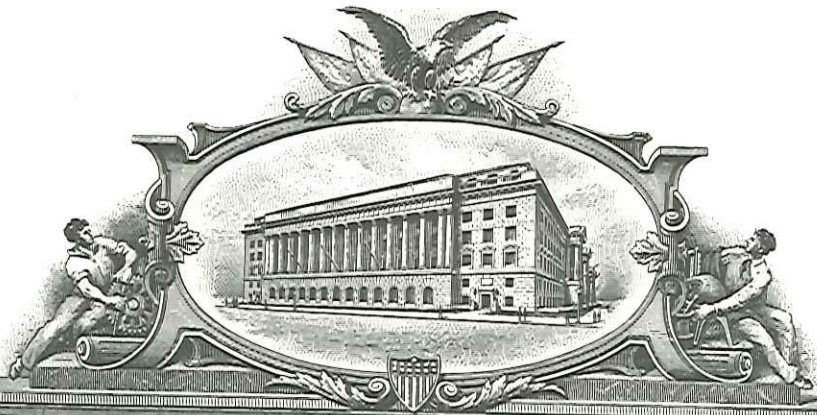




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APPLICATION NUMBER: 16/128,929

FILING DATE: September 12, 2018

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US16/128,929

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EFS ID:	33698922
Application Number:	16128929
International Application Number:	
Confirmation Number:	3741
Title of Invention:	IMPROVED ANEURYSM OCCLUSION DEVICE
First Named Inventor/Applicant Name:	Juan LORENZO
Customer Number:	6980
Filer:	Louis J. DeJuidice/Wendy Higgins
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.17 (Patent application and reexamination processing fees) 37 CFR 1.21 (Miscellaneous fees and charges)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	Transmittal.PDF	222184	no	1
			8a9089a4a70ca093813a1f56c4e9b67f3b1e a446		
Warnings:					
Information:					
2	Application Data Sheet	ads.PDF	1260751	no	8
			627b26ca3d361278ea5716769072befe4d4 b11d7		
Warnings:					
Information:					
3	Oath or Declaration filed	Declaration.PDF	144330	no	1
			34662feff6dc723ec7175135b237e3b507bb 71ed		
Warnings:					
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5	Information Disclosure Statement (IDS) Form (SB08)	IDS.PDF	1043813	no	9
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Warnings:					
Information:					
6		APPLICATION.pdf	217178	yes	21
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	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		

	Specification	1	16
	Claims	17	20
	Abstract	21	21

Warnings:

Information:

7	Drawings-only black and white line drawings	DRAWINGS.pdf	2248175	no	10
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8	Fee Worksheet (SB06)	fee-info.pdf	34945	no	2
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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.

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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 <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	243382.000154
	First Named Inventor	Juan LORENZO
	Title	IMPROVED ANEURYSM OCCLUSION DEVICE
	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
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1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 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 21] 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
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*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).

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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.

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IMPROVED ANEURYSM OCCLUSION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of U.S. patent application serial number 14/230,426, filed on March 31, 2014, the content of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of Invention

The invention relates to implants within body vessels and more particularly to occlusion devices for small vascular openings such as a neck of an aneurysm.

2. Description of the Related Art

Vascular disorders and defects such as aneurysms and other arterio-venous malformations are especially difficult to treat when located near critical tissues or where ready access to a malformation is not available. Both difficulty factors apply especially to cranial aneurysms. Due to the sensitive brain tissue surrounding cranial blood vessels and the restricted access, it is very challenging and often risky to surgically treat defects of the cranial vasculature.

In the treatment of aneurysms by endovascular implants, the goal is to exclude the internal volume of the aneurysm sac from arterial blood pressure and flow. As long as the interior walls of the aneurysm are subjected to blood pressure and/or flow, there is a risk of the aneurysm rupturing.

Non-surgical treatments include vascular occlusion devices such as embolic coils deployed using catheter delivery systems. In a currently preferred procedure to treat a cranial aneurysm, the distal end of an embolic coil delivery catheter is initially inserted into non-cranial vasculature of a patient, typically through a femoral artery in the groin, and guided to a predetermined delivery site in a blood vessel within the cranium. The aneurysm sac is then filled with embolic material that

causes formation of a solid, thrombotic mass that protects the walls from blood pressure and flow. Preferably, the thrombotic mass substantially restores the original blood vessel shape along the plane of the aneurysm's neck. The neck plane is an imaginary surface where the intima of the blood vessel would be if not for formation of the aneurysm. However, simply utilizing embolic coils is not always effective at treating aneurysms as re-canalization of the aneurysm and/or coil compaction can occur over time.

A bag for use in an aneurysm sac is described by Greenhalgh in US Patent Nos. 6,346,117 and 6,391,037, and an aneurysm neck obstruction device is shown in US Patent No. 6,454,780 by Wallace. Detachable neck bridges are disclosed by Abrams et al. in US Patent No. 6,036,720 and by Murphy et al. in US Patent No. 7,410,482 for example. Preferably, one or more embolic coils are delivered within or through the neck bridges or other obstruction devices to fill the sac of the aneurysm.

Yet another type of vaso-occlusive device is illustrated in US Patent No. 5,645,558 by Horton as having one or more strands of flexible material which are wound to form a generally spherical or ovoid vaso-occlusive structure when relaxed after being placed in a vascular cavity such as an aneurysm or fistula. Similarly, US Patent No. 5,916,235 by Guglielmi cites earlier patents describing detachable coils and then discloses an expandable cage as a vaso-occlusive structure that can receive and retain one or more coils after the cage is expanded within an aneurysm. A self-expandable aneurysm filling device is disclosed in US Patent Publication No. 2010/0069948 by Veznedaroglu et al.

It is therefore desirable to have a retrievable, repositionable device that cooperates with one or more embolic coils or other vaso-occlusive structure to effectively occlude a neck of an aneurysm or other arterio-venous malformation in a blood vessel.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved occlusion device which substantially blocks flow into an aneurysm in a blood vessel.

Another object of the present invention is to provide such an occlusion device which can be repositioned or retrieved from a sac of an aneurysm.

This invention features an occlusion device suitable for endovascular treatment of an aneurysm in a blood vessel in a patient, including a substantially tubular structure having a proximal end region and a distal end region, having a first, expanded condition and a second, collapsed condition. The device has dimensions in the second, collapsed condition suitable for insertion through vasculature of the patient and through a neck of the aneurysm. The device further includes a control ring having a substantially annular body disposed on the proximal end region of the structure and at least substantially circumscribing the proximal end region to prevent radial expansion of the proximal end region and to provide an engagement feature during manipulation of the occlusion device.

In a number of embodiments, the control ring defines an inner passage, such as a channel established by an inner sleeve, through which at least one embolic coil is insertable into the aneurysm. Preferably, at least a portion of the proximal end region of the tubular structure defines a plurality of openings having a sufficiently small size to enhance occlusion of the aneurysm. In some embodiments, the tubular structure cooperates with at least one vaso-occlusion structure such as a collapsible cage-like device.

In certain embodiments, the occlusive device is capable of being utilized in combination with a delivery member defining an inner lumen and having a distal end region carrying a grabber having at least two finger elements, each finger element defining a gripping region to mechanically engage the control ring. In one embodiment, the grabber is formed of a metallic material and the

utilizing the vaso-occlusive structure to secure the proximal end region of the tubular structure across the neck of the aneurysm.

BRIEF DESCRIPTION OF THE DRAWINGS

In what follows, preferred embodiments of the invention are explained in more detail with reference to the drawings and photographs, in which:

FIG. 1 is a schematic side cross-sectional view of an inventive occlusion device within a novel catheter delivery system positioned at the neck of an aneurysm of a blood vessel;

FIG. 2 is an enlarged schematic side view of the delivery system of FIG. 1 showing the occlusion device held in a collapsed condition;

FIG. 3 is a schematic side view similar to FIG. 1 showing the occlusion device according to the present invention expanding within the sac of the aneurysm while still being securely held by the delivery system;

FIG. 4 is a schematic side view similar to FIG. 3 showing an embolic coil being advanced through the delivery system and the occlusion device into the aneurysm;

FIG. 5 is a schematic side view similar to FIG. 2 with the microcatheter withdrawn proximally to allow grasper fingers to release the control ring of the occlusion device;

FIG. 6 is a schematic side cross-sectional view similar to FIG. 4 after the delivery system has been withdrawn and with embolic coils securing the occlusion device within the sac of the aneurysm;

FIG. 7 is a schematic cross-sectional view of a spherical mandrel establishing the first, expanded condition for at least one an occlusion device according to the present invention;

FIGS. 8A and 8B are schematic side views of two hemi-spherical occlusion devices according to the present invention derived from the occlusion device of FIG. 7;

FIG. 9 is a schematic side view of a single occlusion device after the mandrel of FIG. 7 has been removed;

FIG. 10 is a schematic side view similar to FIG. 9 after a distal portion of the occlusion device has been removed to generate an alternative open configuration;

FIG. 11 is a side view similar to FIG. 10 of an alternative occlusion device formed utilizing an elliptical, lozenge-shaped mandrel;

FIG. 12 is a view similar to FIG. 3 showing the occlusion device cooperating with a cage-like vaso-occlusive structure within an aneurysm;

FIG. 13 is an enlarged schematic side view of an alternative delivery system for devices similar to those shown in FIG. 12 with an occlusion device and a vaso-occlusive structure held in a collapsed condition being advanced into an aneurysm;

FIG. 14 is a schematic side cross-sectional view similar to FIG. 13 after the delivery system has been withdrawn, and with the vaso-occlusive structure securing the occlusion device within the sac of the aneurysm;

FIG. 15 is a schematic side cross-sectional view of an inventive occlusion device within a novel catheter delivery system positioned at the neck of an aneurysm of a blood vessel and a catheter for delivering an embolic device inserted into the aneurysm sac;

FIG. 16 is a schematic side cross-sectional view showing the occlusion device of FIG. 15 positioned at the neck of an aneurysm of a blood vessel in a partially implanted condition and a catheter for delivering an embolic device inserted into the aneurysm sac;

FIG. 17A is a schematic side view showing the occlusion device of FIG. 16 expanded within the sac of the aneurysm while still being securely held by the delivery system and the catheter for delivering the embolic device jailed between the expanded occlusion device and a wall of the aneurysm;

FIG. 17B is a cross-sectional view of the expanded occlusion device and jailed catheter of FIG. 17A;

FIG. 18 is a schematic side view showing the expanded occlusion device of FIG. 17A and an embolic coil being advanced through the embolic delivery catheter and the occlusion device into the aneurysm;

FIG. 19 is a schematic side view showing the expanded occlusion device of FIG. 18 after completion of implantation and removal of catheters; and

FIG. 20 is a schematic side view showing the release of an expanded occlusion device such as the occlusion device illustrated in FIGs. 15-19.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

This invention may be accomplished by an occlusion device suitable for endovascular treatment of an aneurysm in a blood vessel in a patient, with a substantially tubular structure having a proximal end region and a distal end region, having a first, expanded condition and a second, collapsed condition. The device has dimensions in the second, collapsed condition suitable for insertion through vasculature of the patient, utilizing a catheter such as a microcatheter, and through a neck of the aneurysm. The device further includes a control ring having a substantially annular body disposed on the proximal end region of the structure and at least substantially circumscribing the proximal end region to prevent radial expansion of the proximal end region and to provide an engagement feature during manipulation of the occlusion device.

The control ring is releasably engageable by a releasable feature such as a grabber or at least one frangible member on a delivery member in some mechanical constructions or, in other constructions, by at least one electrolytically severable element. Preferably, the control ring defines an inner passage through which at least one embolic coil is insertable into the aneurysm. In another

construction, the occlusion device is held in place within the aneurysm by at least one vaso-occlusive structure such as a cage-like device.

FIG. 1 schematically illustrates the distal portion of a novel delivery system 10 including a microcatheter 12 and a delivery tube 14 holding a tubular occlusion device 20 according to the present invention to be implanted within sac S of aneurysm A emerging from blood vessel BV. In one construction, the microcatheter 12 has a distal radiopaque marker band 13 and is advanced to the vicinity of neck N of aneurysm A such that marker band 13 is at the level of the neck N as seen under fluoroscopy.

Enlarged views of the distal portion of delivery system 10 and of occlusion device 20 are provided in FIGS. 2 and 5. Occlusion device 20 is shown in a second, collapsed condition in FIG. 2 within catheter lumen 11, with a control ring 22 held by grabber 30 of delivery tube 14. Control ring 22 is disposed about a proximal region 23 of device structure 25 and defines an inner passage 26 through which one or more embolic coils are inserted, as described in more detail below. Structure 25 of occlusion device 20 further includes a mesh body 24 and a distal region 28.

After the delivery system 10 is positioned as shown in FIG. 1, the delivery tube 14 is advanced within lumen 11 of catheter 12 to enable occlusion device 20 to expand into an approximately hemi-spherical shape within sac S as shown in FIG. 3. The shape of occlusion device 20 will conform to the shape of the sac S where device 20 touches the inner wall of the sac S. Grabber 30 continues to be constrained radially by lumen 11 of catheter 12 and maintains its grip on control ring 22 with a plurality of gripping regions such as notches 36 and 38, FIG. 5. In one construction, control ring 22 is radiopaque and is aligned under fluoroscopy relative to marker 13 on catheter 12 as shown in FIGS. 3 and 4.

Once occlusion device 20 is positioned within sac S, at least one embolic coil 40, FIG. 4, is advanced through lumen 15 of delivery tube 14 as indicated by arrow 42, through passage 26 of

control ring 22 as indicated by arrow 44, and is advanced, arrow 46, within aneurysm A to substantially fill sac S and to anchor body 24 of occlusion device 20 against the interior wall of aneurysm A to block neck N as shown in FIG. 6.

After a sufficient amount of embolic coil 40 has been fully deployed within sac S to anchor occlusion device 20 within aneurysm A, the catheter 12 is withdrawn proximally, as indicated by arrow 51 in FIG. 5, while maintaining delivery tube 14 in place, to remove radial constraint on fingers 32 and 34 of grabber 30. Fingers 32 and 34 preferably are biased radially outwardly and move in the direction of arrows 50 and 52, respectively, to disengage control ring 22 from notches 36 and 38 in fingers 32 and 34, respectively.

In one construction, the catheter 12 is a polymeric microcatheter defining an inner lumen 11 having an inner diameter of between 0.020 inch and 0.027 inch, the delivery tube 14 has outer diameter that is slightly less than the inner diameter of the catheter lumen 11, and the grabber 30 with occlusion device 20 in the collapsed condition shown in FIGS. 1 and 2 also have outer diameters that are substantially the same as the inner diameter of the catheter lumen 11, which radially constrains fingers 32 and 34 to engage control ring 22. The lumen 15 of delivery tube 14 has a diameter capable of allowing passage of a conventional embolic coil delivery system having a nominal outer diameter of between 0.010 inch and 0.015 inch.

In some constructions, the delivery tube has at least one region of increased flexibility, especially near the distal end of the delivery tube, to minimize unintended microcatheter movement during translation of the delivery tube relative to the microcatheter. The at least one flexible region is made in one construction by laser-cutting a pattern of interrupted cuts into a medical-grade nitinol (NiTi) tube. In other constructions, a coiled metallic or polymeric cylindrical component and/or a cylindrical section of flexible polymeric material is added to the distal region of the delivery tube. The grabber is created in some constructions by laser-cutting material forming

the grabber to create at least two finger elements, each preferably having a notch to enhance gripping of a control ring according to the present invention. In certain constructions, the grabber is integral, that is, is monolithically formed with the same material as the remainder of the delivery tube and, in other constructions, is fixedly attached to the distal end of the delivery tube.

In one construction, the structure 25 of occlusion device 20 is formed of metallic filaments that establish an expandable braided mesh tube. Suitable materials for the filaments include nitinol wires and other biocompatible metals, such as platinum, that will not remain in a collapsed condition after being ejected from a delivery tube. Preferably, at least one platinum wire is included for radiopacity. In other constructions, the structure 25 is formed of at least one polymeric material that does not become "set" in the collapsed condition.

Suitable materials for control ring 22 discussed above, and for control ring 22a and band 22b discussed below in relation to FIGS. 7-8B, include biocompatible radiopaque materials such as platinum, tantalum and gold. Other suitable metallic materials include cobalt chromium, stainless steel, and combinations of two or more of biocompatible metals. Suitable polymeric materials include biocompatible biodegradable and non-biodegradable materials, as described in more detail below.

One technique for manufacturing an occlusion device according to the present invention is illustrated in FIG. 7. After structure 25a is formed as a braided mesh tube, a control ring 22a is disposed by crimping and/or welding ring material about proximal region 23a to limit radial expansion at that site while defining an inner passage 26a through which one or more embolic coils can be inserted, as described above. Optionally, an inner sleeve such as a grommet (not shown) is inserted within structure 25a and positioned under the control ring 23a to maintain an inner diameter opening of desired dimension for inner passage 26a.

In this technique, a spherical mandrel 60 such as a steel ball bearing is inserted through distal region 28a to enlarge and expand the structure 25a in body region 24a. A clamp-like element such as a band 22b is then crimped over distal region 62 to further shape the body 24a. In some techniques, the assembly is heated to set mesh body 24a in the expanded condition.

When two hemispherical occlusion devices are desired, a cut is made along the circumference of mandrel 60, typically equidistant between control ring 22a and band 22b as indicated by dashed line 63, as well as on the opposite sides of control ring 22a and band 22b as shown by arrows 64 and 66, respectively. This technique creates two separate devices 20a and 20b, as depicted in FIGS. 8A and 8B, respectively. Distal end regions 28a and 28b are both open, such as illustrated for device 20 in FIGS. 1-6. Device 20b also has body 24b, proximal region 23b, and a passage 26b formed by band 22b which serves as a control ring according to the present invention. In other words, band 22b is incorporated into an implantable device 20b in one construction, instead of being a temporary clamp.

In alternative techniques, band 22b is removed and mandrel 60, FIG. 7, is extracted to form the occlusion device 20c, FIG. 9, with a constricted yet un-constrained distal region 28c, having a single control ring 22a. In yet another technique, a cut is made non-equatorially about structure 25a, such as along line 70, to generate device 20d, FIG. 10. In yet other constructions, a non-spherical mandrel such as a lozenge-shaped mandrel, is utilized to form an elongated device 20e, FIG. 11. In other words, the occlusion device according to the present invention can have many shapes such as round, elliptic, oblong, or otherwise asymmetric, and can have an open or a closed distal end. It is expected that an open distal end will typically allow better conformance to the neck and sac of the aneurysm to be treated.

An alternative occlusion device 20f according the present invention is illustrated in FIG. 12 cooperating with a cage-like vaso-occlusive structure 80 formed of strands 82, 84, 86, 88, 90, 92

and 94 in this construction. In some constructions, vaso-occlusive structure 80 is similar to one of the embodiments disclosed in US Patent No. 5,645,558 by Horton and, in certain other constructions, is similar to one of the embodiments disclosed in US Patent No. 5,916,235 by Guglielmi and in US Patent Publication No. 2010/0069948 by Veznedaroglu et al.

After a delivery system 10f is positioned as desired relative to aneurysm A, an elongated delivery member 14f is advanced within lumen 11f of catheter 12f to enable occlusion device 20f and vaso-occlusive structure 80 to expand within sac S as shown in FIG. 12. In this construction, a grabber 30f continues to be constrained radially by lumen 11f of catheter 12f and maintains its grip on control ring 22f with a plurality of gripping regions. In one construction, control ring 22f is radiopaque and is aligned under fluoroscopy in a similar manner as described above relative to FIGS. 3 and 4.

Once vaso-occlusive structure 80 is fully deployed in an expanded condition within sac S, structure 80 presses occlusion device 20f against the interior wall and across the neck N of aneurysm A to secure it in place. In other words, vaso-occlusive structure 80 serves in an expanded condition as a frame or lattice to anchor occlusion device 20f against neck N, and occlusion device 20f, held in place by structure 80, serves as a cover extending at least across neck N, the cover preferably being porous or otherwise defining sufficiently small openings, to enhance occlusion of aneurysm A. Preferably, occlusion device 20f is secured to vaso-occlusive structure 80 by at least one attachment point, being attached to at least one of a portion of the interior surface of device 20f and a portion of the control ring 22f, to maintain an aligned relationship between the device 20f and the structure 80, especially during loading and delivery of structure 80 and device 20f utilizing a delivery cannula.

In certain techniques, if a surgeon or other user desires to substantially fill the interior of sac S, at least one embolic coil is advanced through lumen 15f of delivery tube 14f, through a

passage in control ring 22f, and then is advanced into aneurysm A. In other constructions, for use where insertion of one or more embolic coils is not desired, control ring 22f may lack a passage.

In yet other constructions, such as illustrated in FIGS. 13-14, an occlusion device 20g has a detachment feature 98, representing a conventional detachment joint, instead of a control ring. Examples of electrolytically severable joints and mechanical joints are described in US Patent No. 6,454,780 by Wallace and in US Patent No. 7,410,482 by Murphy et al., for example. Similar detachable joints are described in US Patent No. 5,916,235 by Guglielmi for cage-like vaso-occlusive structures.

After the delivery system 10g is positioned within blood vessel BV as shown in FIG. 13, a delivery member 14g, also referred to as a pusher 14g, is advanced within lumen 11 g of catheter 12g to enable occlusion device 20g and vaso-occlusive structure 80g to expand within aneurysm A as shown in FIG. 14. The connection between severable element 96 and detachment feature 98 is then severed, mechanically and/or electrolytically.

Body 24g is formed of a wire mesh or braid in some constructions. In yet other constructions, the body of the occlusive device is a biocompatible film made from one or more polymeric substances. Suitable biocompatible compositions for film material include films or matrices of cellulose, alginate, cross-linked gels, and very thin polymer films of materials such as urethane, polycaprolactone (PCL), poly-lactic acid (PLA) and/or poly-glycolic acid (PGA). The film need not be erodible or bioabsorbable. In some constructions, microscopic pores or other openings are formed in the film having average diameters which are uniform in some constructions and non-uniform in other constructions. The geometric size of the pores is substantially constant along the length of the structure in some embodiments and, in other embodiments, varies along the length. The number of pores is substantially uniform along the length of the structure in some embodiments and, in other embodiments, varies along the length. Other potential materials include

polysaccharides, colloidal compounds, and some lipid products. In an alternate configuration, at least the body of the occlusive device is made of a durable, non-erodible, non-bioabsorbable material, such as a solidified urethane foam or expanded polytetrafluoroethylene (PTFE). In some embodiments, the material defines openings at least 10 microns in diameter prior to implantation in the patient and has a thickness ranging between 10 microns to 500 microns.

FIG. 15 schematically illustrates the distal portion of a novel delivery system 10h including an occlusion device delivery catheter 12h, a delivery tube 14h positioned within a lumen 11h of the occlusion device delivery catheter 12h holding a tubular occlusion device 20h, and an embolic implant delivery catheter 41h according to the present invention. As illustrated, the embolic implant delivery catheter 41h can be delivered to the aneurysm A separately from the occlusion device 20h. A distal end of the embolic implant delivery catheter 41h can be inserted into the sac S of the aneurysm A, and the occlusion device delivery catheter 12h can be positioned to implant the occlusion device 20h within sac S of aneurysm A. In one construction, the microcatheter 12h has a distal radiopaque marker band 13h and is advanced to the vicinity of neck N of aneurysm A such that marker band 13h is at the level of the neck N as seen under fluoroscopy.

After the delivery system 10h is positioned as shown in FIG. 15, the delivery member 14h is advanced within lumen 11h of catheter 12h to enable occlusion device 20h to expand into an approximately hemi-spherical shape within sac S. FIG. 16 illustrates the expansion of a distal end region 28h of the occlusion device 20h as it exits the occlusion device delivery catheter 12h. FIG. 17A illustrates the tubular body region 24h of the occlusion device 20h expanded to such that an exterior surface of the occlusion device 20h contacts the aneurysm A and the embolic implant delivery catheter 41h. The shape of occlusion device 20h will conform to the shape of the sac S where device 20h touches the inner wall of the sac S and will conform to the embolic implant delivery catheter 41h where device 20h touches the embolic catheter 41h. FIG. 17B is a cross-

sectional view of FIG. 17A illustrating the conformity of the device 20h to the inner wall of the sac S and the embolic implant delivery catheter 41h. The body region 24h of the occlusion device 20h is in the expanded condition provides a force to appose the embolic catheter 41h to the aneurysm wall.

Once occlusion device 20h is positioned within sac S, at least one embolic coil 40h, FIG. 18, is advanced through a lumen of the embolic implant delivery catheter 41h to substantially fill sac S and to anchor body 24h of occlusion device 20h against the interior wall of aneurysm A to block neck N as shown in FIG. 19. As is apparent, once the embolic coil 40h is delivered, the embolic implant delivery catheter 41h can be removed. Once removed from the sac S, the occlusion device 20h can conform to the remaining section of the inner wall.

Referring collectively to FIGS. 15-18, during implantation of the occlusion device 20h and the embolic coil 40h a control ring 22h near a proximal end region 23h of the occlusion device 20h can be held by a grabber 30h on the delivery member 14h. After a sufficient amount of embolic coil 40h has been fully deployed within sac S to anchor occlusion device 20h within aneurysm A, the occlusion device 14h can be released from the delivery member 14h. The grabber 30h can be constrained by the occlusion device delivery catheter 12h, and fingers 32h and 34h of the grabber 30h can expand when exiting the occlusion device delivery catheter 12h to release the control ring 22h as shown in FIG. 20. The grabber 30h can have a plurality of gripping regions such as notches 36h and 38h. In one construction, control ring 22h is radiopaque and is aligned under fluoroscopy relative to marker 13h on catheter 12h as shown in FIGS. 15-18 and 20. Fingers 32h and 34h preferably are biased radially outwardly to disengage control ring 22h from notches 36h and 38h in fingers 32h and 34h, respectively.

An advantage of the system 10h illustrated in FIGS. 15-20 is that the occlusion device delivery catheter 12h, the control ring 22h, and the delivery member 14h need not be sized to

deliver an embolic implant. Because the delivery member 14h need not be sized to delivery an embolic implant, numerous alternative delivery or pusher apparatus can be used in place of or in addition to the delivery members and delivery tubes described herein.

In one construction, the tubular structure, mesh body region 24h of occlusion device 20h is formed of metallic filaments that establish an expandable braided mesh tube. Suitable materials for the filaments include nitinol wires and other biocompatible metals, such as platinum, that will not remain in a collapsed condition after being ejected from a delivery tube. Preferably, at least one platinum wire is included for radiopacity. In other constructions, the tubular structure 24h is formed of at least one polymeric material that does not become "set" in the collapsed condition.

Thus, while there have been shown, described, and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions, substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, it is expressly intended that all combinations of those elements and/or steps that perform substantially the same function, in substantially the same way, to achieve the same results be within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is also to be understood that the drawings are not necessarily drawn to scale, but that they are merely conceptual in nature. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

Every issued patent, pending patent application, publication, journal article, book or any other reference cited herein is each incorporated by reference in their entirety.

Claims

What is claimed is:

1. A system suitable for endovascular treatment of an aneurysm in a blood vessel in a patient, comprising:
 - an occlusion device having a substantially tubular braided mesh structure having a proximal end region and a distal end region and a control ring having a substantially annular body disposed on the proximal end region of the tubular structure, the control ring at least partially circumscribing the proximal end region to prevent radial expansion of the proximal end region and to provide an engagement feature during manipulation of the occlusion device; and
 - an embolic implant delivery catheter capable of delivering an embolic implant to the aneurysm,
 - wherein the tubular structure is expandable from a collapsed condition to an expanded condition,
 - wherein in the collapsed condition, the tubular structure is suitable for insertion through vasculature of a patient and through a neck of the aneurysm, and
 - wherein in the expanded condition, the tubular structure has a substantially hemispherical shape and has an exterior surface capable of contacting the aneurysm and capable of providing a force to appose the embolic implant delivery catheter to the aneurysm.
2. The system of claim 1 further comprising the embolic implant.
3. The system of claim 2 wherein the tubular structure of the occlusion device in the expanded condition is capable of supporting the embolic implant in the aneurysm.
4. The system of claim 1 wherein the control ring is crimped onto the proximal end region of the tubular structure.
5. The system of claim 1 wherein the control ring includes radiopaque material.
6. The system of claim 1 wherein the tubular structure includes a plurality of filaments.

7. The system of claim 1 wherein the tubular structure defines a substantially enclosed volume.
8. The system of claim 1 wherein at least a portion of the proximal end region of the tubular structure defines a plurality of openings having a sufficiently small size to enhance occlusion of the aneurysm.
9. The system of claim 1 further comprising a delivery member having a distal end region carrying a grabber having at least two finger elements, each finger element defining a gripping region to mechanically engage the control ring.
10. The system of claim 9 wherein the delivery member is a tube formed of at least one metallic material.
11. The system of claim 9 wherein the grabber is formed of a metallic material and the gripping regions are notches formed in the finger elements, each notch being sized to mechanically engage a portion of the control ring.
12. The system of claim 9 further including an occlusion device delivery catheter having an inner lumen through which the delivery member is insertable and translatable relative to the occlusion device delivery catheter.
13. A method of treating an aneurysm in a blood vessel in a patient, comprising:
selecting an occlusion device including a substantially tubular structure having a proximal end region and a distal end region, having a first, expanded condition and a second, collapsed condition when drawn into an occlusion device delivery catheter, and further including a control ring having a substantially annular body disposed on the proximal end region of the tubular structure and at least substantially circumscribing the proximal end region to prevent radial expansion of the proximal end region, the tubular structure is a braided mesh tube, the tubular structure having a substantially hemispherical shape in the expanded condition;

drawing the occlusion device into the occlusion device delivery catheter to force the occlusion device into the collapsed condition;

inserting a distal end of an embolic implant delivery catheter into the aneurysm;

inserting the occlusion device delivery catheter with the occlusion device into vasculature of the patient to reach the region of the aneurysm in the blood vessel;

expanding the occlusion device to capture the embolic implant delivery catheter against a wall of the aneurysm;

positioning the occlusion device within the aneurysm; and

releasing the control ring at the proximal end region and withdrawing the occlusion device delivery catheter from the patient.

14. The method of claim 13 wherein the tubular structure includes braided filaments.

15. The method of claim 13 further including delivering at least one embolic coil through the embolic implant catheter to occlude flow into the aneurysm.

16. The method of claim 15 further including providing a force by the embolic coil to secure the occlusion device within the aneurysm.

17. The method of claim 13 further including withdrawing the embolic implant delivery catheter from the aneurysm.

18. The method of claim 13 further including mechanically engaging the control ring with a grabber on a delivery member to enable manipulation of the occlusion device and utilizing the grabber to draw the occlusion device into the occlusion device delivery catheter carrying the delivery member to force the occlusion device into the collapsed condition.

19. A method of treating an aneurysm in a blood vessel in a patient, comprising:

selecting an occlusion device including a substantially tubular structure having a proximal end region and a distal end region, having a first, expanded condition and a second, collapsed condition when drawn into a delivery microcatheter, at least a portion of the proximal end region

defining a plurality of openings having a sufficiently small size to enhance occlusion of the aneurysm, and further including a control ring having a substantially annular body disposed on the proximal end region of the tubular structure and at least substantially circumscribing the proximal end region to prevent radial expansion of the proximal end region, the tubular structure is a braided mesh tube, the tubular structure having a substantially hemispherical shape in the expanded condition;

mechanically engaging the control ring with a grabber on a pusher member to enable manipulation of the occlusion device;

drawing the occlusion device into the delivery microcatheter carrying the pusher member to force the occlusion device into the collapsed condition;

inserting the delivery microcatheter with the occlusion device into the vasculature of the patient to reach the region of the aneurysm in the blood vessel;

inserting a distal end of an embolic implant catheter into the aneurysm;

positioning the occlusion device within the aneurysm;

expanding the occlusion device to capture the embolic implant catheter against a wall of the aneurysm;

delivering at least one embolic coil through the embolic implant catheter to occlude flow into the aneurysm; and

mechanically releasing the control ring and withdrawing the delivery microcatheter and the embolic implant catheter from the patient.

20. The method of claim 19 further including providing a force by the embolic coil to secure the occlusion device within the aneurysm.

Abstract

An occlusion device suitable for endovascular treatment of an aneurysm in a blood vessel in a patient, including a substantially tubular structure having a proximal end region and a distal end region, having a first, expanded condition and a second, collapsed condition. The device has dimensions in the second, collapsed condition suitable for insertion through vasculature of the patient and through a neck of the aneurysm. The device further includes a control ring having a substantially annular body disposed on the proximal end region of the structure and at least substantially circumscribing the proximal end region to prevent radial expansion of the proximal end region and to provide an engagement feature during manipulation of the occlusion device.

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:

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.)

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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 /Eugene L. Szczecina, Jr./ Date (Optional) August 30, 2016

Name Eugene L. Szczecina, Jr.

Title Assistant General Counsel - Patents / DePuy Synthes Products, INC.

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

Total of forms are submitted.

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

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

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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)**Title of
Invention****ANEURYSM OCCLUSION DEVICE**

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 14/230,426filed on 03-31-2014

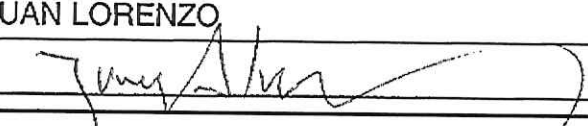
The above-identified application was made or authorized to be made by me.

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:

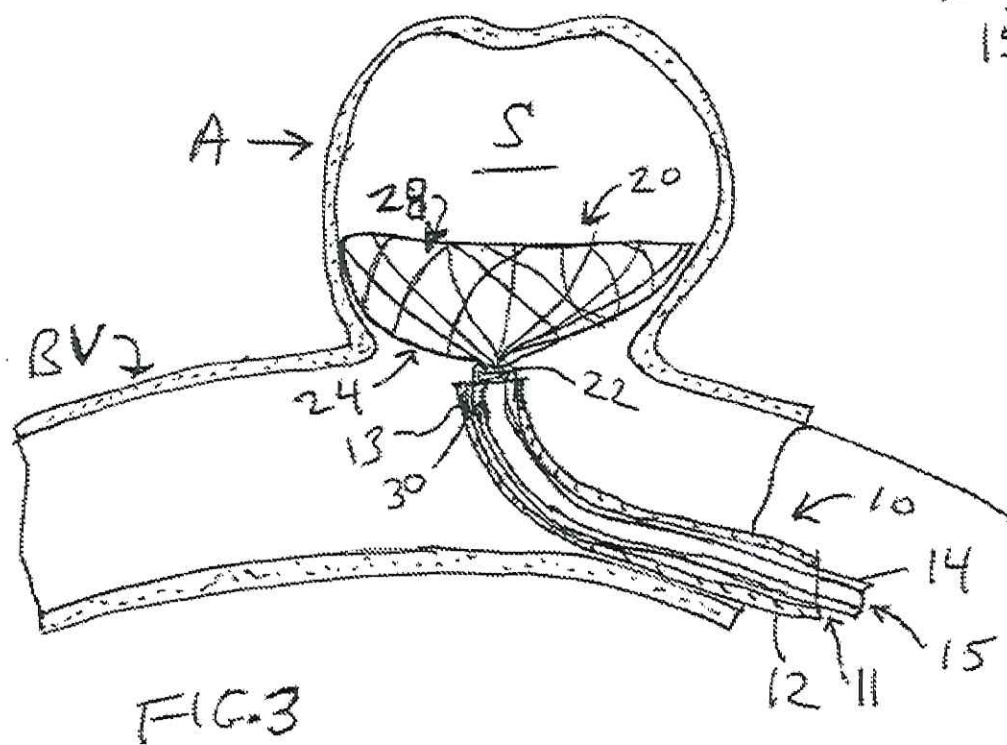
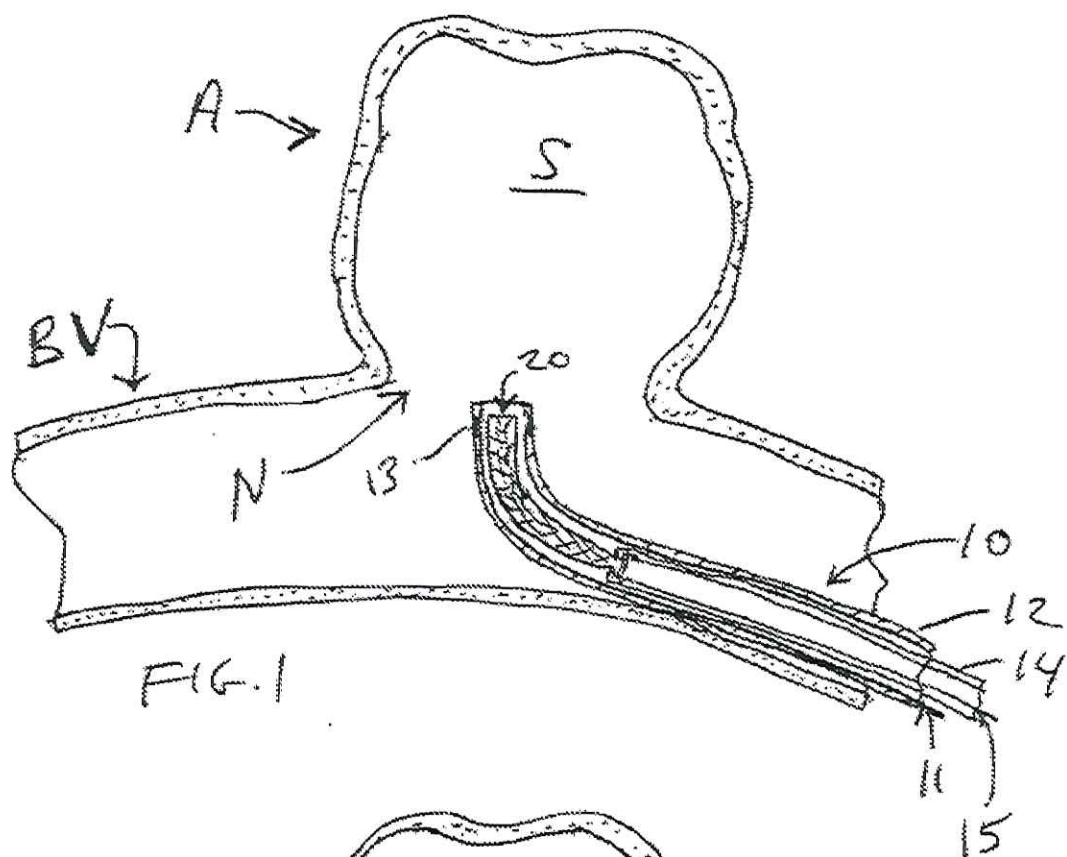
Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization 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.

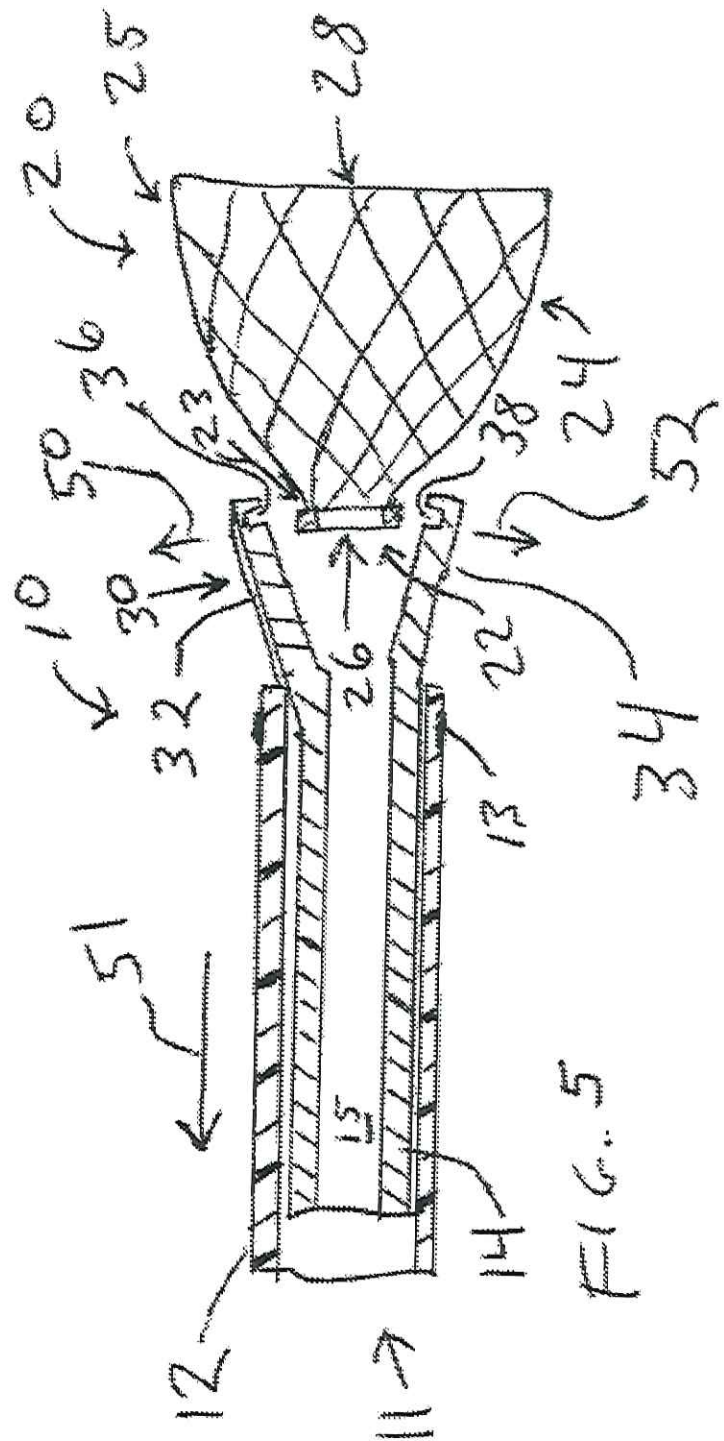
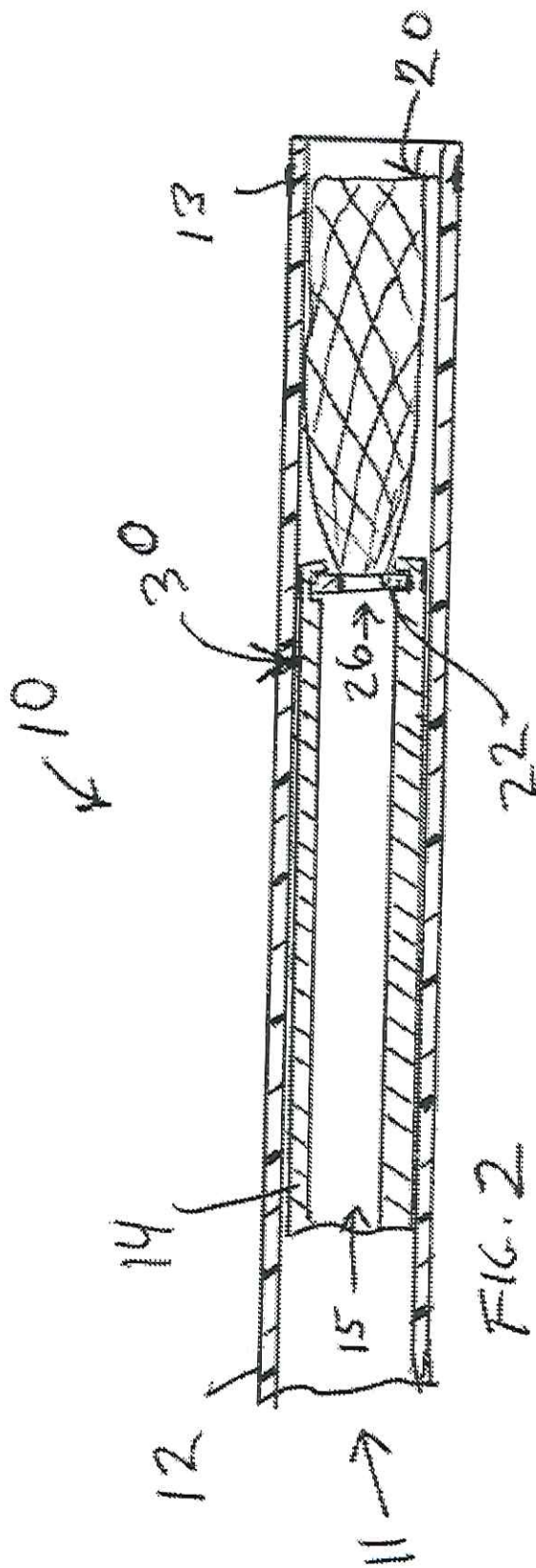
LEGAL NAME OF INVENTORInventor: JUAN LORENZODate (Optional): Aug 6, 2014Signature: 

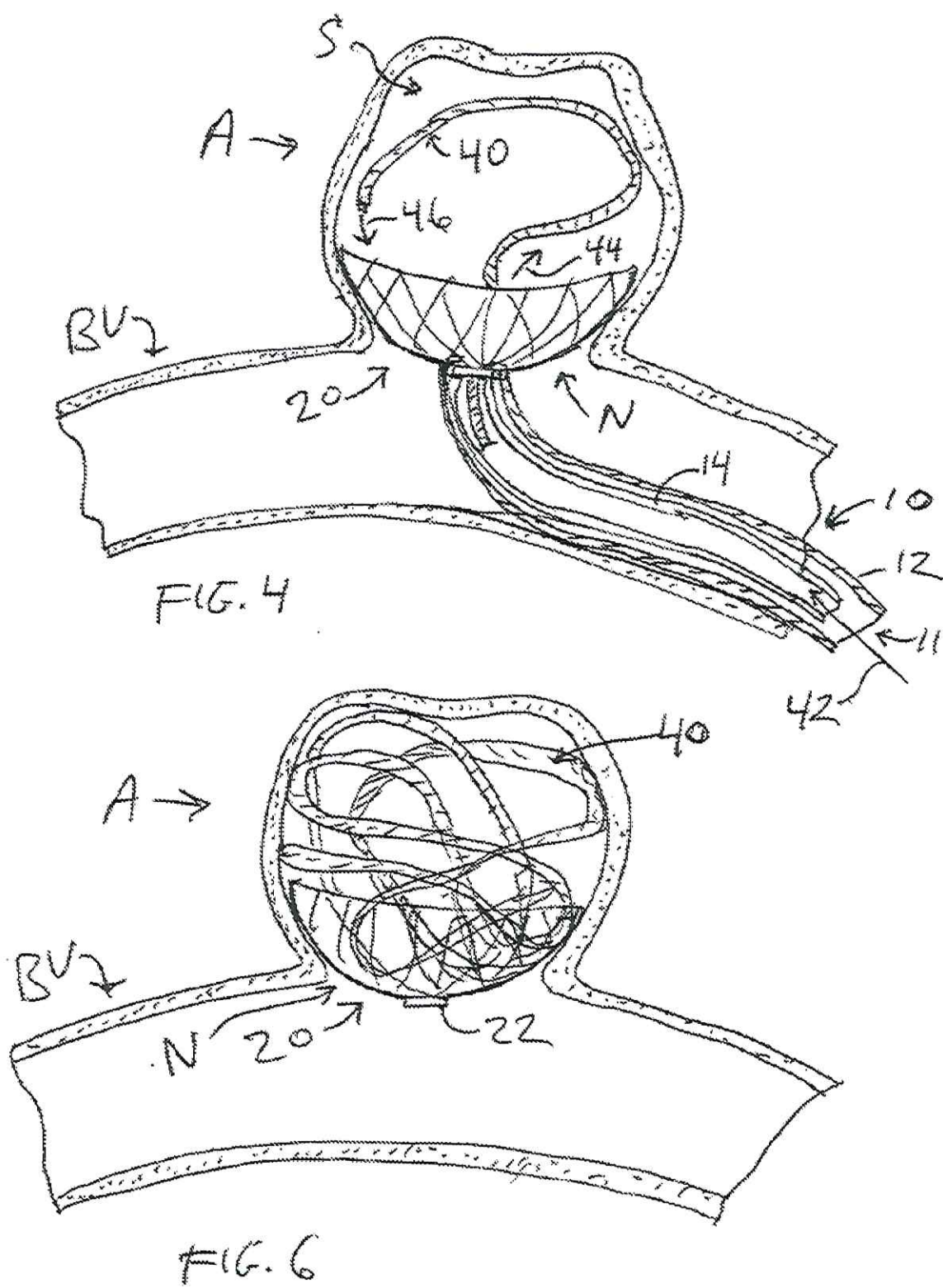
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

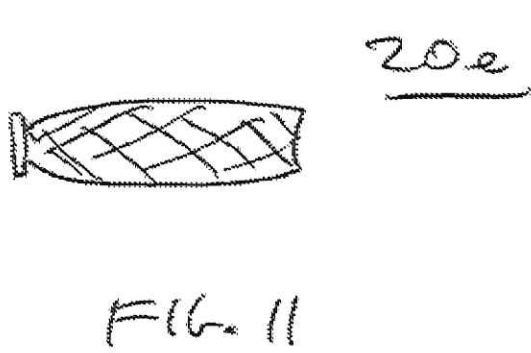
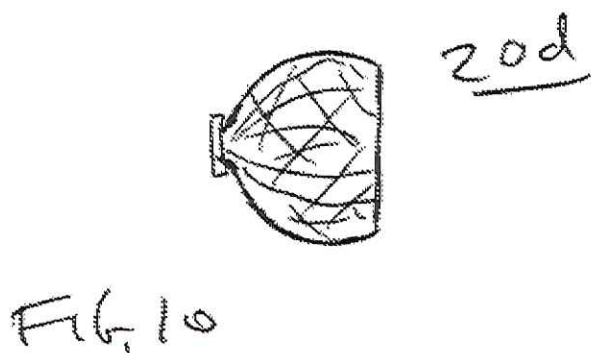
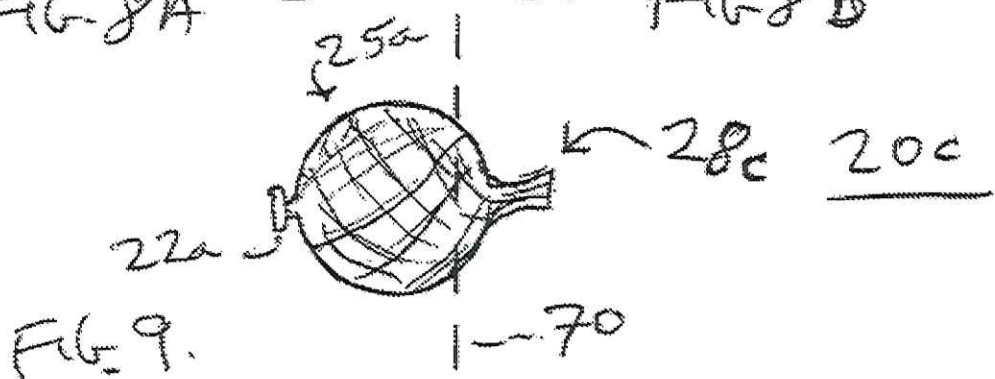
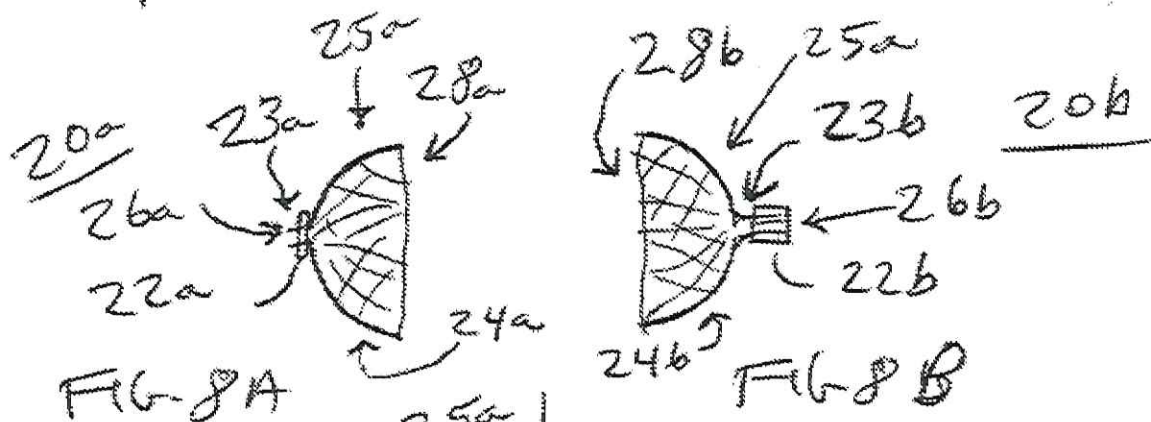
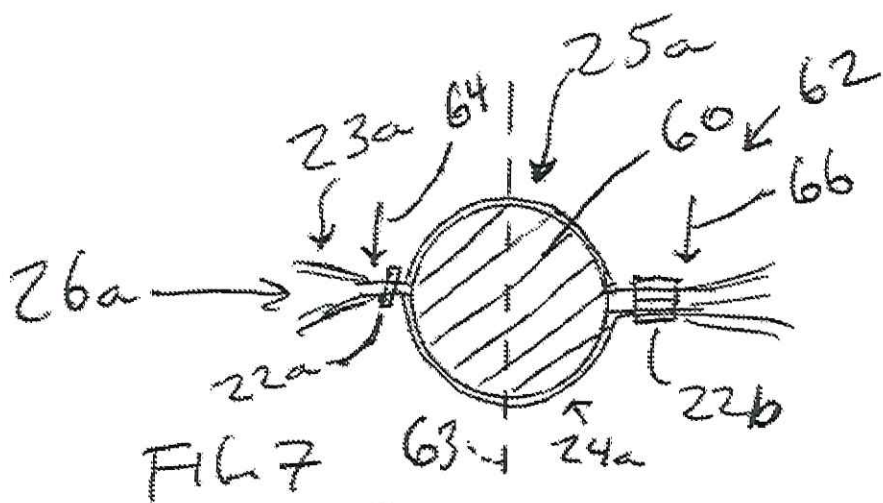
This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is 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.

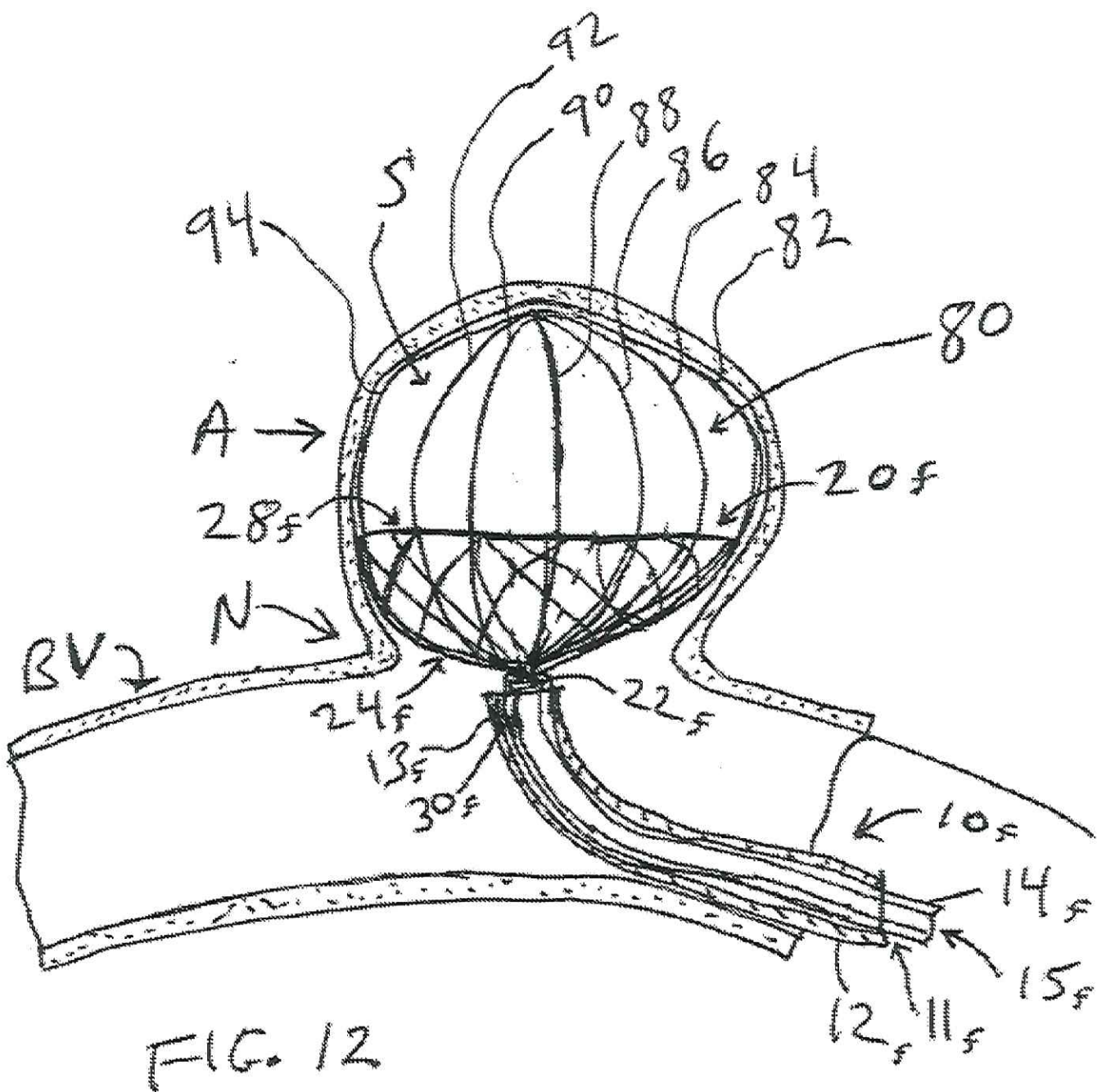
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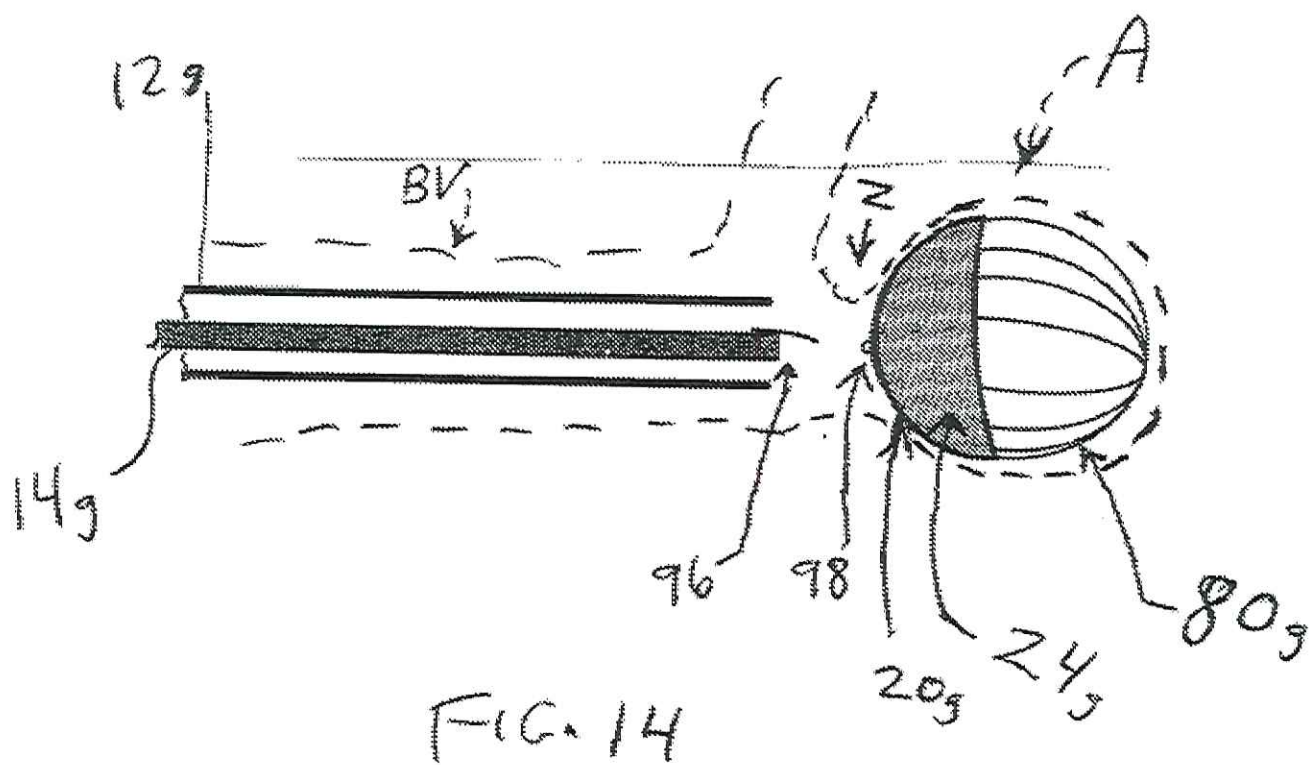
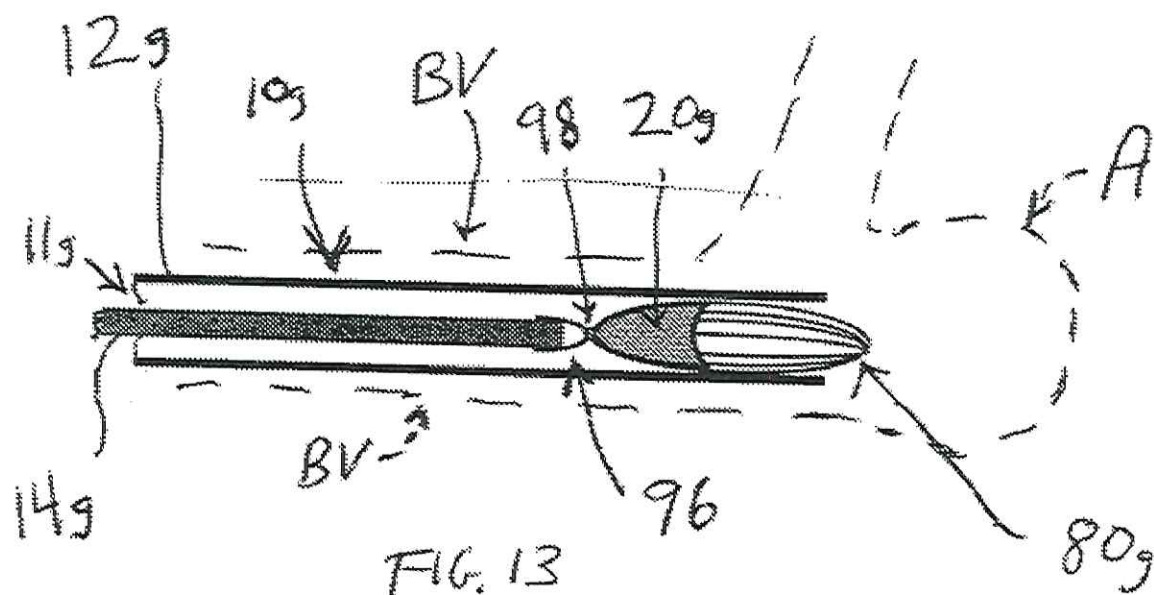


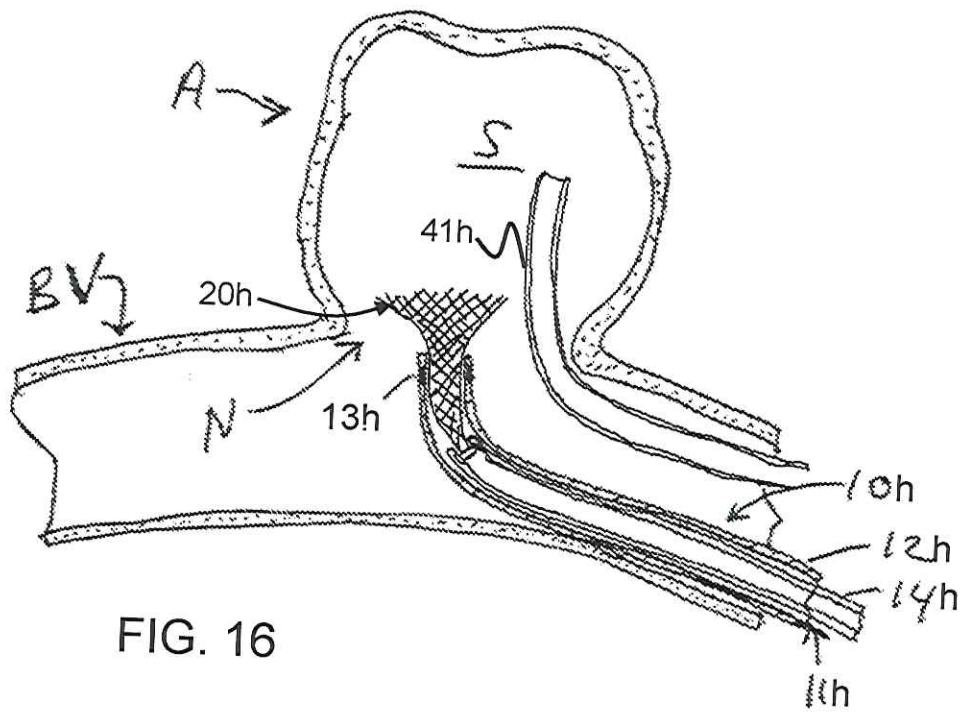
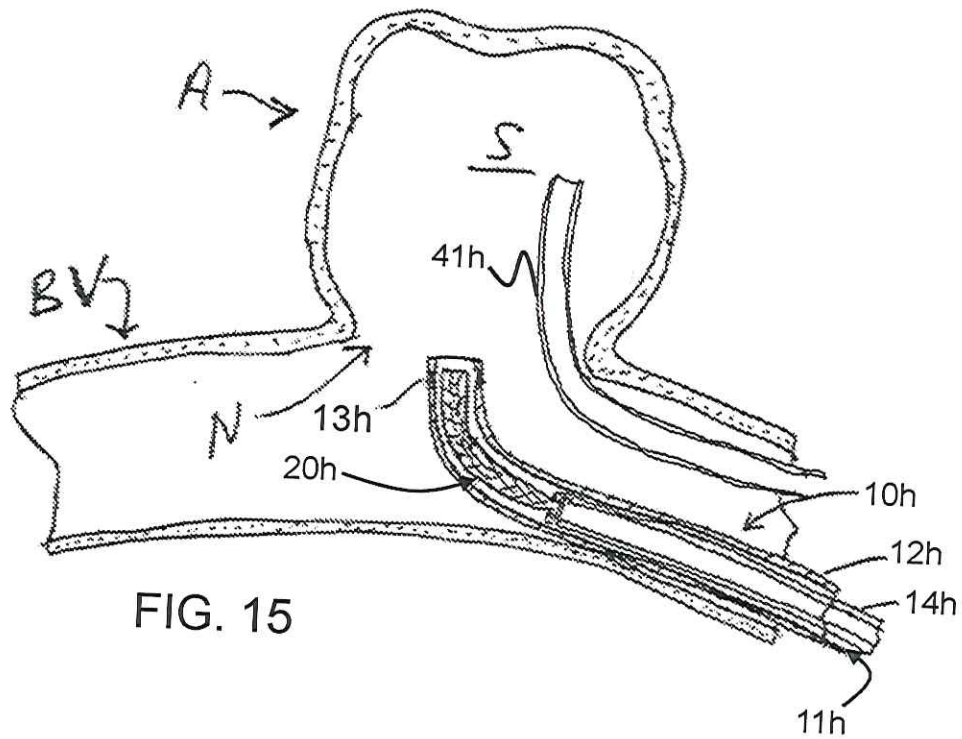


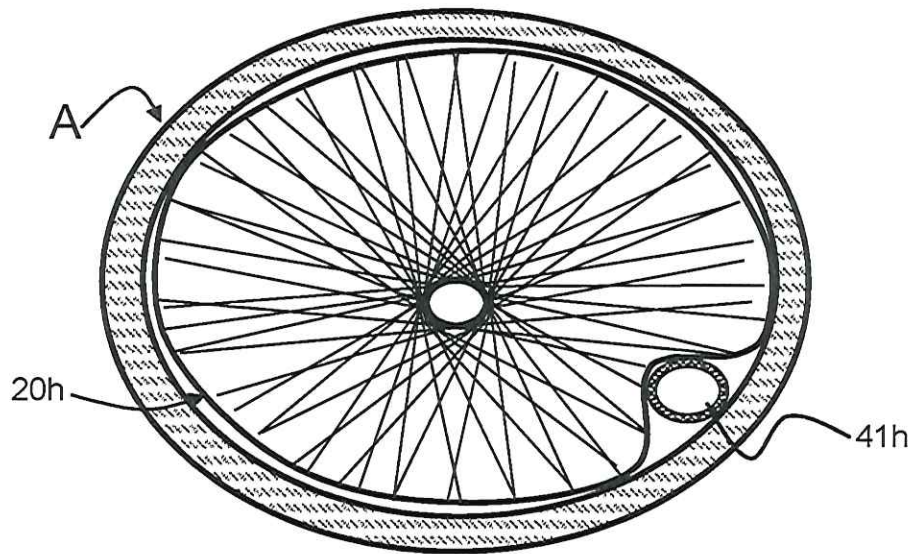
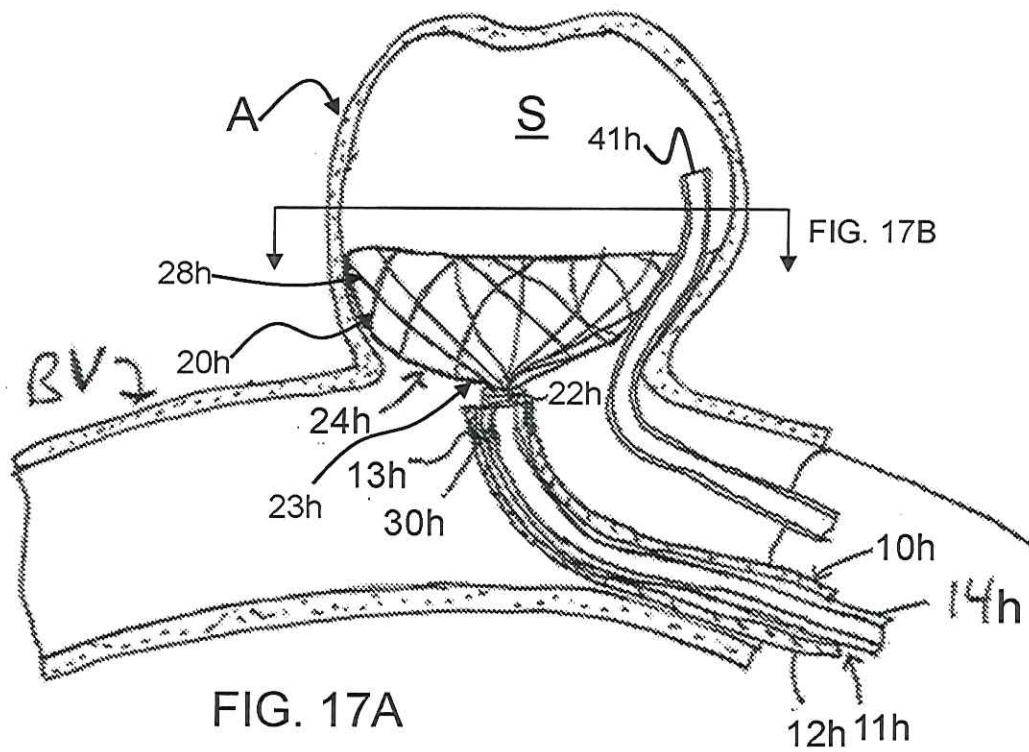


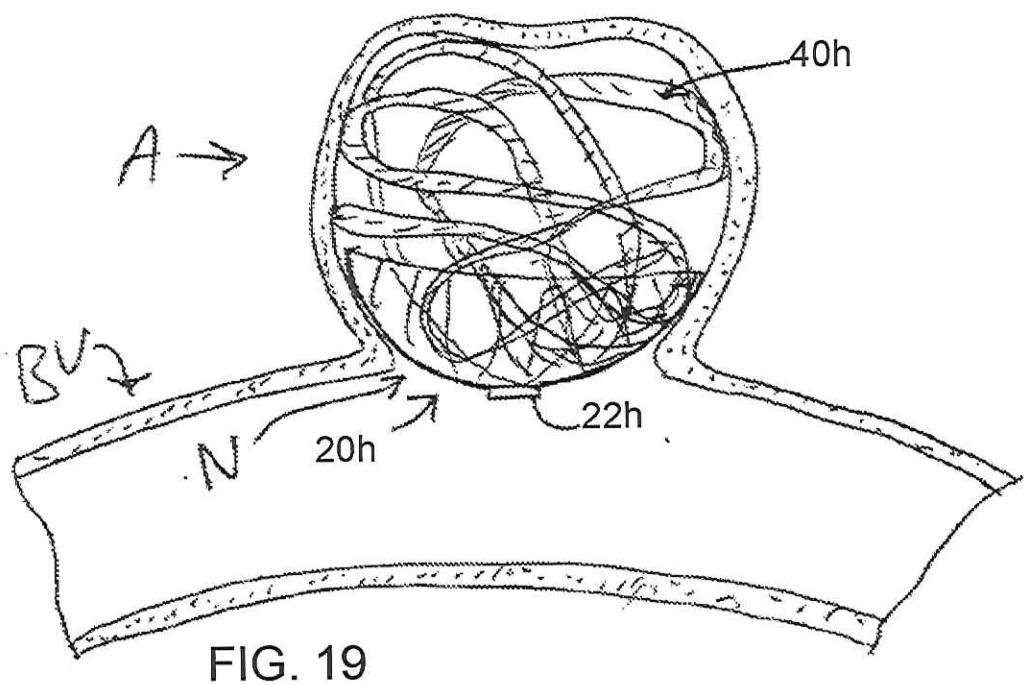
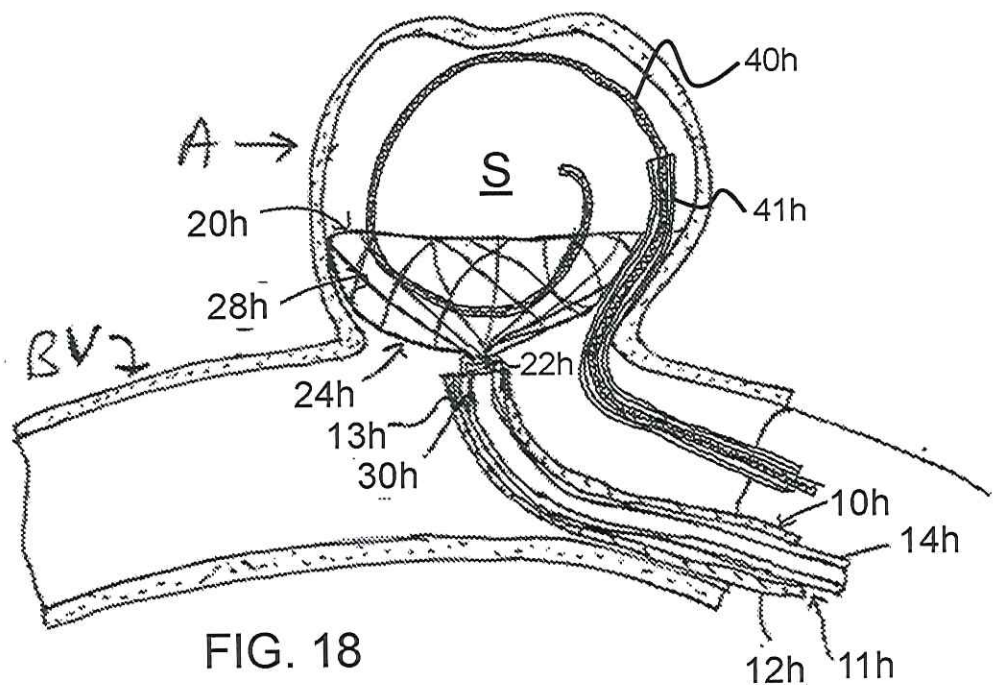












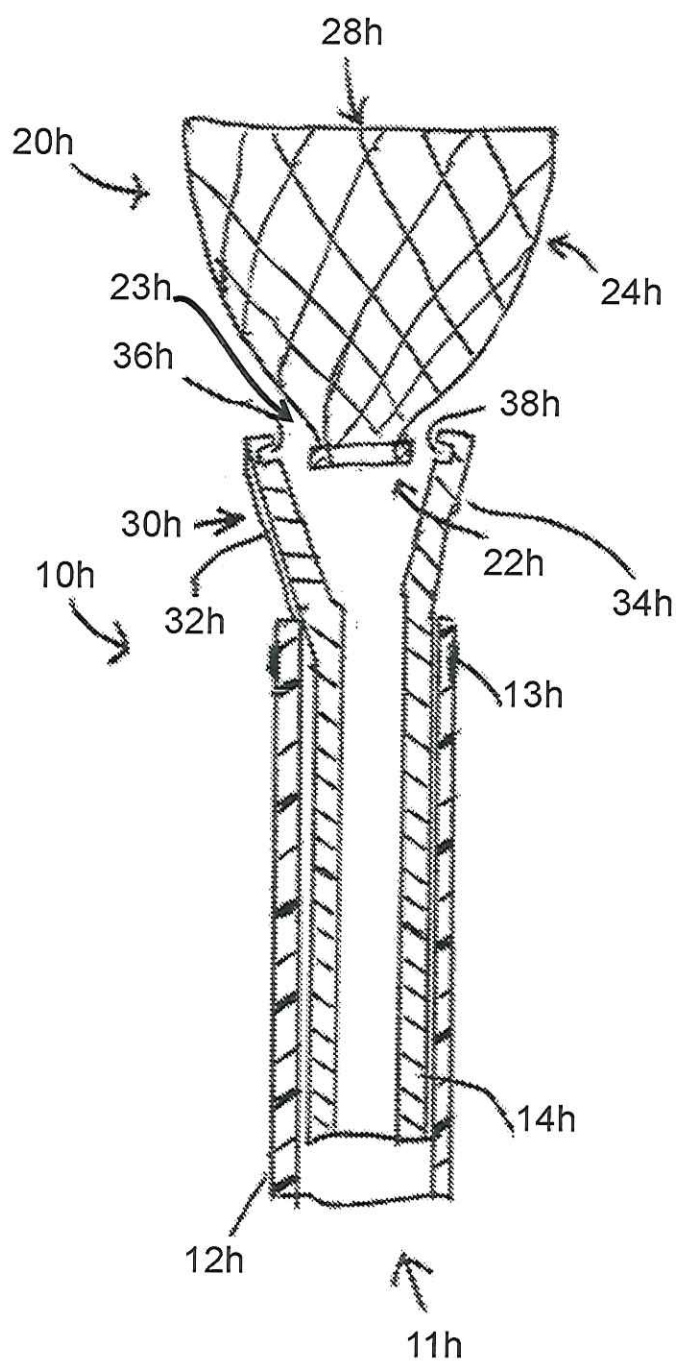


FIG. 20

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000154
		Application Number	
Title of Invention	IMPROVED ANEURYSM OCCLUSION DEVICE		
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	US			
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.						
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Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

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Customer Number	06980		
Email Address	IPServicesNYC@troutmansanders.com	Add Email	Remove Email

Application Information:

Title of the Invention	IMPROVED ANEURYSM OCCLUSION DEVICE		
Attorney Docket Number	243382.000154	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	243382.000154
		Application Number	
Title of Invention	IMPROVED ANEURYSM OCCLUSION DEVICE		

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	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation in part of	14230426	2014-03-31

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	243382.000154
	Application Number	
Title of Invention	IMPROVED ANEURYSM OCCLUSION DEVICE	

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).

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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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000154
		Application Number	
Title of Invention	IMPROVED ANEURYSM OCCLUSION DEVICE		

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	243382.000154
		Application Number	
Title of Invention	IMPROVED ANEURYSM OCCLUSION DEVICE		

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
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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
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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	243382.000154
		Application Number	
Title of Invention	IMPROVED ANEURYSM OCCLUSION DEVICE		

Assignee 1

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

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

Remove

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)	2018-09-12
First Name	Louis John	Last Name	DeJuidice	Registration Number
				47522

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

Add

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. 552a) 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.