be attached to the inner elongated member. In step 830, the expansion component can engage a notch on the delivery tube. In step 840, the braided implant can be implanted into the aneurysm by pushing the inner elongated member distally, thereby pushing a portion of the braided implant into the aneurysm and forming an occlusive sack within the aneurysm, then detaching the braided implant from the inner elongated member. In step 850, the expansion component can be expanded to disengage the expansion component from the notch. In step 860, the expansion component can release the delivery tube, thereby releasing the braided implant from the delivery tube. In step 870, the expansion component can expand to occlude at least a portion of the neck of the aneurysm and extend the occlusive sack across the neck of the aneurysm.

The descriptions contained herein are examples of embodiments of the invention and are not intended to limit the scope of the invention. As described herein, the invention contemplates many variations and modifications of a system, device, or method that can be used to treat an aneurysm with a braided implant. Variations can include but are not limited to alternative geometries of elements and components described herein, utilizing any of numerous materials for each component or element (e.g. radiopaque materials, memory shape metals, etc.), utilizing additional components including components to position the braided implant at a treatment site, extract the braided implant, or eject a portion of the braided implant from the interior of the

delivery tube, utilizing additional components to perform functions described herein, or utilizing additional components to perform functions not described herein, for example. These modifications would be apparent to those having ordinary skill in the art to which this invention relates and are intended to be within the scope of the claims which follow.

Claims

1. A system for releasing an implant, the system comprising:
 - a braided implant comprising a first end and a second end;
 - a delivery tube comprising a distal end and an outer surface comprising a notch thereon approximate the distal end;
 - an inner elongated member comprising a distal end detachably attached to the first end of the braided implant; and
 - an expansion ring mechanically connected to the braided implant near the second end of the braided implant and movable from a collapsed configuration to a deployed configuration, the collapsed configuration engaging with the notch, and the deployed configuration disengaging the notch, thereby releasing the delivery tube.
2. The system of claim 1 wherein the braided implant comprises:
 - a fold positioned distal the distal end of the delivery tube,
 - an outer fold segment extending proximally from the fold and comprising the second end of the braided implant, and
 - an inner fold segment encompassed by the outer fold segment, extending proximally from the fold, and comprising the first end of the braided implant.
3. The system of claim 2 wherein the expansion ring is mechanically connected to a portion of the outer fold segment, the outer fold segment covering at least a portion of the notch and at least a portion of the expansion ring.

4. The system of claim 1 wherein the deployed configuration of the expansion ring comprises:
an attaching segment attached to the braided implant and opening a first region of the occlusive sack to a first circumference; and
an extending portion attached to the attaching segment and opening a second region of the occlusive sack to a second circumference greater than the first circumference.
5. The system of claim 1 wherein the expansion ring comprises a plurality of leaf shaped elements that extend radially as the expansion ring moves from the collapsed configuration to the deployed configuration.
6. The system of claim 1 wherein the expansion ring in the collapsed configuration comprises a plurality of segments joined to form a substantially tubular zig-zag structure.
7. The system of claim 2 wherein the delivery tube further comprises a lumen therethrough and the inner fold segment of the braided implant is positioned within the lumen.
8. The system of claim 1 wherein pushing the inner elongated member distally pushes the braided implant distally to implants at least a portion of the braided implant.
9. A device for treating an aneurysm, the device comprising:
a tubular delivery member comprising a distal end, an interior, an exterior, and a notch positioned on the exterior approximate the distal end;

an inner elongated member positioned within the interior of the tubular delivery member comprising a distal end and a proximal end;

a braided tubular implant movable from a delivery configuration to an implanted configuration, the delivery configuration comprising:

a first end extending proximally within the interior of the tubular delivery member and detachably attached to the distal end of the inner elongated member, and

a second end extending distally from the distal end of the tubular delivery member and folding proximally over at least a portion of the notch; and

an expansion component positioned within the notch and attached to the braided tubular implant approximate the second end, the expansion component movable from a collapsed configuration to a deployed configuration, the collapsed configuration engaging the notch and the deployed configuration disengaging the notch.

10. The device of claim 9 wherein the notch comprises a circumferential indentation on the exterior of the tubular delivery member.

11. The device of claim 10 wherein the expansion component is positioned in the circumferential indentation when in the collapsed configuration.

12. The device of claim 9 wherein the implanted configuration of the braided tubular implant comprises an occlusive sack, and wherein the expansion component is positioned within the occlusive sack.

13. The device of claim 12 wherein the expansion component comprises a plurality of extending members apposing the occlusive sack in the deployed configuration.

14. The device of claim 9 wherein the collapsed configuration of the expansion component comprises an opening through which the braided tubular implant passes through upon movement from the delivery configuration to the implanted configuration.

15. A method for treating an aneurysm, the method comprising:

providing a braided implantation delivery system, wherein the implantation delivery system comprises a braided implant, a delivery tube comprising a notch, and an expansion component;

attaching the braided implant to the expansion component;

engaging the expansion component with the notch;

implanting the braided implant in the aneurysm;

expanding the expansion component to disengage the expansion component from the notch; and

releasing the expansion component from the delivery tube which releases the braided implant from the delivery tube.

16. The method of claim 15 further comprising the step of expanding the expansion component to occlude at least a portion of the neck of the aneurysm.

17. The method of claim 15 wherein the step of implanting the braided implant in the aneurysm comprises the step of forming an occlusive sack, and wherein the step of expanding the expansion component comprises the step of extending the occlusive sack across the neck of the aneurysm.
18. The method of claim 15 wherein the braided implantation delivery system further comprises an inner elongated member, the method further comprising the step of attaching the braided implant to the inner elongated member.
19. The method of claim 18 wherein the step of implanting the braided implant in the aneurysm further comprises the steps of:
- pushing the inner elongated member distally, thereby pushing a portion of the braided implant into the aneurysm; and
 - detaching the braided implant from the inner elongated member.

Abstract

Implant deployment systems can generally include a braided implant that can be detachably attached to a delivery tube by an expansion ring that can be positioned within a notch on an outer surface of the delivery tube near a distal end of the delivery tube. The implant can be positioned within a lumen of the delivery tube and remain attached to the delivery tube as the assembly is fed through a microcatheter to a treatment site. Once the braided implant is implanted, the expansion ring can move from a collapsed configuration that is engaged with the notch of the delivery tube to a deployed configuration that releases the delivery tube, thereby releasing the braided implant from the delivery tube.

POWER OF ATTORNEY BY APPLICANT

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

Application Number
Filing Date

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

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

06980

OR

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

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

The address associated with the above-mentioned Customer Number

OR

The address associated with Customer Number:

OR

Firm or Individual Name
Address
City
State
Zip
Country
Telephone
Email

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

DEPUY SYNTHES PRODUCTS, INC.

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

SIGNATURE of Applicant for Patent

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

Signature
Name
Title
Date (Optional)

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

Total of forms are submitted.

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

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

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of
Invention

INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM

As the below named inventor, I hereby declare that:

This declaration
is directed to:

☒

The attached application, or

☐

United States application or PCT international application number _____

filed on _____.

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.

WARNING:

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

LEGAL NAME OF INVENTOR

Inventor: Juan LORENZO

Date (Optional) : _____

Signature: Juan Lorenzo

Digitally signed by JUAN LORENZO
DN: c=US, o=JL, ou=Subscribers, cn=JUAN
LORENZO, 0.9.2342.19200300.100.1.1=110229
Reason: I attest to the accuracy and integrity of this
document.
Date: 2018.09.19 16:54:39 -0400

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of
Invention

INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM

As the below named inventor, I hereby declare that:

This declaration
is directed to:

☒

The attached application, or

☐

United States application or PCT international application number _____
filed on _____.

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.

WARNING:

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

LEGAL NAME OF INVENTOR

Inventor: Kirk JOHNSON

Date (Optional): 9/24/18

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of
Invention

INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM

As the below named inventor, I hereby declare that:

This declaration
is directed to:



The attached application, or



United States application or PCT international application number _____
filed on _____.

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.

WARNING:

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

LEGAL NAME OF INVENTOR

Inventor: Lacey GOROCHOW

Date (Optional) : _____

Signature: /Lacey Gorochow/

Digitally signed by Lacey Gorochow, DN: cn=Lacey Gorochow, o=USPTO, ou=USPTO, email=Lacey.Gorochow@uspto.gov, c=US

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/A form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

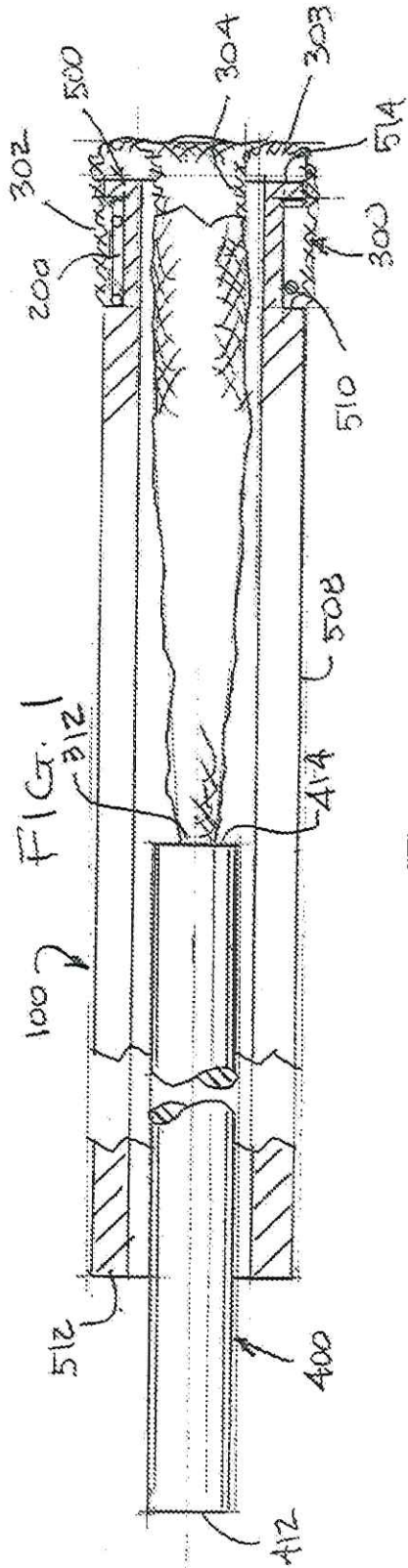


FIG. 2A

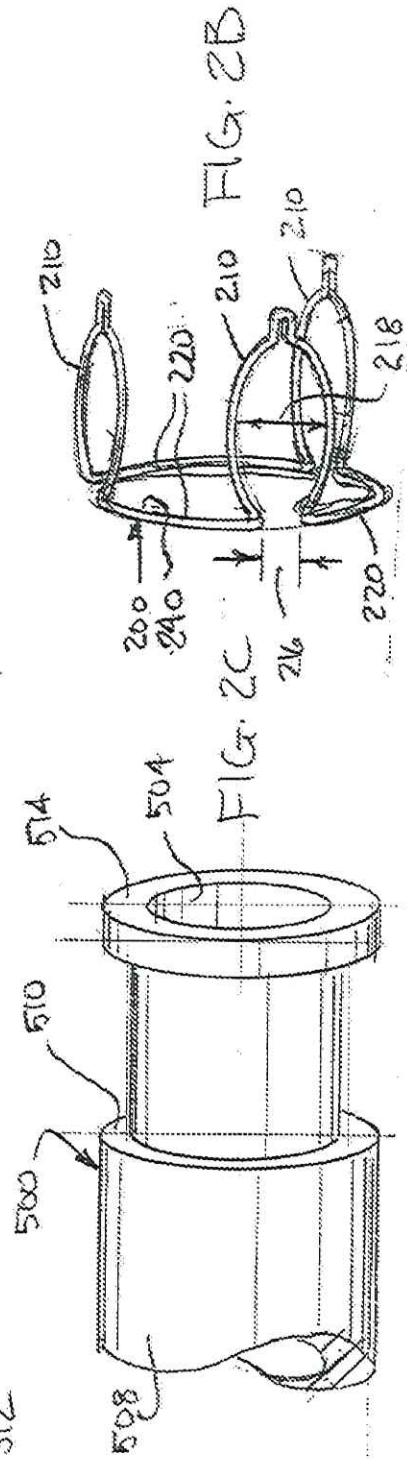
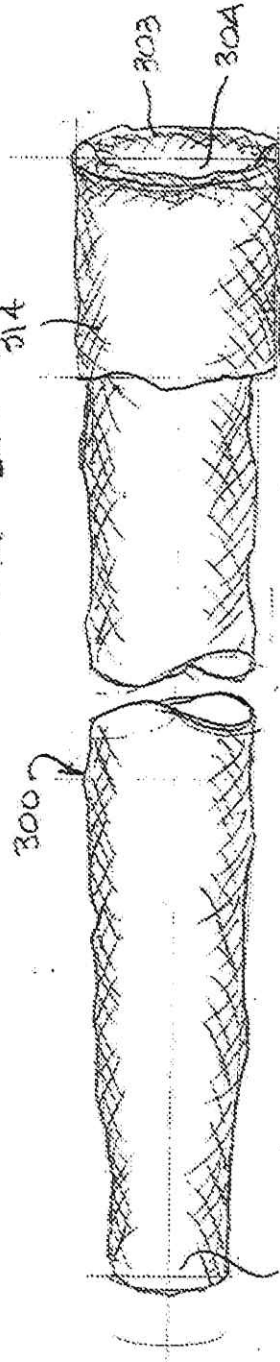


FIG. 2B

FIG. 2C

FIG. 3

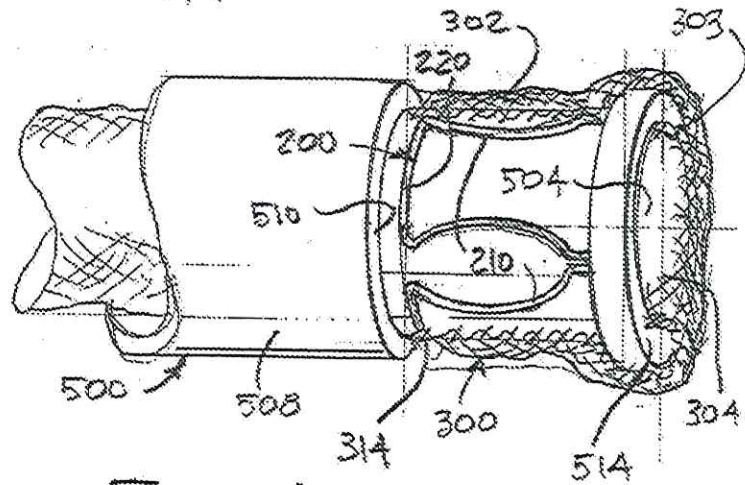


FIG. 4

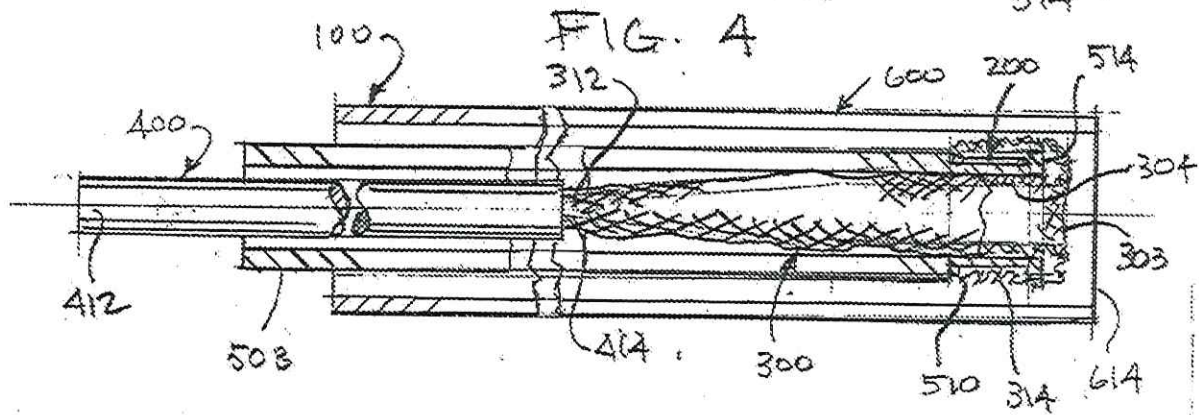


FIG. 5A

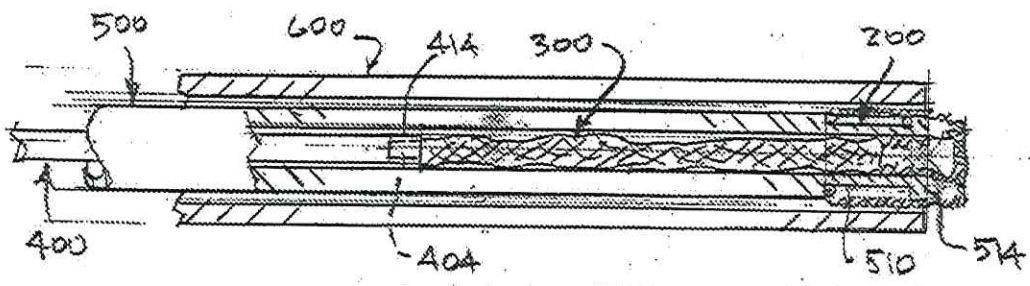


FIG. 5B

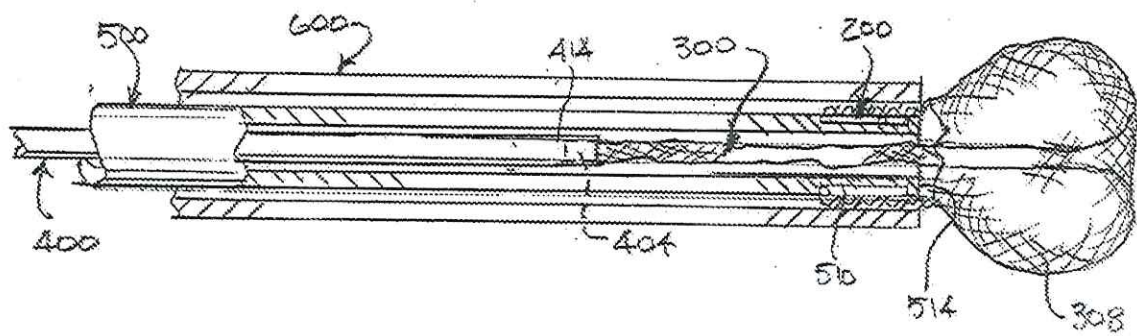


FIG. 5C

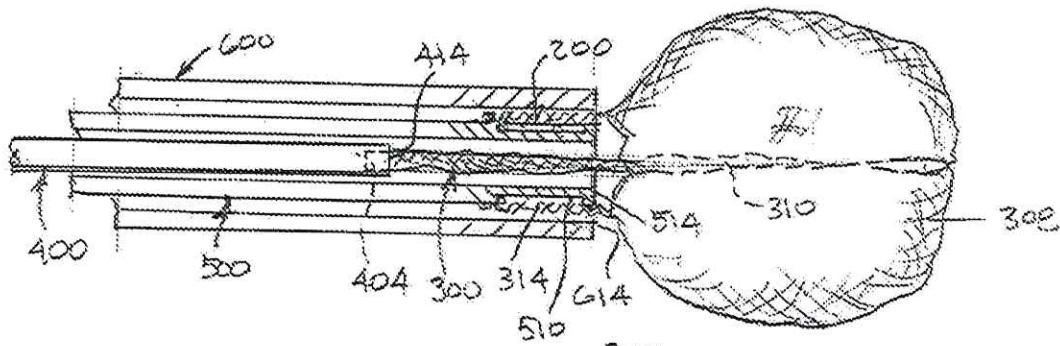


FIG. 5D

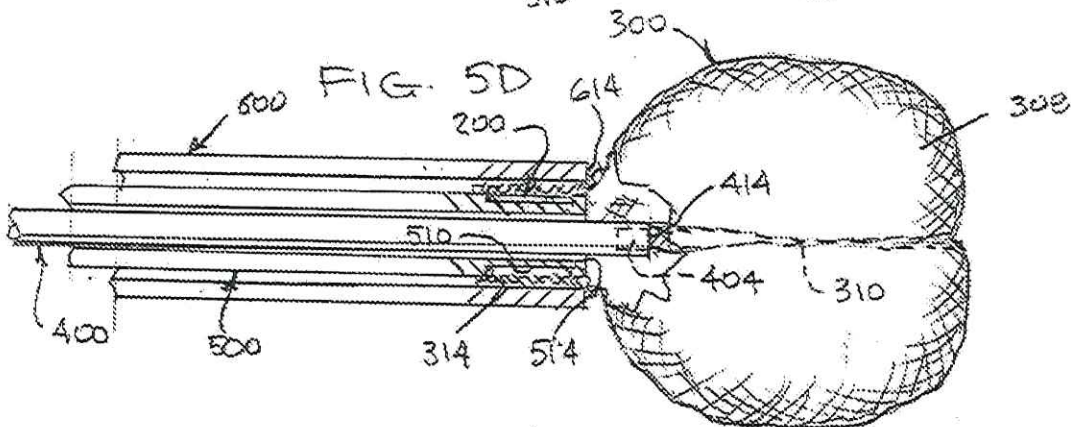


FIG. 5E

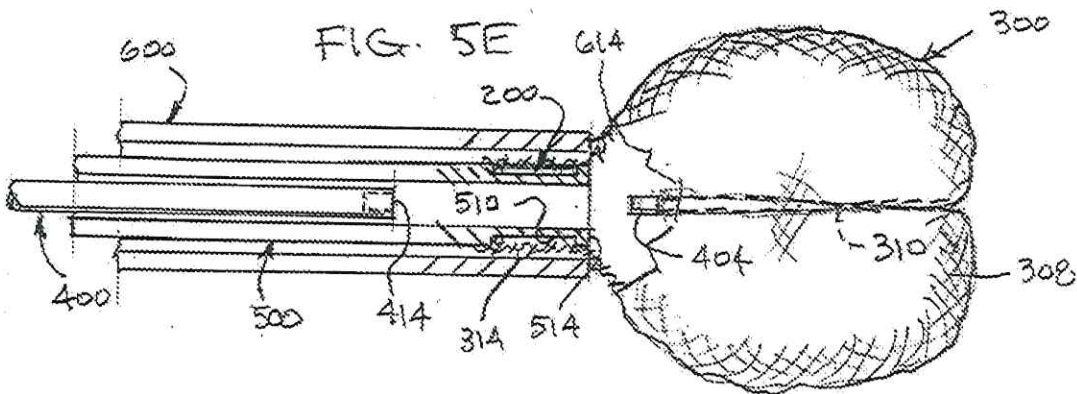


FIG. 5F

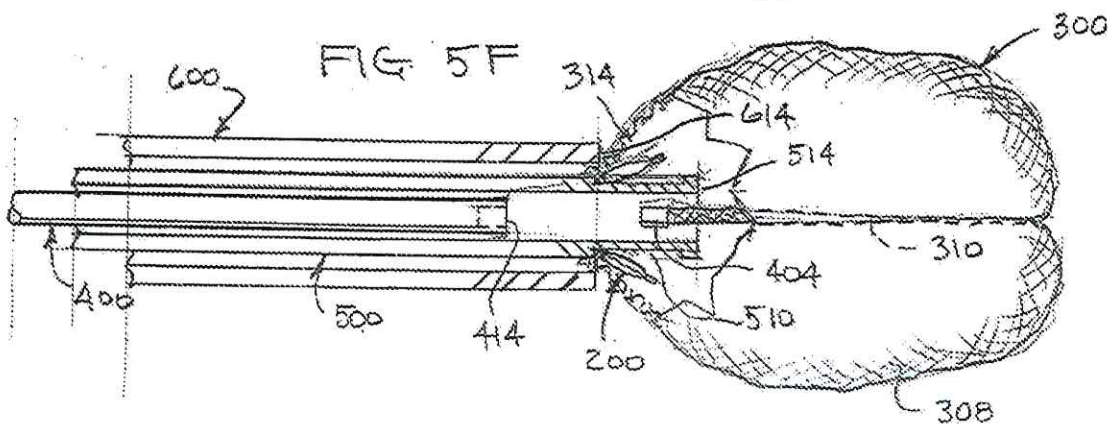


FIG 5G

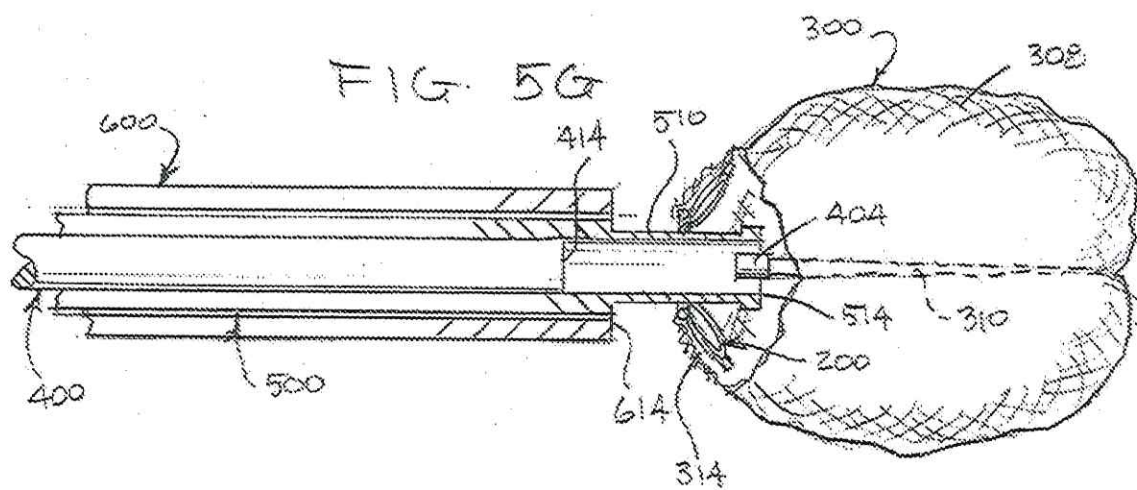
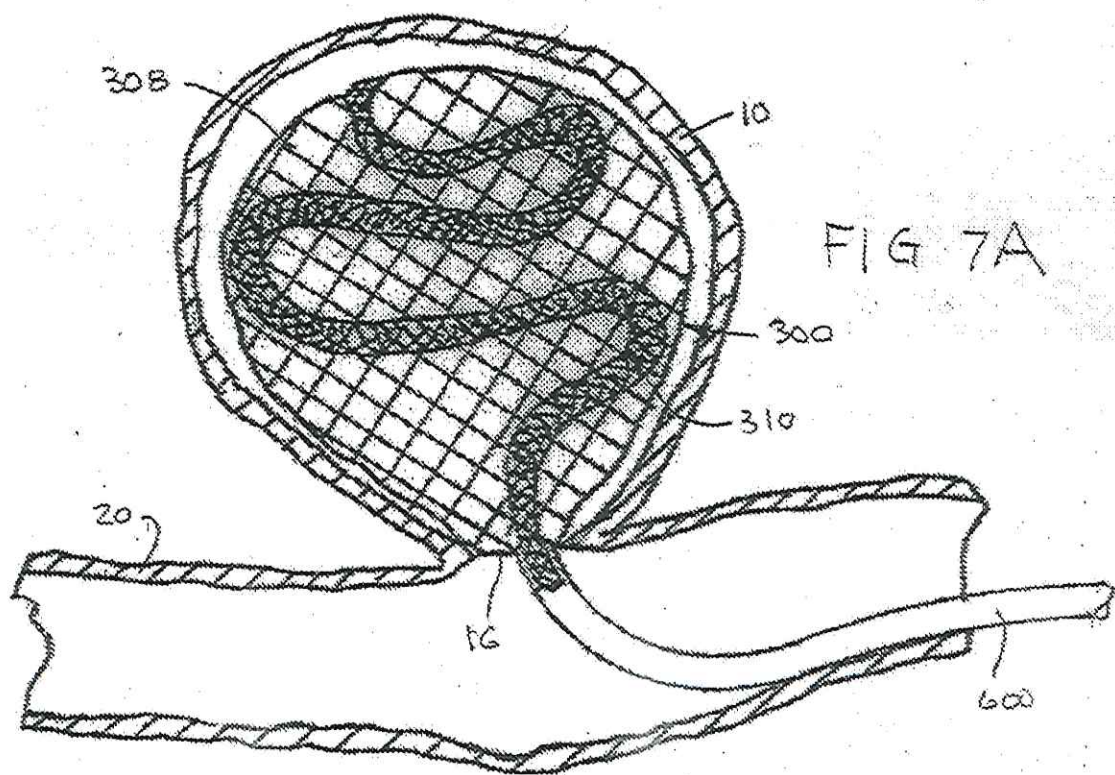
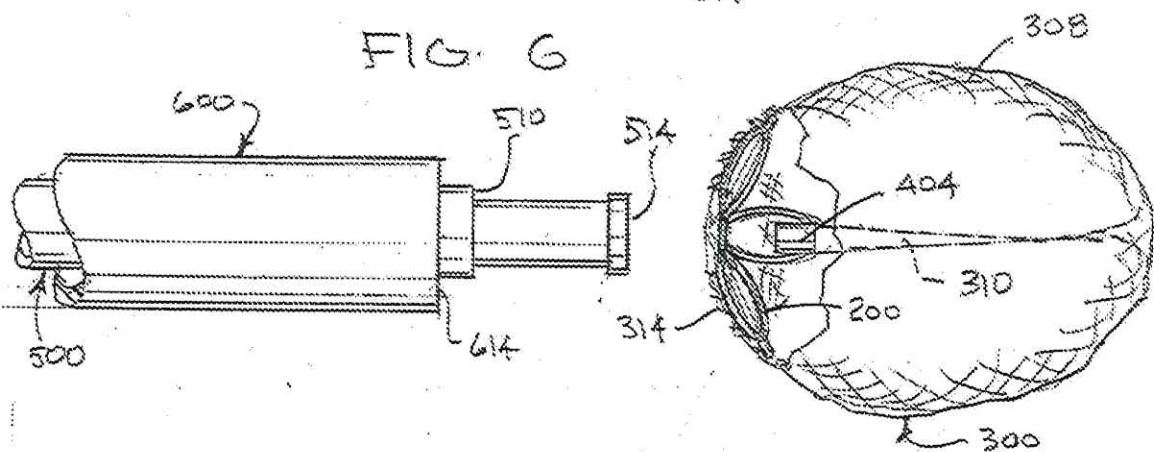


FIG 6



DSP 5391
5/9

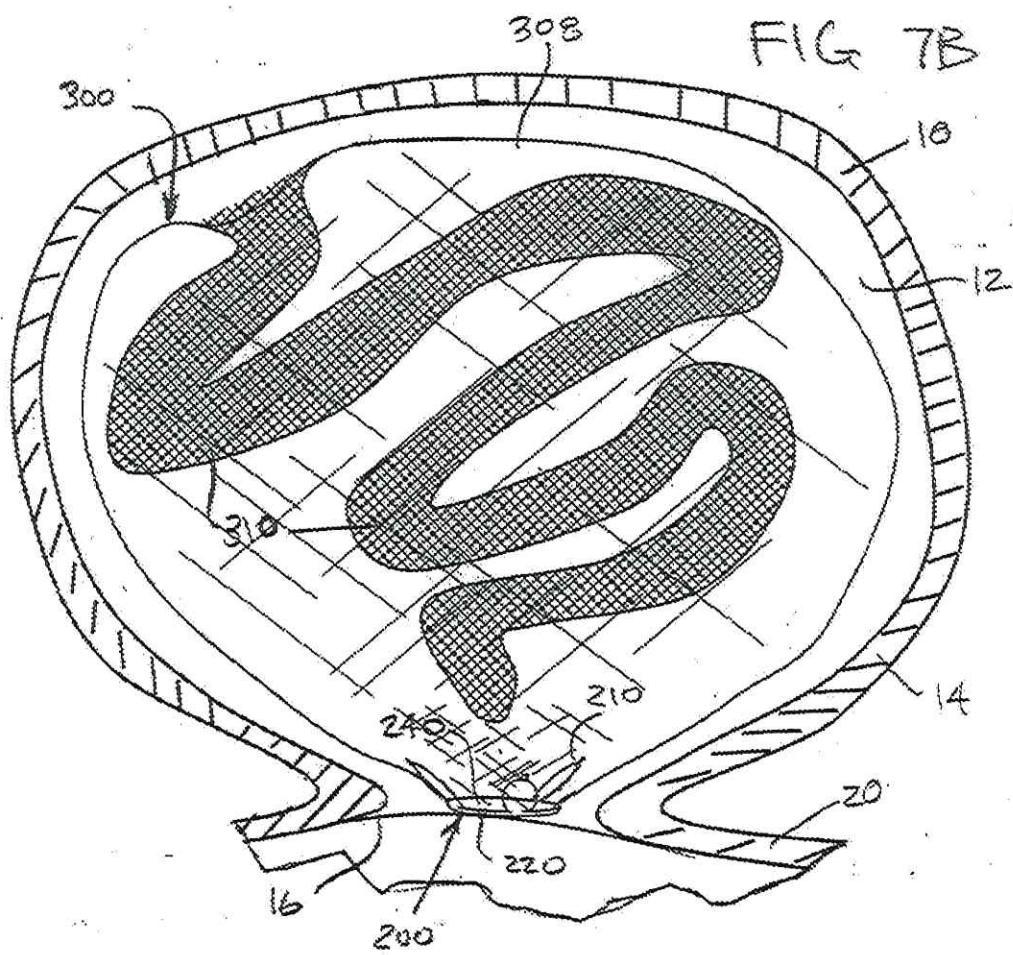
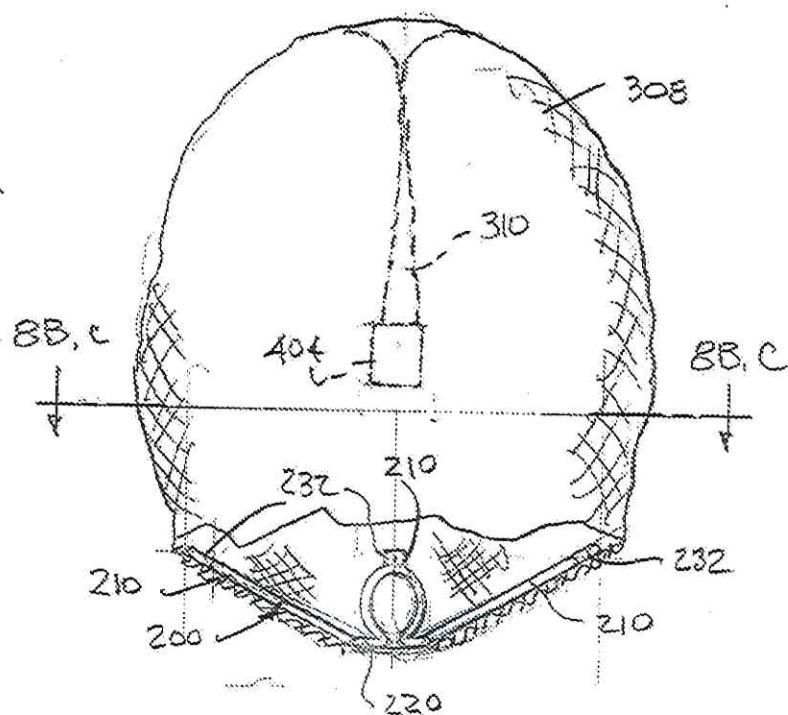


FIG. 8A



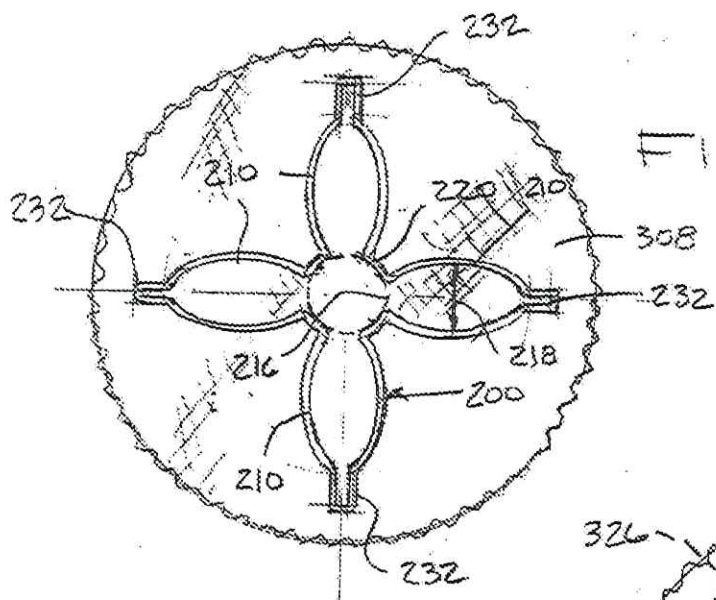


FIG. 8B

FIG. 8C

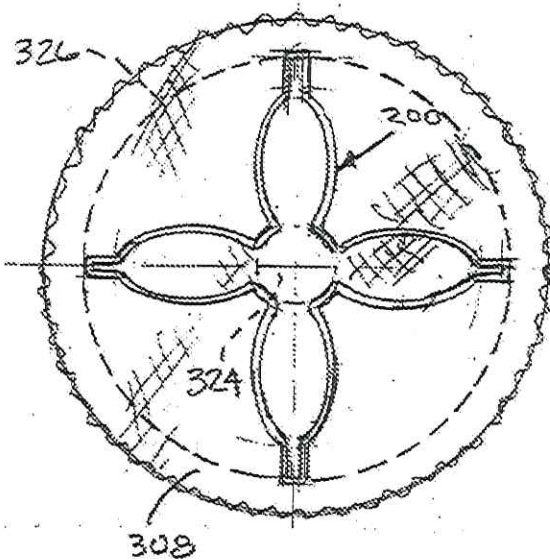


FIG. 9A

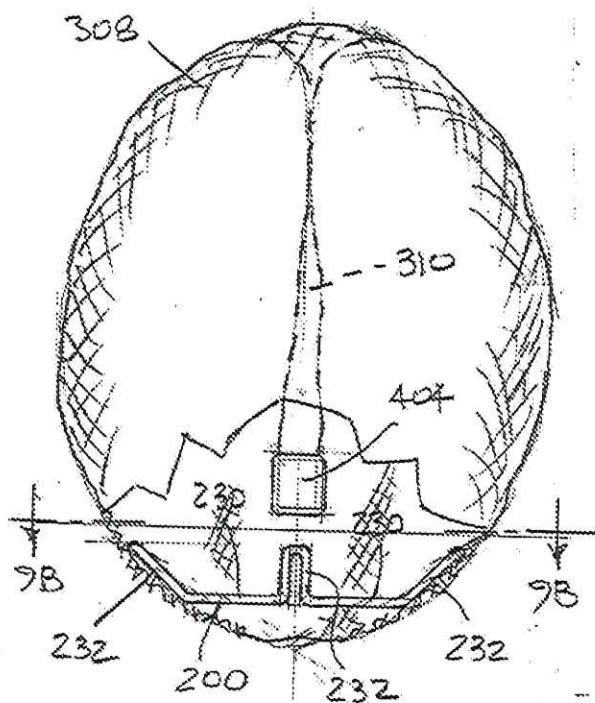
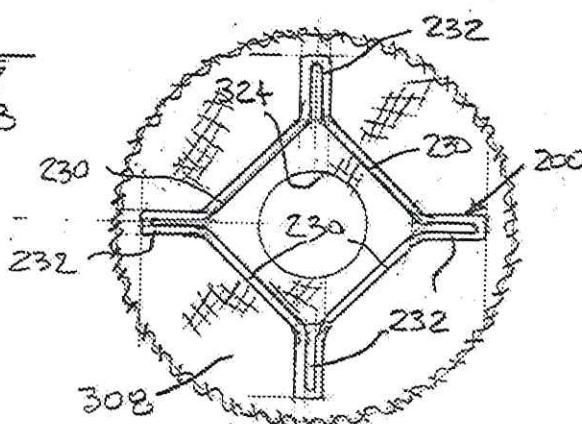


FIG. 9B



DSP 5391
7/9

FIG 10A

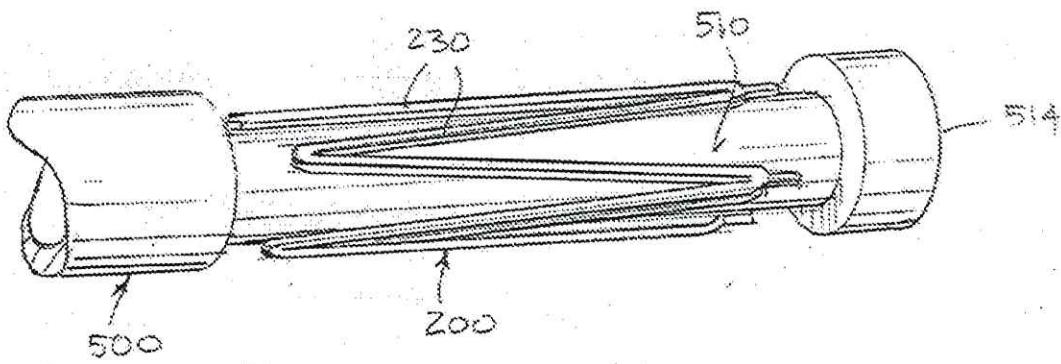
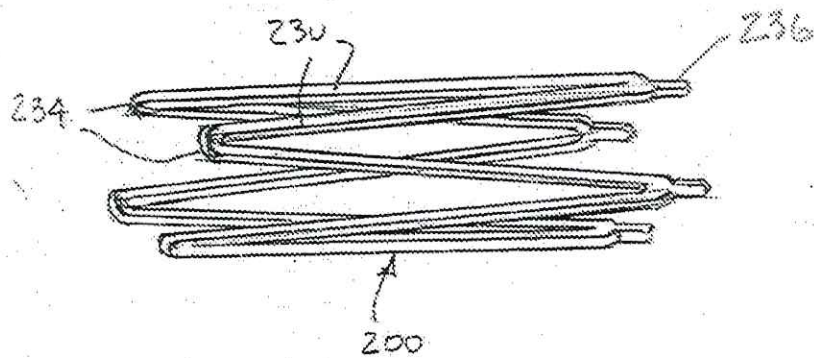


FIG 10B



DSP 5391
(8/9)

FIG. 11

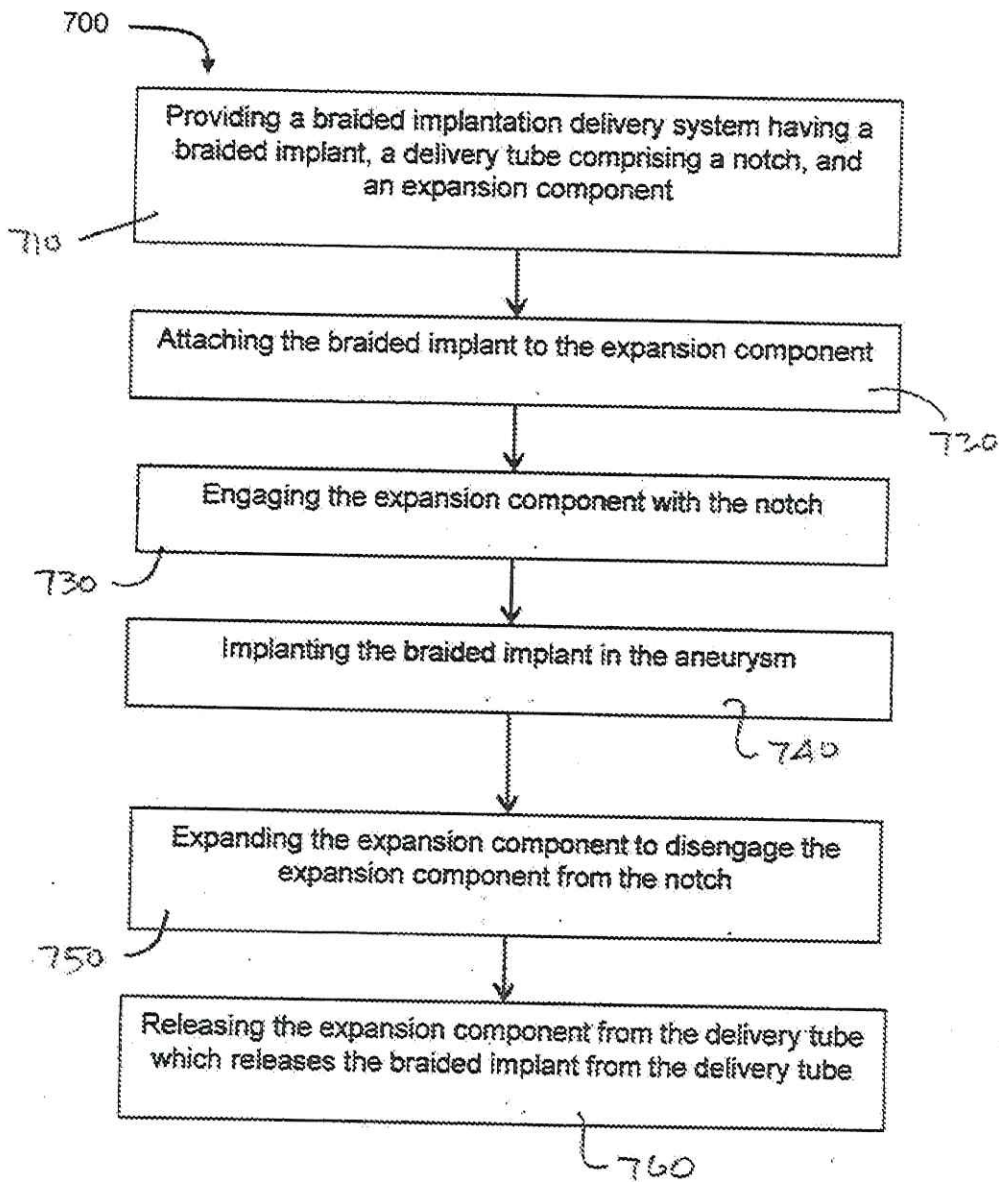
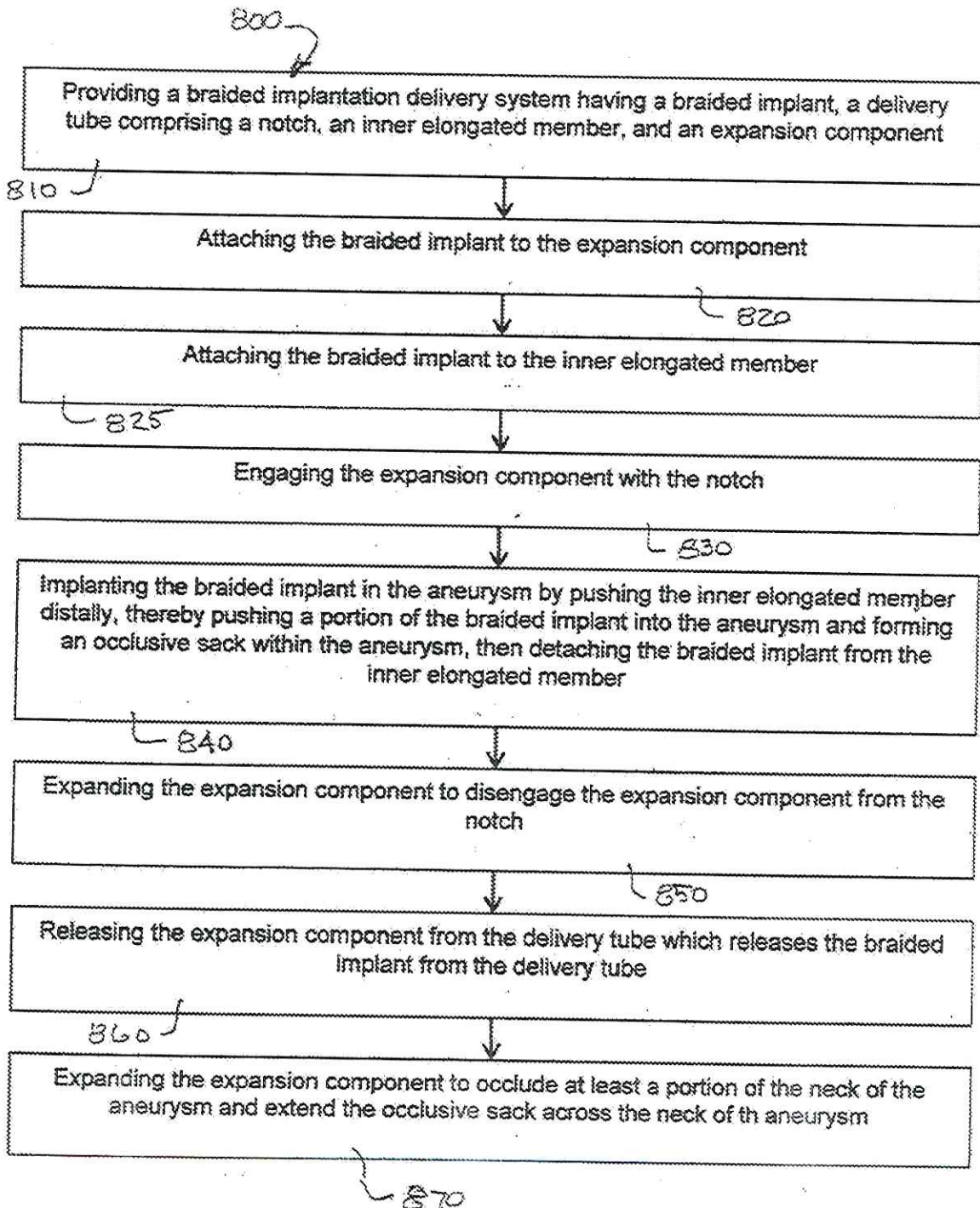


FIG. 12



Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor	1	Remove		
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Juan		LORENZO	
Residence Information (Select One) ☐ US Residency ☐ Non US Residency ☐ Active US Military Service				
City	Raynham	State/Province	MA	Country of Residence
				US
Mailing Address of Inventor:				
Address 1		c/o DePuy Synthes Products, Inc.		
Address 2		325 Paramount Drive		
City	Raynham	State/Province	MA	
Postal Code	02767	Country i	US	
Inventor	2	Remove		
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Kirk		JOHNSON	
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service				
City	Raynham	State/Province	MA	Country of Residence
				US
Mailing Address of Inventor:				
Address 1		c/o DePuy Synthes Products, Inc.		
Address 2		325 Paramount Drive		
City	Raynham	State/Province	MA	
Postal Code	02767	Country i	US	
Inventor	3	Remove		
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Lacey		GOROCHOW	
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service				

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000119		
		Application Number			
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM				
City	Raynham	State/Province	MA	Country of Residence	US
Mailing Address of Inventor:					
Address 1		c/o DePuy Synthes Products, Inc.			
Address 2		325 Paramount Drive			
City	Raynham	State/Province	MA		
Postal Code	02767	Country	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	06980		
Email Address	IPServicesNYC@troutmansanders.com	Add Email	Remove Email

Application Information:

Title of the Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		
Attorney Docket Number	243382.000119	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	9	Suggested Figure for Publication (if any)	

Filing By Reference:

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

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

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

Publication Information:

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

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		

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	06980		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78. When referring to the current application, please leave the "Application Number" field blank.

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

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

[Add](#)

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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

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

[Add](#)

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	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		

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	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		

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	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		

Applicant Information:

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

Applicant	1	Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.		
Clear		
☒ Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		
Name of the Deceased or Legally Incapacitated Inventor:		
If the Applicant is an Organization check here. ☒		
Organization Name	DePuy Synthes Products, Inc.	
Mailing Address Information For Applicant:		
Address 1	325 Paramount Drive	
Address 2		
City	Raynham	State/Province MA
Country	US	Postal Code 02767
Phone Number		Fax Number
Email Address		
Additional Applicant Data may be generated within this form by selecting the Add button.		
Add		

Assignee Information including Non-Applicant Assignee Information:

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		

Assignee	1
----------	---

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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

Organization Name	DePuy Synthes Products, Inc.
-------------------	------------------------------

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	325 Paramount Drive		
Address 2			
City	Raynham	State/Province	MA
Country ⁱ	US	Postal Code	02767
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Add

Signature:

Remove

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

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

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

Signature	/Louis J. DeJuidice - 47,522/		Date (YYYY-MM-DD)	2018-09-25	
First Name	Louis John	Last Name	DeJuidice	Registration Number	47522

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

Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000119
		Application Number	
Title of Invention	INTRASACCULAR DEVICE POSITIONING AND DEPLOYMENT SYSTEM		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

- 1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
- 2 A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4 A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5 A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6 A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7 A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8 A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9 A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.