

P-2019/36003

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIRECCIÓN DE NUEVAS CREACIONES

E. S. D.

Ref.: Expediente No. **NC2019/0008501**

Solicitud de registro de patente de invención a nombre de **DEPUY SYNTHES PRODUCTS, INC.**

Yo, CAROLINA DAZA MONTALVO, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 3, obrando **DEPUY SYNTHES PRODUCTS, INC.**, me permito dar respuesta al Oficio No. 8402 del 15 de agosto de 2019, de la siguiente manera

- 1. Prioridad:** Adjuntamos a la presente comunicación el documento de prioridad con su respectiva traducción.

Habiendo dado cumplimiento al requerimiento de este Despacho, solicito respetuosamente se continúe con el trámite de la referencia.

Atentamente,



CAROLINA DAZA MONTALVO

C.C. 66.783.790 de Palmira Valle

TP-141563 CSJ

notificaciones@clarkemodet.com.co



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

5 de agosto de 2019

POR ESTE MEDIO, SE CERTIFICA QUE EL DOCUMENTO ADJUNTO ES UNA COPIA FIEL DE LOS REGISTROS DE LA OFICINA DE PATENTES Y MARCAS DE LOS ESTADOS UNIDOS DE DICHOS DOCUMENTOS DE LA SOLICITUD DE PATENTE IDENTIFICADA A CONTINUACIÓN QUE CUMPLIÓ CON LOS REQUISITOS PARA QUE SE LE OTORGARA UNA FECHA DE PRESENTACIÓN EN VIRTUD DE LO DISPUESTO EN 35 USC 111.

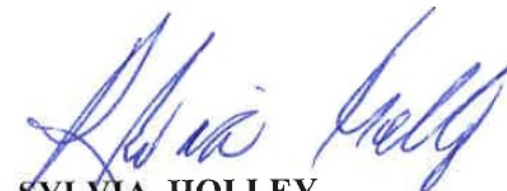
NÚMERO DE SOLICITUD: 16/054.055

FECHA DE PRESENTACIÓN: 3 de agosto de 2018

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, QUE SE USARÁN PARA LA PRESENTACIÓN EN EL EXTRANJERO EN VIRTUD DE LA CONVENCIÓN DE PARÍS, ES US16/054.055

**Por autoridad del
Subsecretario de Comercio para la Propiedad Intelectual
y Director de la Oficina de Patentes y Marcas de los Estados Unidos**




SYLVIA HOLLEY
Funcionario certificador

Reivindicaciones

1. Un sistema para liberar un implante, el sistema comprende:
un tubo de suministro que comprende un lumen a través de este, un extremo proximal, un extremo distal, y una superficie exterior que comprende una
5 ranura espiral en esta cerca del extremo distal; y
un implante trenzado que comprende un segmento espiral móvil desde una configuración de suministro hasta una configuración desplegada por una rotación del tubo de suministro en relación con el implante, la configuración de suministro acopla la ranura espiral y la configuración desplegada desacopla la ranura espiral.
10
2. El sistema de la reivindicación 1 en donde el segmento espiral en la configuración de suministro comprende una primera hélice de forma circular y la ranura espiral comprende una segunda hélice de forma circular, y en donde el segmento espiral está ubicado en la ranura espiral.
15
3. El sistema de la reivindicación 1 en donde el implante trenzado comprende:
un doblez ubicado distal al extremo distal del tubo de suministro;
un segmento de doblez exterior acoplado al segmento espiral y ubicado sobre una porción de la superficie exterior del tubo de suministro; y
20 un segmento de doblez interior que comprende una estructura sustancialmente tubular ubicada dentro del lumen del tubo de suministro.

4. El sistema de la reivindicación 3 que comprende, además, un miembro alargado interior que comprende un extremo proximal que se extiende proximal al extremo proximal del tubo de suministro y un extremo distal ubicado dentro del lumen del tubo de suministro acoplado de manera desmontable a un extremo del segmento de doblez interior.

5

5. El sistema de la reivindicación 1 en donde el implante trenzado comprende, además, un saco oclusivo que comprende una abertura, y en donde la abertura está al menos parcialmente obstruida por el segmento espiral en la configuración desplegada.

10

6. El sistema de la reivindicación 5, en donde la abertura comprende un perímetro y un centro, y en donde el segmento espiral comprende un extremo acoplado acoplado al saco oclusivo cerca del perímetro y un extremo de terminación ubicado cerca del centro de la abertura en la configuración desplegada.

15

7. El sistema de la reivindicación 2 en donde el segmento de doblez exterior y el segmento espiral comprenden cada uno una estructura tejida que comprende una fibra tejida común a ambos el segmento de doblez exterior y el segmento espiral.

20

8. El sistema de la reivindicación 1 en donde el segmento espiral comprende una estructura no tejida.

9. Un dispositivo para tratar un aneurisma, el dispositivo comprende:

un miembro de suministro tubular que comprende un lumen a través de este, un extremo distal, una superficie exterior, y una estructura helicoidal en la superficie exterior;

un implante tubular trenzado móvil de una configuración de suministro a una configuración implantada,

la configuración de suministro comprende un segmento tubular que se extiende proximalmente dentro del lumen del miembro de suministro tubular y un segmento de doblez exterior que cubre una porción de la superficie exterior del miembro de suministro tubular, y

la configuración implantada comprende un saco oclusivo que comprende una abertura; y

un elemento enroscado móvil desde una configuración de acoplamiento a una configuración de oclusión,

la configuración de acoplamiento acopla la estructura helicoidal, y

la configuración de oclusión obstruye al menos una porción de la abertura del saco oclusivo.

10. El dispositivo de la reivindicación 9, en donde, en la configuración acoplada, el elemento enroscado comprende un segmento enroscado en la forma de una hélice circular, el segmento enroscado se acopla a la estructura helicoidal.

11. El dispositivo de la reivindicación 10 en donde la estructura helicoidal es una muesca en la forma de una hélice circular.

12. El dispositivo de la reivindicación 9 en donde, en la configuración ocluida, el elemento enroscado comprende un segmento enroscado en la forma de una hélice cónica o un espiral plano.

5 13. El dispositivo de la reivindicación 12 en donde el elemento enroscado comprende una porción fija fijada al implante trenzado, y en donde el segmento enroscado comprende:

un extremo fijo fijado a la porción fija del elemento enroscado;

un extremo de terminación;

una primera circunferencia medida a lo largo del segmento enroscado desde el

10 extremo fijo a través de un giro de la hélice cónica o espiral plano en la dirección del extremo de terminación; y

una segunda circunferencia medida a lo largo del segmento enroscado del extremo de terminación mediante un giro de la hélice cónica o espiral plano en la dirección del extremo fijo, la segunda circunferencia mide menos que la

15 primera circunferencia.

14. El dispositivo de la reivindicación 9 en donde el elemento enroscado comprende un metal con memoria de forma, y el elemento enroscado se mueve de una forma deformada en la configuración de acoplamiento a una forma

20 predeterminada en la configuración de la oclusión.

15. Un método para tratar un aneurisma, el método comprende:

proporcionar un sistema de suministro de implante trenzado que comprende un implante trenzado que comprende un segmento espiral y un tubo de suministro que comprende una ranura espiral;

acoplar el segmento espiral a la ranura espiral;

5 implantar el implante trenzado en el aneurisma;

hacer girar el tubo de suministro en relación con el segmento espiral del implante trenzado para desacoplar el segmento espiral de la ranura espiral; y liberar el segmento espiral del tubo de suministro que libera el implante trenzado del tubo de suministro.

10

16. El método de la reivindicación 15, que comprende, además, la etapa de oclusión de al menos una porción del cuello del aneurisma con el segmento espiral.

17. El método de la reivindicación 16 en donde la etapa de implantar el implante

15 trenzado en el aneurisma comprende la etapa de formar un saco oclusivo exterior que comprende una abertura, y

en donde la etapa de oclusión de al menos una porción del cuello del aneurisma comprende, además, la etapa de obstruir la al menos una porción de la abertura del saco oclusivo.

20

18. El método de la reivindicación 15 que comprende, además, la etapa de mover una porción del segmento espiral de una hélice de forma circular a una hélice de forma cónica.

19. El método de la reivindicación 15,
 en donde la etapa de implantar el implante trenzado en el aneurisma comprende,
 además, la etapa de formar un saco oclusivo dentro del aneurisma; y
 en donde el método comprende, además, las etapas de:

5 poner en contacto una pared del aneurisma con el saco oclusivo, y
 resistir, a través del contacto entre la pared del aneurisma y el saco
 oclusivo, una rotación del saco oclusivo en respuesta a la rotación del
 tubo de suministro.

10 20. El método de la reivindicación 15,
 en donde el sistema de suministro de implantación trenzada comprende,
 además, un miembro alargado interior y el tubo de suministro comprende un
 lumen a través de este;

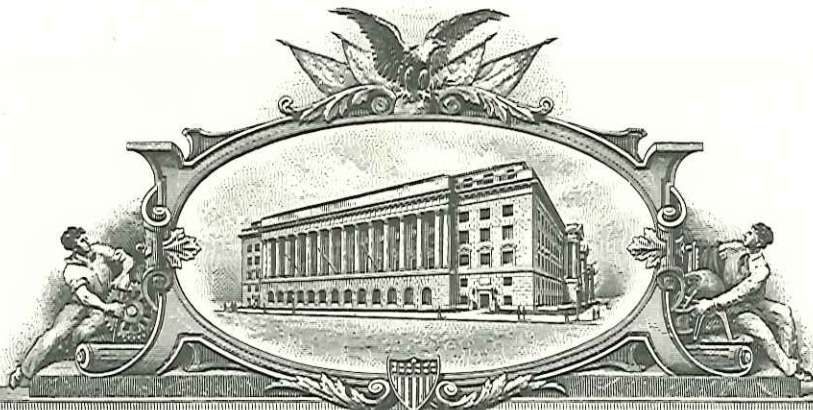
en donde el método comprende, además, las etapas de:

15 ubicar el miembro alargado interior en el lumen del tubo de suministro;
 acoplar el implante trenzado al miembro alargado interior; y

en donde la etapa de implantar el implante trenzado en el aneurisma

comprende, además, las etapas de

 empujar el miembro alargado interior distalmente invirtiendo, de esta manera,
 20 el implante trenzado y formando un saco oclusivo dentro del aneurisma, y
 desacoplar el implante trenzado del miembro alargado interior.



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 05, 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.**

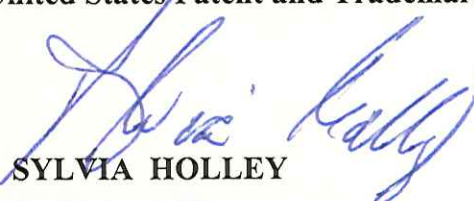
APPLICATION NUMBER: 16/054,055

FILING DATE: August 03, 2018

**THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY
APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS
CONVENTION, IS US16/054,055**

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




SYLVIA HOLLEY
Certifying Officer

Electronic Acknowledgement Receipt	
EFS ID:	33367295
Application Number:	16054055
International Application Number:	
Confirmation Number:	3787
Title of Invention:	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID
First Named Inventor/Applicant Name:	Lacey GOROCHOW
Customer Number:	6980
Filer:	Louis J. DelJuidice/Wendy Higgins
Filer Authorized By:	Louis J. DelJuidice
Attorney Docket Number:	243382.000121
Receipt Date:	03-AUG-2018
Filing Date:	
Time Stamp:	12:21:55
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	080318INTEFSW00010167201507
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	TRANSMITTAL.pdf	219632	no	1
			66ed9fa7925ebc79880a7ab7fd6a4986aad6f1df		
Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1276728	no	8
			e7b85fec6a8a48616a112ad82832fbc6e880bdb9		
Warnings:					
Information:					
3	Oath or Declaration filed	DECLARATION.pdf	54574	no	1
			8dee292b561a9a87f4dc18e7fe372b5a82408a18		
Warnings:					
Information:					
4	Power of Attorney	POA.pdf	727080	no	5
			c4a2b3163b77408e68e9987a9b430148a0c0af5c		
Warnings:					
Information:					
5		SPECIFICATION.pdf	162800	yes	23
			c43473954ccb7b3d5a236fd5ca632d9d4555b983		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Abstract		23	23	
	Claims		17	22	
	Specification		1	16	

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.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	243382.000121
	First Named Inventor	Lacey GOROCHOW
	Title	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID
	Priority Mail Express® Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
--	---

1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent)	ACCOMPANYING APPLICATION PAPERS
2. ☐ Applicant asserts small entity status. See 37 CFR 1.27	
3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.	
4. ☒ 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)	
5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 10]	
6. Inventor's Oath or Declaration [Total Pages 1] (Including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☒ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d))	
7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent)	
8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD	
9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	
10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____	
11. ☒ 37 CFR 3.73(c) Statement (when there is an assignee) ☒ Power of Attorney	
12. ☐ English Translation Document (if applicable)	
13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached	
14. ☐ Preliminary Amendment	
15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized)	
16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)	
17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.	
18. ☐ 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 2018-08-03	
Name (Print/Type) Louis John DelJuidice				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.

Warnings:					
Information:					
6	Drawings-only black and white line drawings	DRAWINGS.pdf	4191962 78194b6806bc5c6b96f82488cbac787ad505a842	no	10
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	34949 46752915387c1a7b389af754d4ae64d06d77b5bc	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			6667725		
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.					

SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID

Field of Invention

This disclosure 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 a 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

vessel shape along the neck plane. However, embolic coils delivered to the neck of the aneurysm can potentially have the adverse effect of impeding the flow of blood in the adjoining blood vessel; at the same time, if the entrance is insufficiently packed, blood flow can persist into the aneurysm. Properly implanting embolic coils is therefore challenging, and once implanted, the coils cannot easily be retracted or repositioned.

Furthermore, embolic coils do not always effectively treat aneurysms as aneurysms treated with multiple coils often recanalize or compact because of poor coiling, lack of coverage across the aneurysm neck, because of flow, or even aneurysm size.

An example alternative occlusion device is described in U.S. Pat. No. 8,998,947. However, this approach relies upon the use of embolic coils or mimics the coil approach and therefore suffers many of the limitations of embolic coil approaches such as difficulty achieving a safe packing density and inability to reposition once implanted.

It is therefore desirable to have a device which easily, accurately, and safely occludes a neck of an aneurysm or other arterio-venous malformation in a parent vessel without blocking flow into perforator vessels communicating with the parent vessel.

Summary

Disclosed herein are various exemplary devices and systems of the present invention that can address the above needs. The devices generally can include a delivery tube having a spiral groove on an outer surface of the delivery tube and a braided implant having a spiral segment. The spiral segment can engage the spiral groove as the braided implant is delivered to an aneurysm treatment site. At the treatment site, the braided implant can be implanted, and the delivery tube can be rotated to disengage the spiral segment from the spiral groove. Once released, the spiral segment can reshape to occlude the neck of the aneurysm.

In one example, a system can include a delivery tube and a braided implant. The delivery tube can have a lumen, a proximal end, a distal end, and an outer surface with a spiral groove positioned near the distal end. The braided implant can have a spiral segment movable from a delivery configuration that engages the spiral groove to a deployed configuration that disengages the spiral groove. A rotation of the delivery tube in relation to the implant can move the spiral segment from the delivery configuration to the deployed configuration.

In the delivery configuration, the spiral segment and the spiral groove can each have a circular helix shape, and the spiral segment can be positioned in the spiral groove.

The braided implant can include an outer fold segment attached to the spiral segment that can be positioned over a portion of the outer surface of the delivery tube, a fold that can be positioned distal the distal end of the delivery tube, and an inner fold segment having a substantially tubular structure that can be positioned within the lumen of the delivery tube.

An inner elongated member can be positioned within the lumen of the delivery tube and can have a proximal end extending proximally from the proximal end of the delivery tube and a distal end positioned within the lumen of the delivery tube detachably attached to an end of the inner fold segment of the braided implant.

The braided implant can form an occlusive sack having an opening, and the opening can be at least partially obstructed by the spiral segment when in the deployed configuration. The opening can have a perimeter and a center. In the deployed configuration, one end of the spiral segment can attach to the occlusive sack near the perimeter while the other end can terminate near the center.

The outer fold segment and the spiral segment can each have a woven structure with a woven fiber common to both segments. Alternatively, the spiral segment can have a non-woven structure.

An example device for treating an aneurysm can include a tubular delivery member, a braided tubular implant, and a coiled element. The tubular delivery member can have a lumen, a distal end, an outer surface, and a helical structure on the outer surface. The braided tubular implant can be movable from a delivery configuration having a tubular segment extending proximally within the lumen of the tubular delivery member and an outer fold segment covering a portion of the outer surface of the delivery tube member to an implanted configuration having an occlusive sack with an opening. The coiled element can be movable from an engaging configuration that engages the helical structure on the tubular delivery member to an occluding configuration that obstructs at least a portion of the opening of the occlusive sack.

In the engaged configuration, the coiled element can have a coiled segment in the shape of a circular helix that can engage the helical structure. The helical structure can be an indentation in the shape of a circular helix.

In the occluding configuration, the coiled element can have a coiled segment in the shape of a conical helix or a planar spiral. The coiled element can have an affixed portion that can be affixed to the braided implant, and the coiled segment can have an affixed end that can be affixed to the affixed portion and a terminating end. The coiled segment can be in a shape having a first circumference measured along the coiled segment from the affixed end through one turn of the conical helix or planar spiral in the direction of the terminating end and a second circumference measured along the coiled segment from the terminating end through one turn of the conical helix or planar spiral in the direction of the affixed end such that the second circumference measures shorter than the first circumference.

The coiled element can be made of a memory shape metal, and the coiled element can move from a deformed shape in the engaging configuration to a predetermined shape in the occluding configuration.

An example method for treating an aneurysm can include the steps of providing a braided implant delivery system having a delivery tube and a braided implant, engaging a spiral segment of the braided implant with a spiral groove of the delivery tube, implanting the braided implant in the aneurysm, rotating the delivery tube in relation to the spiral segment to disengage the spiral segment from the spiral groove, and releasing the spiral segment from the delivery tube which releases the braided implant from the delivery tube.

The step of implanting the braided implant in the aneurysm can include the step of forming an occlusive sack within an aneurysm, the occlusive sack having an opening.

The method can include the step of occluding at least portion of the neck of the aneurysm with the spiral segment, and the neck can be occluded by obstructing the at least a portion of the opening of the occlusive sack.

The method can include the step of moving a portion of the spiral segment from a circular helix shape to a conical helix shape.

The method can include the steps of contacting a wall of the aneurysm with the occlusive sack, and resisting, via the contact between the aneurysm wall and the occlusive sack, a rotation of the occlusive sack in response to the rotating of the delivery tube.

The step of providing the braided implantation delivery system can include providing a delivery system that additionally includes an inner elongated member, and the method can further comprise the steps of positioning the inner elongated member in a lumen of the delivery tube and attaching the braided implant to the inner elongated member. The step of implanting the braided implant in the aneurysm can further include the steps of pushing the inner elongated member distally to invert the braided implant and form an occlusive sack within 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.

Figs. 1a illustrates an exploded view of a braided implant and a delivery tube according to the present invention;

Fig. 1b illustrates a braided implant engaged with a delivery tube according to the present invention;

Fig. 1c illustrates a cross-sectional view of the braided implant and the delivery tube of Fig. 1b according to the present invention;

Fig. 2 illustrates a cut-sectional view delivery system according to the present invention;

Fig. 3 illustrates a cut-away of an aneurysm during treatment according to the present invention;

Figs. 4a to 4e illustrate a method of use of a device of the present invention;

Fig. 5 illustrates a cut-away of an aneurysm implanted with a braided implant according to the present invention;

Fig. 6 illustrates a view of a braided implant as viewed at the neck of an aneurysm treated according to the present invention;

Figs. 7a to 7b illustrate a braided implant and a coiled element according to the present invention;

Fig. 8a illustrates a braided implant and a coiled element according to the present invention;

Fig. 8b illustrates a view of the braided implant and coiled element of Fig. 8a as viewed at the neck of an aneurysm treated according to the present invention; and

Figs. 9 to 11 are flow diagrams outlining example method steps for use of a device 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 a higher packing density, ability to retract and reposition the implant during the implantation procedure, ability to be implanted without ancillary devices such as stents or balloons, reduced risk of recanalizing 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 the implant and the delivery system until the implant is in place at the treatment site, then detach the implant so that the delivery system can be extracted. When implanted in an aneurysm, for example, the delivery system can also serve to 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.

Fig. 1a illustrates an exploded view of a braided implant 300 and a delivery tube 500. The braided implant 300 is shown in a delivery configuration, shaped to be delivered to a treatment site by the delivery tube 500. Fig. 1b illustrates the braided implant 300 engaged with the delivery tube 500. The assembly illustrated in Fig. 1b is sized to be inserted into and travel through a

microcatheter 600 to a treatment site. The microcatheter 600 is shown cut-away in Fig. 1b, and the delivery system is shown approaching a distal end 614 of the microcatheter 600. Fig. 1c illustrates a cross-section of the braided implant 300, delivery tube 500, and microcatheter as indicated in Fig. 1b.

Referring to Figs. 1a to 1c collectively, the braided implant 300 can have an inner fold segment 304 shaped to be positioned within a lumen 504 of the delivery tube 500, a fold 303 that can be positioned distal a distal end 514 of the delivery tube 500, an outer fold segment 302 that can extend proximally from the fold 303 to cover a portion of an outer surface 508 of the delivery tube 500, and a spiral segment 350 that can engage a spiral groove 550 on the delivery tube 500.

The spiral segment 350 can be elongated with a helical, coiled, or spiral shape. The spiral segment 350 can have an attached end 354 attached to the outer fold segment 302 and can extend proximally to a terminating end 352. The spiral segment 350 can include a woven material with a weave that is common to the braided implant 300 such that the weave of the outer fold segment 302 and the weave of the spiral segment 350 share a common fiber. Alternatively, the spiral segment 350 can include a non-woven material and can be attached to the braided implant 300 by some other means.

The spiral segment 350 and the spiral groove 550 can be compatibly dimensioned so that the spiral segment 350 stays in place within the groove as the system is delivered through a catheter 600 to a treatment site. The groove can be deep enough for the spiral segment 350 to fit in without falling out. The width of the groove can be dimensioned to a fit such that the spiral segment 350 has minimal room to move within the groove.

Fig. 2 shows a cross-section of a delivery system including a delivery tube 500, a braided implant 300, and an inner elongated member 400. The length of the delivery system has been truncated for the purposes of the illustration.

The delivery system can be sized to be delivered to a treatment site through a catheter or microcatheter 600. The proximal end 412 of the inner elongated member 400 can extend from the proximal end 512 of the delivery tube 500, which can in turn extend from the proximal end 612 of the delivery catheter 600. The proximal end of the delivery system can be made available to a user to facilitate positioning and implantation of the braided implant 300 at a treatment site.

The braided implant 300 can include an inner fold segment 304, extending proximally during delivery and attaching at a first end 312 to the inner elongated member 400. A first end 312 of the braided implant 300 can be detachably attached to the inner elongated member 400 at a distal end 414 by a braid release 404. The inner elongated member 400 can be positioned within the lumen 504 of the delivery tube 500 having a proximal end 412 extending proximal from a proximal end 512 of the delivery tube 500.

During delivery, the inner fold segment 304 can be enveloped by the delivery tube 500 and held at the first end 312 by the inner elongated member 400. Once the delivery system is positioned at a treatment site, the inner elongated member 400 can be pushed distally, causing the inner fold segment 304 of the braided implant 300 to exit the distal end 514 of the delivery tube 500. The first end 312 of the braided implant 300 can be detached from the inner elongated member 400 at the braid release 404.

As shown in Fig. 2, the braided implant 300 can have a fold 303 distal the distal end 514 of the delivery tube 500 and an outer fold segment 302 extending proximally over an outer surface 508 of the delivery tube 500 to a second end 314 of the braided implant 300. The second end 314 of the braided implant 300 can be attached to a spiral segment 350 that can engage a spiral groove 550 in the outer surface 508 of the delivery tube 500.

Fig. 3 illustrates a cut-away of an aneurysm 10 during treatment of a delivery system including a braided implant 300. The braided implant 300 can be delivered through a blood vessel

20 to an opening 16 in the blood vessel wall 22 by a microcatheter 600. As shown, the braided implant 300 can invert to form an occlusive sack 308 that can extend to contact the aneurysm wall 14 and fill the aneurysm sac 12. Portions of the braided implant 300 not inverted can be pushed into the occlusive sack 308 by the inner elongated member 400, forming an embolic filler braid 310. Fig. 3 shows the braided implant 300 partially implanted, such that a portion of the inner fold segment 304 remains in the delivery catheter 600.

Figs. 4a to 4e illustrate a method of treating an aneurysm 10 with a braided implant delivery system. Fig. 4a shows the system positioned within a blood vessel 20 at the aneurysm neck 16. Fig. 4a shows the braided implant 300 in a delivery configuration and the spiral segment 350 in an engaging configuration engaging the delivery tube 500.

Fig. 4b shows an occlusive sack 308 and an embolic filler braid 310 that can be formed by inverting a portion of an inner fold segment 304 of the braided implant 300 and ejecting a non-inverted portion of the inner fold segment 304 respectively.

Fig. 4c shows the spiral segment 350 moving distally in response to a rotation of the delivery tube 500. The spiral segment 350 can be sized to easily glide within the spiral groove 550 as the delivery tube 500 is rotated. The occlusive sack 308 can contact the aneurysm wall 14, providing a resistance to prevent the implant 300 from rotating in response to the rotation of the delivery tube 500. As shown, the spiral segment 350 can exit the distal end 614 of the microcatheter 600 as it moves distally in response to the rotation. Alternatively (not shown), the microcatheter 600 can be retracted before rotation of the delivery tube 500.

Fig. 4d shows the spiral segment 350 continuing to move distally in response to continued rotation of the delivery tube 500. As portions of the spiral segment 350 disengage the spiral groove 550, the spiral segment 350 can begin to flatten or reshape.

Fig. 4e shows the spiral segment 350 disengaged with the delivery tube 500 and reshaped to an occluding configuration. As shown, the spiral segment 350 can move from a circular helix shape in the engaged configuration to a conical helix shape in the occluding configuration. Alternatively, the spiral segment 350 can be otherwise shaped in either the engaging or occluding configuration as will be understood by a person of ordinary skill in the art; for example, the spiral segment 350 can occlude an aneurysm neck with a shape such as a planar spiral.

Movement of the spiral segment 350 from the engaged configuration to the occluding configuration can be accomplished by various means. For example, the spiral segment 350 can be made with a memory shape metal having a predetermined shape and a deformed shape. In such an example, the spiral segment 350 can have a deformed shape in the engaging configuration; a rotation of the delivery tube 500 can cause the spiral segment 350 to contact bodily fluid as the spiral segment 350 exits the microcatheter 600; and the spiral segment 350 can move to the predetermined shape in response to contacting the bodily fluids, the spiral segment 350 having the predetermined shape in the occluding configuration.

Alternatively, the spiral segment 350 can be made with an elastically deformable material. In such an example, the spiral segment 350 can have a stretched shape in the engaging configuration and can be sized to fit within a spiral groove 550 on an outer surface 508 of the delivery tube 500; a rotation of the delivery tube 500 can cause the spiral segment 350 to glide off of the distal end 514 of the delivery tube 500; and the spiral segment 350, now uninhibited by the delivery tube 500, can return to its original shape, the spiral segment 350 having the original shape in the occluding configuration.

Fig. 5 shows a cut-away view of an aneurysm 10 implanted with a braided implant 300. The braided implant 300 can form an occlusive sack 308 that can extend to the aneurysm wall 14, and the occlusive sack 308 can be filled with an embolic braid 310. The occlusive sack 308 and

the embolic braid 310 can pack the aneurysm 10 to create a thrombotic mass, thereby providing one method of treatment to the aneurysm 10. As shown, the occlusive sack 308 can at least partially occlude the neck 16 of the aneurysm 10 reducing blood flow across the entrance to the aneurysm 10 and thereby providing a second method of treatment to the aneurysm 10. However, the occlusive sack 308 can have an opening 309 positioned in the aneurysm neck 16. Blood flow across the entrance of the aneurysm 10 can be further inhibited by obstructing the opening 309. As shown in Fig. 5, the spiral segment 350 can obstruct at least a portion of the opening 309, thereby occluding at least a portion of the neck 16 of the aneurysm 10.

Fig. 6 depicts braided implant 300 having a spiral segment 350 implanted into an aneurysm 10 as viewed from within a blood vessel 20. From this perspective, the blood vessel wall 22 surrounds the aneurysm neck 16, and the occlusive sack 308 is shown occluding the aneurysm neck 16 around the perimeter of the aneurysm neck 16. The occlusive sack 308 is shown having an opening 309 with a perimeter 319 that is measured from the attached end 354 of the spiral segment 350, around the perimeter 319 of the opening 309 one turn. The spiral segment 350 is shown spiraling counterclockwise inward from the attached end 354 to a terminating end 352. As shown, the spiral segment 350 can have an outer circumference 358 measured starting from the attached end 354 counterclockwise in the direction of the terminating end 352 through one turn, and an inner circumference 356 measured starting from the terminating end 352 clockwise in the direction of the attached end 354 through one turn. Because the spiral segment 350 spirals inward from the attached end 354, the outer circumference 358 measures greater than the inner circumference 356. As shown, the terminating end 352 can be positioned near a center 329 of the occlusive sack opening 309.

Figs. 7a to 7b illustrate a braided implant 300 and a coiled element 200. As shown, the coiled element 200 can include an affixed portion 210 that is affixed to an end 314 of the outer

fold segment 302 of the braided implant 300 and a coiled segment 220 extending from the affixed portion 210 to a terminating end 222. The affixed portion 210 can be circular, having a circumference sized to fit over an outer surface of a delivery tube (not shown), and the coiled segment 220 can have a helical shape sized to engage a helical structure on the outside of a delivery tube (not shown). Figs. 7a and 7b show the braided implant 300 in a delivery configuration and the coiled element 200 in an engaged configuration, each configured to be delivered by a delivery tube 500 through a catheter 600 to a treatment site.

Fig. 8a shows a braided implant 300 in a deployed configuration and a coiled element 200 in an occluding configuration. The braided implant 300 can invert to form an occlusive sack 308, and the coiled segment 220 can move to obstruct an opening 309 in the occlusive sack 308. The occlusive sack 308 and the affixed portion 210 of the coiled element 200 can be joined at the opening 309 of the occlusive sack 308. The braided implant 300 can collapse to form a conical helix, a flattened spiral, or some other shape to obstruct the opening 309 of the occlusive sack 308.

Fig. 8b depicts a braided implant 300 and a coiled element 200 implanted into an aneurysm 10 as viewed from within a blood vessel 20. From this perspective, the blood vessel wall 22 surrounds the aneurysm neck 16. The implant 300, as shown, can include an occlusive sack 308, and the coiled element can be in an occluding configuration, for example as shown in Fig. 8a. The occlusive sack 308 can occlude a portion of the aneurysm neck 16. Fig. 8b shows the occlusive sack 308 occluding a portion of the aneurysm neck 16 around a perimeter of the aneurysm neck 16. The affixed portion 210 of the coiled element 200 can define an opening 309 of the occlusive sack 308 that is not occluded by the occlusive sack 308. The coiled element can have a coiled structure that obstructs the opening 309 of the occlusive sack 308 thereby occluding a portion of the neck 16 of the aneurysm 10.

The coiled segment 220 can rotate clockwise (as shown) or counterclockwise. The coiled segment 220 can have an outer circumference 228 measured starting at the end 224 affixed to the affixed portion 210 of the coiled element in the direction of the terminating end 222 through one turn and an inner circumference 226 measured starting at the terminating end 222 through one turn in the direction of the affixed end 224. The terminating end 222 can be positioned near the center 329 of the opening 309 of the occlusive sack 308, and the affixed end 224 can be positioned at the perimeter of the opening 309. So oriented, the outer circumference 228 can measure greater than the inner circumference 226.

Figs. 9 to 11 are flow diagrams outlining example method steps for use of a device or system for treating an aneurysm 10. 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. 9, in step 710 a braided implant delivery system having a delivery tube and a braided implant can be provided. The braided implant can have a spiral segment and the delivery tube can have a spiral groove. The braided implant delivery system can be any of the delivery systems described herein having any combination of the features described herein, as well as any features that would be known to one skilled in the art. In step 720 the spiral segment of the braided implant can be engaged with the spiral groove of the delivery tube. In step 730 the braided implant can be implanted in the aneurysm. In step 740 the delivery tube can be rotated in relation to the spiral segment to disengage the spiral segment from the spiral groove. In step 750 the spiral segment can be released from the delivery tube thereby releasing the braided implant from the delivery tube.

Referring to a method 800 outlined in Fig. 10, in step 810 a braided implant delivery system having a braided implant and a delivery tube can be provided. The braided implant can have a spiral segment and the delivery tube can have a spiral groove. The braided implant delivery system

can be any of the delivery systems described herein having any combination of the features described herein, as well as any features that would be known to one skilled in the art. In step 820 the spiral segment of the braided implant can be engaged with the spiral groove of the delivery tube. In step 830 the braided implant can be implanted in the aneurysm by forming an occlusive sack having an opening within the aneurysm. In step 835 the occlusive sack can contact a wall of the aneurysm. In step 840 the delivery tube can be rotated in relation to the spiral segment to disengage the spiral segment from the spiral groove. In step 845 a contact between the aneurysm wall and the occlusive sack can resist a rotation of the occlusive sack in response to the rotation of the delivery tube. In step 850 the spiral segment can be released from the delivery tube thereby releasing the braided implant from the delivery tube. In step 860 a portion of the spiral segment can be moved from a circular helix shape to a conical helix or flat spiral shape. In step 870 at least a portion of the neck of the aneurysm can be occluded by obstructing at least a portion of the opening of the occlusive sack with the spiral segment.

Referring to method 900 outlined in Fig. 11, in step 910 a braided implant delivery system having a braided implant, a delivery tube, and an inner elongated member can be provided. The braided implant can have a spiral segment and the delivery tube can have a spiral groove and a lumen. The braided implant delivery system can be any of the delivery systems described herein having any combination of the features described herein, as well as any features that would be known to one skilled in the art. In step 920 the spiral segment of the braided implant can be engaged with the spiral groove of the delivery tube. In step 923 the inner elongated member can be positioned in the lumen of the delivery tube. In step 927 the braided implant can be attached to the inner elongated member. In step 930 the braided implant can be implanted in the aneurysm by pushing the inner elongated member distally, thereby inverting the braided implant and forming an occlusive sack within the aneurysm then detaching the braided implant from the inner elongated

member. In step 940 the delivery tube can be rotated in relation to the spiral segment of the braided implant to disengage the spiral segment from the spiral groove. In step 950 the spiral segment can be released from the delivery tube thereby releasing the braided implant from the delivery tube.

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 delivery tube comprising a lumen therethrough, a proximal end, a distal end, and an outer surface comprising a spiral groove thereon approximate the distal end; and

a braided implant comprising a spiral segment movable from a delivery configuration to a deployed configuration by a rotation of the delivery tube in relation to the implant, the delivery configuration engaging the spiral groove and the deployed configuration disengaging the spiral groove.

2. The system of claim 1 wherein the spiral segment in the delivery configuration comprises a first circular helix shape and the spiral groove comprises a second circular helix shape, and wherein the spiral segment is positioned in the spiral groove.

3. 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 attached to the spiral segment and positioned over a portion of the outer surface of the delivery tube; and

an inner fold segment comprising a substantially tubular structure positioned within the lumen of the delivery tube.

4. The system of claim 3 further comprising an inner elongated member comprising a proximal end extending proximal the proximal end of the delivery tube and a distal end positioned within the lumen of the delivery tube detachably attached to an end of the inner fold segment.
5. The system of claim 1 wherein the braided implant further comprises an occlusive sack comprising an opening, and wherein the opening is at least partially obstructed by the spiral segment in the deployed configuration.
6. The system of claim 5,

wherein the opening comprises a perimeter and a center, and

wherein the spiral segment comprises an attached end attached to the occlusive sack approximate the perimeter and a terminating end positioned approximate the center of the opening in the deployed configuration.
7. The system of claim 2 wherein the outer fold segment and the spiral segment each comprise a woven structure comprising a woven fiber common to both the outer fold segment and the spiral segment.
8. The system of claim 1 wherein the spiral segment comprises a non-woven structure.

9. A device for treating an aneurysm, the device comprising:

a tubular delivery member comprising a lumen therethrough, a distal end, an outer surface, and a helical structure on the outer surface;

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

the delivery configuration comprising a tubular segment extending proximally within the lumen of the tubular delivery member and an outer fold segment covering a portion of the outer surface of the tubular delivery member, and

the implanted configuration comprising an occlusive sack comprising an opening; and

a coiled element movable from an engaging configuration to an occluding configuration,

the engaging configuration engaging the helical structure, and

the occluding configuration obstructing at least a portion of the opening of the occlusive sack.

10. The device of claim 9 wherein, in the engaged configuration, the coiled element comprises a coiled segment in the shape of a circular helix, the coiled segment engaging the helical structure.

11. The device of claim 10 wherein the helical structure is an indentation in the shape of a circular helix.

12. The device of claim 9 wherein, in the occluding configuration, the coiled element comprises a coiled segment in the shape of a conical helix or a planar spiral.

13. The device of claim 12 wherein the coiled element comprises an affixed portion affixed to the braided implant, and wherein the coiled segment comprises:

an affixed end affixed to the affixed portion of the coiled element;

a terminating end;

a first circumference measured along the coiled segment from the affixed end through one turn of the conical helix or planar spiral in the direction of the terminating end; and

a second circumference measured along the coiled segment from the terminating end through one turn of the conical helix or planar spiral in the direction of the affixed end, the second circumference measuring shorter than the first circumference.

14. The device of claim 9 wherein the coiled element comprises a memory shape metal, and the coiled element moves from a deformed shape in the engaging configuration to a predetermined shape in the occluding configuration.

15. A method for treating an aneurysm, the method comprising:
- providing a braided implant delivery system comprising a braided implant comprising a spiral segment and a delivery tube comprising a spiral groove;
- engaging the spiral segment with the spiral groove;
- implanting the braided implant in the aneurysm;
- rotating the delivery tube in relation to the spiral segment of the braided implant to disengage the spiral segment from the spiral groove; and
- releasing the spiral segment from the delivery tube which releases the braided implant from the delivery tube.
16. The method of claim 15 further comprising the step of occluding at least portion of the neck of the aneurysm with the spiral segment.
17. The method of claim 16 wherein the step of implanting the braided implant in the aneurysm comprises the step of forming an occlusive sack comprising an opening, and
- wherein the step of occluding at least a portion of the neck of the aneurysm further comprises the step of obstructing the at least a portion of the opening of the occlusive sack.
18. The method of claim 15 further comprising the step of moving a portion of the spiral segment from a circular helix shape to a conical helix shape.

19. The method of claim 15,

wherein the step of implanting the braided implant in the aneurysm further comprises the step of forming an occlusive sack within the aneurysm; and

wherein the method further comprises the steps of

contacting a wall of the aneurysm with the occlusive sack, and

resisting, via the contact between the aneurysm wall and the occlusive sack, a rotation of the occlusive sack in response to the rotating of the delivery tube.

20. The method of claim 15,

wherein the braided implantation delivery system further comprises an inner elongated member and the delivery tube comprises a lumen therethrough;

wherein the method further comprises the steps of:

positioning the inner elongated member in the lumen of the delivery tube;

attaching the braided implant to the inner elongated member; and

wherein the step of implanting the braided implant in the aneurysm further comprises the steps of

pushing the inner elongated member distally, thereby inverting the braided implant and forming an occlusive sack within the aneurysm, and

detaching the braided implant from the inner elongated member.

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.

Table with 2 columns: 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:

OR

06980

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

Form with fields: 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).

Form with fields: 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

SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID

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.

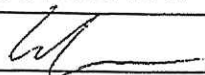
WARNING:

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): 7-24-2018

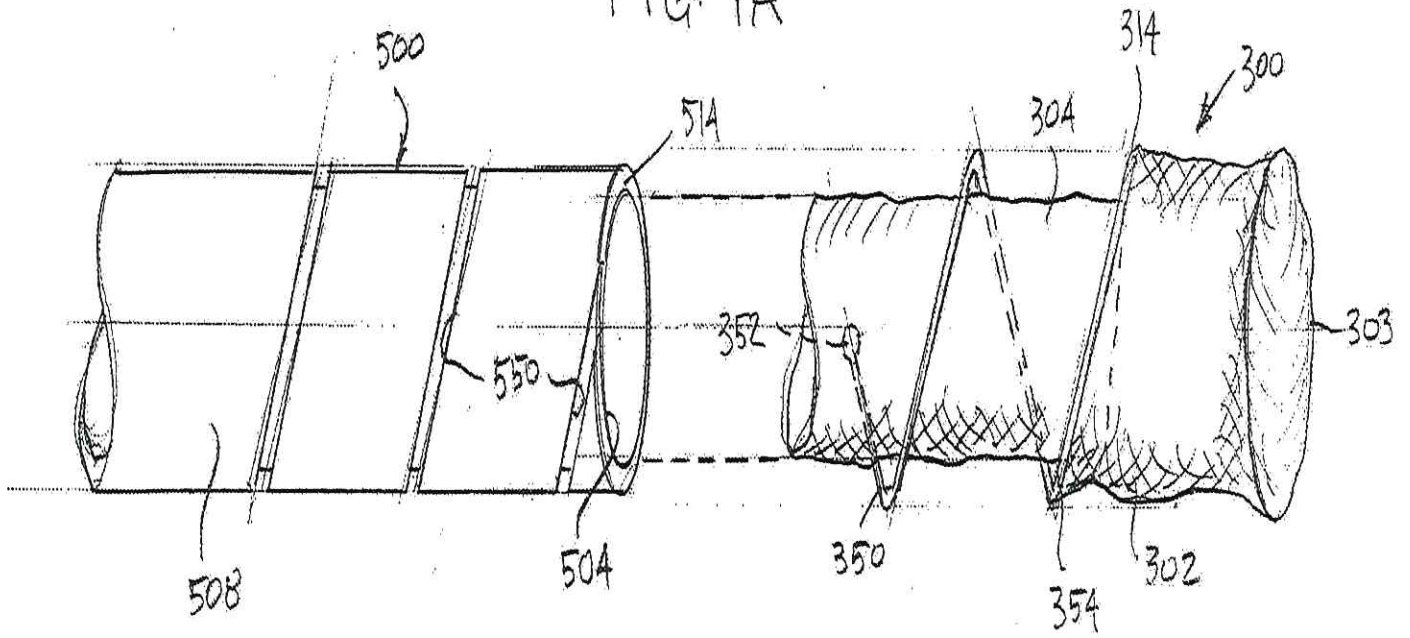
Signature: 

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.

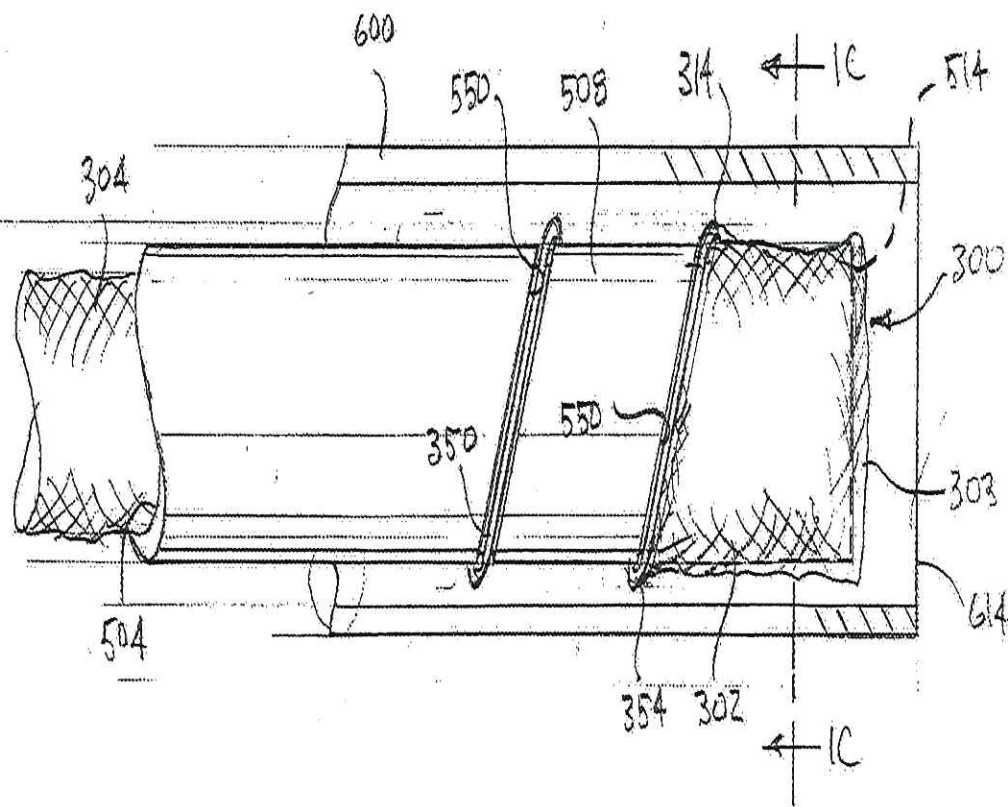
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

FIG. 1A



DP 5435
(6/10)

FIG. 1B



DP 5455
(2/10)

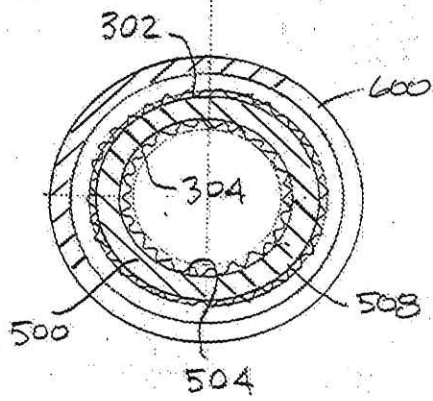


FIG. 1C

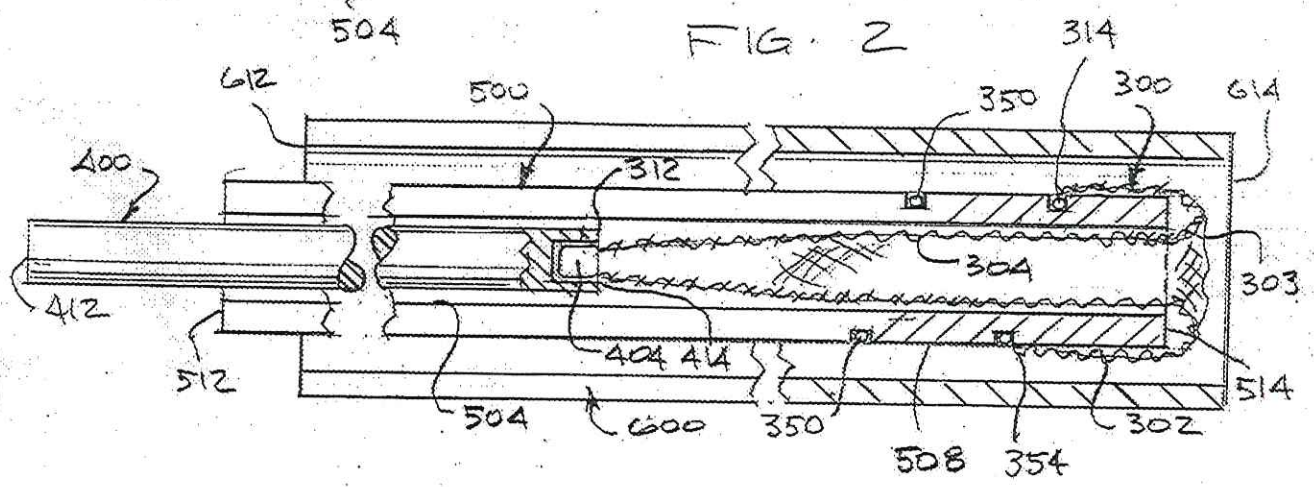


FIG. 2

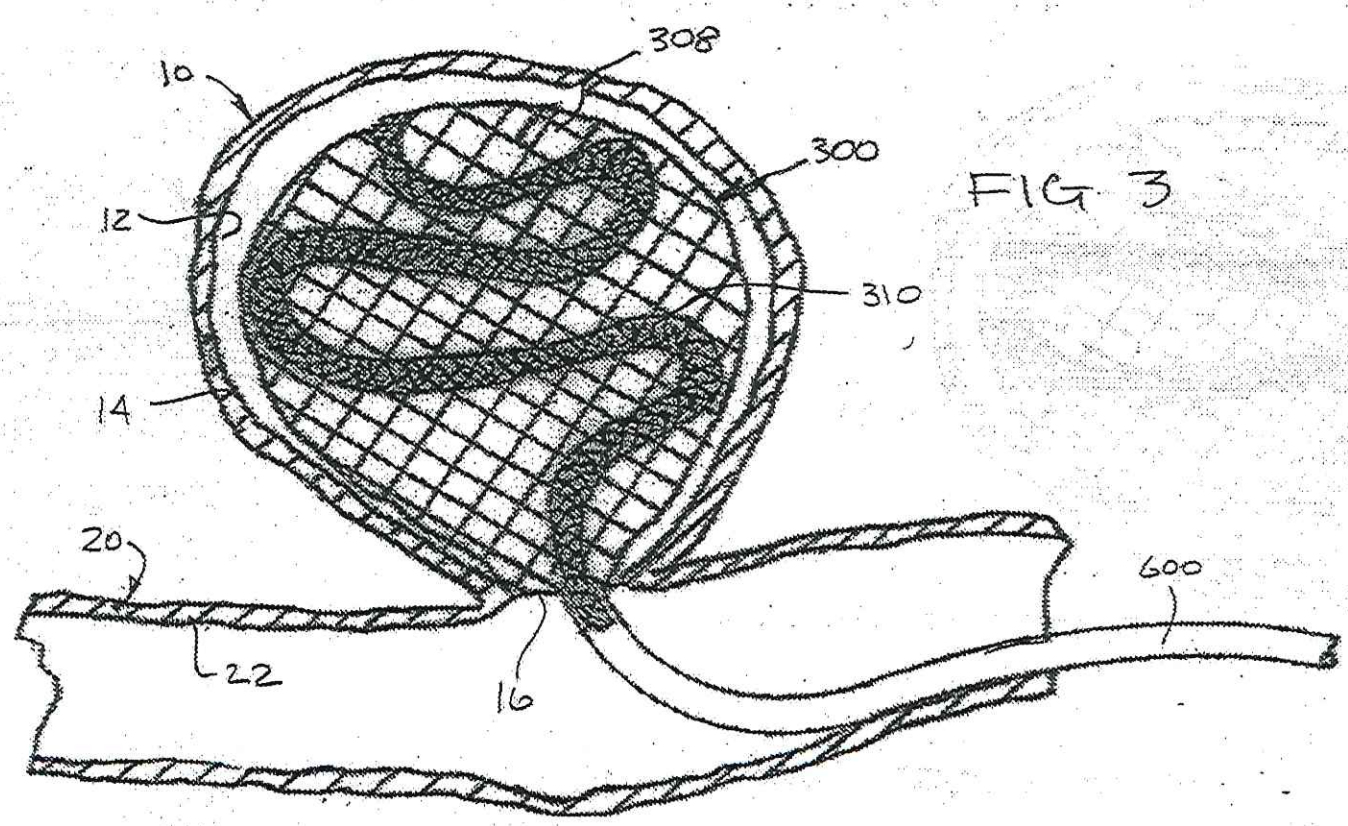


FIG. 3

FIG. 4a

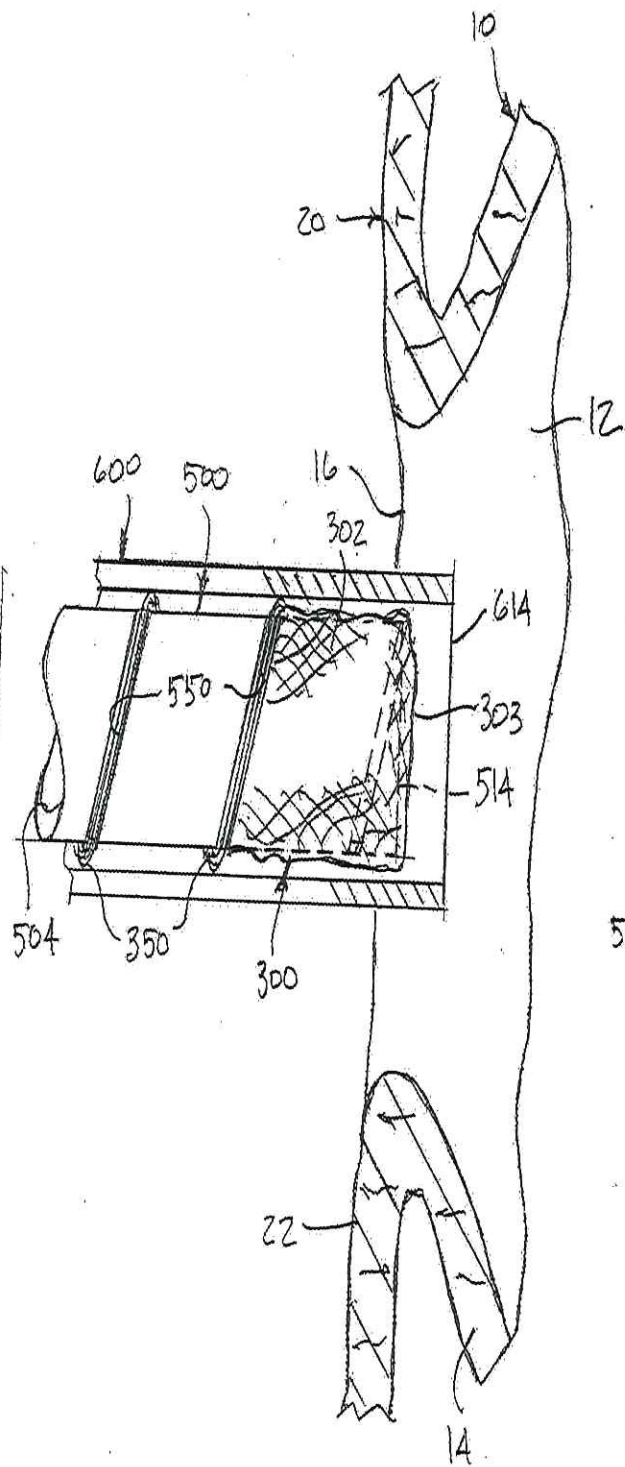
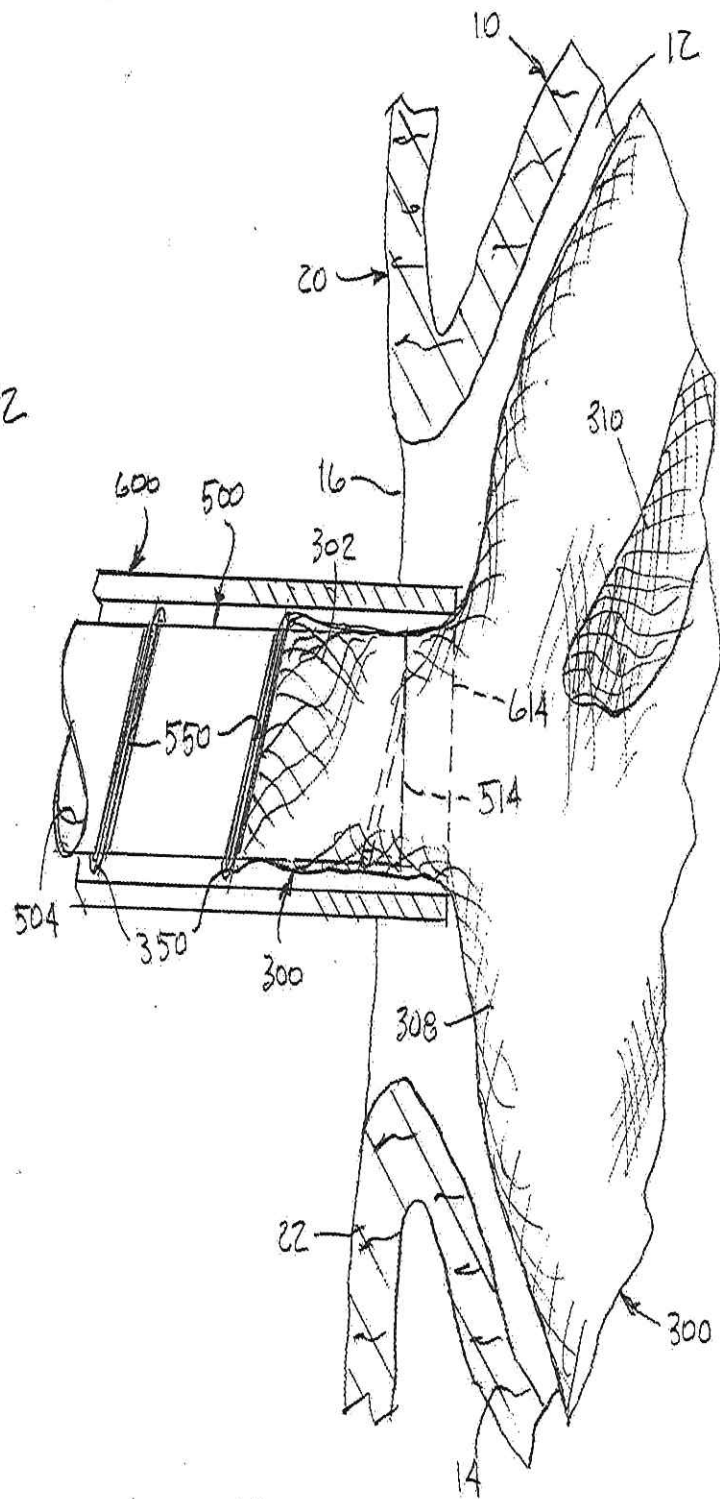


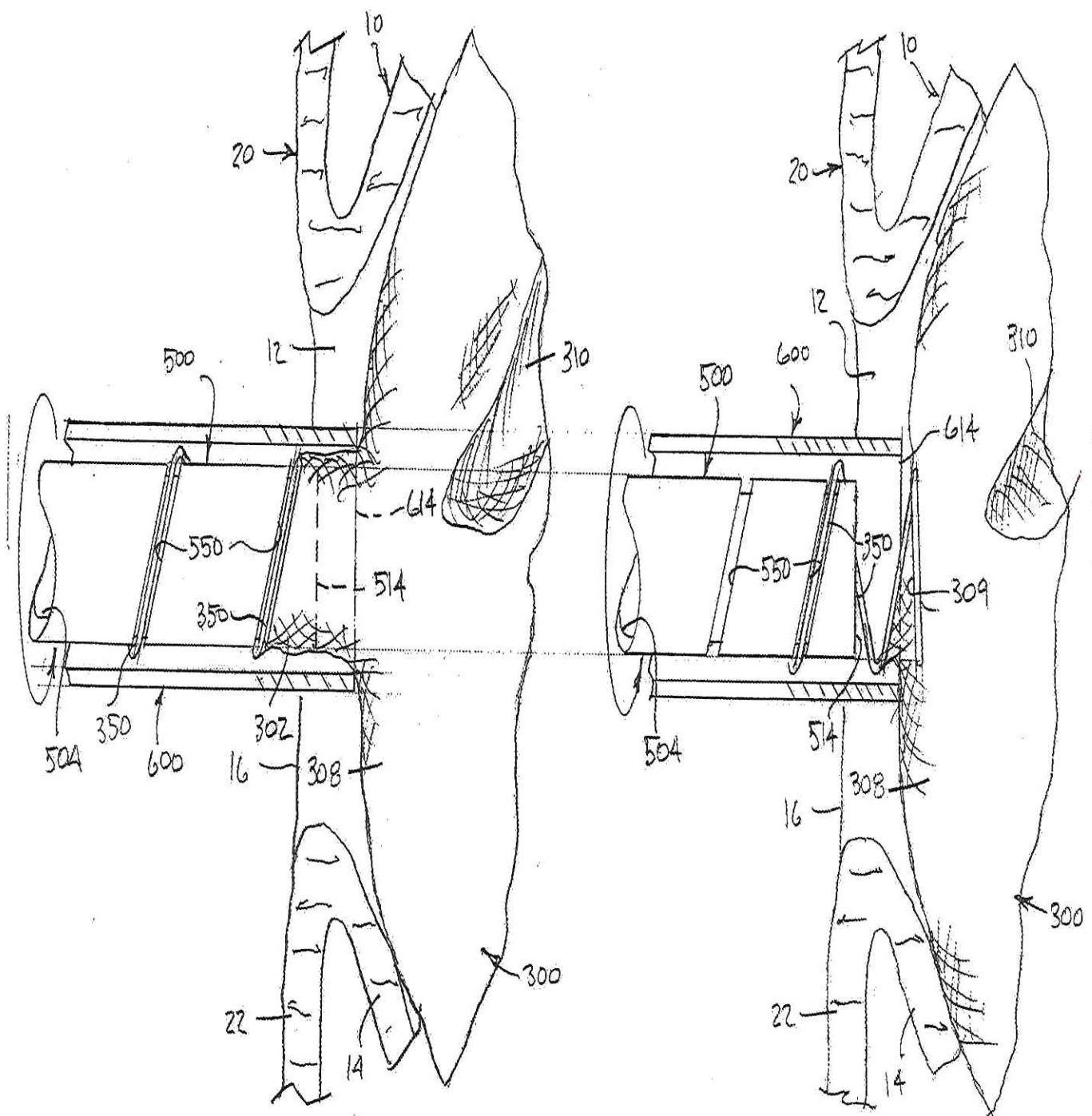
FIG. 4b



DP 5455
(3/10)

FIG. 4C

FIG. 4D



TP 5455
(2/10)

FIG. 4E

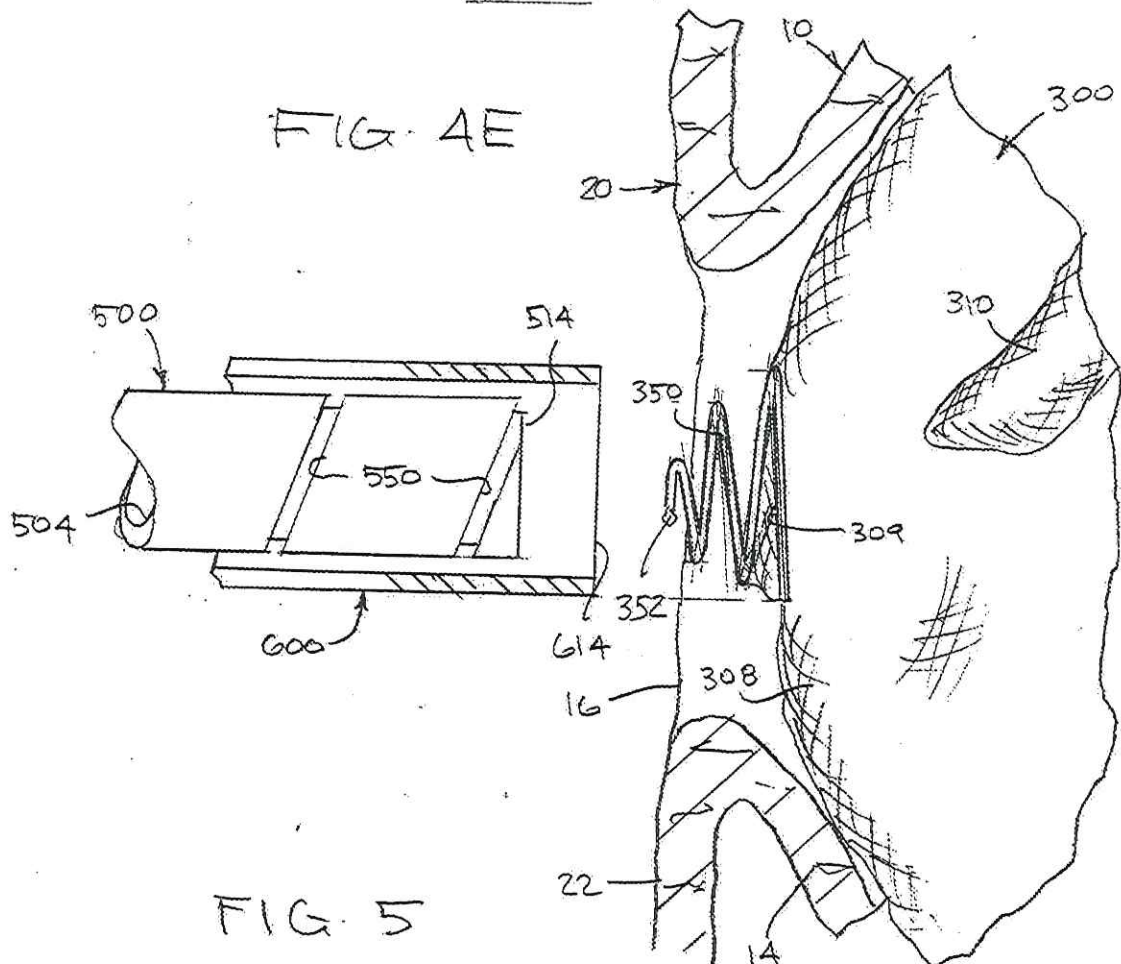


FIG. 5

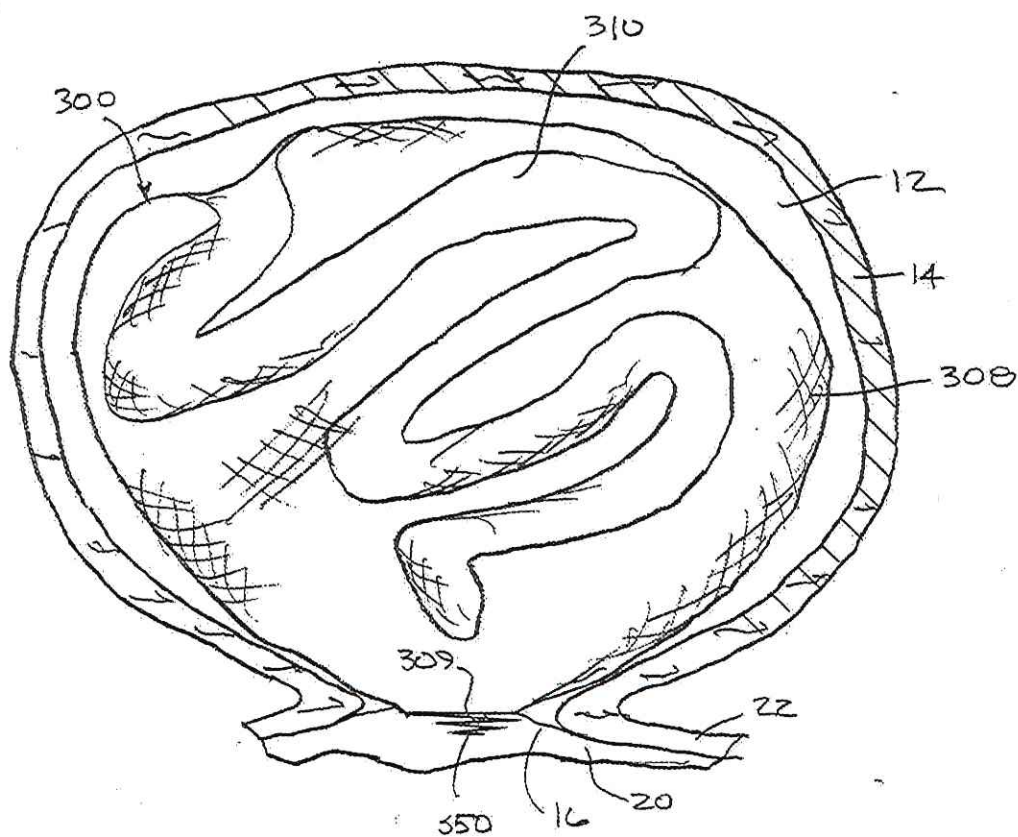


FIG. 6

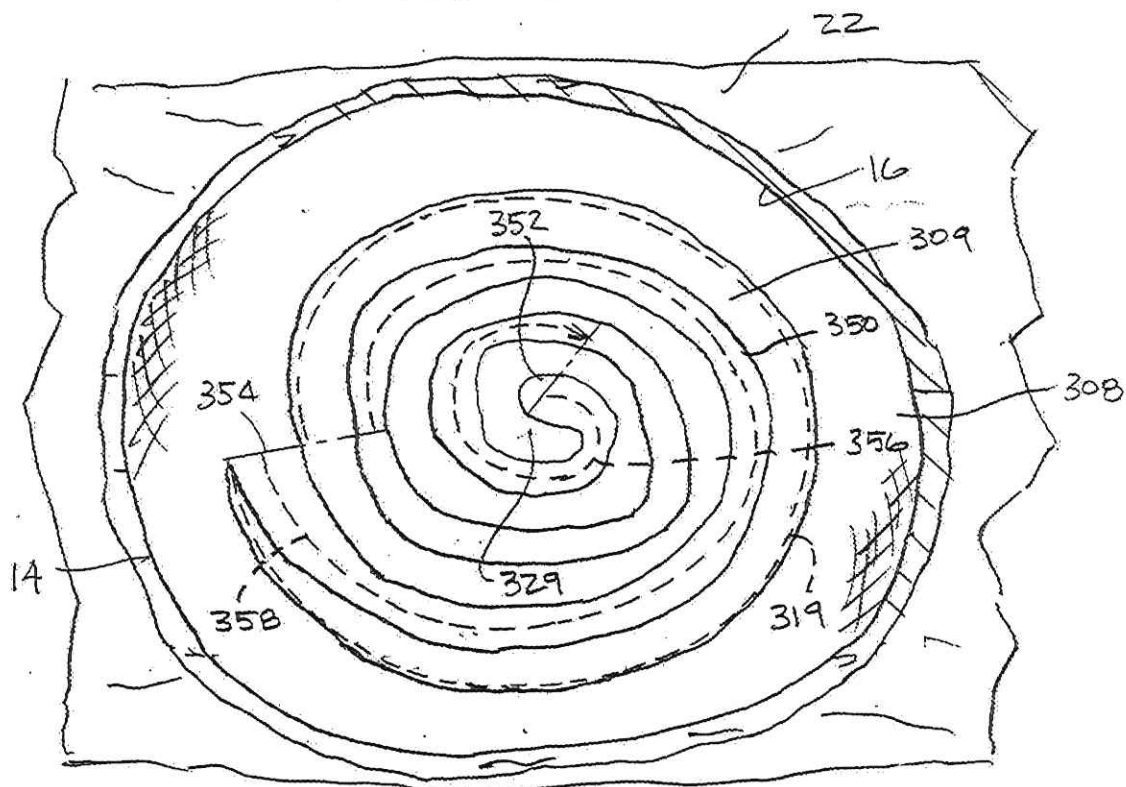


FIG. 7A

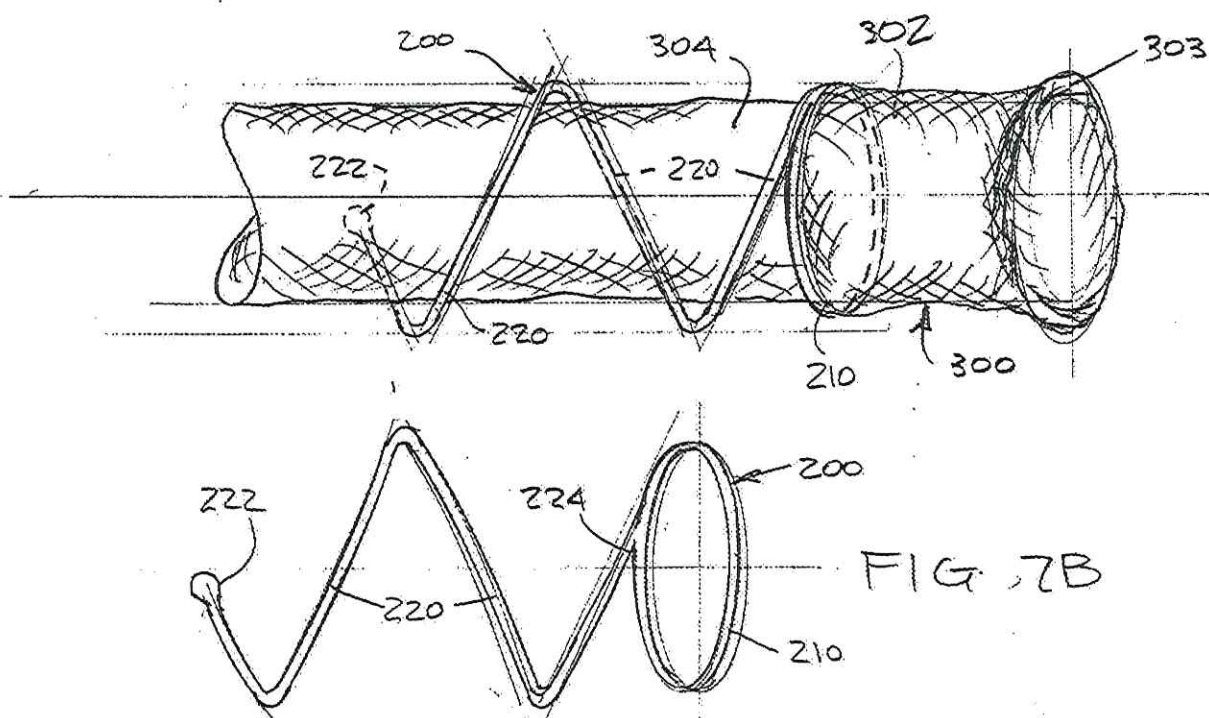


FIG. 8A

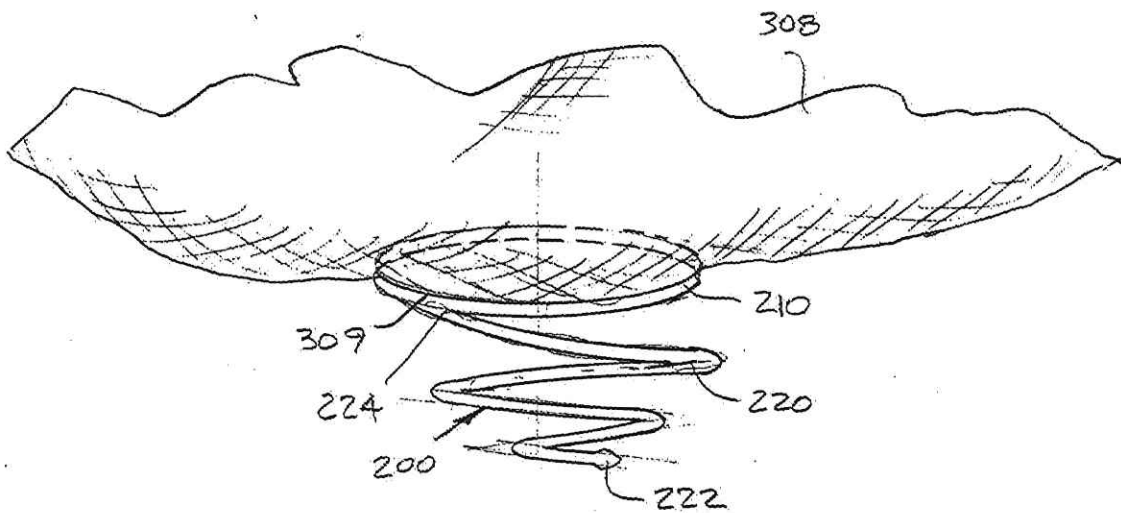
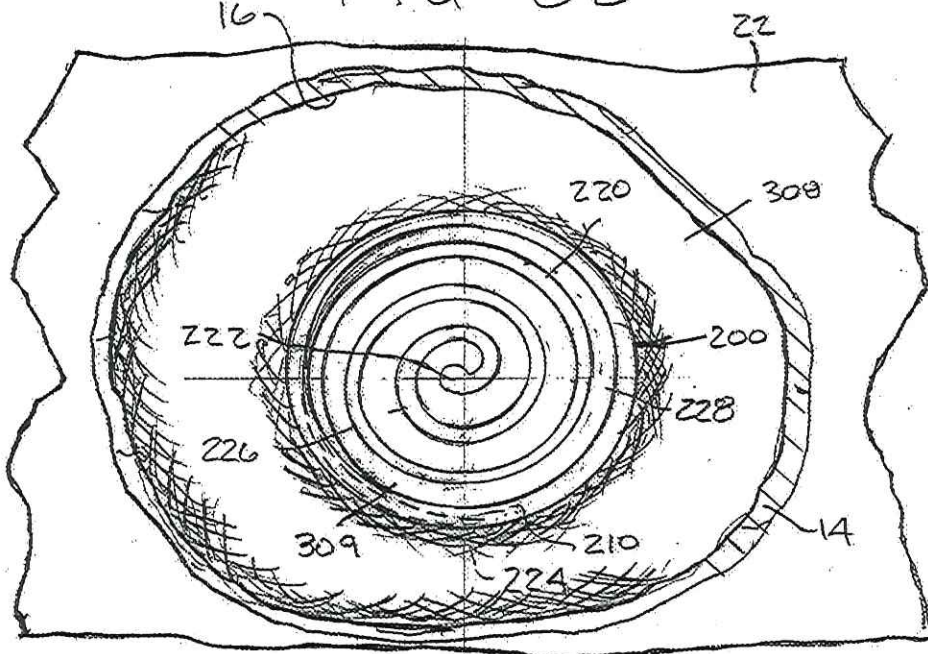
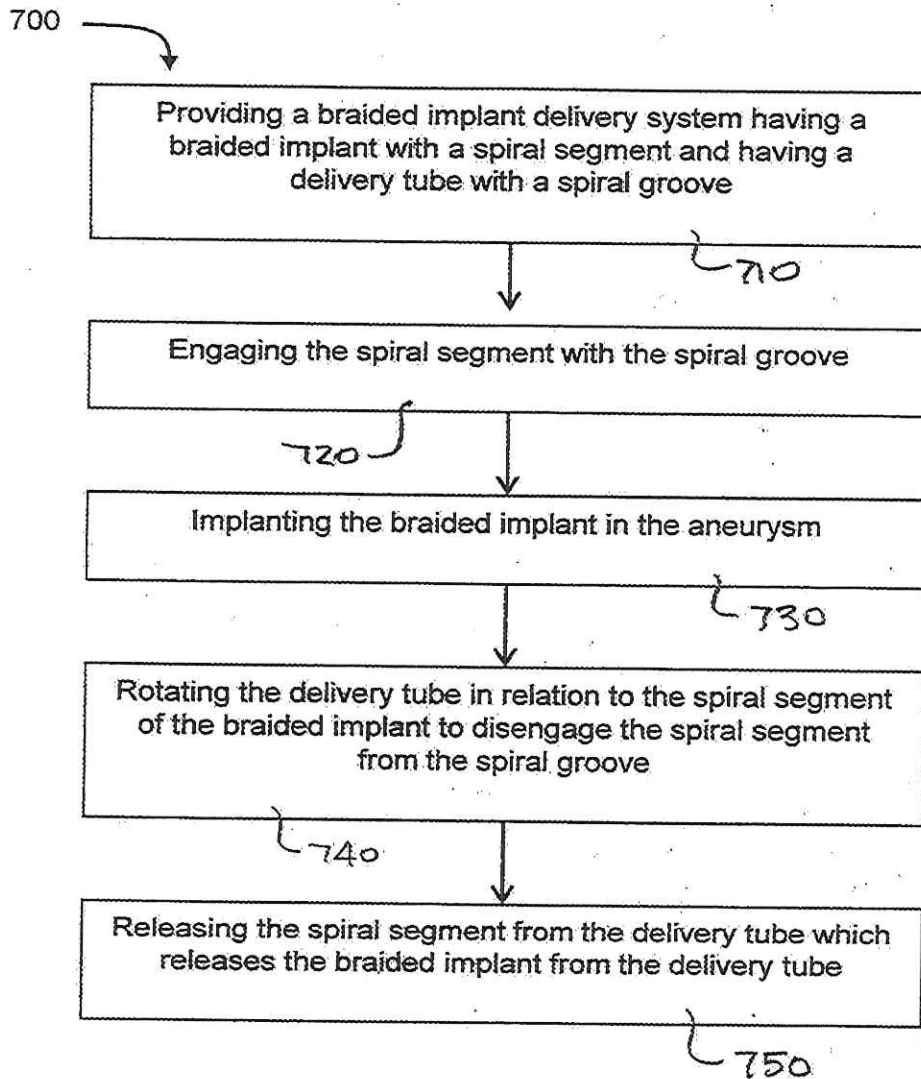


FIG. 8B



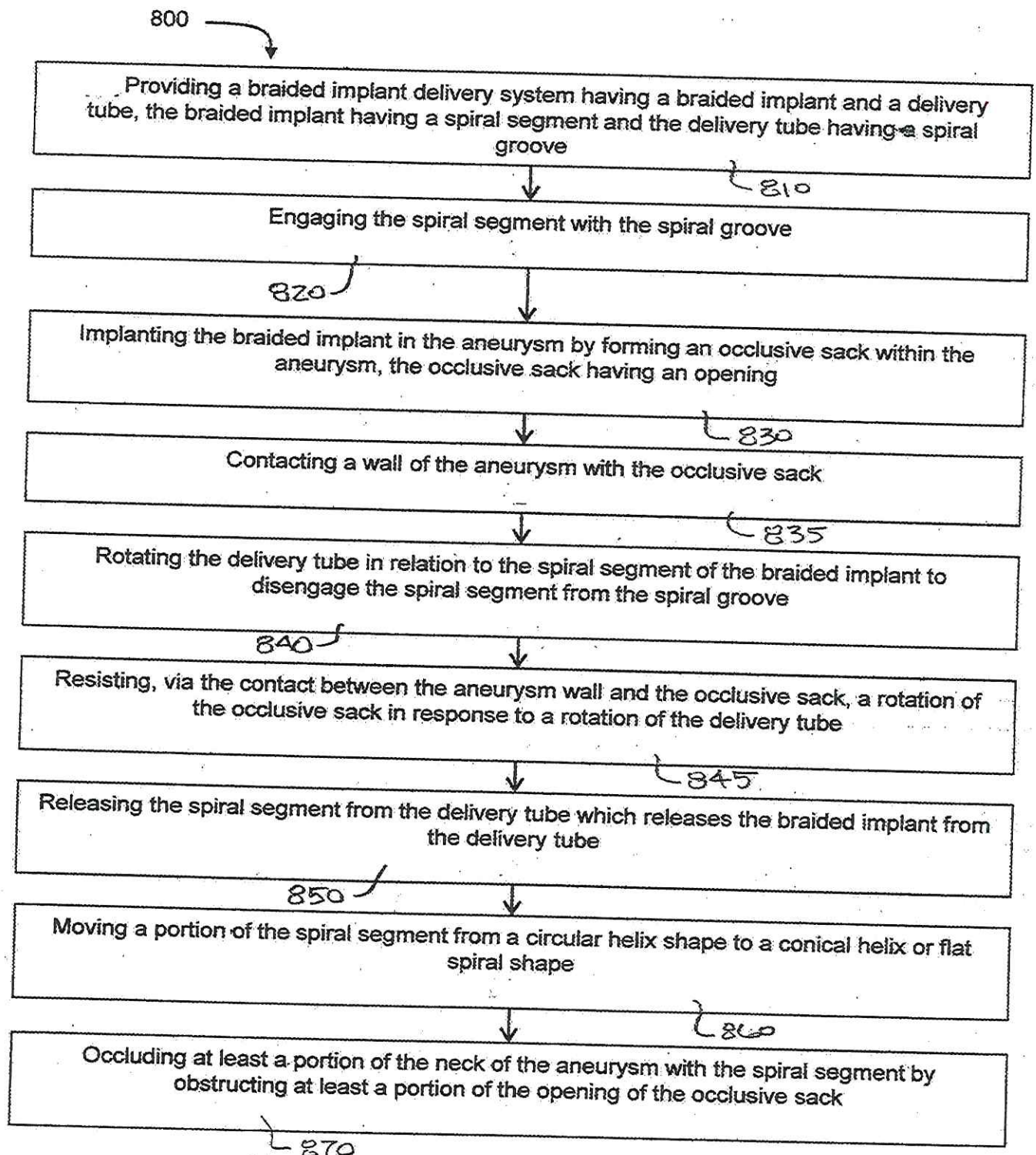
DP 5455
(8/10)

FIG. 9



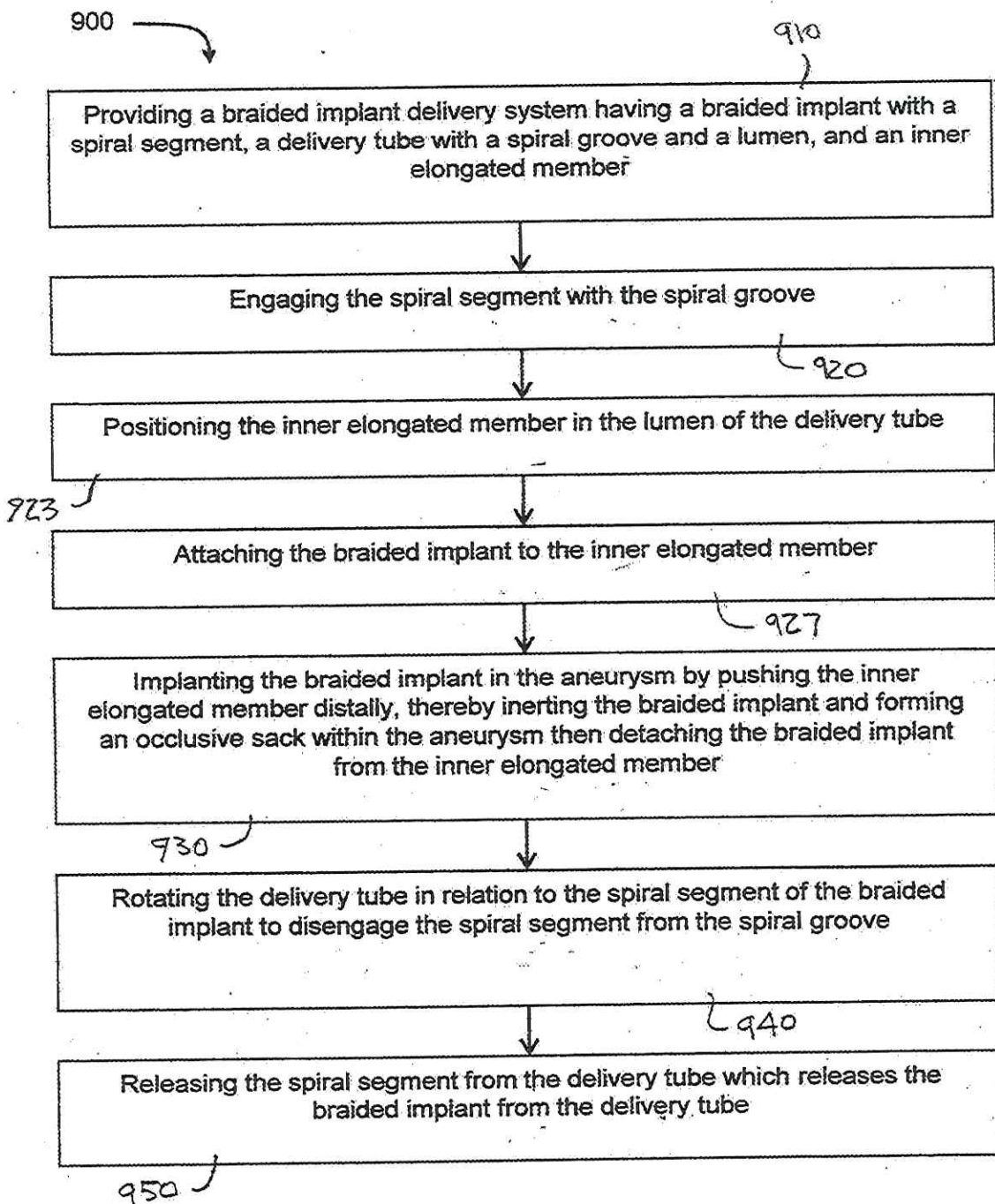
DP 5455
(9/10)

FIG. 10



PP 5455
(10/10)

FIG. 11



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	243382.000121
		Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID		
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		
	Lacey		GOROCHOW			
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	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	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID		
Attorney Docket Number	243382.000121	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000121
		Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID		

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.

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000121
		Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID		

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).

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

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

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.

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	243382.000121
		Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID		

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	243382.000121
		Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID		

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.

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	243382.000121
	Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID	

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:

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)	2018-08-03	
First Name	Louis John	Last Name	DeJuidice	Registration Number	47522
Additional Signature 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	243382.000121
	Application Number	
Title of Invention	SPIRAL DELIVERY SYSTEM FOR EMBOLIC BRAID	

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.