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28 de septiembre de 2017

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: **15/337,827**
Fecha de Presentación: **28 de octubre de 2016**

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, PARA SER USADA EN LA PRESENTACIÓN EXTRANJERA BAJO EL CONVENIO DE PARÍS ES **US 15/337,827**

Por la autoridad de
Bajo el Secretario de Comercio para la Propiedad Intelectual y el Director de la Oficina de Patentes y Marcas de los Estados Unidos de América

(fdo) **W. MONTGOMERY**
Oficial Certificador
(Sello oficial de la Oficina de Patentes y Marcas de los Estados Unidos de América)

Reivindicaciones

1. Una unidad de válvula implantable que tiene una vida útil operativa extendida, que comprende:

un catéter de drenaje que tiene un extremo proximal y un extremo distal opuesto; el catéter de drenaje comprende un solo lumen central ubicado cerca de su extremo proximal que tiene un solo conducto central definido longitudinalmente a través de él; entre el extremo proximal y el extremo distal del catéter de drenaje, el lumen central único se convierte, en un punto de contacto, en una pluralidad de lúmenes ramificados distintos fabricados de un material con memoria de forma; cada uno de la pluralidad de lúmenes ramificados tiene asociado con él un solo conducto ramificado definido longitudinalmente a través de él; el conducto ramificado único de cada uno de la pluralidad de lúmenes ramificados está en comunicación continua con el conducto central único del lumen central único;

un recubrimiento por inmersión de material bioabsorbible colocado en el extremo distal del catéter de drenaje; en el momento de la implantación, el recubrimiento por inmersión fija la pluralidad de lúmenes ramificados distintos en contacto físico directo entre sí desde el extremo distal del catéter de drenaje hasta el punto de contacto con el lumen central;

en donde cada uno de la pluralidad de lúmenes ramificados distintos tiene un perímetro externo que comprende al menos una de una primera sección de superficie externa y una segunda sección de superficie externa; conjuntamente, la primera y la segunda secciones de superficie externa de un lumen ramificado distinto particular comprenden su perímetro radial externo completo; mientras se encuentra

en un estado fijo con la pluralidad de lúmenes ramificados distintos mantenidos juntos por el recubrimiento por inmersión: (i) la primera sección de superficie externa de cada uno de la pluralidad de lúmenes ramificados distintos está en contacto físico directo con la primera sección de superficie externa de al menos otro lumen ramificado en una dirección longitudinal desde el punto de contacto hasta el extremo distal del catéter; y (ii) la segunda sección de superficie externa de cada uno de la pluralidad de lúmenes ramificados distintos no está en contacto físico con la primera o la segunda sección de superficie externa de cualquier otro lumen ramificado;

en donde cada uno de la pluralidad de lúmenes ramificados distintos tiene una pluralidad de orificios definidos radialmente hacia afuera a través de ellos en la primera y la segunda secciones de superficie externa; mientras que en el estado fijo con la pluralidad de lúmenes ramificados distintos mantenidos juntos por el recubrimiento por inmersión, un líquido no puede pasar a través de la pluralidad de orificios definidos en las primeras secciones de superficie externa de cualquiera de la pluralidad de lúmenes ramificados distintos.

2. La unidad de conformidad con la reivindicación 1, en donde, en una dirección axial, los centros de orificios adyacentes de los orificios definidos en la primera y la segunda secciones de superficie externa, respectivamente, de un lumen ramificado particular de la pluralidad de lúmenes ramificados distintos están espaciados entre sí por una distancia de desplazamiento lateral predeterminada de manera que los centros de orificios adyacentes definidos en la primera y la segunda secciones de

superficie externa del lumen ramificado particular no están dispuestos linealmente en una dirección axial.

3. La unidad de conformidad con la reivindicación 3, en donde la distancia de desplazamiento lateral predeterminada es mayor o igual que un diámetro del orificio, en donde el diámetro de cada orificio es sustancialmente igual.

4. La unidad de conformidad con la reivindicación 1, en donde el material bioabsorbible del recubrimiento por inmersión es absorbido después de la expiración de un primer período de tiempo predeterminado en un intervalo de aproximadamente 72 horas a aproximadamente 168 horas.

5. La unidad de conformidad con la reivindicación 1, en donde en ausencia de una fuerza externa aplicada, la pluralidad de lúmenes ramificados distintos se extienden radialmente hacia afuera desde el lumen central; después de la aplicación de la fuerza externa, la pluralidad de lúmenes ramificados distintos se pueden deformar radialmente hacia adentro de modo que estén en contacto físico entre sí en una dirección axial desde el punto de contacto con el lumen central hasta el extremo distal del catéter de drenaje para formar un cilindro ensamblado que tiene un diámetro sustancialmente igual a y coaxial con aquel del lumen central.

6. La unidad de conformidad con la reivindicación 1, que comprende, además, al menos un miembro de bloqueo fabricado de un material

bioabsorbible que tapa los orificios dispuestos a aproximadamente la misma distancia axial desde el extremo distal del catéter de drenaje en las segundas secciones de superficie externa de cada uno de la pluralidad de lúmenes ramificados distintos para impedir que cualquier fluido entre en ellos.

7. La unidad de conformidad con la reivindicación 6, en donde en un momento (t_o) de implantación de la válvula, con la excepción de al menos dos orificios externos visibles ubicados más cerca del extremo distal del catéter de drenaje y definidos en la segunda sección de superficie externa de la pluralidad de lúmenes ramificados distintos que no están tapados y permiten la entrada de fluido en ellos, el paso del fluido a través de todos los orificios restantes definidos en la primera y segunda secciones de superficie externa de la pluralidad de lúmenes ramificados distintos es impedido por un miembro de bloqueo correspondiente o el contacto físico entre las primeras secciones de superficie externa de la pluralidad de lúmenes ramificados distintos.

8. La unidad de conformidad con la reivindicación 6, en donde con el transcurso del tiempo, para cada miembro de bloqueo que es absorbido completamente, se destapan al menos dos orificios por cada uno de la pluralidad de lúmenes ramificados distintos para permitir el paso del fluido a través de ellos.

9. La unidad de conformidad con la reivindicación 6, en donde la válvula comprende una pluralidad de miembros de bloqueo dispuestos secuencialmente uno después del otro en una dirección axial alrededor de un perímetro del catéter de drenaje; cada uno de la pluralidad de miembros de bloqueo está fabricado de un material bioabsorbible seleccionado con una formulación y/o dimensión para ser absorbido completamente en diferentes períodos de tiempo espaciados secuencialmente de tal forma que: un primer miembro de bloqueo colocado más cercano al extremo distal del catéter de drenaje tiene una vida útil más corta antes de ser absorbido completamente; avanzando en una dirección axial en sentido contrario al extremo distal del catéter de drenaje, cada miembro de bloqueo sucesivo tiene una vida útil más larga, antes de ser absorbido completamente, que la de su predecesor más cercano al extremo distal del catéter de drenaje; y un último miembro de bloqueo más lejano al extremo distal del catéter de drenaje tiene una vida útil más larga, antes de ser absorbido completamente, que la de cualquiera de sus predecesores más cercanos al extremo distal del catéter de drenaje.

10. La unidad de conformidad con la reivindicación 1, que comprende, además, un estilete de desplazamiento lateral.

11. Un método para utilizar una unidad de válvula implantable que tiene una vida útil operativa extendida, en donde la unidad de válvula implantable incluye un catéter de drenaje que tiene un extremo proximal y un extremo

distal opuesto; el catéter de drenaje tiene un solo lumen central ubicado cerca de su extremo proximal que tiene un solo conducto central definido longitudinalmente a través de él; entre el extremo proximal y el extremo distal del catéter de drenaje, el lumen central único se convierte, en un punto de contacto, en una pluralidad de lúmenes ramificados distintos fabricados de un material con memoria de forma; cada uno de la pluralidad de lúmenes ramificados tiene asociado con él un solo conducto ramificado definido longitudinalmente a través de él; el conducto ramificado único de cada uno de la pluralidad de lúmenes ramificados está en comunicación continua con el conducto central único del lumen central único; un recubrimiento por inmersión de material bioabsorbible se coloca en el extremo distal del catéter de drenaje; en donde cada uno de la pluralidad de lúmenes ramificados distintos tiene un perímetro externo que comprende al menos una de una primera sección de superficie externa y una segunda sección de superficie externa; conjuntamente, la primera y la segunda secciones de superficie externa de un lumen ramificado distinto particular comprenden su perímetro radial externo completo; en donde cada uno de la pluralidad de lúmenes ramificados distintos tiene una pluralidad de orificios definidos radialmente hacia afuera a través de ellos en la primera y la segunda secciones de superficie externa, el método comprende las etapas de:

durante la implantación, hacer avanzar el catéter de drenaje hasta un lugar deseado, mientras que la pluralidad de lúmenes ramificados distintos se fijan en contacto físico directo entre sí desde el extremo distal del catéter de drenaje hasta el

punto de contacto con el lumen central mediante el recubrimiento por inmersión; mientras se encuentra en un estado fijo con la pluralidad de lúmenes ramificados distintos mantenidos juntos por el recubrimiento por inmersión: (i) la primera sección de superficie externa de cada uno de la pluralidad de lúmenes ramificados distintos está en contacto físico directo con la primera sección de superficie externa de al menos otro lumen ramificado en una dirección longitudinal desde el punto de contacto con el lumen central hasta el extremo distal del catéter, lo que impide que el líquido entre en los orificios definidos en las primeras secciones de superficie externa de cualquiera de los lúmenes de la pluralidad de lúmenes ramificados distintos; y (ii) la segunda sección de superficie externa de cada uno de la pluralidad de lúmenes ramificados distintos no está en contacto físico con la primera o la segunda sección de superficie externa de cualquier otro lumen ramificado.

12. El método de conformidad con la reivindicación 11, en donde en el estado fijo, sujeto a una fuerza externa aplicada ejercida por el recubrimiento por inmersión, la pluralidad de lúmenes ramificados distintos se deforman radialmente hacia adentro de modo que están en contacto físico entre sí en una dirección longitudinal desde el punto de contacto con el lumen central hasta el extremo distal del catéter de drenaje para formar un cilindro ensamblado que tiene un diámetro sustancialmente igual a y coaxial con aquel del lumen central.

13. El método de conformidad con la reivindicación 11, en donde, en una dirección axial, los centros de orificios adyacentes de los orificios

definidos en la primera y la segunda secciones de superficie externa, respectivamente, de un lumen ramificado particular de la pluralidad de lúmenes ramificados distintos están espaciados entre sí por una distancia de desplazamiento lateral predeterminada de manera que los centros de orificios adyacentes definidos en la primera y la segunda secciones de superficie externa del lumen ramificado particular no están dispuestos linealmente en una dirección axial.

14. El método de conformidad con la reivindicación 11, que comprende, además, después de la expiración de un primer transcurso de tiempo predeterminado en el que el recubrimiento por inmersión es absorbido completamente, la etapa en la que el material con memoria de forma de la pluralidad de lúmenes ramificados distintos regresa automáticamente a su forma original extendiéndose radialmente hacia afuera desde el lumen central de manera que, comenzando desde el extremo distal del catéter, una porción de las primeras secciones de superficie externa de la pluralidad de lúmenes ramificados distintos se separa de las otras permitiendo que el fluido entre en los orificios expuestos en la primera sección de superficie externa que se ha separado de las otras.

15. El método de conformidad con la reivindicación 12, en donde la válvula incluye al menos un miembro de bloqueo fabricado de un material bioabsorbible que tapa los orificios dispuestos a aproximadamente la misma distancia axial desde el extremo distal del catéter de drenaje en las segundas secciones de

superficie externa de cada uno de la pluralidad de lúmenes ramificados distintos para impedir que cualquier fluido entre ellos.

16. El método de conformidad con la reivindicación 15, en donde durante la implantación de la válvula, con la excepción de al menos dos orificios externos visibles ubicados más cerca del extremo distal del catéter de drenaje y definidos en la segunda sección de superficie externa de la pluralidad de lúmenes ramificados distintos que no están tapados y permiten la entrada de fluido en ellos, el paso del fluido a través de todos los orificios restantes definidos en la primera y segunda secciones de superficie externa de la pluralidad de lúmenes ramificados distintos es impedido por un miembro de bloqueo correspondiente o el contacto físico entre las primeras secciones de superficie externa de la pluralidad de lúmenes ramificados distintos.

17. El método de conformidad con la reivindicación 15, en donde después de la absorción completa de cada uno de la pluralidad de miembros de bloqueo, se destapan al menos dos orificios por cada uno de la pluralidad de lúmenes ramificados distintos para permitir el paso del fluido a través de ellos.

18. El método de conformidad con la reivindicación 15, en donde la válvula comprende una pluralidad de miembros de bloqueo dispuestos secuencialmente uno después del otro en una dirección axial alrededor de

un perímetro del catéter de drenaje; cada uno de la pluralidad de miembros de bloqueo está fabricado de un material bioabsorbible seleccionado con una formulación y/o dimensión para ser absorbido completamente en diferentes períodos de tiempo espaciados secuencialmente de tal forma que: un primer miembro de bloqueo colocado más cercano al extremo distal del catéter de drenaje tiene una vida útil más corta antes de ser absorbido completamente; avanzando en una dirección axial en sentido contrario al extremo distal del catéter de drenaje, cada miembro de bloqueo sucesivo tiene una vida útil más larga, antes de ser absorbido completamente, que la de su predecesor más cercano al extremo distal del catéter de drenaje; y un último miembro de bloqueo que está más lejano al extremo distal del catéter de drenaje tiene una vida útil más larga, antes de ser absorbido completamente, que la de cualquiera de sus predecesores más cercanos al extremo distal del catéter de drenaje.

19. El método de conformidad con la reivindicación 11, en donde la etapa de hacer avanzar el catéter de drenaje hacia el lugar deseado se realiza mediante el uso de un estilete de desplazamiento lateral.

PA 2017789

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

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September 28, 2017

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: *15/337,827*
FILING DATE: *October 28, 2016*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US15/337,827*

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

W. MONTGOMERY
Certifying Officer

Electronic Acknowledgement Receipt	
EFS ID:	27359505
Application Number:	15337827
International Application Number:	
Confirmation Number:	5542
Title of Invention:	Improved Implantable Valve Assembly With Extended Lifespan
First Named Inventor/Applicant Name:	Thomas Boden
Customer Number:	33766
Filer:	Cheryl F. Cohen
Filer Authorized By:	
Attorney Docket Number:	DSP5186USNP
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Application Type:	Utility under 35 USC 111(a)

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RAM confirmation Number	103116INTEFSW16462900
Deposit Account	503462
Authorized User	Cheryl Cohen
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	102816ApplicationDataSheetaia0014.pdf	1823011 80c6090b4cec020f5cc4371daf10d4da4d2c0436	no	8
Warnings:					
Information:					
2		PatentApplication.pdf	9669624 5775939c502dcc43f3cc47076e5281fe010f1352	yes	22
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	15	
	Claims		16	21	
	Abstract		22	22	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	FormalDrawings.pdf	1005373 4de2e93afe8b6e11ba063dce396f928f27ebc8a5	no	7
Warnings:					
Information:					
4	Oath or Declaration filed	ExecutedCombinationDeclarationAndAssignmentBODEN.pdf	451671 97373aa3b0779eb28f1a221ee539d9aa94c5e32b	no	1
Warnings:					
Information:					
5	Oath or Declaration filed	ExecutedCombinationDeclarationAndAssignmentDEXTRADEUR.pdf	468535 0de9488b634308a146a714e41bb2ebdd2309836f	no	1

Warnings:					
Information:					
6	Power of Attorney	ExecutedPowerOfAttorneyaia82AandB.pdf	247371 6a0fdfbfb815bb4b7eaa804b14231d860f40f2d8	no	3
Warnings:					
Information:					
7	Non Patent Literature	PublicationLIN.pdf	451035 c7509cc982a93f974e1300e21c6781e69d25488c	no	6
Warnings:					
Information:					
8	Information Disclosure Statement (IDS) Form (SB08)	102816InformationDisclosureStatement.pdf	1036510 d2f4aa2cd40c55588ea2e12ff5fe2bf92c991eab	no	7
Warnings:					
Information:					
9	Non Patent Literature	WebsiteALCYONELS.pdf	1106961 1cb2cec0ed15bee907071fd72d0ff4e9274bbbd6	no	3
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	35311 f853047c2236e8b3d733de6e07ba98b09ecd9a3e	no	2
Warnings:					
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		Total Files Size (in bytes):	16295402		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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.

Atty. Ref. No.: DSP5186USNP

Improved Implantable Valve Assembly With Extended Lifespan

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a valve for implantation in the body. More particularly, the invention relates to an improved valve assembly for implantation in the body to drain a bodily fluid, in particular, cerebral spinal fluid (CSF), wherein the catheter is specifically designed to extend its operational lifespan in the presence of undesirable obstruction or clogging that restricts the flow of bodily fluid therethrough.

Description of Related Art

[0002] Catheters are used to perform various diagnostic and therapeutic procedures at target sites within the body. One such use for catheters is in treating the condition of hydrocephalus. Hydrocephalus is the accumulation of cerebrospinal fluid (CSF) in the brain, resulting from increased production, or more commonly, pathway obstruction or decreased absorption of the fluid. Cerebrospinal fluid is a clear, colorless fluid that is primarily produced by the choroid plexus and surrounds the brain and spinal cord. Shunts have been used for decades for the treatment of hydrocephalus. CSF shunts establish an accessory pathway for the movement of CSF to bypass an obstruction of the natural pathways.

[0003] The shunt is positioned to enable the CSF to be drained from the cerebral ventricles or sub-arachnoid spaces into another absorption site (e.g., the right atrium of the heart or the peritoneal cavity) through a system of relatively small catheters. Figure 1 is an exemplary illustration of a conventional shunt valve assembly 10 disclosed in US Patent No. 4,595,390, which is herein incorporated by reference in its entirety. The shunt valve assembly 10 includes one or more one-way shunt valves 12, 14 separated by a pumping chamber 16 that maintain the CSF flowing away from the brain and moderate the pressure or flow rate. Ventricular catheter 18 is connected to the inlet of the valve assembly while a drainage

catheter 20 is connected to the outlet of the valve assembly. Ventricular catheter 18 has a plurality of pores, holes or openings defined in its walls proximate its distal end for receiving therethrough the CSF from the ventricle. The diameter of such pores is relatively small (generally, approximately 0.25 mm – approximately 0.50 mm; or approximately 250 micrometers – approximately 500 micrometers). The drainage system using catheters and valves enables the excess CSF within the brain to be evacuated and, thereby, the pressure within the cranium to be maintained within an appropriate range. This valve assembly may be surgically implanted using well known procedures. During implantation a burr hole is bored through the skull. A stylet is typically utilized as an introducer to properly position the ventricular catheter made of a flexible material (e.g., soft plastic tube) at the desired target site within the brain ventricle. The valve and drainage catheters are fluidly connected to a reservoir disposed proximate the burr hole under the skin. The CSF enters the distal holes of the ventricular catheter and is transported to the abdomen by the drainage catheter. Flow of CSF fluid away from the brain is insured by the one way shunt valve.

[0004] At tremendous cost to the health care system ranging in billions of dollars, each year tens of thousands of invasive brain surgeries are required to replace or revise hydrocephalus shunts that have malfunctioned due to mechanical failure. Blockage, occlusion or clogging of the relatively small diameter pores defined in the wall of the catheter, primarily in the ventricular catheter, is the leading cause of mechanical shunt failure and malfunction in hydrocephalus treatment. Specifically, the distal holes defined in the ventricular catheter become occluded and blocked when choroid plexus (a fibrous tissue in the ventricles that produces CSF), blood and other debris enters the openings due to the pulsatile nature of CSF circulation. Those pores defined in the wall of the catheter that are closest to its proximal end are particularly susceptible to undesirable blockage due to its close physical proximity to the choroid plexus. To reduce the occurrence of such growth, the catheter is ideally positioned in an area away from the choroid plexus and not in close proximity to the ventricular wall. Despite such efforts, entry of the choroid plexus and other debris into the pores of the catheter may still occur partially or completely obstructing the openings and, in turn, hampering or even prohibiting removal of the catheter if blockage becomes to significant.

[0005] It is therefore desirable to develop an improved implantable drainage catheter for the drainage of CSF or other bodily fluid having an extended operational lifespan despite obstruction and clogging of the pores defined in its wall.

Summary of the Invention

[0006] An aspect of the present invention is an improved implantable drainage catheter for the drainage of CSF or other bodily fluid having an extended operational lifespan despite obstruction and clogging of the pores defined in its wall.

[0007] The present invention is directed to an implantable valve assembly including a drainage catheter having a central lumen transitioning into a plurality of distinct branch lumen made of a shape memory material. A bioabsorbable dip coating secures the distal end of the plural distinct branch lumen together in physical contact with one another. Each branch lumen has an outer perimeter comprising at least one of a first outer surface section and a second outer surface section. In a secured state with the plural distinct branch lumen held together by the dip coating fluid is prohibited from passing through the holes defined in the first outer surface section. Bioabsorbable blocking members disposed about the outer perimeter of the assembled branch lumen mask holes defined in the second outer surface section prohibiting fluid from entering therein. In a time staggered fashion, the bioabsorbable elements absorb exposing new holes through which the fluid drains.

[0008] The invention is further directed to a method for using the implantable valve assembly as described in the preceding paragraph. The method comprising the steps of during implantation, advancing the drainage catheter to a target site while the plural distinct branch lumen are secured in direct physical contact with one another from the distal end of the drainage catheter to the interface of the central lumen via the dip coating. While in a secured state with the plural distinct branch lumen held together by the dip coating: (i) the first outer surface section of each of the plural distinct branch lumen is in direct physical contact with the first outer surface section of at least one other branch lumen in a longitudinal direction from the interface with the central lumen to the distal end of the catheter prohibiting fluid from entering holes defined in the first outer surface sections of any of the plural distinct branch lumen; and (ii) the second outer surface section of each of the plural distinct branch

lumen is not in physical contact with either the first or second outer surface sections of any other branch lumen.

Brief Description of the Drawing

[0009] The foregoing and other features of the present invention will be more readily apparent from the following detailed description and drawings of illustrative embodiments of the invention wherein like reference numbers refer to similar elements throughout the several views and in which:

[0010] Figure 1 is a perspective view of a prior art shunt valve assembly including two shunt valves;

[0011] Figure 2A is a partial side view of a distal end of an exemplary drainage catheter in accordance with the present invention, prior to implantation in the human body, having two branch lumen;

[0012] Figure 2B is a cross-sectional view of the catheter of Figure 2A along line I-I;

[0013] Figures 3A-3D are partial side views of the drainage catheter of Figure 2A at four different stages in time;

[0014] Figure 4 shows a side view of a lateral offset stylet to aid in insertion of the catheter of Figure 2A;

[0015] Figure 5A is a partial side view of a distal end of another exemplary drainage catheter in accordance with the present invention, prior to implantation in the human body, having three branch lumen;

[0016] Figure 5B is a cross-sectional view of the catheter of Figure 5A along line II-II; and

[0017] Figures 6A-6D are partial side views of the drainage catheter of Figure 5A at four different stages in time.

Detailed Description of the Invention

[0018] By way of illustrative example only, the present invention is shown and described as an implantable catheter for the drainage of a bodily fluid, for example, CSF. It is contemplated and within the intended scope of the present invention for the implantable catheter to be employed for the drainage of other types of bodily fluid.

[0019] The terms "proximal"/"proximally" and "distal"/"distally" refer to a direction closer to or away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, user, etc.) who would insert the medical device into the patient, with the opposite tip-end (i.e., distal end or leading end) of the device inserted inside a patient's body. Thus, for example, a "proximal direction" would refer to the direction towards the operator, whereas "distal direction" would refer to the direction away from the operator towards the leading or tip-end of the medical device.

[0020] Figure 2A is a partial side view of a distal end of an exemplary drainage catheter 100 in accordance with the present invention, prior to implantation into the human body or body of an animal. Catheter 100 has a proximal end 105 and an opposite distal end 110. The distal end 110 of the catheter 100 is split or separable into a plurality of two or more distinct branch lumen 120 each having its own passageway defined therethrough. In the exemplary embodiment illustrated in Figure 2A, the catheter 100 has two distinct branch lumen 120a, 120b. Any number of two or more separable distinct branch lumen 120 are possible and within the intended scope of the present invention. Regardless of the number, the plural distinct branch lumen at the distal end of the catheter all feed into a single common or shared central lumen 123 at the opposite proximal end 105 of the catheter. Each distinct branch lumen is preferably approximately 2cm in length as measured from its most distal tip of the catheter to an interface with the single central lumen.

[0021] The present invention will hereinafter be described with respect to the illustrative embodiment in Figure 2A in which the catheter 100 has two distinct branch lumen 120a, 120b. However, similar principles and description apply regardless of the number of two or more branch lumen. Branch lumen 120a, 120b are made of a shape memory material, that is

deformable upon the application of an external force, but automatically returns to its original (non-deformed) shape when the applied external force is withdrawn or removed. By way of non-limiting examples, the shape memory material may be a shape memory metal (e.g., Nitinol (NiTi) alloys) and/or a shape memory polymer (e.g., Poly(methyl methacrylate) (PMMA), polyurethanes (PU), poly(ethylene terephthalate) (PET), or polystyrenes (PS)). In its non-deformed shape (i.e., in the absence of the applied external force) the plural branch lumen 120a, 120b extend radially outward from the common central lumen 123 like petals of a flower. Upon the application of an external force, the distinct branch lumen 120a, 120b are deformable radially inward so as to physically contact one another in a longitudinal direction from its distal end to the interface with the common central lumen. The assembled distinct branch lumen together form a tube-like structure having the same diameter and coaxial with that of the central lumen 123.

[0022] Prior to implantation, a dip coating or covering 115 is disposed at the distal end 110 of the catheter 100. On the one hand, the dip coating or covering 115 is made of a material sufficient to secure the separable plural distinct branch lumen 120a, 120b together and prevent separation from one another during insertion of the drainage catheter 100 via a ventricle or other body passageway to a target site in the body. On the other hand, the dip coating or covering 115 is made of a bioabsorbable, biodegradable or bioresorbable material, i.e., a material that dissolves in the body once its intended purpose has been served (i.e., upon expiration of time t_1, preferably with the range of approximately 72 hrs. to 168 hrs. (one week)). For instance, the bioabsorbable, biodegradable or bioresorbable material may be a polymer or copolymers made from lactic acid or glycolic acid.

[0023] The outer perimeter of each of the plural distinct branch lumen 120a, 120b includes a first outer surface section 135 and a second outer surface section 140. Together the first and second outer surface sections 135, 140 of a particular branch lumen comprise its entire outer radial perimeter. Prior to implantation, while in a secured or assembled state with the plural distinct branch lumen 120a, 120b held together by the dip coating 115: (i) the first outer surface section 135 of each of the plural distinct branch lumen is in direct physical contact with the first outer surface section 135 of at least one other branch lumen; (ii) while the second outer surface section 140 of each of the plural distinct branch lumen is not in physical

contact with the first or second outer surface sections of any other distinct branch lumen. As clearly illustrated in Figure 2B depicting a cross-sectional view of the catheter of Figure 2A along line I-I, prior to implantation, when the plural distinct branch lumen 120a, 120b are assembled or secured together by the dip coating or covering 115 the first outer surface section 135 of each of the two branch lumen 120a, 120b are in physical contact with one another in a longitudinal direction from the interface with the central lumen 123 to the distal end 110 of the catheter.

[0024] Figures 3A-3D depict the drainage catheter of Figure 2A at four sequential stages in time following implantation. As seen in the different stages depicted in Figures 3A-3D, each branch lumen 120a, 120b has a plurality of holes, openings or pores defined radially outward therethrough its outer perimeter wall. The holes 125 are differentiated based on their location, i.e., whether the hole is defined in the first outer surface section 135 (as denoted by reference element numbers 125, 125A, 125B, 125C) or in the second outer surface section 140 (as denoted by reference element number 125') of the outer perimeter of a single distinct branch lumen. Except for an inlet opening at the interface with the plural branch lumen 120A, 120B and an opposite outlet opening, no other holes, openings or pores are defined in the outer radial perimeter of the central lumen 123. Adjacent, proximate, neighboring or closest hole centers (when viewed in an axial direction) defined in the first and second outer surface sections 135, 140, respectively, of a single distinct branch lumen are preferably offset or staggered from one another in a lateral direction by a lateral offset distance "X" (as illustrated in Figure 3D) so that no two hole centers defined in the first and second outer surface sections of a single branch lumen are aligned at the same position in an axial direction relative to its distal end (i.e., non-coaxial). Such staggering or lateral offset distance "X" between hole centers of adjacent/opposing holes is preferably greater than or equal to the hole diameter, wherein the diameter of all holes are equal. Such offset of the holes 125' defined in the first outer surface section 135 relative to the holes (125, 125A, 125B, 12C) defined in the second outer surface section 140 for a single distinct branch lumen reduces or prohibits ingrowth of the choroid plexus through the holes between the first and second outer surface sections. If not for the inventive lateral offset distance, alignment at the same axial position relative to the distal end of the holes defined in the first and second outer surface sections of a single branch

lumen, the catheter would be more susceptible to ingrowth of the choroid plexus therethrough the holes and potential clogging.

[0025] Prior to implantation (as depicted in Figures 2A & 2B), direct physical contact among the first outer surface sections 135 of the plural branch lumen 120A, 120B prevent or prohibit passage of any fluid through holes (125') defined in the first outer surface sections 135 of each of the distinct branch lumen 120A, 120B. Accordingly, the first outer surface sections 135 among the plural distinct branch lumen 120A, 120B are complementary in shape so that when in direct physical contact with one another the passage of any bodily fluid through the holes 125' defined therein is prevented or prohibited.

[0026] Blocking members 130 (e.g., radial straps, rings or bands) close off, mask or otherwise prohibit any fluid passing through the holes (125, 125A, 125B, 125C) defined in the second outer surface sections 140 of each of the plural distinct branch lumen 120A, 120B. At time zero (t_0) (i.e., at time of implantation), at least two outer patent holes 125 allow for drainage of bodily fluid immediately upon implantation. These two outer patent holes 125 positioned closest to the distal end 110 and defined in the second outer surface section 140 remain unmasked, patent or open at all times (including prior to and during implantation in the body). With the subsequent passage of time, for each blocking member 130 that dissolves, absorbs or degrades at least two holes per each distinct branch lumen will be unmasked/patent. In a preferred embodiment, each distinct branch lumen 120a, 120b has two outer patent holes 125 defined in the second outer surface section 140 closest to the distal end 110 that remain unmasked, patent or open at all times (i.e., these outer patent holes 125 are never deliberately closed off or masked by a blocking member or any other structural feature). Thus, outer patent holes 125 closest to the distal end 110 remain open at all times to allow, immediately upon implantation of the catheter in the body (while the remaining holes are masked or closed off either by a blocking member or physical contact among the first outer surface sections of the branch lumen), drainage therethrough the bodily fluid at a desired pressure or flow rate.

[0027] Starting from the distal end 110 and advancing axially toward the proximal end 105 of the catheter 100, the remaining holes 125A, 125B, 125C disposed at different positions in an

axial direction and defined in the outer perimeter wall of the second outer surface section 140 of each distinct branch lumen 120A, 120B are temporarily completely deliberately masked, closed off or completely occluded by a corresponding blocking member (for example, radial strap, ring or band) 130A, 130B, 130C made of bioabsorbable, biodegradable or bioresorbable material that prohibits or prevents the passage of any bodily fluid through any of the holes covered by that particular blocking member. In a one-to-one correspondence, a single blocking member may be sized and configured to close off and prevent fluid from entering one or more holes defined in the second outer surface section 140 associated with a single branch lumen 120A, 120B. Preferably, a single blocking member may be sized and configured to mask or close off one or more holes associated with each of the plural distinct branch lumen 120A, 120B thereby preventing bodily fluid from entering therethrough. With the exception of the one or more holes 125 disposed closest to the distal end 110 of the catheter which remain unmasked, open or unobstructed at all times (i.e., not deliberately masked or closed off by a blocking member or other structural feature), all remaining holes 125A, 125B, 125C defined in the second outer surface section 140 of each of the plural branch lumen 120A, 120B are initially and temporarily (for a predetermined period of time following implantation and prior to being completely absorbed, degraded or dissolved in the body) closed off or masked by an associated or corresponding blocking member 130A, 130B, 130C made of bioabsorbable, biodegradable or bioresorbable material prohibiting any bodily fluid from entering therein.

[0028] Referring to the exemplary embodiment illustrated in Figure 2A, three blocking members 130A, 130b, 130c of bioabsorbable, biodegradable or bioresorbable material are depicted to mask, cover, block or obstruct holes 125A, 125B, 125C defined in the second outer surface section 140 of each of the plural distinct branch lumen 120A, 120B. Of course, the present invention may be modified, as desired, whereby the catheter has any number of one or more blocking members 130 so long as, with the exception of at least two holes 125 disposed closest to the distal end 110 of the catheter, all remaining holes 125A, 125B, 125C defined in the second outer surface section 140 of each of the plural branch lumen 120A, 120B are deliberately, initially and temporarily masked, covered or closed off by a corresponding blocking member.

[0029] In accordance with the present invention, each blocking member 130A, 130B, 130C is made of a bioabsorbable, biodegradable or bioresorbable material that is designed to completely absorb, degrade or dissolve in the body at different sequentially staggered time intervals or periods. By way of illustrative example only, a first blocking member 130A masks a hole 125A defined in the second outer surface section 140 of each of the plural distinct branch lumen 120A, 120B. The first blocking member130A is made of a bioabsorbable, biodegradable or bioresorbable material that is designed to completely absorb, degrade or dissolve in the body upon the passage of a second time period or interval (t_2) following implantation in the body (representative of a second stage). A second blocking member 130B masks a hole 125B defined in the second outer surface section 140 of each of the plural branch lumen 120A, 120B. The second blocking member 130B is made of a bioabsorbable, biodegradable or bioresorbable material that is designed to completely absorb, degrade or dissolve in the body upon the passage of a third time period or interval (t_3) following implantation in the body (representative of a third stage). A third blocking member 130C masks a hole 125C defined in the second outer surface section 140 of each of the plural branch lumen 120A, 120B. The third blocking member 130C is also made of a bioabsorbable, biodegradable or bioresorbable material that is designed to completely absorb, degrade or dissolve in the body upon the passage of a fourth time period or interval (t_4) following implantation in the body (representative of a fourth stage). In this illustrative example the second time period or interval (t_2) = 1 week; the third time period or interval (t_3) = 6 weeks; while the fourth time period or interval (t_4) = 6 months. Hence, the bioabsorbable material blocking members (130A, 130B, 130C) are designed to completely absorb, degrade or dissolve in the body in a time sequential staggered manner wherein the time intervals are selected so that $t_1<t_2<t_3<t_4$. Preferably, all blocking members are dissolved and hence all drainage holes are exposed, within approximately one year of implantation. Thus, the blocking member 130A closest to the distal end 110 has the shortest life span prior to completely dissolving or absorbing in the body. Each successive blocking member 130B advancing axially toward the proximal end 105 of the catheter has a longer life span (i.e., passage of time prior to completely dissolving or absorbing in the body) than its predecessor. While the blocking member 130C that is closest to the proximal end 105 (farthest from the distal end 110) of the catheter has the longest life span prior to completely dissolving, degrading or absorbing in the body. The formulation and/or dimensions (e.g., thickness) of

the bioabsorbable material for manufacturing each blocking member may be selected to achieve the desired time period for complete absorption, degradation or dissolution in the body. Thus, the blocking members may be made of different materials or the same material and/or differ or be the same in dimension. It is also noted that despite the exemplary embodiment depicting any one blocking member masking only a single hole defined in each branch lumen, it is contemplated and within the intended scope of the present invention for any one blocking member to mask more than one hole defined in any particular branch lumen, or that any one blocking member need not necessarily mask off a hole defined in every one of the plural lumen (e.g., a single blocking member may be configured to mask a hole defined in only one branch lumen). The holes in the second outer surface section 140 masked off by a particular blocking member 130 need not be the same in number for each distinct branch lumen. It is also contemplated that a particular blocking member need not mask off or cover any hole defined in the second outer surface section 140 of certain distinct branch lumen.

[0030] Those holes in the drainage catheter closest to the valve (i.e., closest to the proximal end 105 of the drainage catheter) drain approximately 80% of the bodily fluid. Thus, in the unfortunate event that these holes in the drainage catheter closest to the valve become obstructed, clogged or occluded the drainage catheter may undesirably cease to operate as intended to maintain a desired pressure or flow rate. Staggering the time period for degrading, dissolving or absorbing of the blocking members exposes over time new open holes closer to the valve (i.e., closer to the proximal end 105 of the catheter) thereby extending the lifespan and operation of the drainage catheter even in the presence of obstruction or blockage of open holes.

[0031] Referring to Figure 2A, prior to implantation in the body, the dip coating or covering 115 of bioabsorbable, biodegradable or bioresorbable material covering the distal tip of the catheter secures the plural separate distinct branch lumen 120A, 120B together thereby aiding insertion of the catheter through the ventricle or other passageway to a desired target location or site within the body. Immediately upon implantation at a target location or site within the body (at time t=0), the drainage catheter 100 in accordance with the present invention allows for free passage of body fluid at the desired pressure or flow rate through the two or more patent holes 125 disposed closest to the distal end 110 of the catheter that are never

intentionally masked, covered or closed off by a blocking member (i.e., prior to implantation as well as over the entire operating lifespan of the catheter, these holes 125 are never masked off). Once implanted, over time the dip coating or covering 115 of the catheter begins to absorb, degrade or dissolve in the body. Once the dip coating or covering 115 has completely absorbed, degraded or dissolved (as shown in Figure 3A, after passage of a time (t_1)), in the absence of such external applied force applied by the dip coating, the distal end of the distinct branch lumen 120A, 120B (as a result of the shape memory material from which it is manufactured) automatically returns to its non-deformed state and begins separating from one another starting at the distal end 110. Separation of the distinct branch lumen 120A, 120B in an axial direction is stopped by the presence of the first blocking member 130A secured about the outer perimeter (i.e., disposed about the second outer surface sections 140 of the plural distinct branch lumen 120A, 120B). In the exemplary embodiment depicted in Figure 3A, such initial separation, starting from its distal end, of the branch lumen 120A, 120B from one another exposes a hole 125' defined in the first outer surface section 135 of each of the distinct branch lumen (previously masked or covered by the complementary mating first outer surface sections 135 of the branch lumen 120A, 120B in direct physical contact with one another).

[0032] Figure 3B depicts the catheter after the passage of a second time period (t_2) following implantation of the catheter in the body, wherein the first blocking member 130A closest to the distal end 110 of the catheter 100 is completely dissolved, degraded or absorbed in the body. The complete dissolution, degradation or absorption of the first blocking member 130A automatically triggers the following simultaneous events: (i) the hole 125A defined in the second outer surface section 140 of each of the plural branch lumen 120A, 120B is now completely exposed allowing the free flow of bodily fluid therethrough; and (ii) due to the shape memory material from which it is manufactured, in response to the withdrawal of the external force previously applied by the first blocking member 130A, the plural distinct branch lumen 120A, 120B begin to further separate and flare radially outward exposing another hole 125' defined in the first outer surface section 135 of each of the plural branch lumen 120A, 120B allowing the free passage of bodily fluid therethrough.

[0033] With the passage of time, at the expiration of a third time period (t_3) following implantation of the catheter in the body, the second blocking member 130B completely dissolves, degrades or absorbs in the body, as shown in Figure 3C. As additional blocking members dissolve, degrade or absorb new holes defined in both the first outer surface section 135 and the second outer surface section 140 of each of the plural branch lumen 120A, 120B become exposed allowing the free passage of bodily fluid therethrough. Figure 3D shows the catheter after the passage of a fourth time period (t_4) following implantation of the catheter in the body with the third blocking member 130C farthest from the distal end 110 of the catheter 100 completely dissolved, degraded or absorbed in the body. All holes in the first and second outer sections of all of the branch lumen are now exposed allowing the free passage of bodily fluid therethrough.

[0034] Configuration of the two branch lumen 120A, 120B feeding into a common central lumen 123 introduces a lateral offset of the center of the passageway of the central lumen 123 relative to that of the center of the passageway of either respective distinct branch lumen 120A, 120B. To aid in insertion of the catheter into a ventricle or other passageway of the body an offset stylet 200 (as depicted in Figure 4) is employed. The lateral offset (d) of the stylet 200 corresponds to the distance separation of the center of the passageway of the common central lumen 123 relative to that of the center of the passageway of either distinct branch lumen 120A, 120B.

[0035] In an alternative embodiment, the distal end of the catheter 100 may be split or separable into three distinct branch lumen 120A, 120B, 120C, rather than two. Figure 5A is a partial side view of an exemplary catheter in accordance with the present invention having three branch lumen. The features shown are the same as those discussed above with respect to Figure 2A and thus will not be described further. A cross-sectional view of the catheter of Figure 5A along the lines II-II is depicted in Figure 5B. From this cross-sectional view, the different configuration is evident from that of Figure 2B. A third branch lumen 120C, coaxial with the common central lumen 123, is completely surrounded or radially enclosed by the other two distinct branch lumen 120A, 120B, while in an assembled or secured state (prior to implantation). In this alternative embodiment, the outer perimeter of each of the first and second branch lumen 120A, 120B includes a first outer surface section 135 and a second outer

surface section 140. The third branch lumen 120C has an outer perimeter comprising only a first outer surface section 135. The third branch lumen 120C does not have an associated second outer surface section 140 since, while in an assembled or secured state, every portion of its outer perimeter is in direct physical contact with the first outer surface sections 135 of the other two branch lumen 120A, 120B. Due to the fact that the third branch lumen 120C is coaxial with the common central lumen 123, this specific configuration eliminates the need for an offset stylet (as shown in Figure 4). Instead a conventional linear stylet may be utilized to aid in insertion of the catheter shown in Figure 5A & 5B during implantation.

[0036] As depicted in the time sequential staggered illustrations of Figures 6A-6D, the dissolving, degrading or absorption of the tip coating 115, followed thereafter by the first blocking member 130A, the second blocking member 130B and lastly the third blocking member 130C over time exposes new holes defined in: (i) the first outer surface sections 135 of the first, second and third branch lumen 120A, 120B, 120C; and (ii) the second outer surface sections 140 of only the first and second branch lumen (120A, 120B). With this particular three branch lumen configuration, in the assembled and secured state prior to implantation, all holes (excluding the inlet opening and outlet opening of the axial passageway through the lumen) defined in the outer radial perimeter of the third branch lumen 120C are masked, covered or closed off by the first outer surface section 135 of the other two branch lumen 120A, 120B. No portion of the outer perimeter of the third branch lumen 120C is deliberately masked off or covered at any time by a blocking member of bioabsorbable material. Other configurations for three branch lumen are contemplated and within the intended scope of the present invention. For example, similar to the two hemispherical cross-sectional shaped branch lumen depicted in Figure 2B, the cross-sectional shape of the three branch lumen may represent three equal one third wedges together forming a complete circle. In such design, the outer perimeter of each of the three branch lumen has a first outer surface section 135 in direct physical contact with one another and a second outer surface section 140 that is not in physical contact with any other first or second outer surface section. Of course, the cross-sectional shape of the plural branch lumen may be modified.

[0037] Thus, the present inventive drainage catheter has an extended lifespan in comparison to that of conventional devices by exposing, unmasking or uncovering new holes in a time

sequential staggered manner. If one or more holes in the drainage catheter become obstructed, blocked or occluded, at a subsequent point in time new holes (previously masked, covered or closed off) will be exposed for the first time to allow the free passage of bodily fluid therethrough thereby extending the operational lifespan of the drainage catheter. Furthermore, in the event that a single branch or leg of the catheter should become obstructed, blocked or occluded, the bodily fluid may continue to be drained through the remaining one or more branches or legs of the catheter.

[0038] 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.

[0039] 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. An implantable valve assembly having an extended operational lifespan, comprising:

a drainage catheter having a proximal end and an opposite distal end; the drainage catheter comprising a single central lumen disposed proximate its proximal end having a single central passageway defined longitudinally therethrough; between the proximal and distal ends of the drainage catheter, the single central lumen transitions at an interface into a plurality of distinct branch lumen made of a shape memory material; each of the plural branch lumen having associated therewith a single branch passageway defined longitudinally therethrough; the single branch passageway of each of the plural branch lumen being in fluid communication with the single central passageway of the single central lumen;

a dip coating of bioabsorbable material disposed at the distal end of the drainage catheter; at the time of implantation the dip coating securing the plural distinct branch lumen in direct physical contact with one another from the distal end of the drainage catheter to the interface with the central lumen;

wherein each of the plural distinct branch lumen has an outer perimeter comprising at least one of a first outer surface section and a second outer surface section; together the first and second outer surface sections of a particular distinct branch lumen comprise its entire outer radial perimeter; while in a secured state with the plural distinct branch lumen held together by the dip coating: (i) the first outer surface section of each of the plural distinct branch lumen is in direct physical contact with the first outer surface section of at least one other branch lumen in a longitudinal direction from the interface to the distal end of the catheter; and (ii) the second outer surface section of each of the plural distinct branch lumen is not in physical contact with either the first or second outer surface sections of any other branch lumen;

wherein each of the plural distinct branch lumen has a plurality of holes defined radially outward therethrough in the first and the second outer surface sections; while in

the secured state with the plural distinct branch lumen held together by the dip coating a fluid is prohibited from passing through the plurality of holes defined in the first outer surface sections of any of the plural distinct branch lumen.

2. The assembly in accordance with claim 1, wherein in an axial direction adjacent hole centers of the holes defined in the first and second outer surface sections, respectively, of a particular branch lumen of the plural distinct branch lumen are staggered from one another by a predetermined lateral offset distance so that the adjacent hole centers defined in the first and second outer surface sections of the particular branch lumen are non-linearly arranged in an axial direction.

3. The assembly in accordance with claim 3, wherein the predetermined lateral offset distance is greater than or equal to a diameter of the hole, wherein the diameter of each hole is substantially equal.

4. The assembly in accordance with claim 1, the bioabsorbable material of the dip coating is absorbed upon expiration of a first predetermined time period in a range of approximately 72 hrs. to approximately 168 hrs.

5. The assembly in accordance with claim 1, wherein in an absence of an applied external force, the plural distinct branch lumen extend radially outward from the central lumen; upon the application of the external force, the plural distinct branch lumen are deformable radially inward so as to physically contact one another in an axial direction from the interface with the central lumen to the distal end of the drainage catheter forming an assembled cylinder having a diameter substantially equal to and coaxial with that of the central lumen.

6. The assembly in accordance with claim 1, further comprising at least one blocking member made of a bioabsorbable material masking the holes disposed at approximately the same axial distance from the distal end of the drainage catheter in the second outer surface sections of each of the plural distinct branch lumen prohibiting any fluid entering therein.

7. The assembly in accordance with claim 6, wherein at a time (t_o) of implantation of the valve, with the exception of at least two outer patent holes positioned closest to the distal end of the drainage catheter and defined in the second outer surface section of the plural distinct branch lumen that are unmasked allowing entry of fluid therein, the passage of the fluid through all remaining holes defined in the first and second outer surface sections of the plural distinct branch lumen is prohibited by a corresponding blocking member or physical contact among the first outer surface sections of the plural distinct branch lumen.

8. The assembly in accordance with claim 6, wherein with the passage of time, for each blocking member that completely absorbs, at least two holes per each of the plural distinct branch lumen are unmasked allowing passage of the fluid therein.

9. The assembly in accordance with claim 6, wherein the valve comprises a plurality of blocking members sequentially arranged one-after-the other in an axial direction about a perimeter of the drainage catheter; each of the plural blocking members is made of a bioabsorbable material selected with a formulation and/or dimension to completely absorb at different sequentially staggered time periods such that: a first blocking member disposed closest to the distal end of the drainage catheter has a shortest life span prior to completely absorbing; advancing in an axial direction away from the distal end of the drainage catheter, each successive blocking member has a longer life span prior to completely absorbing than its predecessor closer to the distal end of the drainage catheter; and, a last blocking member farthest from the distal end of the drainage catheter has a longest life span prior to completely absorbing than any of its predecessors closer to the distal end of the drainage catheter.

10. The assembly in accordance with claim 1, further comprising a lateral offset stylet.

11. A method for using an implantable valve assembly having an extended operational lifespan, wherein the implantable valve assembly includes a drainage

catheter having a proximal end and an opposite distal end; the drainage catheter having a single central lumen disposed proximate its proximal end having a single central passageway defined longitudinally therethrough; between the proximal and distal ends of the drainage catheter, the single central lumen transitions at an interface into a plurality of distinct branch lumen made of a shape memory material; each of the plural branch lumen having associated therewith a single branch passageway defined longitudinally therethrough; the single branch passageway of each of the plural branch lumen being in fluid communication with the single central passageway of the single central lumen; a dip coating of bioabsorbable material is disposed at the distal end of the drainage catheter; wherein each of the plural distinct branch lumen has an outer perimeter comprising at least one of a first outer surface section and a second outer surface section; together the first and second outer surface sections of a particular distinct branch lumen comprise its entire outer radial perimeter; wherein each of the plural distinct branch lumen has a plurality of holes defined radially outward therethrough in the first and the second outer surface sections, the method comprising the steps of:

during implantation, advancing the drainage catheter to a target site while the plural distinct branch lumen are secured in direct physical contact with one another from the distal end of the drainage catheter to the interface of the central lumen via the dip coating; while in a secured state with the plural distinct branch lumen held together by the dip coating: (i) the first outer surface section of each of the plural distinct branch lumen is in direct physical contact with the first outer surface section of at least one other branch lumen in a longitudinal direction from the interface with the central lumen to the distal end of the catheter prohibiting fluid from entering holes defined in the first outer surface sections of any of the plural distinct branch lumen; and (ii) the second outer surface section of each of the plural distinct branch lumen is not in physical contact with either the first or second outer surface sections of any other branch lumen.

12. The method in accordance with claim 11, wherein in the secured state subject to an external applied force exerted by the dip coating the plural distinct branch

lumen are deformed radially inward so as to physically contact one another in a longitudinal direction from the interface with the central lumen to the distal end of the drainage catheter forming an assembled cylinder having a diameter substantially equal to and coaxial with that of the central lumen.

13. The method in accordance with claim 11, wherein in an axial direction adjacent hole centers of the holes defined in the first and second outer surface sections, respectively, of a particular branch lumen of the plural distinct branch lumen are staggered from one another by a predetermined lateral offset distance so that the adjacent hole centers defined in the first and second outer surface sections of the particular branch lumen are non-linearly arranged in an axial direction.

14. The method in accordance with claim 11, further comprising the step of, upon expiration of a first predetermined passage of time in which the dip coating is completely absorbed, automatically the shape memory material of the plural distinct branch lumen returning to its original shape extending radially outward from the central lumen so that starting from the distal end of the catheter a portion of the first outer surface sections of the plural distinct branch lumen separate from one another allowing fluid to enter the holes exposed in the first outer surface section that have separated from one another.

15. The method in accordance with claim 12, wherein the valve includes at least one blocking member made of a bioabsorbable material masking the holes disposed at approximately the same axial distance from the distal end of the drainage catheter in the second outer surface sections of each of the plural distinct branch lumen prohibiting any fluid entering therein.

16. The method in accordance with claim 15, wherein during implantation of the valve, with the exception of at least two outer patent holes positioned closest to the distal end of the drainage catheter and defined in the second outer surface section of the plural distinct branch lumen that are unmasked allowing entry of

fluid therein, the passage of the fluid through all remaining holes defined in the first and second outer surface sections of the plural distinct branch lumen is prohibited by a corresponding blocking member or physical contact among the first outer surface sections of the plural distinct branch lumen.

17. The method in accordance with claim 15, upon complete absorbing of each of the plural blocking members, at least two holes per each of the plural distinct branch lumen are unmasked allowing passage of the fluid therein.

18. The method in accordance with claim 15, wherein the valve comprises a plurality of blocking members sequentially arranged one-after-the other in an axial direction about a perimeter of the drainage catheter; each of the plural blocking members is made of a bioabsorbable material selected with a formulation and/or dimension to completely absorb at different sequentially staggered time periods such that: a first blocking member disposed closest to the distal end of the drainage catheter has a shortest life span prior to completely absorbing; advancing in an axial direction away from the distal end of the drainage catheter, each successive blocking member has a longer life span prior to completely absorbing than its predecessor closer to the distal end of the drainage catheter; and, a last blocking member that is farthest from the distal end of the drainage catheter has a longest life span prior to completely absorbing than any of its predecessors closer to the distal end of the drainage catheter.

19. The method in accordance with claim 11, wherein the step of advancing the drainage catheter to the target site is performed using a lateral offset stylet.

Abstract

An implantable valve assembly including a drainage catheter having a central lumen transitioning into a plurality of distinct branch lumen made of a shape memory material. A bioabsorbable dip coating secures the distal end of the plural distinct branch lumen together in physical contact with one another. Each branch lumen has an outer perimeter comprising at least one of a first outer surface section and a second outer surface section. In a secured state with the plural distinct branch lumen held together by the dip coating fluid is prohibited from passing through the holes defined in the first outer surface section. Bioabsorbable blocking members disposed about the outer perimeter of the assembled branch lumen mask holes defined in the second outer surface section prohibiting fluid from entering therein. In a time staggered fashion, the bioabsorbable elements absorb exposing new holes through which the fluid drains.

COHEN & HILDEBRAND, PLLC
Attorney Docket No. DSP5186USNP

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

Title of Invention	IMPROVED IMPLANTABLE VALVE ASSEMBLY WITH EXTENDED LIFESPAN

As the below named inventor, I hereby declare that:

This declaration is directed to: X The above-identified application, or

☐ United States application _____, filed on _____or

☐ PCT 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.

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above,

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including further continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each undersigned inventor has sold and assigned, and by these presents hereby sells and assigns, unto: **DePuy Synthes Products, LLC**, whose address is **325 Paramount Drive, Raynham MA 02767**, a **Delaware** corporation (hereinafter named "Assignee"), its successors, legal representatives and assigns, the entire right, title and interest in and to said invention for Letters Patent of the United States, filed as said application and to the entire right, title and interest in any and all inventions, whether joint or sole, disclosed in said application for Letters Patent, and in any and all divisional or continuation or renewal applications that may be filed for United States Letters Patent for any and all of said inventions, and in and to any and all patents that may be granted on the foregoing applications and any reissue or extension thereof.

I hereby authorize and request the Commissioner of Patents to issue any and all of said Letters Patent to said Assignee.

For said consideration, I hereby agree upon the request of said Assignee, its successors, legal representatives or assigns, to execute any and all United States divisional, continuation and renewal applications for said invention, and any and all necessary oaths, supplemental oaths or declarations or supplemental declarations or affidavits relating thereto, and any application for the reissue or extension of any United States Letters Patent that may be granted upon said application that said Assignee, its successors, legal representatives or assigns may deem necessary or expedient.

For the said consideration, I further agree upon the request of said Assignee, its successors, legal representatives or assigns, in the event of said application or any division thereof, or Letters Patent issued thereon or any reissue or application for the reissue thereof, becoming involved in interference, to cooperate to the best of my ability with said Assignee, its successors, legal representatives or assigns in the matters of preparing and executing the Preliminary Statement and giving and producing evidence in support thereof, I hereby agree to perform upon such request, any and all affirmative acts necessary to obtain said Letters Patent and vest all rights therein hereby conveyed in said Assignee, its successors, legal representatives or assigns as fully and entirely as the same would have been held and enjoyed if this assignment and sale had not been made.

I hereby bind myself, my heirs, legal representatives, administrators, and assign properly to execute without further consideration, any and all applications, petitions, oaths, assignments or other papers and instruments which may be necessary in order to carry into full force and effect the sale, assignment and transfer hereby made, or intended or agreed to be made.

And for said considerations, I hereby assign to said Assignee, its successors, legal representatives and assigns, the entire right, title and interest in said invention or improvement for any and all foreign countries and agree upon the request of said Assignee, its successors, legal representatives or assigns to execute any and all documents that shall be required to be executed in connection with any and all applications for foreign Letters Patent therefor, including the prosecution thereof, and to execute any and all documents necessary to invest title in said foreign applications and patents in said Assignee, its successors, legal representatives or assigns.

LEGAL NAME OF INVENTOR

Inventor: Thomas Boden Jr Date: Oct 12 2016

Signature: _____

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Alan J. Dextradeur Date: October 19, 2016

Signature: Alan J Dextradeur

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA01 form for each additional inventor.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	To be assigned
Filing Date	October 28, 2016
First Named Inventor	BODEN et al.
Title	Improved Implantable Valve Assembly With Extended Lifespan
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	DSP5186USNP

SIGNATURE of Applicant or Patent Practitioner

Signature	/Cheryl F. Cohen/	Date (Optional)	2016-10-28
Name	Cheryl F. Cohen	Registration Number	40,361
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

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

☑ *Total of 1 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.

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POWER OF ATTORNEY BY APPLICANT

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

☒ I hereby appoint 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 equivalent):

33766

OR

☐ I hereby appoint Practitioner(s) named below 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 equivalent):

Name	Registration Number	Name	Registration Number

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

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant:

☐ Inventor or Joint Inventor

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)

SIGNATURE of Applicant for Patent

Signature	/Eugene L. Szczecina, Jr./	Date	March 21, 2013
Name	Eugene L. Szczecina, Jr.	Telephone	732-524-1479
Title and Company	Assistant Secretary, DePuy Synthes Products, LLC		

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. Submit multiple forms for more than one signature, see below *.

☒ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 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.**

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Privacy Act Statement

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

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

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

504072785 10/28/2016

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT4119452

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT

CONVEYING PARTY DATA

Name	Execution Date
THOMAS BODEN JR.	10/12/2016
ALAN J. DEXTRADEUR	10/19/2016

RECEIVING PARTY DATA

Name:	DEPUY SYNTHES PRODUCTS, LLC
Street Address:	325 PARAMOUNT DRIVE
City:	RAYNHAM
State/Country:	MASSACHUSETTS
Postal Code:	02767

PROPERTY NUMBERS Total: 1

Property Type	Number
Application Number:	15337827

CORRESPONDENCE DATA

Fax Number: (856)414-1058

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 856-414-1055
Email: cherylcohen@aol.com
Correspondent Name: COHEN & HILDEBRAND, PLLC
Address Line 1: 2409 CHURCH ROAD
Address Line 4: CHERRY HILL, NEW JERSEY 08002

ATTORNEY DOCKET NUMBER:	DSP5186USNP
NAME OF SUBMITTER:	CHERYL F. COHEN
SIGNATURE:	/Cheryl F. Cohen/
DATE SIGNED:	10/28/2016
	This document serves as an Oath/Declaration (37 CFR 1.63).

Total Attachments: 2
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source=ExecutedCombinationDeclarationAndAssignmentDEXTRADEUR#page1.tif

COHEN & HILDEBRAND, PLLC
Attorney Docket No. DSP5186USNP

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LEGAL NAME OF INVENTOR

Inventor: Thomas Boden Jr Date: Oct 12, 2016

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: Alan J. Dextradeur Date: October 19, 2016

Signature: Alan J Dextradeur

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA01 form for each additional inventor.

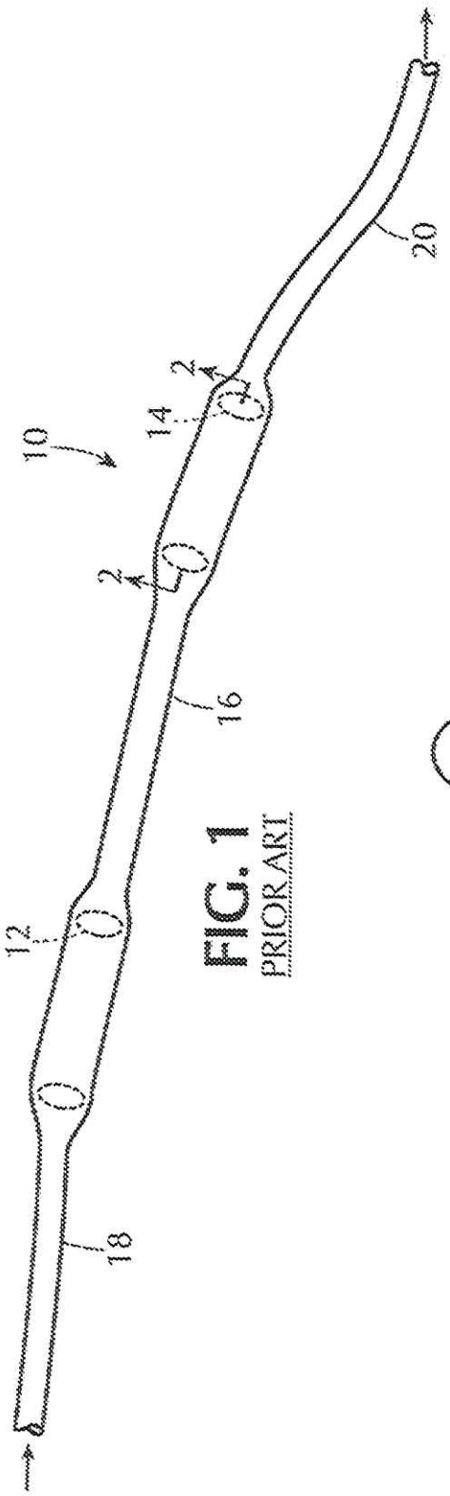

FIG. 1
PRIOR ART

FIG. 4

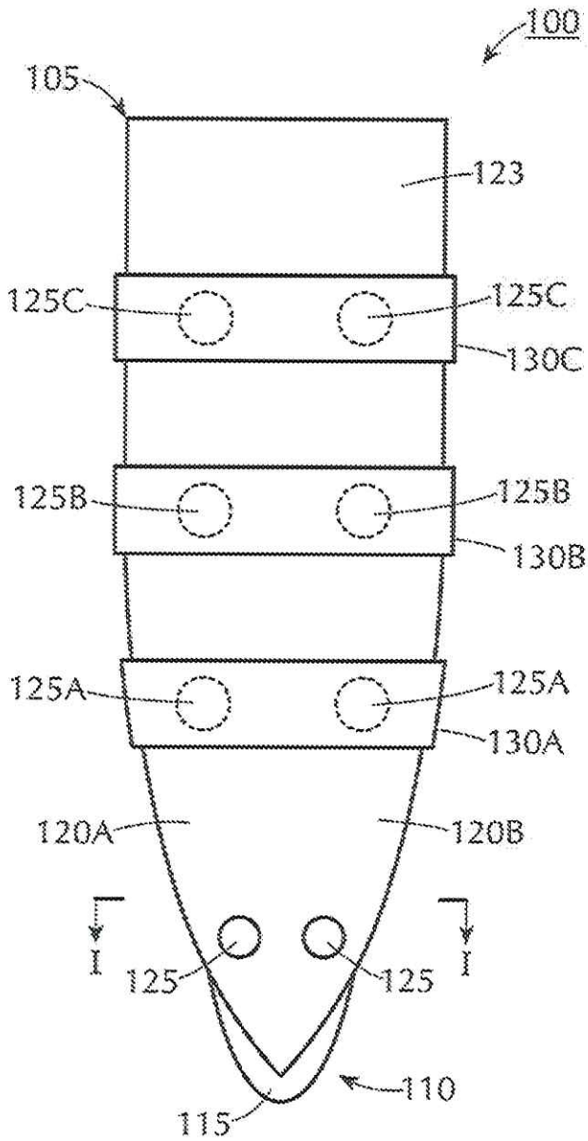

FIG. 2A

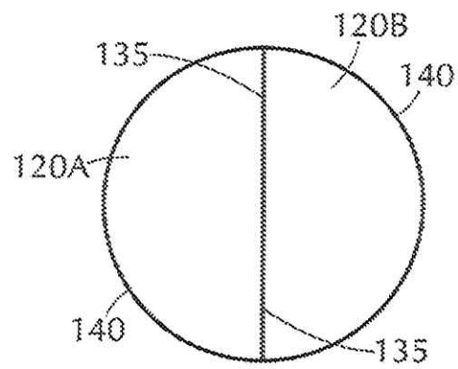

FIG. 2B

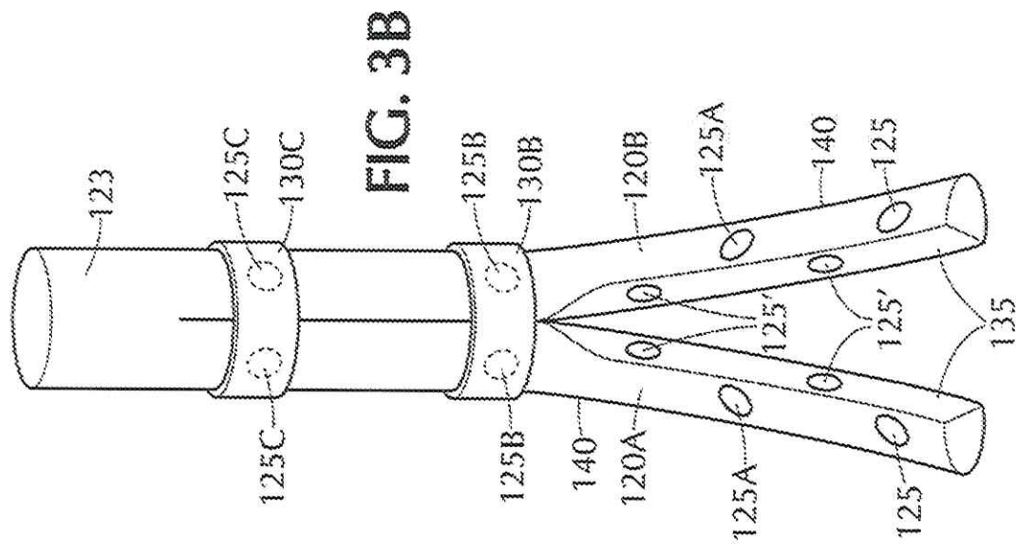

FIG. 3B

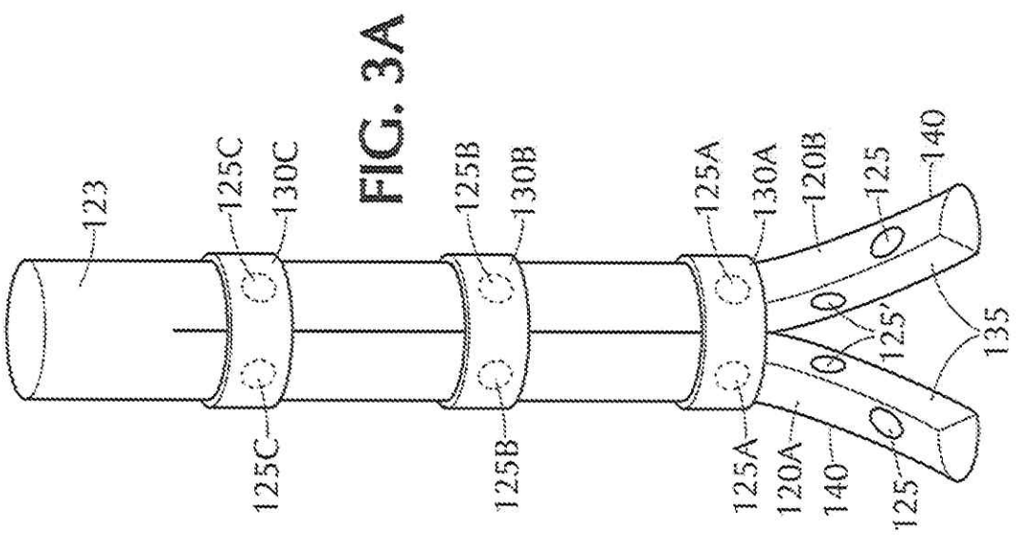

FIG. 3A

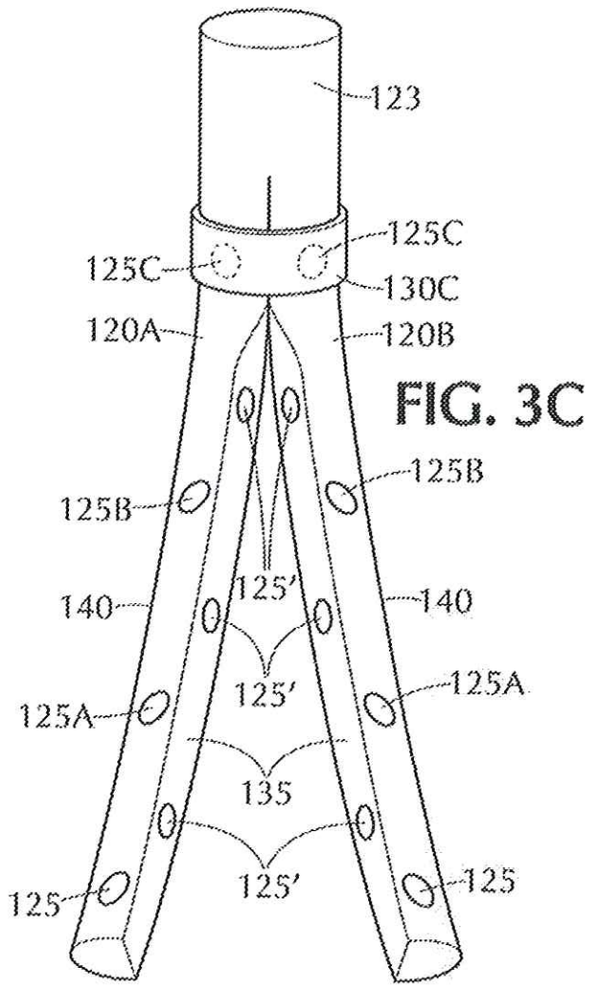

FIG. 3C

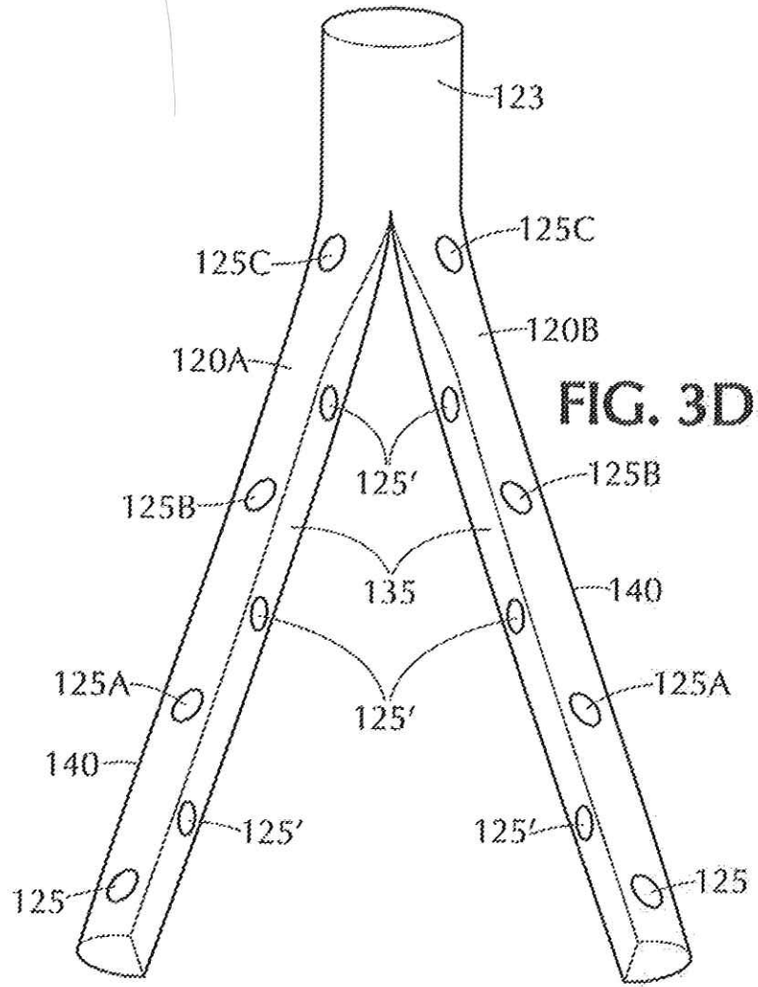

FIG. 3D

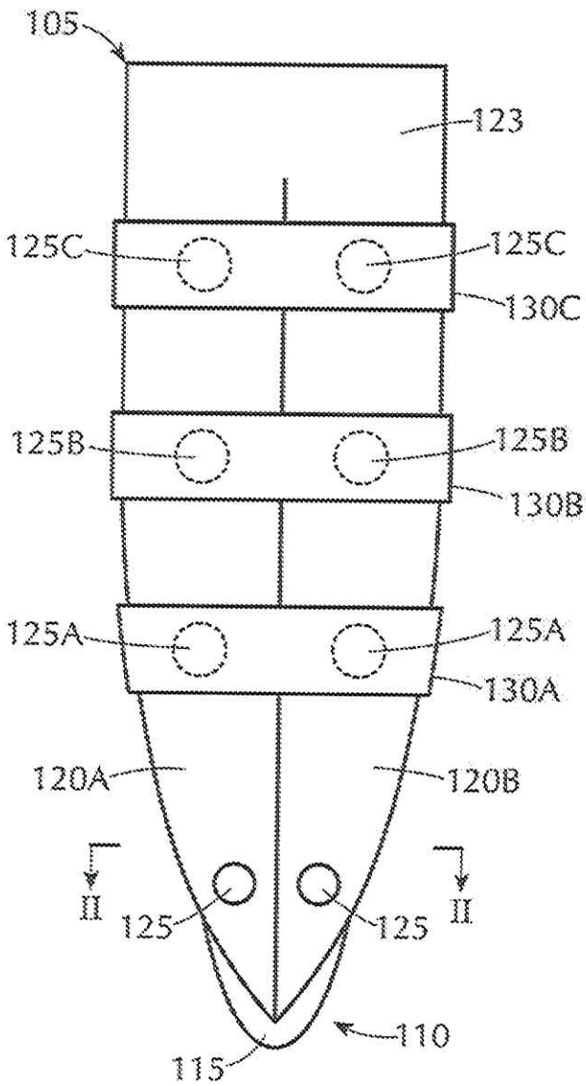

FIG. 5A

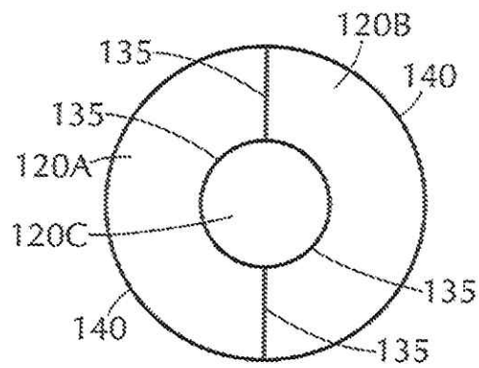

FIG. 5B

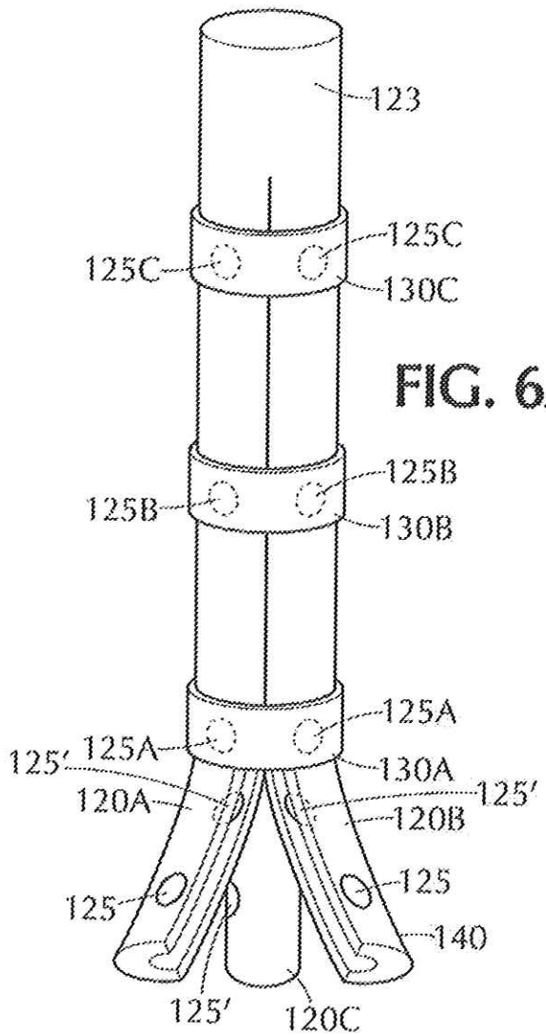

FIG. 6A

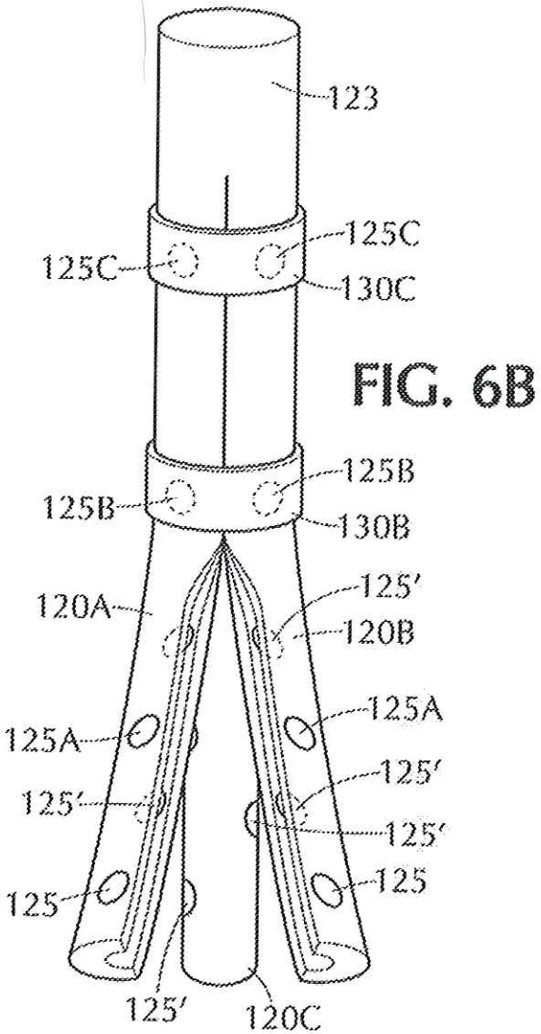

FIG. 6B

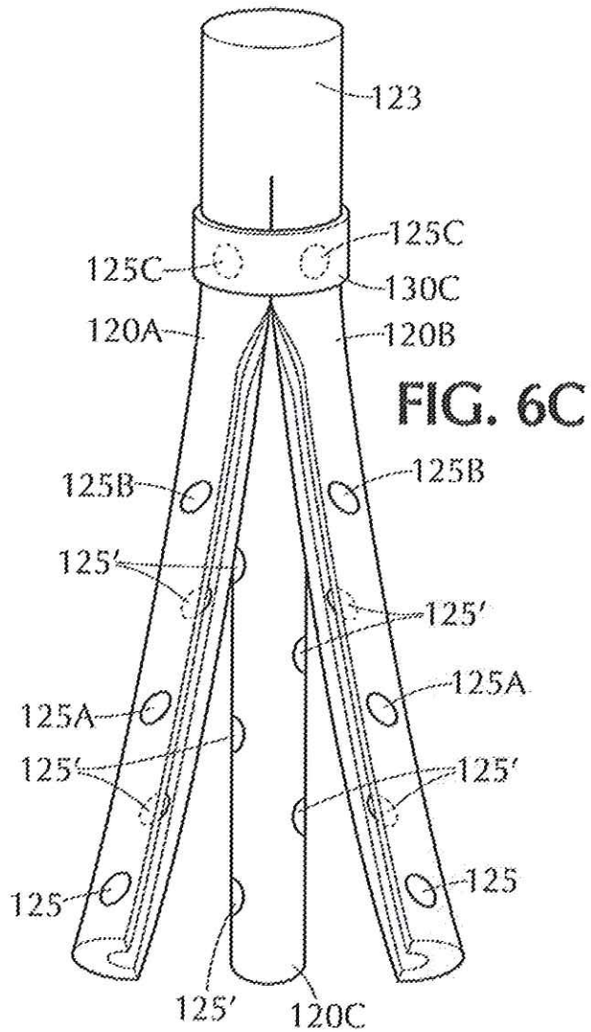

FIG. 6C

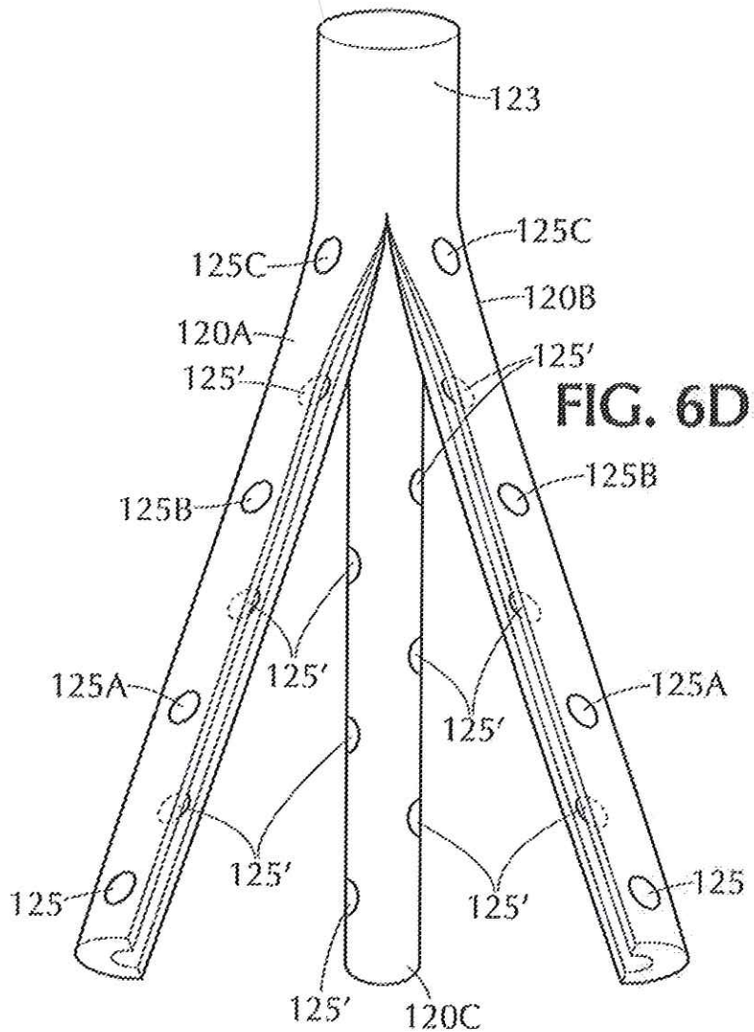

FIG. 6D

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
	Application Number	
Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

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
	Thomas		Boden	Jr.

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Middleboro	MA	US

Mailing Address of Inventor:

Address 1	c/o DePuy Synthes Products, LLC
Address 2	325 Paramount Drive
City	Raynham
State/Province	MA
Postal Code	02767
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alan	J.	Dextradeur	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Franklin	MA	US

Mailing Address of Inventor:

Address 1	c/o DePuy Synthes Products, LLC
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).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
	Application Number	
Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	33766		
Email Address	cherylcohen@aol.com	Add Email	Remove Email

Application Information:

Title of the Invention	Improved Implantable Valve Assembly With Extended Lifespan		
Attorney Docket Number	DSP5186USNP	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	7	**Suggested Figure for Publication (if any)**	

Filing By Reference:

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

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

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

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

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

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	33766		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
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Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

Domestic Benefit/National Stage Information:

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

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

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

Foreign Priority Information:

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

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
	Application Number	
Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
	Application Number	
Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

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, LLC		
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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
	Application Number	
Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

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. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
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	/Cheryl F. Cohen/			Date (YYYY-MM-DD)	2016-10-28
First Name	Cheryl	Last Name	Cohen	Registration Number	40361

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DSP5186USNP
	Application Number	
Title of Invention	Improved Implantable Valve Assembly With Extended Lifespan	

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 CooperationTreaty.

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.