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07 de agosto de 2019

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

NÚMERO DE SOLICITUD: 16/056.065

FECHA DE PRESENTACIÓN: 06 de agosto de 2018

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, QUE SE USARÁN PARA LA PRESENTACIÓN EN EL EXTRANJERO EN VIRTUD DE LA CONVENCIÓN DE PARÍS, SON *US16/056.065*

**Autorizado por el
Subsecretario de Comercio para la Propiedad Intelectual
y Director de la Oficina de Patentes y Marcas de Estados Unidos**



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Funcionario certificador

Reivindicaciones

1. Un aparato para el tratamiento vascular, que comprende:
 - un catéter que comprende un lumen interior;
 - un elemento expandible que comprende:
 - 5 un extremo proximal;
 - un extremo distal;
 - una porción trenzada ubicada entre el extremo proximal y el extremo distal;
 - un miembro de anclaje proximal dispuesto en el extremo proximal;
 - un miembro de anclaje distal dispuesto en el extremo distal;
 - 10 una configuración comprimida dimensionada para encajar dentro del lumen interno del catéter; y
 - una configuración parcialmente implantada en donde el extremo proximal está dimensionado para encajar dentro del lumen interno del catéter y el extremo distal está dimensionado más grande que el catéter; y
 - 15 un cable de suministro dispuesto dentro y que se extiende a través del lumen interior y el elemento expandible, que comprende:
 - una porción proximal;
 - un miembro de protuberancia proximal ubicado en un extremo distal de la porción proximal;
 - 20 una porción distal;
 - un miembro de protuberancia distal ubicado en un extremo proximal de la porción distal; y

una porción moldeable ubicada entre el miembro de protuberancia proximal y la protuberancia distal, la porción moldeable puede desplazarse de una configuración sustancialmente recta a una configuración curvada al salir del lumen interno del catéter,

5 en donde el elemento expandible es móvil desde la configuración comprimida a la configuración parcialmente implantada por un movimiento distal del cable de suministro que hace que el miembro de protuberancia distal del cable de suministro se acople con el miembro de anclaje distal del elemento expandible y empuje distalmente el miembro de anclaje distal expulsando, de
10 esta manera, el miembro de anclaje distal del catéter,

 en donde el alambre de suministro es desplazable distal, proximal, y rotacionalmente en relación con el elemento dilatable en la configuración parcialmente implantada, y

 en donde la porción moldeable del alambre de suministro es desplazable para
15 proporcionar una fuerza radial desde dentro de la porción trenzada del elemento dilatable cuando el elemento dilatable está en la configuración parcialmente implantada.

2. El aparato de la reivindicación 1 en donde la porción moldeable es desplazable a al
20 menos una de una forma de arco simétrica, una forma de arco asimétrica, una forma de “S” aproximada y una forma atraumática en la configuración curvada.

3. El aparato de la reivindicación 1 en donde,

el elemento expandible está en la configuración comprimida y está ubicado completamente dentro del lumen interior del catéter,

la porción moldeada está en la configuración sustancialmente recta y está ubicada dentro de un lumen de la porción trenzada del elemento dilatable,

5 el miembro de protuberancia distal está ubicado dentro del lumen de la porción trenzada del elemento dilatable, y

el miembro de protuberancia proximal está ubicado proximal al miembro de anclaje proximal.

10 4. El aparato de la reivindicación 1 en donde,

el elemento expandible está en la configuración parcialmente implantada,

el extremo distal del elemento expandible está ubicado fuera del catéter,

el extremo proximal y el anclaje proximal del elemento dilatable están ubicados dentro del lumen interno del catéter, y

15 la porción moldeable del alambre de suministro está en la configuración curvada y ubicada fuera del catéter.

5. El aparato de la reivindicación 4 en donde una rotación del alambre de suministro en relación con el elemento dilatable expande un radio del elemento dilatable.

20

6. Un método para implantar un stent que comprende:

proporcionar un sistema de implantación que comprende un catéter, un elemento dilatable, y un alambre de suministro;

desplazar una primera porción del elemento dilatable para salir del catéter;
 mantener una segunda porción del elemento dilatable dentro del catéter
 para establecer una configuración parcialmente implantada;

5 desplazar el alambre de suministro independiente del elemento dilatable
 a la configuración parcialmente implantada; y
 ampliar una circunferencia del elemento dilatable en respuesta al
 desplazamiento del alambre de suministro.

7. El método de la reivindicación 6 que comprende, además, las etapas de:

10 ubicar un anclaje proximal en un extremo proximal del elemento expandible;
 ubicar un anclaje distal en un extremo distal del elemento expandible;
 ubicar una protuberancia distal en el cable de suministro;
 ubicar una protuberancia proximal en el alambre de suministro proximal a
 la protuberancia distal;

15 ubicar la protuberancia distal dentro de un lumen del elemento dilatable;
 ubicar la protuberancia proximal al elemento expandible;
 ubicar el elemento expandible y al menos una porción del cable de suministro
 dentro de un lumen del catéter;

20 desplazar el anclaje distal y el elemento dilatable distalmente a través del
 lumen del catéter al empujar el alambre de suministro distalmente y de esta
 manera empujar la protuberancia distal contra el anclaje distal;

expulsar el anclaje proximal del extremo distal del catéter al empujar el alambre de suministro distalmente y de esta manera empujar la protuberancia proximal contra el anclaje proximal; y

expandir el anclaje proximal expulsado,

5 en donde la etapa de desplazar una primera porción del elemento dilatable para salir del catéter comprende las etapas de:

expulsar el anclaje distal de un extremo distal del catéter al empujar el alambre de suministro distalmente y, de esta manera, empujar la protuberancia distal contra el anclaje distal; y

10 expandir el anclaje distal expulsado,

en donde la etapa de desplazar el alambre de suministro independiente del elemento dilatable a la configuración parcialmente implantada comprende, además, la etapa de mantener el anclaje proximal dentro del lumen del catéter, y

15 en donde la etapa de ampliar una circunferencia del elemento dilatable en respuesta al desplazamiento del alambre de suministro comprende la etapa de proporcionar una fuerza radial del alambre de suministro contra el elemento dilatable desde el interior del lumen del elemento dilatable.

8. El método de la reivindicación 6 que comprende, además, la etapa de formar una
20 porción del alambre de suministro de una configuración sustancialmente recta a una configuración curvada después de un movimiento distal de la porción desde el interior del lumen del catéter hasta una posición fuera del lumen del catéter.

9. El método de la reivindicación 8 que comprende, además, la etapa de deslizar la porción moldeada del alambre de suministro contra el elemento dilatable desde el interior del lumen del elemento dilatable.
- 5 10. El método de la reivindicación 8 que comprende, además, la etapa de extender una porción del elemento dilatable a una pared de un vascular al desplazar la porción moldeada contra el elemento dilatable.
- 10 11. El método de la reivindicación 6 que comprende, además, la etapa de desplazar la segunda porción del elemento dilatable para que salga del catéter y se implante al empujar el elemento dilatable distalmente con un movimiento distal del alambre de suministro.
12. Un sistema para implantar un stent que comprende:
un catéter;
15 un stent trenzado desplazable a una configuración parcialmente implantada en donde una porción del stent trenzado está fuera del catéter y una porción del stent trenzado está dentro del catéter; y
un alambre de suministro desplazable independiente del stent trenzado y desplazable para proporcionar una fuerza para abrir el stent trenzado cuando el
20 stent trenzado está en una configuración parcialmente implantada.
13. El sistema de la reivindicación 12,

en donde el stent trenzado comprende un primer anclaje dilatante en un extremo distal y un segundo anclaje dilatante en un extremo proximal,

en donde el stent trenzado es desplazable en una configuración comprimida a través del catéter,

5 en donde el stent trenzado es desplazable de la configuración comprimida a la configuración parcialmente implantada de tal manera que el primer anclaje dilatante se expande en una posición implantada distal al catéter y el segundo anclaje dilatante se comprime dentro del catéter,

10 en donde el alambre de suministro comprende una protuberancia empujadora y un segmento moldeable,

en donde el cable de suministro se extiende a través del stent trenzado cuando el stent trenzado está en la configuración comprimida y cuando el stent trenzado está en la configuración parcialmente implantada,

15 en donde la protuberancia empujadora se ubica proximal al segundo anclaje expandible cuando el stent trenzado está en la configuración comprimida y cuando el stent trenzado está en la configuración parcialmente implantada,

en donde el segmento moldeable está ubicado dentro del stent trenzado cuando el stent trenzado está en la configuración comprimida y cuando el stent trenzado está en la configuración parcialmente implantada,

20 en donde el segmento moldeable es desplazable de una configuración sustancialmente recta cuando el stent trenzado está en la configuración comprimida a una configuración curvada cuando el stent trenzado está en la configuración parcialmente implantada, y

en donde el segmento moldeable es desplazable independiente del stent trenzado cuando el stent trenzado está en la configuración parcialmente implantada.

14. El sistema de la reivindicación 13 en donde la protuberancia empujadora es desplazable para empujar distalmente el segundo anclaje dilatante y de esta manera empujar el stent trenzado distalmente cuando el stent trenzado está en la configuración parcialmente implantada.

15. El sistema de la reivindicación 13 en donde el alambre de suministro comprende, además, una protuberancia jaladora ubicada distal a la protuberancia empujadora y el segmento moldeable y ubicada proximal al primer anclaje dilatante cuando el stent trenzado está en la configuración comprimida.

16. El sistema de la reivindicación 12 en donde el segmento moldeable es desplazable a una forma de arco en la configuración curvada.

17. El sistema de la reivindicación 13 en donde el segmento moldeable es desplazable a una forma ondulada en la configuración curvada.

18. El sistema de la reivindicación 12 en donde el alambre de suministro es desplazable en una dirección distal, una dirección proximal, y en una dirección rotacional independiente del stent trenzado cuando el stent trenzado está en la configuración parcialmente implantada.



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August 07, 2019

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

APPLICATION NUMBER: 16/056,065

FILING DATE: August 06, 2018

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US16/056,065

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Under Secretary of Commerce for Intellectual Property
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W. Montgomery
W. MONTGOMERY
Certifying Officer

Electronic Acknowledgement Receipt	
EFS ID:	33386560
Application Number:	16056065
International Application Number:	
Confirmation Number:	7200
Title of Invention:	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE
First Named Inventor/Applicant Name:	Robert SLAZAS
Customer Number:	6980
Filer:	Louis J. DeJuidice
Filer Authorized By:	
Attorney Docket Number:	243382.000145
Receipt Date:	06-AUG-2018
Filing Date:	
Time Stamp:	17:33:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

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Payment Type	DA
Payment was successfully received in RAM	\$5860
RAM confirmation Number	080718INTEFSW00004987201507
Deposit Account	
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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	DEPUY145_Track_1.pdf	153961	no	1
			c7a1b105a75389d761972fd490a4268bb7f8fd31		
Warnings:					
Information:					
2	Transmittal of New Application	DEPUY145_Transmittal.pdf	279936	no	1
			cfa38bdc02aecd4d532b79b3f17ab182e4d49684		
Warnings:					
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3	Application Data Sheet	DEPUY145_ADS.pdf	1276643	no	9
			0eb66f875cbff2c4e895367c0c11322fd76c3700		
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4	Power of Attorney	DEPUY145_POA.pdf	736596	no	2
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5	Drawings-only black and white line drawings	DEPUY145_DRWGS.pdf	3105089	no	14
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Multipart Description/PDF files in .zip description			
	Document Description	Start	End
	Specification	1	15
	Claims	16	22
	Abstract	23	23

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Information:

7	Fee Worksheet (SB06)	fee-info.pdf	40219	no	2
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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.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	243382.000145
	First Named Inventor	Robert SLAZAS
	Title	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE
	Priority Mail Express® Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☐ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>23</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets <u>14</u>] 6. Inventor's Oath or Declaration [Total Pages _____] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	

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

19. CORRESPONDENCE ADDRESS					
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Name (Print/Type)	Louis John DeJuidice			Registration No. (Attorney/Agent)	47522

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

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STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE

Field of Invention

The present invention generally relates to devices for interventional therapeutic treatment or vascular surgery for treatment of defects in the vasculature, and more particularly to delivering a stent to a treatment site in a body lumen of a patient and opening the stent at the treatment site.

Background

Stents are inserted into a blood vessel to provide an open path within the blood vessel, and they have been widely used intravascular angioplasty treatment of occluded blood vessels and other applications. Stents can be self-expanding or can be expanded by a radial force applied from inside the stent, for example when the stent is fitted with a balloon.

A braided stent can be characterized by a tube of metal wires woven together with a plain weaving technique. During delivery to a treatment site, a braided stent can travel through a catheter in an elongated, collapsed configuration, having a small diameter, and the braided stent can enlarge in diameter at a treatment site. Proper treatment with a braided stent can require that the stent extend radially to the walls of the body lumen in which the stent is implanted. Although braided stents can be self-expanding, such implants typically open with low opening forces, and therefore may not fully open to conform to a vessel wall. Post deployment, ancillary devices such as guidewires, catheters, balloons, etc. can be used to cross the braid and attempt to further expand the braided stent to improve vessel wall conformity. Issues such as unintentional braid movement or inability to fully open the braid commonly occur. Further, a braided implant that is separated from a delivery wire cannot be recovered for repositioning.

Summary

It is an object of the present invention to provide systems, devices, and methods for improving vessel wall conformity of a braided stent. Generally, an expandable element having a distal anchor member at a distal end, a proximal anchor member at a proximal end, and a braided intermediate portion can be delivered to a treatment site through a catheter by a delivery wire having a first, distal bump that can be translated distally to push the distal anchor distally and release the distal anchor upon exiting a distal end of the catheter, a shaped segment that can be moved to apply a radial force from within the braided intermediate portion to expand the braided intermediate portion, and a second, proximal bump that can be translated distally to push the proximal anchor distally and expel the expandable element from the catheter.

The delivery wire can also have a third, recapture bump positioned proximal the distal bump and distal the proximal bump that can be translated proximally to push the proximal anchor proximally. A partially implanted expandable element having a distal portion expelled from the catheter and released from the delivery wire and a proximal anchor positioned within the catheter can be retracted by translating the delivery wire proximally to push the proximal anchor proximally, thereby pulling the braided portion and distal anchor proximally into the catheter.

An example vascular treatment apparatus can include a catheter, an expandable element, and a delivery wire. The catheter can have an inner lumen through which the expandable element can be delivered by the delivery wire to a treatment site. The expandable element can have a proximal end, a distal end, a braided portion located between the proximal end and the distal end, a proximal anchor member disposed at the proximal end, and a distal anchor member disposed at the distal end.

The expandable element can have a compressed configuration dimensioned to fit within the inner lumen of the catheter for delivery to the treatment site and a partially implanted

configuration when the expandable element is not fully implanted at the treatment site. In the partially implanted configuration, the proximal end of the expandable element can be dimensioned to fit within the inner lumen of the catheter, and the distal end can be dimensioned larger than the catheter.

The delivery wire can be disposed within and extend through the inner lumen of the catheter and the expandable element, the expandable element having a substantially tubular shape. The delivery wire can have a proximal portion, a proximal bump member located at a distal end of the proximal portion, a distal portion, a distal bump member located at a proximal end of the distal portion, and a shapeable portion located between the proximal bump member and the distal bump. The shapeable portion can be movable from a substantially straight configuration to a curved configuration upon exiting the inner lumen of the catheter.

The expandable element can be movable from the compressed configuration to the partially implanted configuration by a distal movement of the delivery wire which can cause the distal bump member of the delivery wire to engage with the distal anchor member of the expandable element and push the distal anchor member distally. The distal anchor member can be expelled from the catheter pushing the distal anchor member out of the catheter with the distal bump member.

The delivery wire can be moved distally, proximally, and rotationally in relation to the expandable element in the partially implanted configuration, and the shapeable portion of the delivery wire can be moved to provide a radial force from within the braided portion of the expandable element when the expandable element is in the partially implanted configuration.

The shapeable portion can be movable to at least one of a symmetrical arc shape, an asymmetrical arc shape, or an approximate "S" shape in the curved configuration.

The expandable element can be in the compressed configuration and positioned entirely within the inner lumen of the catheter. When the expandable element is in the compressed

configuration and positioned entirely within the inner lumen of the catheter, the shaped portion can be in the substantially straight configuration and can be positioned within a lumen of the braided portion of the expandable element, the distal bump member can be positioned within the lumen of the braided portion of the expandable element, and the proximal bump member can be positioned proximal the proximal anchor member.

The expandable element can be in the partially implanted configuration such that the distal end of the expandable element is positioned outside the catheter and the proximal end and the proximal anchor of the expandable element are positioned within the inner lumen of the catheter. When the expandable element is in the partially implanted configuration, the shapeable portion of the delivery wire can be in the curved configuration and positioned outside the catheter, and a rotation of the delivery wire in relation to the expandable element can expand a radius of the expandable element.

An example method for implanting a stent can include the steps of: providing an implantation system comprising a catheter, an expandable element, and a delivery wire; moving a first portion of the expandable element to exit the catheter; maintaining a second portion of the expandable element within the catheter to establish a partially implanted configuration; moving the delivery wire independent of the expandable element in the partially implanted configuration; and enlarging a circumference of the expandable element in response to the moving the delivery wire. The method can further include the steps of positioning a proximal anchor at a proximal end of the expandable element; positioning a distal anchor at a distal end of the expandable element; positioning a distal bump on the delivery wire; positioning a proximal bump on the delivery wire proximal to the distal bump; positioning the distal bump within a lumen of the expandable element; positioning the proximal bump proximal to the expandable element; positioning the expandable element and at least a portion of the delivery wire within a lumen of the catheter; and moving the

distal anchor and the expandable element distally through the lumen of the catheter by pushing the delivery wire distally thereby pushing the distal bump against the distal anchor; expelling the proximal anchor from the distal end of the catheter by pushing the delivery wire distally thereby pushing the proximal bump against the proximal anchor; and expanding the expelled proximal anchor.

The step of moving a first portion of the expandable element to exit the catheter can include the steps of expelling the distal anchor from a distal end of the catheter by pushing the delivery wire distally thereby pushing the distal bump against the distal anchor; and expanding the expelled distal anchor.

The step of moving the delivery wire independent of the expandable element in the partially implanted configuration can include the step of maintaining the proximal anchor within the lumen of the catheter.

The step of enlarging a circumference of the expandable element in response to the moving the delivery wire can include the step of providing a radial force from the delivery wire against the expandable element from within the lumen of the expandable element.

The method can further include the steps of shaping a portion of the delivery wire from a substantially straight configuration to a curved configuration upon a distal movement of the portion from within the lumen of the catheter to a position outside the lumen of the catheter; sliding the shaped portion of the delivery wire against the expandable element from within the lumen of the expandable element; extending a portion of the expandable element to a wall of a vascular by moving the shaped portion against the expandable element; and moving the second portion of the expandable element to exit the catheter and become implanted by pushing the expandable element distally with a distal movement of the delivery wire.

An example system for implanting a stent or other such expandable element can include a catheter, a braided stent, and a delivery wire. The braided stent can be movable to a partially implanted configuration characterized by a portion of the braided stent exterior to the catheter and a portion of the braided stent within the catheter, and the delivery wire can be movable independent of the braided stent and movable to provide a force to open the braided stent when the braided stent is in a partially implanted configuration.

The braided stent can be moved in a compressed configuration through the catheter and can be movable from the compressed configuration to the partially implanted configuration. The braided stent of the system can have a first expandable anchor at a distal end and a second expandable anchor at a proximal end, such that, in the partially implanted configuration, the first expandable anchor is expanded in an implanted position distal to the catheter and the second expandable anchor is compressed within the catheter.

The delivery wire can be movable in a distal direction, a proximal direction, and in a rotational direction independent of the braided stent when the braided stent is in the partially implanted configuration. The delivery wire can extend through the braided stent when the braided stent is in the compressed configuration and when the braided stent is in the partially implanted configuration.

The delivery wire can include a pusher bump that can be positioned proximal the second expandable anchor when the braided stent is in the compressed configuration and when the braided stent is in the partially implanted configuration. The pusher bump can be movable to push the second expandable anchor distally thereby pushing the braided stent distally when the braided stent is in the partially implanted configuration.

The delivery wire can include a shapeable segment that can be positioned within the braided stent when the braided stent is in the compressed configuration and when the braided stent is in the partially implanted configuration. The shapeable segment can be movable from a substantially straight configuration when the braided stent is in the compressed configuration to a curved configuration when the braided stent is in the partially implanted configuration, and the shapeable segment can be movable independent of the braided stent when the braided stent is in the partially implanted configuration. The shapeable segment can be movable to form an arc shape, an undulating shape, or other atraumatic shape when in the curved configuration.

The delivery wire can include a puller bump positioned distal the pusher bump and the shapeable segment and also positioned proximal the first expandable anchor when the braided stent is in the compressed configuration.

Brief Description of the Drawings

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

Figure 1 is a drawing depicting an implantation system in a delivery configuration according to the present invention;

Figures 2A to 2H are drawings illustrating steps for use of an implantation system according to the present invention;

Figures 3A to 3C are drawings depicting shapes of a delivery wire portion according to the present invention;

Figure 4 is an image depicting a braided implant having a segment poorly apposed to a vessel wall as known in the art;

Figure 5 is an image depicting an implantation system during implantation according to the present invention;

Figures 6A to 6C are images illustrating steps for use of an implantation system according to the present invention; and

Figure 7 is a flow diagram outlining example method steps for use of an apparatus or system for deploying an implant according to the present invention.

Detailed Description

In the following detailed description, numerous specific details are set forth by way of examples in order to provide a thorough understanding of the relevant teachings. However, it should be apparent to those skilled in the art that the present teachings may be practiced without such details. In other instances, well known methods, procedures, components, and/or circuitry have been described at a relatively high-level, without detail, in order to avoid unnecessarily obscuring aspects of the present teachings.

An example of an implantation system 100, as illustrated in Figure 1 can have a catheter 102, an expandable element 200, and a delivery wire 106. The catheter 102 can have an inner lumen 104, and the expandable element 200 can be formed into a compressed configuration that is dimensioned to fit within the inner lumen 104 of the catheter 102. The expandable element 200 can have a proximal end 202, a distal end 204, a braided portion 206 located between the proximal end 202 and the distal end 204, a proximal anchor member 208 disposed at the proximal end 202,

and a distal anchor member 210 disposed at the distal end 204. The delivery wire 106 can be disposed within and extend through the inner lumen 104 of the catheter 102 and the expandable element 200 and can be used to deliver the expandable element 200 to a treatment site and position the expandable element 200 at the treatment site. The delivery wire 106 can have a proximal portion 108, a distal portion 110, a proximal bump member 114 located at a distal end of the proximal portion 108, a distal bump member 114 located at a proximal end of the distal portion 110, and a shapeable portion 112 located between the proximal bump member 116 and the distal bump member 114. When the expandable element 200 is in the compressed configuration for delivery through the catheter 102, the shapeable portion 112 can have a substantially straight shape that has flexibility to navigate through a catheter 102 to a treatment site.

The delivery wire 106 can further include a recapture bump 120 positioned between the distal bump 114 and the proximal bump 116. Delivery, positioning, retraction of an expandable element such as a stent within a body lumen utilizing a delivery wire having a distal bump member, proximal bump member, and a recapture bump is the subject of another patent application filed concurrently with this application.

One or all of the bump members 114, 116, 120 can include a radiopaque material to allow the location of the bumps 114, 116, 120 to be readily visible during an implanting procedure.

The one or more anchor members 208, 210, can be projections which extend generally parallel to a longitudinal axis of the expandable element 200 and extend downward toward the longitudinal axis of the expandable element 200. The anchor members 208, 210 can serve as a radiopaque marker for improved visualization during the deployment of the expandable element 200 within the body lumen 10. The anchor members 208, 210 can be used to align the expandable element 200 so it can be pushed and pulled through the catheter 102 without damage or deformation. The anchor members 208, 210 can also be used to move the braided portion 206 into

an expanded/implanted configuration. An example of the anchor member 208, 210 can be found in U.S. Serial No. 15/299,918, the entirety of which is incorporated herein by reference.

Typically, the expandable element 200 can have a compressed configuration and an expanded, implanted, configuration. In the compressed configuration the expandable element 200 can be dimensioned to fit within the inner lumen 104 of the catheter 102. In certain examples, the catheter 102 can aid in constraining the expandable element 200 so it does not expand when contained within the catheter 102. Other elements can be used to constrain the expandable element 200 as are known in the art.

The expandable element 200 can also have a partially implanted configuration where the proximal end 202 is dimensioned to fit within the inner lumen 104 of the catheter 102 and the distal end 204 is dimensioned larger than the catheter 102.

Figures 2A to 2H are drawings illustrating steps for use of an implantation system. When the expandable element 200 is in the collapsed configuration, the distal bump 114 can be positioned inside the expandable element 200 such that a distal movement of the delivery wire 106 can cause the distal bump 114 to push against the distal anchor 210, pulling the expandable anchor 200 through the catheter 102 to a treatment site. The distal bump member 114 can push the distal anchor member 210 to expel the distal anchor member 210 from the catheter 102, thereby moving the expandable element 200 to a partially implanted configuration as illustrated in Figure 2A.

Upon exiting the catheter, the shapeable portion 112 of the delivery wire 106 can move from a straight shape to a curved shape as illustrated in Figures 2A to 2H. The shapeable portion 112 can provide a radial force from within the braided portion 206 of the expandable element 200 when the expandable element is in the partially implanted configuration.

In an example, the entire delivery wire 106, including the shapeable portion 112, can be made of stainless steel. In other examples, the delivery wire 106 and/or the shapeable portion 112

can be made of a memory shape material including a memory shape metal such as Nitinol or a polymeric memory shape material. The shapeable portion 112 can move from a substantially straight flexible configuration while in the catheter 102 to a curved configuration upon contacting bodily fluid when exiting the catheter 102. Additionally or alternatively, the shapeable portion 112 can curve to conform to the shape of a curved bodily lumen such that distal and proximal movements of the expandable element 200, delivery wire 106, and catheter 102 can cause the delivery wire 106 to move to provide a radial force from within the braided portion 206.

As illustrated in Figure 2A, during treatment, because self-expanding braided implants may provide a low radial force during implantation, at least some of the intermediate portion 206 of the expandable element 200 may not fully conform to the walls of a body lumen 10.

As illustrated in Figure 2B, the delivery wire 106 can be rotatable in relation to the expandable element 200, and the rotation can cause the shaped portion 112 of the delivery wire 106 to provide a force against the expandable element 200, pushing portions of the expandable element to conform to the walls of the body lumen 10.

As illustrated in Figure 2C, the delivery wire 106 can be movable in a distal and a proximal direction in relation to the expandable element 200 without disturbing the placement of the partially implanted expandable element 200. The distal and proximal movement can also cause the shaped portion 112 of the delivery wire 106 to move against the expandable element 200, causing portions of the expandable element 200 to better conform to the walls of the body lumen 10.

As illustrated in Figure 2D, the delivery wire 106 can be subsequently rotated to improve conformity of the expandable element 200 to the walls of the body lumen 10.

As illustrated in Figure 2E, when the expandable element 200 is in the partially implanted configuration, the delivery wire 106 can further be moved distally to engage the proximal, pusher bump 116 with the proximal anchor 208.

As illustrated in Figure 2F, further distal movement of the delivery wire 106 can expel the proximal anchor 208 from the catheter 102. Once the proximal anchor 208 is expelled from the catheter 102, the proximal anchor can expand to engage the walls of the body lumen 10. Once the proximal anchor 208 is expanded, the expandable element 200 can be disengaged from the delivery wire 106. As illustrated in Figure 2F, portions of the expandable element 200 may remain not completely conforming to the walls of the body lumen 10.

As illustrated in Figure 2G, the delivery wire 106 can subsequently be moved proximally to side against portions of the braid, resulting in better conformity to the walls of the body lumen 10.

As illustrated in Figure 2H, the delivery wire 106 can subsequently be rotated, and the shaped portion 112 can slide against portions of the braid, resulting in better conformity to the walls of the body lumen 10.

In the expanded configuration, as illustrated in Figure 2H, the expandable element 200 can be expanded to conform to the dimensions of the patient's body lumen 10. The expanded dimension of the expandable element 200 allows the apparatus 100 to pass therethrough, to either advance to a second location or be withdrawn. The expandable element 200 can be expandable at least in part under its inherent properties, based at least on its original shape and the nature of the materials that make up the element, and further expanded by movement of the delivery wire 106 as described herein. Examples of the expandable element 200 can be one of pear shaped, ovoid, and elliptical when at its expanded diameter. The construction of the expandable element 200 is known to those of skill in the art. Other embodiments are contemplated for expandable elements 200 of this disclosure and can also be observed in U.S. Pat. Pub. 2016/0058524, a reference that is incorporated in its entirety herein.

Figures 3A to 3C illustrate some potential shapes that a shapeable portion 112 of the delivery wire 106 can have when the expandable element is in a partially implanted configuration. Arced, curved, "S" and "C" shaped are some examples. In one example, the shapeable portion 112 presents an atraumatic section 113 to contact both the braided implant 200 and possibly the wall of the body lumen 10. This atraumatic section 113 minimizes damage to one or both of the implant 200 and lumen 10. Another example of an atraumatic section 113 is to minimize the amount of radial force applied once the shapeable portion 112 deforms from the straight to curved shape. Too much force, even applied by an atraumatic shape 113, can still damage the implant/lumen. Too little force or shape and the implant will not open to its full potential shape.

Figure 4 depicts a braided implant having a segment poorly apposed to a vessel wall as known in the art. It is an object of the present invention to provide devices, systems, and methods of treatment for improving conformity of an implant to a vessel wall.

Figure 5 depicts a partially implanted expandable element that is a braided implant 200 having a distal end 204 positioned outside a catheter 102 and a delivery wire 106 positioned inside the implant 200, the delivery wire 106 having a distal coil 220 positioned distal the implant 200, a distal bump 114 positioned inside the implant, a recapture bump 120 positioned inside the implant 200 proximal the distal bump 114, and proximal bump 116 positioned proximal the implant 200 inside the catheter 102. The implant 200 as depicted in Figure 5 has a poorly apposed portion 201 that is not extended to conform to the vasculature 10.

Figures 6A to 6C illustrate movement of the delivery wire 106 within the system illustrated in Figure 5 to provide an outward radial force from within the poorly apposed portion 201 and other portions of the implant 200 not fully apposed to the walls to move those portions closer to the walls of the vascular 10. Progressing from Figures 6A to 6B, the delivery wire 106 can be moved distally to extend against an outer curved portion of the implant 200 and/or to provide a

pushing force by the proximal bump 116 against a proximal anchor (not shown) of the implant 200. Progressing from Figures 6B to 6C, the delivery wire 106 can be pulled proximally to press against an inner curved portion of the implant 200 and/or to retract at least a portion of the implant 200 into the catheter 102.

In the example illustrated in Figures 6A to 6C, the shaped portion 112 of the delivery wire 106 can be flexible to curve to the shape of a curved vasculature 10 and need not reshape as a result of being made from a memory shape material. The shapeable portion 112 can solely curve to conform to the shape of a curved bodily lumen such that distal and proximal movements of the expandable element 200, delivery wire 106, and catheter 102 can cause the delivery wire to move to provide a radial force from within the braided portion 206. In this example, the non-preshaped shapeable portion 112 can curve based on bringing the delivery wire 106 through the inside of the curve and the outside of a curve of a vasculature where the braided portion 206 is to be implanted.

Figure 7 is a flow diagram outlining example method steps for use of an apparatus or system for deploying an implant. The method steps can be implemented by any of the example means described herein or by any means that would be known to one of ordinary skill in the art.

Referring to method 700 illustrated in Figure 7, in step 710 an implantation delivery system having a catheter, an expandable element, and a delivery wire can be provided. The implantation delivery system can be any of the delivery systems described herein having any combination of the features described here, as well as any features that would be known to one skilled in the art. In step 720 a first portion of the expandable element can be moved to exit the catheter. In step 730 a second portion of the expandable element can be maintained within the catheter to establish a partially implanted configuration. In step 740 the delivery wire can be moved independent of the expandable element in the partially implanted configuration. In step 750 a circumference of the expandable element can be enlarged in response to the movement of the delivery wire in step 740.

The descriptions contained herein are examples of embodiments of the invention and are not intended in any way to limit the scope of the invention. As described herein, the invention contemplates many variations and modifications of the implantation system and methods of use thereof, including various shapes of the shapeable portion of the delivery wire, various materials, various treatments, and various stent geometries. These modifications would be apparent to those having ordinary skill in the art to which this invention relates and are intended to be within the scope of the claims which follow.

Claims

1. A vascular treatment apparatus, comprising:
 - a catheter comprising an inner lumen;
 - an expandable element comprising:
 - a proximal end;
 - a distal end;
 - a braided portion located between the proximal end and the distal end;
 - a proximal anchor member disposed at the proximal end;
 - a distal anchor member disposed at the distal end;
 - a compressed configuration dimensioned to fit within the inner lumen of the catheter; and
 - a partially implanted configuration wherein the proximal end is dimensioned to fit within the inner lumen of the catheter and the distal end is dimensioned larger than the catheter; and
 - a delivery wire disposed within and extending through the inner lumen and the expandable element, comprising:
 - a proximal portion;
 - a proximal bump member located at a distal end of the proximal portion;
 - a distal portion;
 - a distal bump member located at a proximal end of the distal portion; and
 - a shapeable portion located between the proximal bump member and the distal bump, the shapeable portion movable from a substantially straight configuration to a curved configuration upon exiting the inner lumen of the catheter,

wherein the expandable element is movable from the compressed configuration to the partially implanted configuration by a distal movement of the delivery wire causing the distal bump member of the delivery wire to engage with the distal anchor member of the expandable element and push the distal anchor member distally, thereby expelling the distal anchor member from the catheter,

wherein the delivery wire is movable distally, proximally, and rotationally in relation to the expandable element in the partially implanted configuration, and

wherein the shapeable portion of the delivery wire is movable to provide a radial force from within the braided portion of the expandable element when the expandable element is in the partially implanted configuration.

2. The apparatus of claim 1 wherein the shapeable portion is movable to at least one of a symmetrical arc shape, an asymmetrical arc shape, an approximate "S" shape and an atraumatic shape in the curved configuration.

3. The apparatus of claim 1 wherein,

the expandable element is in the compressed configuration and is positioned entirely within the inner lumen of the catheter,

the shaped portion is in the substantially straight configuration and is positioned within a lumen of the braided portion of the expandable element,

the distal bump member is positioned within the lumen of the braided portion of the expandable element, and

the proximal bump member is positioned proximal the proximal anchor member.

4. The apparatus of claim 1 wherein,
 - the expandable element is in the partially implanted configuration,
 - the distal end of the expandable element is positioned outside the catheter,
 - the proximal end and the proximal anchor of the expandable element are positioned within the inner lumen of the catheter, and
 - the shapeable portion of the delivery wire is in the curved configuration and is positioned outside the catheter.
5. The apparatus of claim 4 wherein a rotation of the delivery wire in relation to the expandable element expands a radius of the expandable element.
6. A method for implanting a stent comprising:
 - providing an implantation system comprising a catheter, an expandable element, and a delivery wire;
 - moving a first portion of the expandable element to exit the catheter;
 - maintaining a second portion of the expandable element within the catheter to establish a partially implanted configuration;
 - moving the delivery wire independent of the expandable element in the partially implanted configuration; and
 - enlarging a circumference of the expandable element in response to the moving the delivery wire.

7. The method of claim 6 further comprising the steps of:

- positioning a proximal anchor at a proximal end of the expandable element;
- positioning a distal anchor at a distal end of the expandable element;
- positioning a distal bump on the delivery wire;
- positioning a proximal bump on the delivery wire proximal to the distal bump;
- positioning the distal bump within a lumen of the expandable element;
- positioning the proximal bump proximal to the expandable element;
- positioning the expandable element and at least a portion of the delivery wire within a lumen of the catheter;

- moving the distal anchor and the expandable element distally through the lumen of the catheter by pushing the delivery wire distally thereby pushing the distal bump against the distal anchor;

- expelling the proximal anchor from the distal end of the catheter by pushing the delivery wire distally thereby pushing the proximal bump against the proximal anchor; and
- expanding the expelled proximal anchor,

- wherein the step of moving a first portion of the expandable element to exit the catheter comprises the steps of:

- expelling the distal anchor from a distal end of the catheter by pushing the delivery wire distally thereby pushing the distal bump against the distal anchor; and
 - expanding the expelled distal anchor,

- wherein the step of moving the delivery wire independent of the expandable element in the partially implanted configuration further comprises the step of maintaining the proximal anchor within the lumen of the catheter, and

wherein the step of enlarging a circumference of the expandable element in response to the moving the delivery wire comprises the step of providing a radial force from the delivery wire against the expandable element from within the lumen of the expandable element.

8. The method of claim 6 further comprising the step of shaping a portion of the delivery wire from a substantially straight configuration to a curved configuration upon a distal movement of the portion from within the lumen of the catheter to a position outside the lumen of the catheter.
9. The method of claim 8 further comprising the step of sliding the shaped portion of the delivery wire against the expandable element from within the lumen of the expandable element.
10. The method of claim 8 further comprising the step of extending a portion of the expandable element to a wall of a vascular by moving the shaped portion against the expandable element.
11. The method of claim 6 further comprising the step of moving the second portion of the expandable element to exit the catheter and become implanted by pushing the expandable element distally with a distal movement of the delivery wire.
12. A system for implanting a stent comprising:
 - a catheter;
 - a braided stent movable to a partially implanted configuration wherein a portion of the braided stent is exterior to the catheter and a portion of the braided stent is within the catheter; and

a delivery wire movable independent of the braided stent and movable to provide a force to open the braided stent when the braided stent is in a partially implanted configuration.

13. The system of claim 12

wherein the braided stent comprises a first expandable anchor at a distal end and a second expandable anchor at a proximal end,

wherein the braided stent is movable in a compressed configuration through the catheter,

wherein the braided stent is movable from the compressed configuration to the partially implanted configuration such that first expandable anchor is expanded in an implanted position distal to the catheter and the second expandable anchor is compressed within the catheter,

wherein the delivery wire comprises a pusher bump and a shapeable segment,

wherein the delivery wire extends through the braided stent when the braided stent is in the compressed configuration and when the braided stent is in the partially implanted configuration,

wherein the pusher bump is positioned proximal the second expandable anchor when the braided stent is in the compressed configuration and when the braided stent is in the partially implanted configuration,

wherein the shapeable segment is positioned within the braided stent when the braided stent is in the compressed configuration and when the braided stent is in the partially implanted configuration,

wherein the shapeable segment is movable from a substantially straight configuration when the braided stent is in the compressed configuration to a curved configuration when the braided stent is in the partially implanted configuration, and

wherein the shapeable segment is movable independent of the braided stent when the braided stent is in the partially implanted configuration.

14. The system of claim 13 wherein the pusher bump is movable to push the second expandable anchor distally thereby pushing the braided stent distally when the braided stent is in the partially implanted configuration.

15. The system of claim 13 wherein the delivery wire further comprises a puller bump positioned distal the pusher bump and the shapeable segment and positioned proximal the first expandable anchor when the braided stent is in the compressed configuration.

16. The system of claim 12 wherein the shapeable segment is movable to an arc shape in the curved configuration.

17. The system of claim 13 wherein the shapeable segment is movable to an undulating shape in the curved configuration.

18. The system of claim 12 wherein the delivery wire is movable in a distal direction, a proximal direction, and in a rotational direction independent of the braided stent when the braided stent is in the partially implanted configuration.

Abstract

An expandable element having a distal anchor member at a distal end, a proximal anchor member at a proximal end, and a braided intermediate portion can be delivered to a treatment site through a catheter by a delivery wire having a first, distal bump that can be translated distally to push the distal anchor distally and release the distal anchor upon exiting a distal end of the catheter, a shaped segment that can be moved to apply a radial force from within the braided intermediate portion to expand the braided intermediate portion, and a second, proximal bump that can be translated distally to push the proximal anchor distally and expel the expandable element from the catheter. The delivery wire can also have a third, recapture bump positioned between the proximal and distal bumps that can be translated proximally to retract a partially implanted expandable element into the catheter.

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Application Number: Not Yet Assigned
Filing Date: Filed Concurrently Herewith
First Named Inventor: Robert SLAZAS
Title: STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE
Art Unit: Not Yet Assigned
Examiner Name: Not Yet Assigned
Attorney Docket Number: 243382.000145

SIGNATURE of Applicant or Patent Practitioner
Signature: /Louis J. DelJuidice - 47,522/
Date (Optional): 2018-08-06
Name: Louis John DelJuidice
Registration Number: 47522
Applicant Name (if Applicant is a juristic entity): DePuy Synthes Products, Inc.
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SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).
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Name Eugene L. Szczecina, Jr.
Title Assistant General Counsel - Patents / DePuy Synthes Products, INC.

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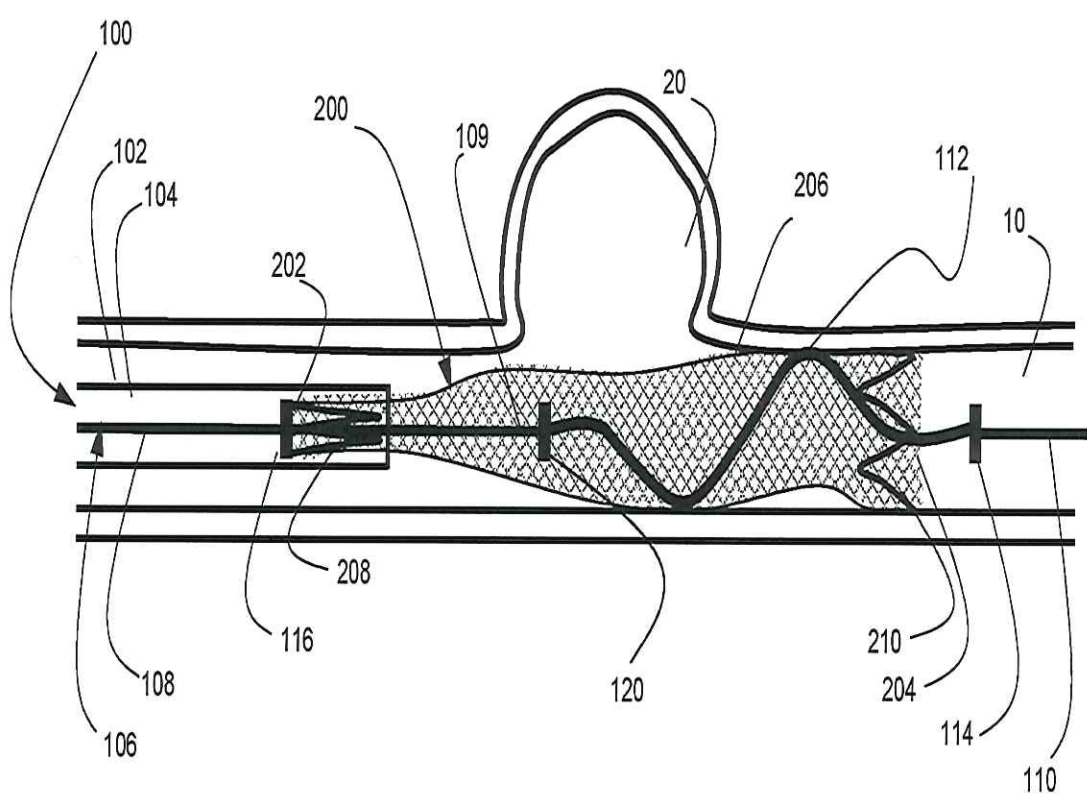


FIG. 2A

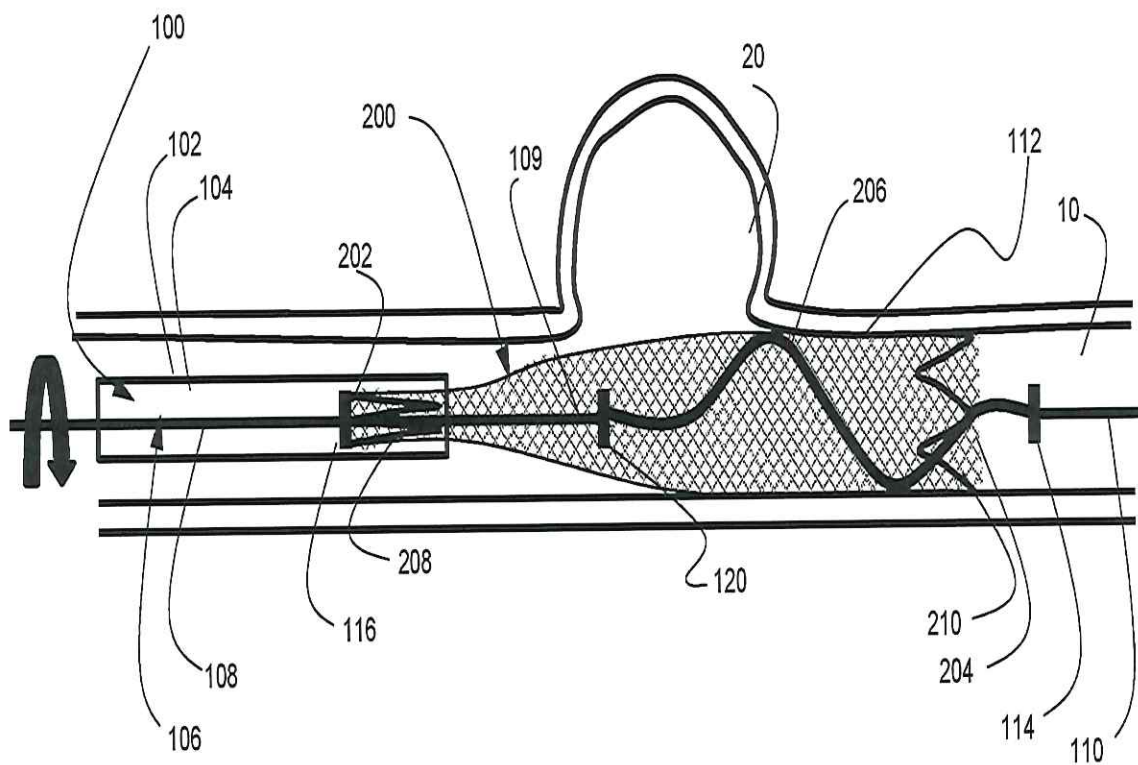


FIG. 2B



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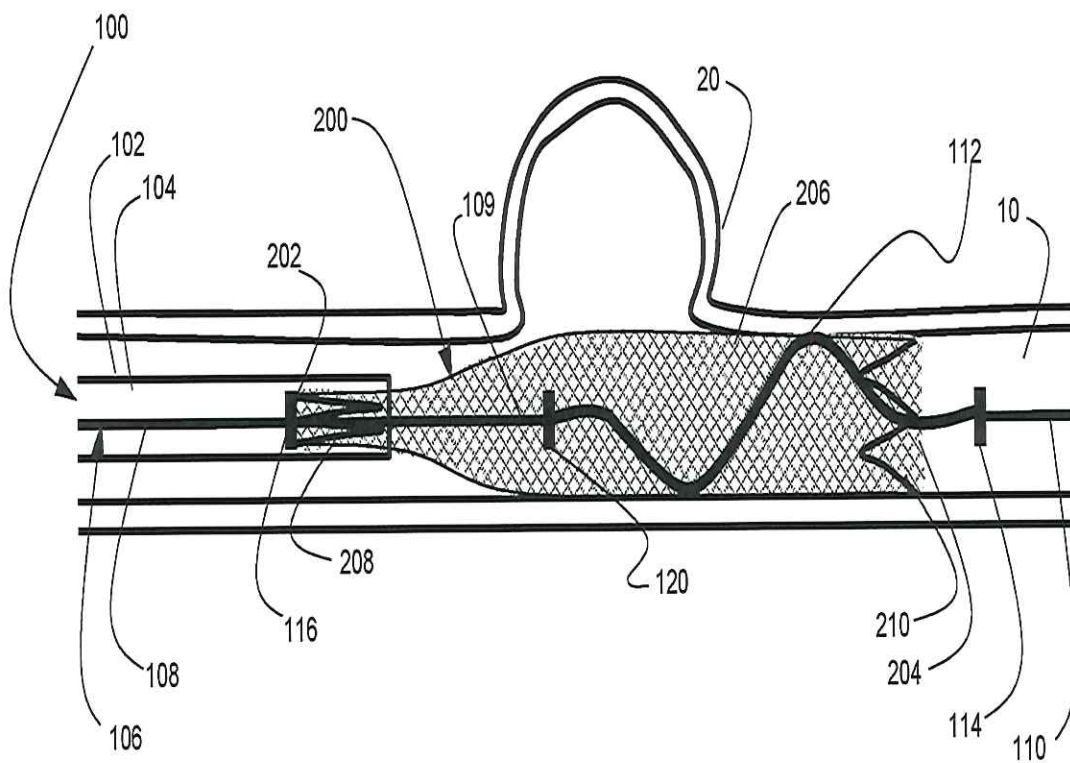


FIG. 2E

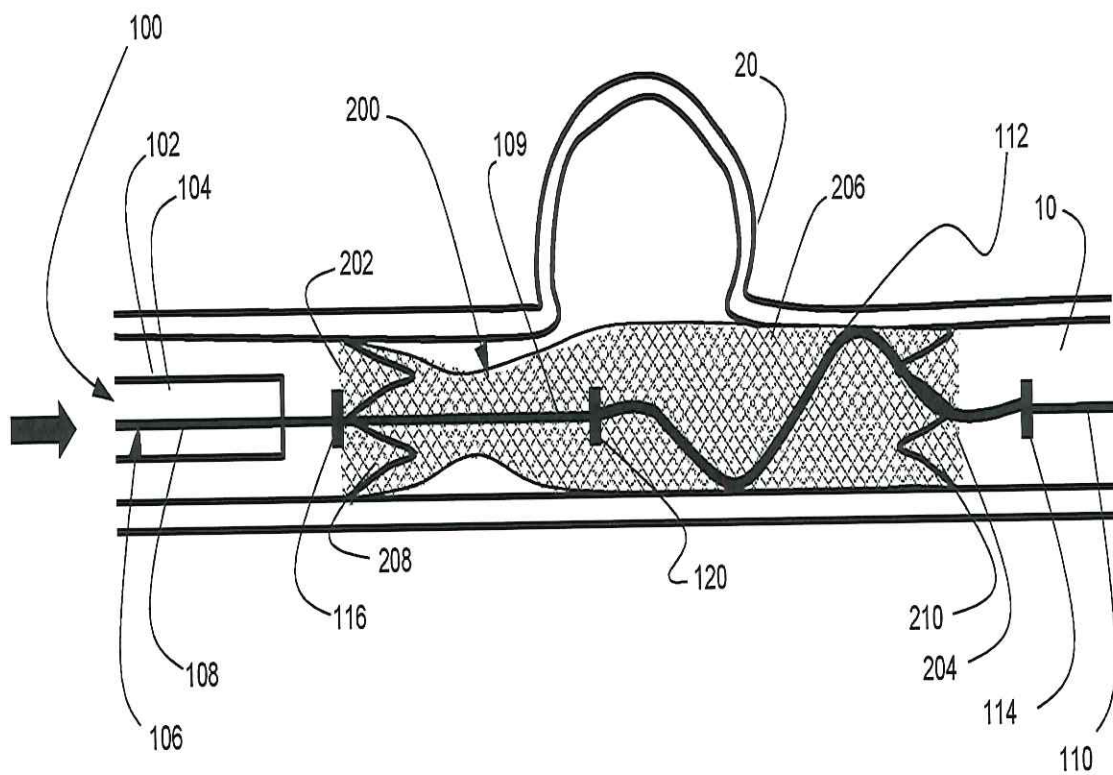


FIG. 2F



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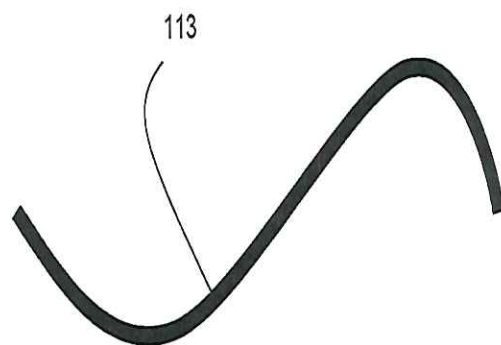


FIG. 3A

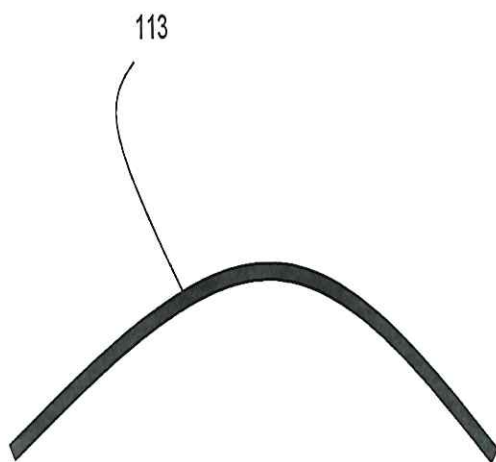


FIG. 3B

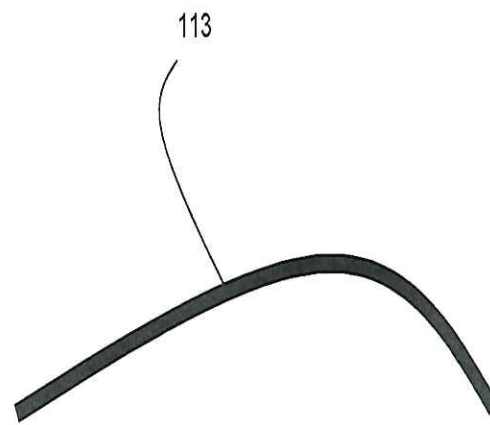


FIG. 3C

Prior Art

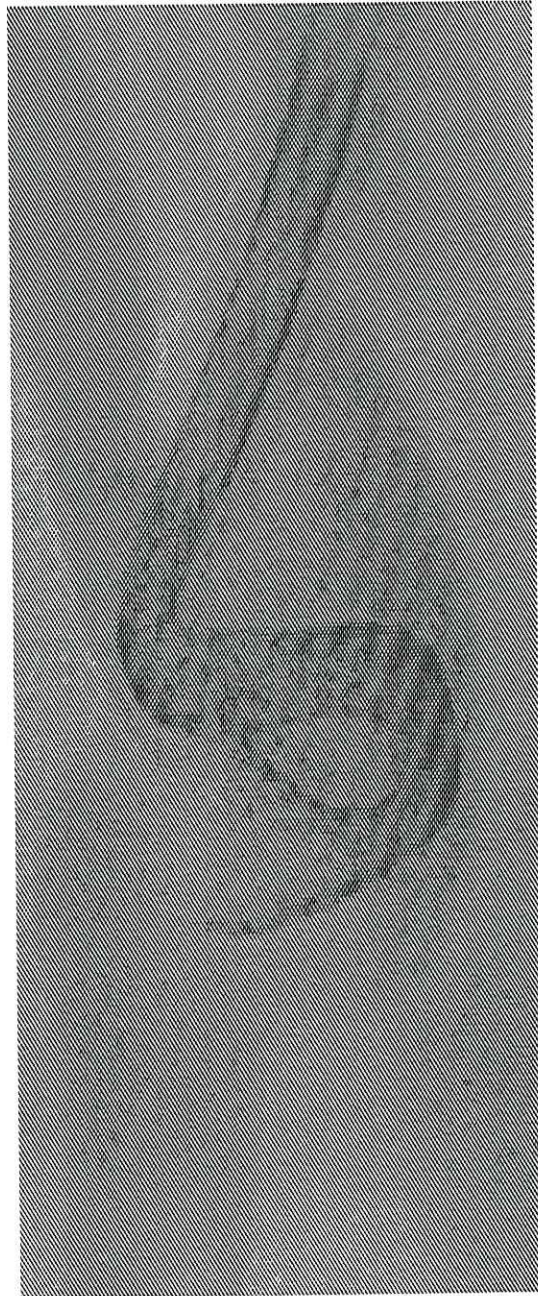


FIG. 4

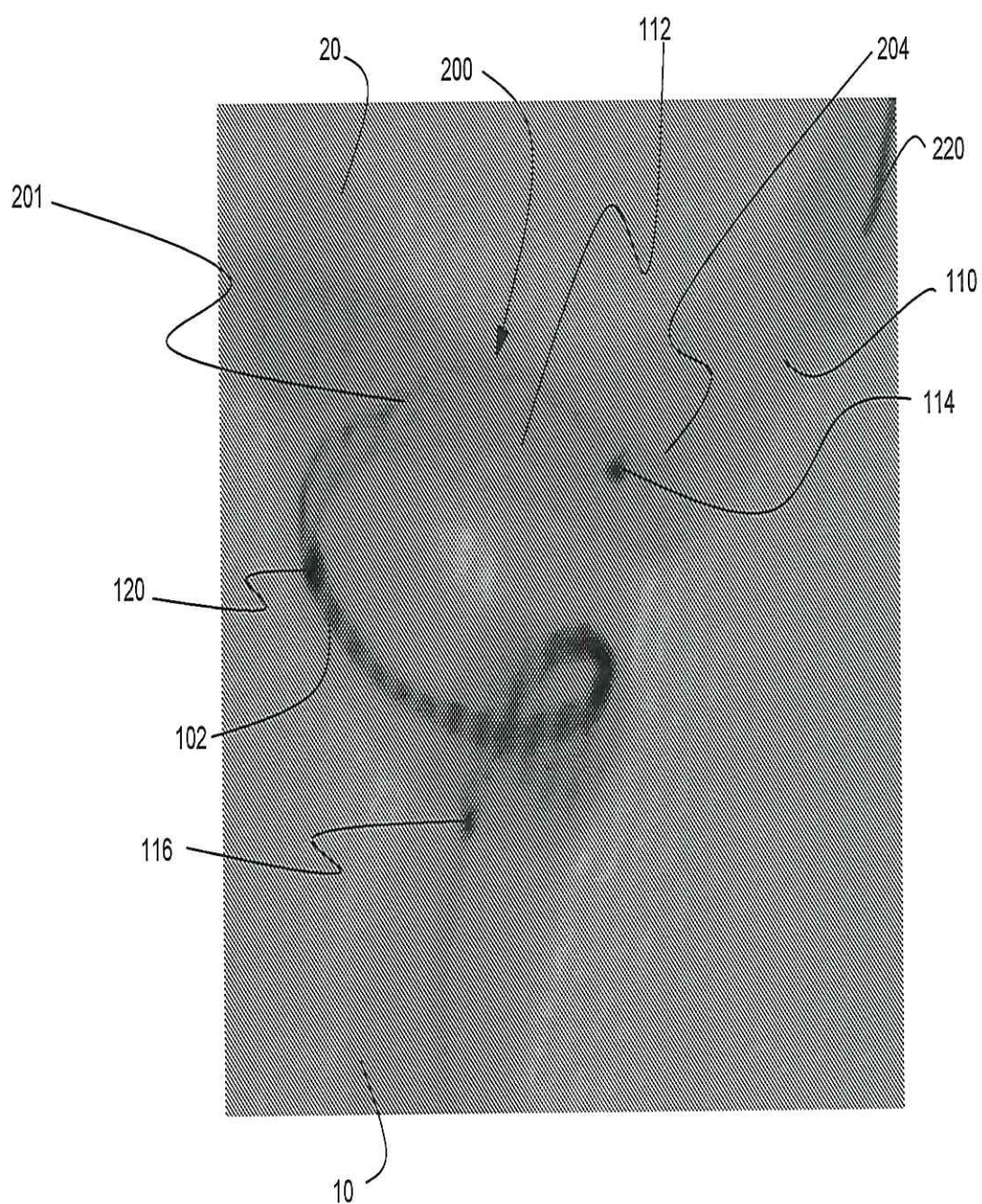


FIG. 5

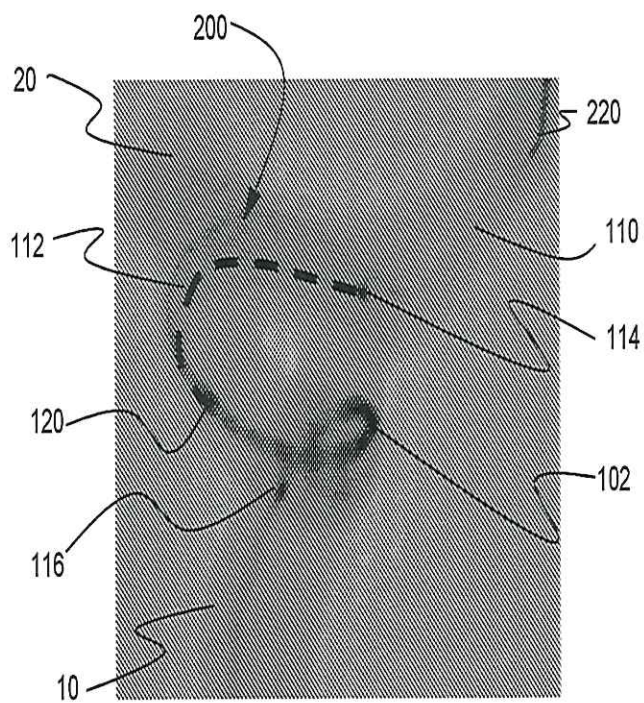


FIG. 6A

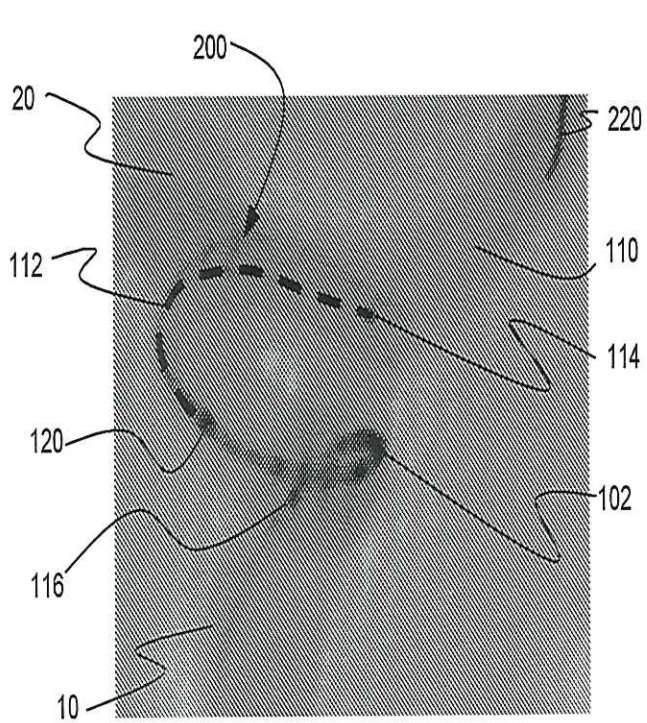


FIG. 6B

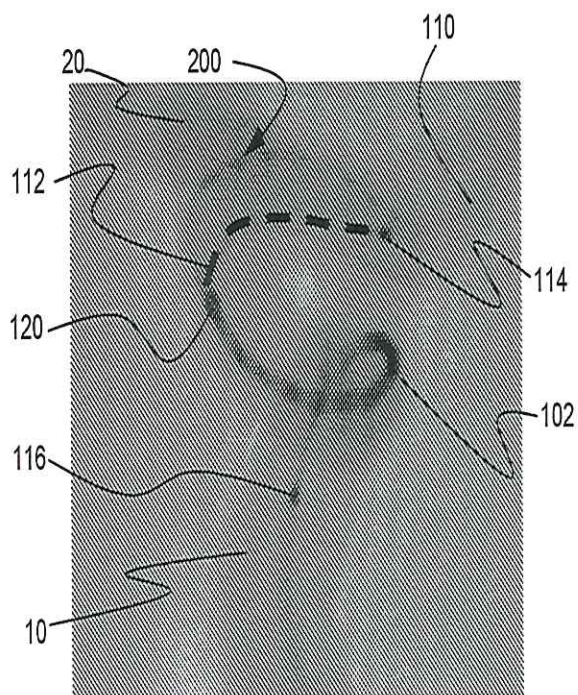


FIG. 6C

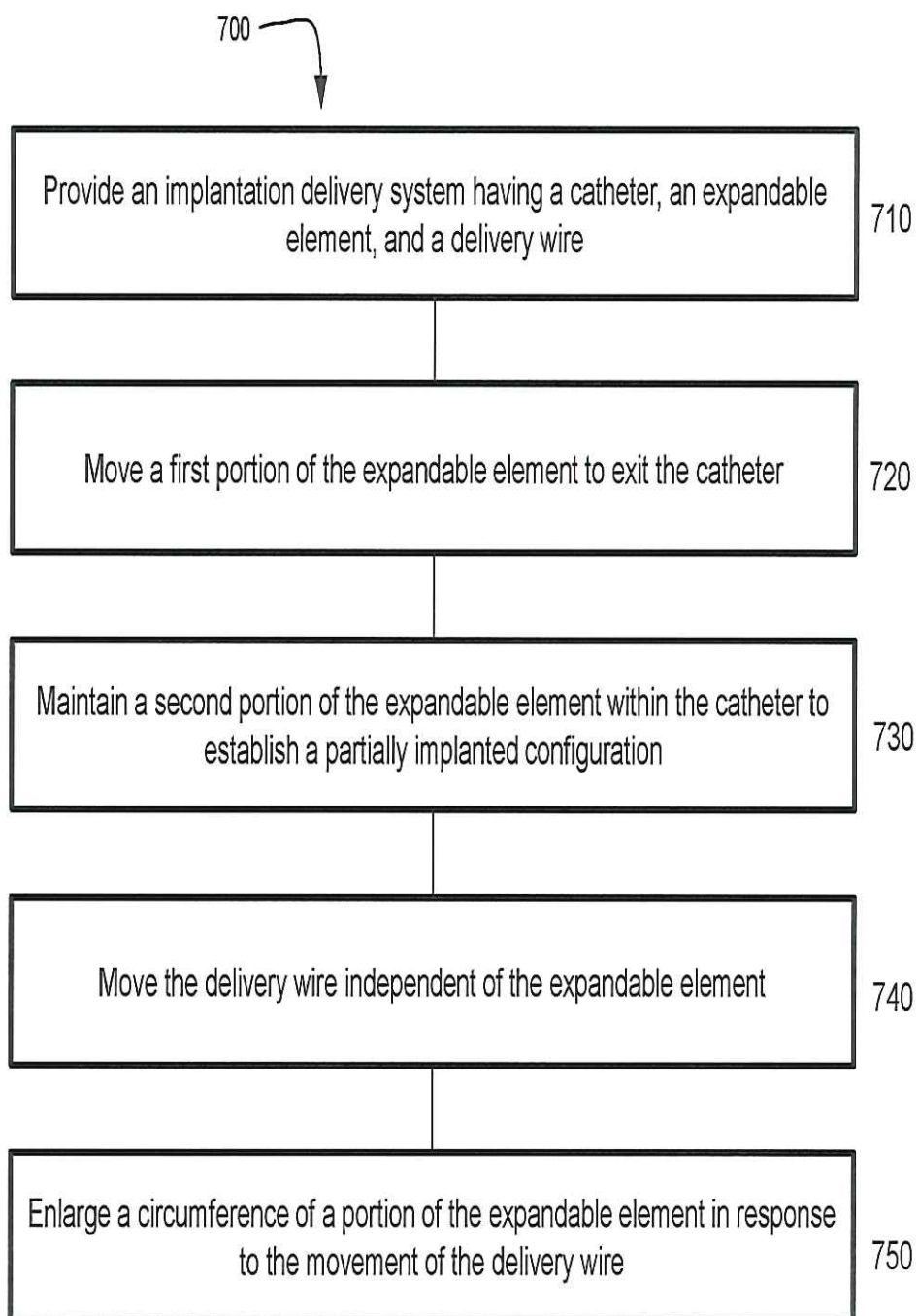


FIG. 7

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000145
		Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE		
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
	Robert		SLAZAS	

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

City	Raynham	State/Province	MA	Country of Residence	US
------	---------	----------------	----	----------------------	----

Mailing Address of Inventor:

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

Inventor 2

Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Juan		LORENZO	

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

City	Raynham	State/Province	MA	Country of Residence	US
------	---------	----------------	----	----------------------	----

Mailing Address of Inventor:

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

Inventor 3

Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Lacey		GOROCHOW	

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

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000145
		Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE		

City	Raynham	State/Province	MA	Country of Residence	US
------	---------	----------------	----	----------------------	----

Mailing Address of Inventor:

Address 1	c/o DePuy Synthes Products, Inc.				
Address 2	325 Paramount Drive				
City	Raynham	State/Province	MA		
Postal Code	02767	Country	US		
Inventor	4				<button>Remove</button>
Legal Name					

Prefix	Given Name	Middle Name	Family Name	Suffix	
	Pedro		PEDROSO		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Raynham	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o DePuy Synthes Products, Inc.				
Address 2	325 Paramount Drive				
City	Raynham	State/Province	MA		
Postal Code	02767	Country	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					

Correspondence Information:

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

Application Information:

Title of the Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE		
Attorney Docket Number	243382.000145	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	14	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000145
		Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE		

Filing By Reference:

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

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

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

Publication Information:

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

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

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	06980		

Domestic Benefit/National Stage Information:

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

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			
Add			

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	243382.000145
	Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE	

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.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

- ☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
- NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000145
		Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	243382.000145
	Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE	

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.

☒ Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
---	--	----------------

Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest
---	--

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

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

Mailing Address Information For Applicant:

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

Additional Applicant Data may be generated within this form by selecting the Add button. [Add](#)

Assignee Information including Non-Applicant Assignee Information:

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

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	243382.000145
		Application Number	
Title of Invention	STENT DELIVERY WITH EXPANSION ASSISTING DELIVERY WIRE		

Assignee	1		
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
			Remove
If the Assignee or Non-Applicant Assignee is an Organization check here.			☒
Organization Name	DePuy Synthes Products, Inc.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	325 Paramount Drive		
Address 2			
City	Raynham	State/Province	MA
Country ⁱ	US	Postal Code	02767
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			Add

Signature:

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

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

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

Signature	/Louis J. DeJuidice - 47,522/		Date (YYYY-MM-DD)	2018-08-06	
First Name	Louis John	Last Name	DeJuidice	Registration Number	47522
Additional Signature may be generated within this form by selecting the Add button.					Add

Privacy Act Statement

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

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

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

P-2019/36065

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIRECCIÓN DE NUEVAS CREACIONES

E. S. D.

Ref.: Expediente No. **NC2019/0008555**

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

Yo, CAROLINA DAZA MONTALVO, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 3, obrando **DEPUY SYNTHES PRODUCTS, INC.**, me permito dar respuesta al Oficio No. 8189 del 12 de agosto de 2019, de la siguiente manera

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

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

Atentamente,



CAROLINA DAZA MONTALVO

C.C. 66.783.790 de Palmira Valle

TP-141563 CSJ

notificaciones@clarkemodet.com.co