

(12) United States Patent

Patsalides

(54) INTRACRANIAL STENT FOR INSERTION INTO THE CEREBRAL VENOUS SINUS SYSTEM AND METHODS OF USE

(71) Applicant: Sonorous NV, Lake Forest, CA (US)

(72) Inventor: Athos Patsalides, New York, NY (US)

(73) Assignee: SONOROUS NV, Lake Forest, CA (US)

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

(21) Appl. No.: 18/614,410

(22)Filed: Mar. 22, 2024

(65)**Prior Publication Data**

> US 2024/0225872 A1 Jul. 11, 2024

Related U.S. Application Data

- (63) Continuation of application No. 17/393,120, filed on Aug. 3, 2021, now Pat. No. 12,285,347.
- (60) Provisional application No. 63/060,218, filed on Aug. 3, 2020.
- (51) **Int. Cl.** A61F 2/86 (2013.01)A61F 2/90 (2013.01)A61F 2/966 (2013.01)A61F 2/95 (2013.01)

(52) U.S. Cl.

CPC A61F 2/86 (2013.01); A61F 2/90 (2013.01); A61F 2/966 (2013.01); A61F 2002/9528 (2013.01); A61F 2002/9534 (2013.01); A61F 2240/002 (2013.01)

US 12,390,352 B2 (10) **Patent No.:**

(45) Date of Patent: Aug. 19, 2025

(58) Field of Classification Search

CPC A61F 2/966; A61F 2/90; A61F 2/86; A61F 2002/9534; A61F 2002/9528; A61F 2240/002

See application file for complete search history.

(56)References Cited

U.S. PATENT DOCUMENTS

7,326,225 B2	2/2008	Ferrera et al.
7,645,275 B2	1/2010	O'Connor et al
8,066,757 B2	11/2011	Ferrera et al.
8,070,791 B2	12/2011	Ferrera et al.
8,088,140 B2	1/2012	Ferrera et al.
	(Continued)	

FOREIGN PATENT DOCUMENTS

EP	1486186	12/2004
JP	2019-069290 A	5/2019
	(Con	tinued)

OTHER PUBLICATIONS

Boddu et al., "Anatomic measurements of cerebral venous sinuses in idiopathic intrascranial hypertension patients," PLoS ONE, Jun. 2018, 13(6): e0196275, 10 pages.

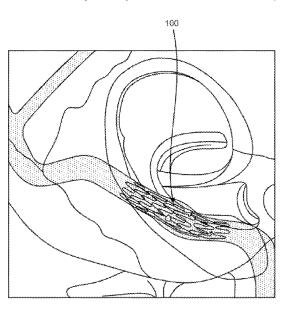
(Continued)

Primary Examiner — Sarah A Long (74) Attorney, Agent, or Firm — Fish & Richardson P.C.

ABSTRACT

A stent for insertion into an intracranial blood vessel of the cerebral venous sinus system includes a proximal end, a distal end, a body between the proximal end and the distal end, the body comprising a plurality of wires in a closed pattern, wherein the stent is configured for insertion into an intracranial blood vessel of the cerebral venous sinus system. The stent is further capable of being repositioned, retrieved/re-sheathed, and removed for more precise deliv-

20 Claims, 9 Drawing Sheets



(56) Refere	ences Cited	2024/0139471 A1 5/2024 Kessler et al. 2024/0164927 A1 5/2024 Stout
U.S. PATEN	T DOCUMENTS	2024/0268976 A1 8/2024 Amans et al. 2024/0366360 A9 11/2024 Takahashi et al.
8,545,514 B2 10/201	2 Ferrera et al. 3 Ferrera	FOREIGN PATENT DOCUMENTS
8,574,262 B2 11/201	3 Ensing et al. 3 Ferrera et al.	WO WO 2014150288 A2 9/2014
	Ferrera et al. Ferrera et al.	WO WO 2019135220 7/2019 WO WO 2020109979 6/2020
	5 Ferrera et al. 5 Gross et al.	WO WO 2022031730 2/2022 WO WO 2022165166 8/2022
9,198,687 B2 12/201	5 Fulkerson et al.	WO WO 2022165166 8/2022 WO WO 2023220571 A1 11/2023
· · · · · · · · · · · · · · · · · · ·	5 Fulkerson et al. 6 Ferrera et al.	
9,387,098 B2 7/201	6 Ferrera et al.	OTHER PUBLICATIONS
	6 Vong et al. 7 Takahashi et al.	Boddu et al., "Resolution of Pulsatile Tinnitus after Venous Sinus
9,566,072 B2 2/201	7 Le et al.	Stenting in Patients with Idiopathic Intracranial Hypertension,"
	7 Ma 7 Walzman	PLoS ONE, Oct. 2016, 11(10): e0164466, 13 pages. Bosstent System Product, Novel Neuro Interventional BosStent
	7 Ferrera et al. 8 Boasso	System, Jan. 2023, 17 pages.
10,016,211 B2 7/201	8 Ferrera et al.	Extended European Search Report in European Appln. No. 21854427.
	8 Ma 8 Ferrera et al.	8, mailed on Jul. 30, 2024, 8 pages. fwmetals.com[online], "Composite Materials: DFT® wire," retrieved
10,143,310 B1 12/201	8 Wang	on Apr. 22, 2024, retrieved from URL https://www.fwmetals.com/
	9 Pung et al. 9 Lam et al.	products/composites-dft-wire/dft-wire/>, 1 page. Haley et al., A Rational Approach to Meshing Cerebral Venous
10,335,299 B2 7/201	9 Lam et al.	Geometries for High-Fidelity Computational Fluid Dynamics, Jun.
10,342,546 B2 7/201 10,383,751 B2 8/201	9 Sepetka et al. 9 Ferrera et al.	2023, 24 pages. International Preliminary Report on Patentability in International
	9 Vitullo et al. 0 Sepetka et al.	Appln. No. PCT/US2021/044382, mailed on Feb. 16, 2023, 8 pages.
10,722,242 B2 7/202	0 Le et al.	International Search Report and Written Opinion in International Appln. No. PCT/US2021/044382, mailed on Nov. 18, 2021, 8
	0 Shimizu et al. 2 Horzewski et al.	pages.
2009/0132024 A1 5/200	9 Berkhoff	International Search Report and Written Opinion in International Appln. No. PCT/US2022/014297, mailed on May 18, 2022, 10
	0 Avior 1 Ferrera et al.	Appin. No. FC1/OS2022/014297, maned on May 18, 2022, 10 pages.
	1 Kao	Mayo Foundation for Medical Education and Research (MFMER),
	1 Ferrera et al. 2 Ferrera et al.	"Tinnitus symptoms & causes," Mayo Clinic, Mar. 5, 2019, 1998-2020, CON-20118272, 8 pages.
	2 Martin et al. 3 Nitzan et al.	Mayo Foundation for Medical Education and Research, "Tinnitus
2013/0304193 A1 11/201	3 Osman	diagnosis & treatment," Mayo Clinic, available on or before Jun. 14, 2019, via Internet Archive: Wayback Machine URL <a diagnosis-treatment="" diseases-conditions="" drc-20350162"="" href="https://www.</td></tr><tr><td></td><td>4 Rosenbluth et al.
4 Ma</td><td>mayoclinic.org/diseases-conditions/tinnitus/diagnosis-treatment/drc-</td></tr><tr><td>2014/0309673 A1 10/201</td><td>4 Dacuycuy et al.</td><td>20350162>, URLhttps://www.mayoclinic.org/diseases-conditions/tinnitus/diagnosis-treatment/drc-20350162 , 7 pages.
	6 Hebert et al. 6 Berez et al.	Park et al., "Awake embolization of sigmoid sinus diverticulum
	6 Ma 6 Turjman et al.	causing pulsatile tinnitus: simultaneous confirmative diagnosis and treatment," Interventional Neuroradiology, Oct. 2011, 17:376-379.
	7 Ferrera et al.	Schaller, "Physiology of cerebral venous blood flow: from experi-
2017/0196717 A1 7/201 2018/0250498 A1 9/201	7 Fulkerson et al. 8 Stern et al.	mental data in animals to normal function in humans," Brain
2018/0256378 A1* 9/201	8 Callister A61F 2/915	Research Reviews, Nov. 2004, 46(3):243-260. steegerusa.com [online], "Catheter Braid Patterns for Medical Braid-
	8 Kong 9 Tieu	ing," retrieved on Apr. 22, 2024, retrieved from URL https://
2019/0298977 A1 10/201	9 Heilman et al.	steegerusa.com/typical-braid-patterns-for-medical-braiding/#:~:text= Braid%20density%2C%20also%20known%20as,pushability%2C%
2019/0364374 A1 11/201 2020/0021929 A1 1/202	9 Jensen et al. 0 Farrar-Ganes et al.	20torque%20requirements%20and%20more>, 8 pages.
2020/0069410 A1 3/202 2020/0146852 A1 5/202		Sundararajan et al., "Dural Venous Sinus Stenosis: Why Distinguishing Intrinsic-versus-Extrinsic Stenosis Matters," AJNR Am J
2020/0368388 A1* 11/202	0 You A61L 27/56	Neuroradiol, Feb. 2021, available online Jan. 7, 2021, 42(2):288-
2021/0100667 A1 4/202 2021/0137715 A1 5/202		296. The Pulse Clinic: Advanced Pulsatile Tinnitus & Intracranial Hyper-
2021/0205105 A1 7/202	1 Stout	tension Assessment; Jun. 2023, 36 pages.
2022/0031488 A1 2/202 2022/0096792 A1 3/202	2 Patsalides 2 Bednarek	Venous Stenting Landscape, Jul. 2023, 22 pages.
2022/0226136 A1 7/202	2 Stout	Office Action in Japanese Appln. No. 2023-507704, mailed on May 8, 2025, 10 pages (with English translation).
	2 Fischell et al. 3 Amans	Office Action in European Appln. No. 21854427.8, mailed on Feb. 14, 2025, 6 pages.
	3 Takahashi et al. 4 Ferrera et al.	* cited by examiner

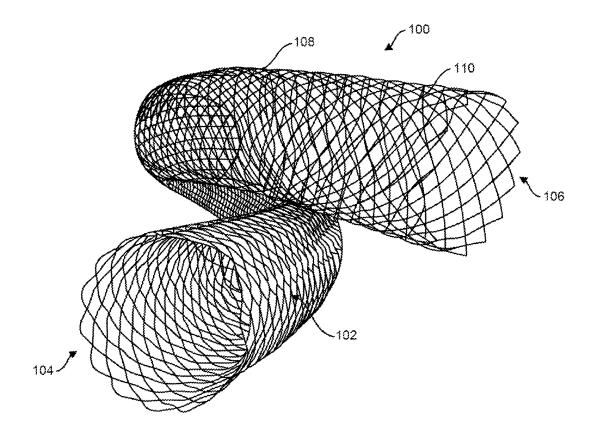
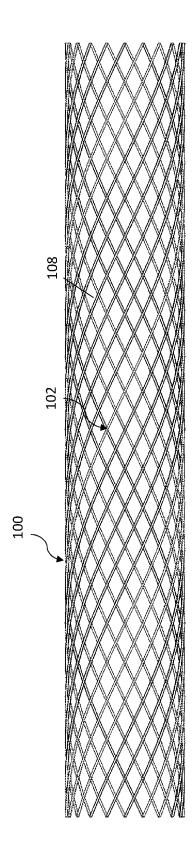
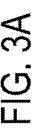
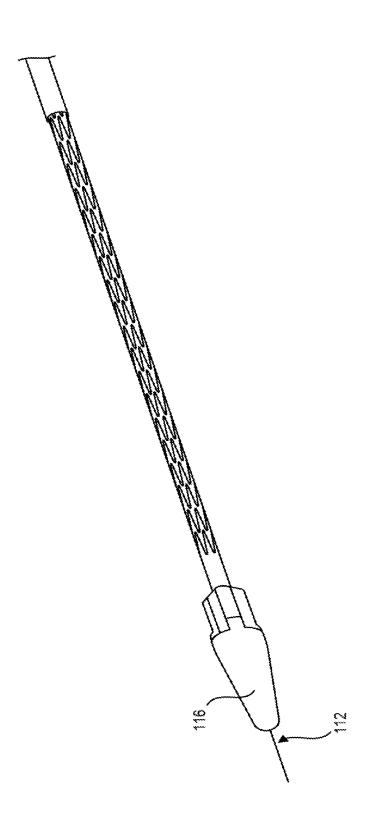
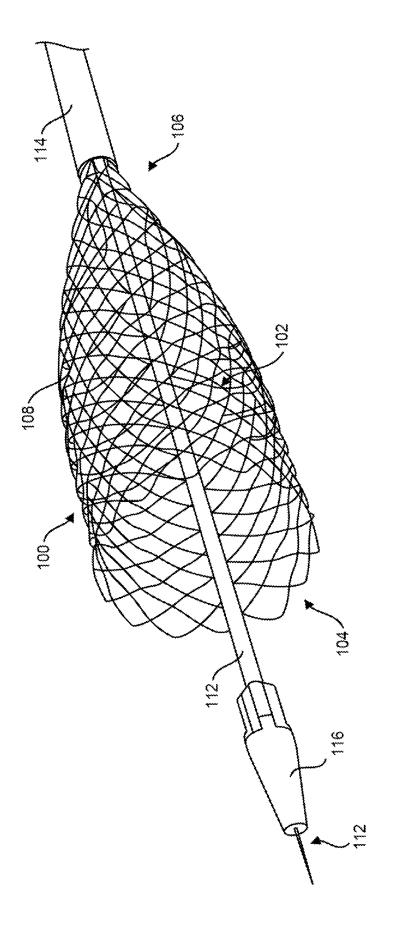


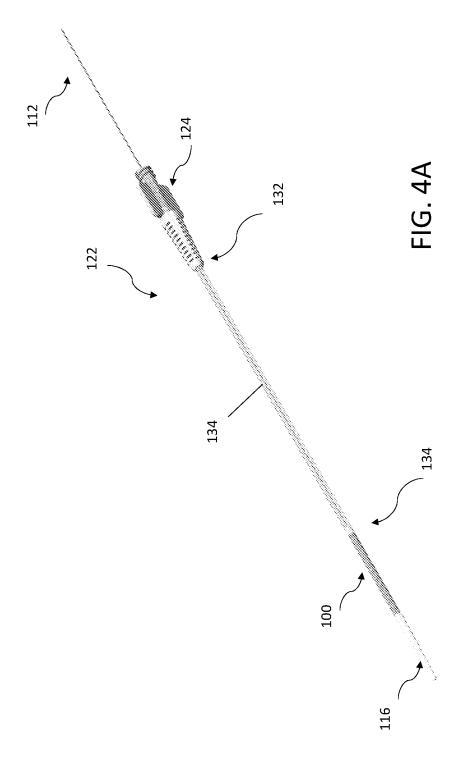
FIG. 1

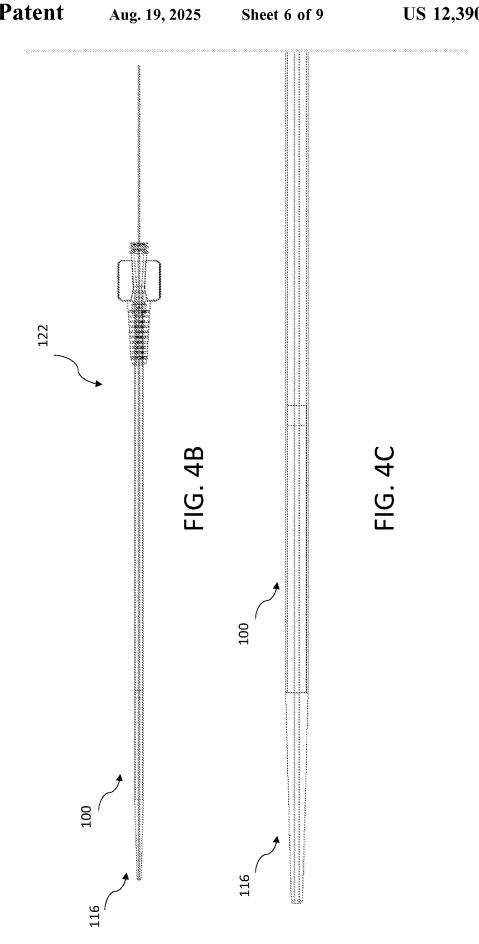


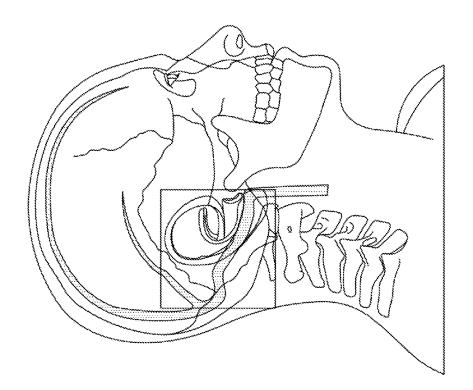


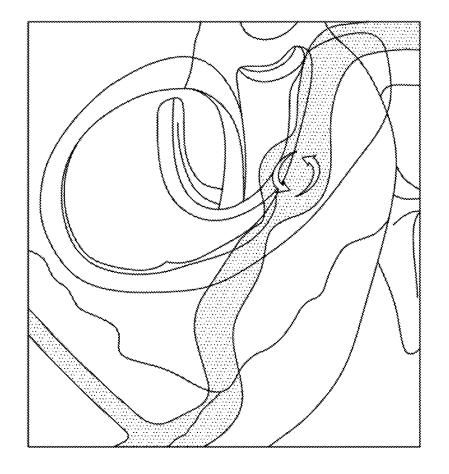


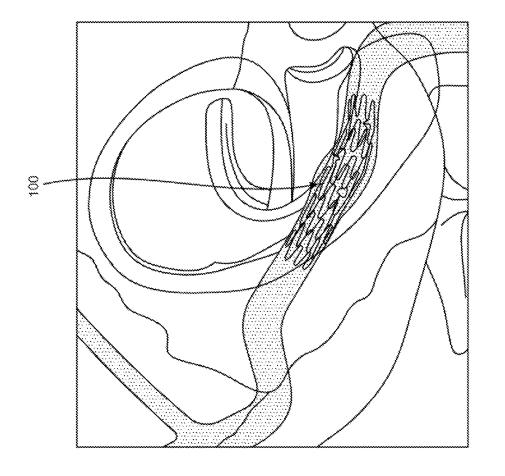












INTRACRANIAL STENT FOR INSERTION INTO THE CEREBRAL VENOUS SINUS SYSTEM AND METHODS OF USE

RELATED APPLICATIONS

This application claims priority to U.S. application Ser. No. 17/393,120, filed on Aug. 3, 2021, which claims the benefit of U.S. Provisional Application No. 63/060,218, filed on Aug. 3, 2020, the entire contents of which are hereby 10 incorporated by reference in their entirety.

FIELD OF THE DISCLOSURE

The present disclosure relates to stents suitable for treating conditions or diseases in the intracranial/cerebral veins. In particular, the present disclosure relates to expandable, retrievable, and re-sheathable structures configured to reduce restenosis and thrombus formation in the intracranial/ cerebral veins.

BACKGROUND

Generally, stents are commonly indicated for a variety of intravascular and non-vascular applications, including res- 25 toration and/or maintenance of patency within a patient's vessel. Stents are also used to reduce restenosis of a blood vessel post-dilation, thereby ensuring adequate blood flow through the vessel.

A new procedure has been carried out that involves 30 placing a stent in the cerebral venous sinuses of patients to ameliorate a collapse of and/or a stenosis in the sigmoid and/or transverse sinus and/or superior sagittal sinus and to restore blood flow out of the brain. The cerebral venous sinus system (also known as dural venous sinus system) 35 includes the large veins of the brain, namely the superior sagittal venous sinus, the transverse venous sinus, the sigmoid venous sinus and the straight venous sinus. The transverse and sigmoid venous sinuses are collectively called the "lateral" venous sinus. The cerebral venous 40 has a diameter between about 6 mm and 10 mm. sinuses receive blood from tributaries called cortical veins that drain in the side wall of the venous sinuses.

The stent used in the new procedure typically is the same stent used for procedures in other parts of the body, such as the carotid/peripheral arteries or even the biliary system. The 45 cerebral venous sinus structure, for instance, does not resemble any vein or arteries of other parts of the body. Instead, the venous sinus is a void created where the dura joins and forms a cavity (i.e., sinus) primarily along the inside of the skull. In this regard, the dura has no smooth 50 muscle cell lining and is inelastic when compared to veins and arteries. In addition, the cerebral venous sinus system does not have a cylindrical shape, and is instead ovoid or even triangular.

Another limitation of the current stent systems used in the 55 cerebral venous sinuses is that the length of cerebral venous sinus stenosis often exceeds the length of existing stents, often leading to placement of more than one stents adjacent to each other. A stent specifically designed for this anatomic location needs to have longer length in order to treat the 60 entire length of the stenosis.

Current stent designs have struts designed to expand a stiff calcified atherosclerotic plaque. These struts are numerous and thick, leading to increased risk of obstructing flow from a tributary vein into the cerebral venous sinus.

The first stent that was designed for the intracranial veins (River Stent, Serenity Medical, Inc.) is being currently

evaluated in clinical trials. The River stent is an open cell, self-expandable, Nitinol stent delivered over 0.014 wire. However, even this stent experiences some shortcomings. Namely, once this stent is positioned in the desired location, it cannot be repositioned, retrieved/re-sheathed, or removed.

There is therefore a need for a stent that is capable of being inserted into the cerebral venous sinus system and that can also be repositioned, retrieved, or removed to allow for more precise delivery. This and other benefits the present disclosure provides.

SUMMARY

There is a need for developing a stent that is capable of being inserted into cerebral venous sinus system. The present disclosure is directed toward further solutions to address this need, in addition to having other desirable characteristics. For example, the stent of the present disclosure can also be repositioned, retrieved, or removed to allow for more precise delivery into the cerebral venous sinus system than 20 previously known stents.

According to some embodiments of the present disclosure, a stent includes a proximal end, a distal end, a body between the proximal end and the distal end, the body comprising a plurality of wires interbraided in a closed cell pattern, wherein the stent is configured for insertion into an intracranial target blood vessel.

The stent is self-expandable or self-expanding, meaning the stent is constrained within a sheath of a delivery catheter until positioned and deployed in a desired location in the target blood vessel.

According to aspects of the present disclosure, the stent can be reconstrained and retrieved within the delivery system and repositioned in the blood vessel even after partial deployment.

According to aspects of the present disclosure, if the stent is partially deployed, it can be retrieved from the blood vessel after an interval of time.

According to aspects of the present disclosure, the stent can be re-sheathed after it has begun expanding.

According to aspects of the present disclosure, the body

According to aspects of the present disclosure, the body has a length between about 40 mm and about 80 mm.

According to aspects of the present disclosure, the stent is capable of transitioning between a collapsed configuration and an expanded configuration.

According to some embodiments of the present disclosure, the body is formed of a combination of platinum, cobalt, chromium, stainless steel, nickel and titanium alloy.

According to some aspects of the present disclosure, the target blood vessel for stent deployment can include at least one, or any one of, the cerebral venous sinus, the superior sagittal venous sinus, transverse venous sinus, sigmoid venous sinus and straight venous sinus.

According to aspects of the present disclosure, stent is used to treat any one of a variety of medical conditions including idiopathic intracranial hypertension, pulsatile tinnitus, cerebral venous insufficiency, intracranial venous thrombosis, and intracranial venous stenosis, which venous stenosis includes compression from tumor, compression from brain parenchyma, compression from arachnoid granulation, and compression from blood clot (thrombus).

BRIEF DESCRIPTION OF THE DRAWINGS

These and other characteristics of the present disclosure 65 will be more fully understood by reference to the following detailed description in conjunction with the attached drawings, in which:

FIG. 1 is an exemplary stent in accordance with an embodiment of the present disclosure;

FIG. 2 is an exemplary stent in accordance with an embodiment of the present disclosure;

FIG. 3A and FIG. 3B illustrate an exemplary stent delivery system, in accordance with an embodiment of the present disclosure. FIG. 3A is a schematic view illustrating the stent in a closed position. FIG. 3B is a schematic view illustrating the stent in a deployed position; and

FIG. 4A-FIG. 4C illustrate an exemplary stent delivery system, in accordance with an embodiment of the present disclosure:

FIG. 5A-FIG. 5C are schematic isometric views illustrating the basic structure of a stent of the present disclosure in use. FIG. 5A is a schematic isometric view illustrating the lateral venous sinus in the brain. FIG. 5B is a schematic isometric view illustrating a close-up of the lateral venous sinus in the brain. FIG. 5C is a schematic isometric view illustrating an exemplary stent in accordance with an 20 embodiment of the present disclosure secured in the lateral venous sinus in the brain.

DETAILED DESCRIPTION OF EMBODIMENTS

An illustrative embodiment of the present disclosure relates to a stent that is capable of being inserted into the cerebral venous sinuses and that is also capable of being repositioned, retrieved, or removed to allow for more precise delivery.

FIGS. 1 through FIG. 4A-FIG. 4C, wherein like parts are designated by like reference numerals throughout, illustrate an example embodiment or embodiments of stent that is capable for being inserted into the cerebral venous sinuses, according to the present disclosure. Although the present 35 disclosure will be described with reference to the example embodiment or embodiments illustrated in the figures, it should be understood that many alternative forms can embody the present disclosure. One of skill in the art will additionally appreciate different ways to alter the parameters of the embodiment(s) disclosed, such as the size, shape, or type of elements or materials, in a manner still in keeping with the spirit and scope of the present disclosure.

As used herein, an element or step recited in the singular and proceeded with the word "a" or "an" should be under- 45 stood as not excluding plural of said elements or steps, unless such exclusion is explicitly stated. Furthermore, references to "one embodiment" are not intended to be interpreted as excluding the existence of additional embodiments that also incorporate the recited features. Moreover, 50 unless explicitly stated to the contrary, embodiments "comprising" or "having" an element or a plurality of elements having a particular property can include additional elements not having that property. As referred to herein, the terms "proximal" and "distal" are in relation to the delivery handle 55 of the stent delivery system (also referred to as a catheter). For example, the distal end 104 of the stent 100 and the catheter is the end that is inserted first into a body of a patient and the proximal end 106 is opposite the distal end 104.

FIG. 1 and FIG. 2 illustrate an exemplary stent 100 in 60 accordance with various embodiments of the present disclosure. The stent 100 is shown in an expanded configuration. Stent 100 comprises a tubular flexible body 102 having a distal end 104 and a proximal end 106. Stent 100 further comprises a web structure 108 that is configured to allow the 65 stent 100 to expand from a contracted delivery configuration to an expanded deployed configuration.

4

In an embodiment, the web structure 108 can have a braided or closed design. As shown in FIG. 1 and FIG. 2, the stent 100 is formed by having a plurality of elongate wires 110 formed into the web structure 108. The elongate wires 110 traverse the length of the stent 100 in a direction traverse to the longitudinal length of the stent 100. The elongate wires 110 can be formed into the web structure 108 by braiding the wires 110, winding the wires 110, knitting the wires 110, and combinations thereof. In one embodiment, the wires 110 are laser-cut in a closed cell pattern to form the web structure 108. The diameter of the struts in the web structure 108 will be carefully optimized to modulate the radial outward force across the entire length of the stent. The diameter of the struts will vary from about 0.1 mm to about 1 mm. As used herein, the term "about" or "approximately" refers to a variation of 10% from the indicated values (e.g., 0.1 mm, 1 mm, etc.), or in case of a range of values, means a 10% variation from both the lower and upper limits of such ranges. For instance, "about 1 mm" refers to a range of between 0.9 mm and 1.1 mm.

In accordance with an embodiment of the present disclosure, the web structure 108 is configured to allow the stent 100 to self-expand and contract as many times as necessary until the stent 100 reaches the correct location and can be deployed and secured. A stent that is able to contract after it has expanded to a certain point and move back into its delivery system is referred to as a stent that is "retrievable" or "re-sheatheable." In an embodiment, the stent 100 is capable of being retrieved or re-sheathed even when the stent 100 is between about seventy percent (70%) and eighty-five percent (85%) expanded. In an embodiment, the stent 100 is capable of being retrieved or re-sheathed even when the stent 100 is about eighty-five percent (85%) expanded. In an embodiment, the stent 100 is capable of being retrieved or re-sheathed even when the stent 100 is about eighty percent (80%) expanded. In an embodiment, the stent 100 is capable of being retrieved or re-sheathed even when the stent 100 is about seventy-five percent (75%) expanded. In an embodiment, the stent 100 is capable of being retrieved or re-sheathed even when the stent 100 is about seventy percent (70%) expanded. By being retrievable or re-sheathable, the stent 100 of the present disclosure is capable of being repositioned multiple times before being secured into place. This allows the stent 100 to be positioned, repositioned, and even removed until the desired location is found. In this way, the stent 100 of the present disclosure allows for more precise delivery of the stent 100.

Stents are typically implemented in either a closed cell pattern, an open cell pattern, or a braided cell pattern. A stent with a "closed cell pattern" has each peak and valley of each strut segment connected to a peak or valley of an adjacent strut segment, with the exception of the strut segments on the proximal and distal ends. Stents with an "open cell pattern," on the other hand, have some peaks and/or valleys that are not connected to peaks and/or valleys of adjacent strut segments. Stents with braided patterns include a one over and one under pattern, but other patterns can suitably be used, knitting wires or wire filaments into a braided loop, the pattern of which loops are formed from a relaxed state, where each row of loops is axially and independently of the rows on either side. In an embodiment, the stent 100 can have a closed cell pattern design, for example, to allow the stent 100 to expand and collapse multiple times before being secured. Moreover, a closed cell pattern stent structure has an enhanced ability to expand and conform to a non-circular cavity wall, such as the sinuses, when compared to an open cell pattern structure. For example, the individual segments

of a closed cell pattern stent have more flexibility than the segments of an open cell pattern stent. Such flexibility beneficially increases a clinician's ability to guide the stent to a target site within a patient's vessel. Accordingly, the closed cell pattern segments are better suited for conforming to irregularities of a non-circular cavity.

Furthermore, stents of the present invention preferably exhibit high radial stiffness in the deployed configuration. Implanted stents therefore are capable of withstanding compressive forces applied by a vessel wall, thereby alleviating stenosis and maintaining vessel patency. The web structure 108 of the present disclosure provides the desired combination of flexibility in the delivery configuration to allow for safe navigation and radial stiffness in the deployed configuration to allow for excellent apposition to the vessel wall. In addition, the flexibility of the web structure 108 of the present disclosure allows the stent 100 to conform to the anatomy of the intracranial veins.

The stent 100 of the present disclosure can be sized to 20 cover the anatomy of the intracranial veins. For example, depending on the area of need, the length of the stent 100 can be between about 40 mm to about 80 mm long. In an embodiment, the length of the stent 100 is between about 40 mm to about 45 mm. In an embodiment, the length of the 25 stent 100 is between about 45 mm to about 50 mm. In an embodiment, the length of the stent 100 is between about 50 mm to about 55 mm. In an embodiment, the length of the stent 100 is between about 55 mm to about 60 mm. In an embodiment, the length of the stent 100 is between about 60 30 mm to about 65 mm. In an embodiment, the length of the stent 100 is between about 65 mm to about 70 mm. In an embodiment, the length of the stent 100 is between about 70 mm to about 75 mm. In an embodiment, the length of the stent 100 is between about 75 mm to about 80 mm. As used 35 herein, the term "about" or "approximately" refers to a variation of 10% from the indicated values (e.g., 40 mm, 45 mm, 50 mm, etc.), or in case of a range of values, means a 10% variation from both the lower and upper limits of such ranges. For instance, "about 40 mm" refers to a range of 40 between 36 mm and 44 mm.

Depending on the area of treatment, the diameter of the stent **100** can be between about 6 mm to about 10 mm. In an embodiment, the diameter of the stent **100** is between about 6 mm and about 7 mm. In an embodiment, the diameter of 45 the stent **100** is between about 7 mm and about 8 mm. In an embodiment, the diameter of the stent **100** is between about 8 mm and about 9 mm. In an embodiment, the diameter of the stent **100** is between about 9 mm and about 10 mm. The diameter can be the same from one end to the other end or 50 the diameter can be tapered. In one embodiment, for example, the stent **100** can be 7 mm at one end and gradually increase to 9 mm at the other end.

The stent 100 of the present disclosure can be made of wires comprising a combination of suitable materials, 55 including platinum, cobalt, chromium, stainless steel, nickel and titanium. Since the stent 100 of the present disclosure is self-expanding and also retrievable/re-sheathable, the web structure 108 in an embodiment is fabricated from an elastic material. In accordance with further embodiments of the 60 present disclosure, stent 100 is fabricated from biocompatible and/or biodegradable materials. Biocompatible material can comprise a biocompatible polymer, for example, a modified thermoplastic Polyurethane, Polyethylene Terephthalate, Polyethylene Tetraphthalate, expanded Polytetrafluoroethylene, Polypropylene, Polyester, Nylon, Polyethylene, Polyurethane, or combinations thereof.

6

In some embodiment, stent 100 can contain an external coating or attached active groups C configured for localized delivery of radiation, gene therapy, medicaments, thrombin inhibitors, or other therapeutic agents. For example, stent 100 can be coated with therapeutic agents to help prevent or delay thrombus formation or restenosis within a vessel. Coatings or active groups C can, in an embodiment, be absorbed or adsorbed onto the surface, can be attached physically, chemically, biologically, electrostatically, covalently, or hydrophobically, or can be bonded to the surface through VanderWaal's forces, or combinations thereof, using a variety of techniques that are well-known in the art.

Referring now to FIG. 3A and FIG. 3B, stent 100 is depicted in operation. Using known methods, stent 100 can be delivered over a guide wire 112 via a small incision basilic, femoral, or internal jugular veins and the use of fluoroscopic guidance. To deliver the stent 100 to its desired location, the stent 100, in a collapsed configuration as shown in FIG. 3A, is first inserted into a lumen 114, then guided through the veins with the help of the guide wire 112. The guide wire 112 can be any known guide wire used in the art that is sufficiently sized to navigate through a venous sinus. In one embodiment, the guide wire 112 may be about 0.014 mm in diameter. Once at the desired location, the lumen 114 can be pulled back to expose the stent 100 as shown in FIG. 3B. Upon exposure, the stent self-expands and secures itself to the surrounding vessel walls.

To assist in delivering stent 100 to its desired location, stent 100 may have a tip 116 at its distal end 104. This will allow for atraumatic advancement of the stent through a blood vessel or narrowed venous sinus, especially in cases where there is an abnormality within the lumen of the venous sinus (clot, arachnoid granulation). The tip 116 may be shaped as a cone, a wedge, or other similar shape with a tapered end that allows it to maneuver through the venous sinus. The tip 116 may be approximately 20 mm in length but can also be between approximately 10 mm in length to approximately 25 mm in length. The diameter of tip 116 can be same from one end to the other end or the diameter can be tapered. In one embodiment, for example, the diameter of tip 116 can be 7 mm in one end and gradually increase to 9 mm at the other end.

If necessary, the stent 100 can be retrieved or re-sheathed after it has been deployed. For instance, if the user (e.g., physician) determines that the stent 100 is not in the proper location after the stent 100 has begun to self-expand, the user can still retrieve the stent by causing the stent 100 to collapse back into the lumen 114. In an embodiment, the stent 100 can still be retrieved or re-sheathed with the lumen 114, even when the stent 100 is about eighty percent expanded.

FIG. 4A, FIG. 4B, and FIG. 4C illustrate an implant delivery system 120 in accordance with an embodiment of the present disclosure. In an embodiment, the implant delivery system 120 may include stent 100, a catheter 122 with hub 124 and guide wire 112 extending through catheter 122 and hub 124. In an embodiment, catheter 122 may have a distal end 130, a proximal end 132, and a lumen 134 extending between the distal end 130 and the proximal end 132. Catheter 122 is relatively flexible, may be comprised of a polymeric material such as nylon or PEBAX, and may range in length from 60 cm to 300 cm. Guide wire 112 diameter may be large enough to allow passage of guidewires ranging in diameter from 0.009 mm to 0.038 mm. Hub 124 is removably attached to the proximal end 132 of catheter 122, is adapted to reversibly connect to other medical devices, and may be comprised of polycarbonate or

any other suitable material. At the distal end 130 of catheter 122 is stent 100. At distal end 104 of stent 100 is tip 116.

An exemplary method of using a stent 100 with implant delivery system 120 is now described. A guide wire 112 is advance into a patient's peripheral vein (femoral vein, basilic vein, internal jugular vein) using known techniques, through a patient's vessel and to a treatment site. Stent 100 is loaded onto implant delivery system 120 in a collapsed position and introduced over the guidewire into the patient's vessel. The stent 100 and implant delivery system 120 combination is advanced over the guidewire 112 and through the patient's vessel until stent 100 is located at a treatment site, for example within a stenosis in the cerebral venous sinus system. Stent 100 is deployed by releasing the $_{15}$ stent 100 thereby allowing stent 100 to self-expand. If necessary to reposition stent 100, stent 100 may be retrieved or re-sheathed by collapsing the stent 100 within the catheter 122. Once the stent 100 is deployed, catheter 122 is then withdrawn through the patient's vessel and out of the 20 patient's body.

Referring to FIG. 5A, FIG. 5B, and FIG. 5C, the stent 100 is shown in use in an intracranial vessel. In operation, the stent is shown secured in the lateral venous sinus which is located within the brain as depicted in FIG. 5C.

With any embodiment, the stent 100 can be inserted into an intracranial vessel which includes, without limitation, the dural venous sinuses (the superior sagittal sinus, transverse sinus, sigmoid sinus, the straight sinus).

With any embodiment, the stent 100 can be used for a 30 number of purposes including to maintain patency of a cerebral venous sinus. Medical conditions that are suited to be treated using the stent 100 of the present disclosure include, without limitation, idiopathic intracranial hypertension, pulsatile tinnitus, cerebral venous insufficiency, intracranial venous thrombosis, and intracranial venous stenosis, including compression from tumor, compression from brain parenchyma, compression from arachnoid granulation, and thrombus

The stent **100** of the present disclosure provides several 40 notable advantages over stents currently used. First, the stent **100** is specifically designed for use in cerebral venous sinuses rather than for other parts of the body such as the carotid/peripheral arteries. As such, the stent **100** has enhanced conformability to the anatomy of cerebral venous 45 sinuses as compared to stents that were not designed for use in this region. In addition, the stent **100** of the present disclosure is retrievable and re-sheathable which allow it to be positioned, repositioned, and removed prior to being secured. This enhances the ability of the stent **100** to be 50 precisely delivered to its desired location.

Other notable advantages of the stent 100 of the present disclosure include its flexibility to allow for safe navigation through the intracranial veins, its ability to secure itself to the vessel walls, and its ability to alleviate stenosis and 55 restore patency in the veins. These features of the stent 100 are in part due to the unique combination of materials that provide the stent 100 with the required flexibility, stability, and strength.

To treat different conditions in different vessels, the stent 60 100 of the present disclosure can be customized. In an embodiment, the stent 100 of the present disclosure can have customized, variable zones of chronic outward force that mimic the compliance and adapt to the anatomy of the cerebral venous sinuses (e.g., target vessel). This means that 65 the stent 100 may be stiffer or firmer in some areas and not in others. The stiffer sections can help open, and keep open,

8

those areas of the vessel that are more difficult to open. In one embodiment, the stent 100 may be stiffer in the middle.

In another embodiment, the stent can have customized, variable cell size to adapt to the non-cylindrical shape of cerebral venous sinuses (e.g., target vessel) and achieve excellent apposition to the wall of the cerebral venous sinus. This means that certain sections of the stent 100 may have different spacing between the cells to help conform to the shape of the vessel. This allows the stent 100 of the present disclosure to be used to treat various conditions in different vessels.

In another embodiment, the stent can have customized, variable cell size to prevent obstruction of flow from a tributary vein into the cerebral venous sinus.

Numerous modifications and alternative embodiments of the present disclosure will be apparent to those skilled in the art in view of the foregoing description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the best mode for carrying out the present disclosure. Details of the structure can vary substantially without departing from the spirit of the present disclosure, and exclusive use of all modifications that come within the scope of the appended claims is reserved. Within this specification embodiments have been described in a way which enables a clear and concise specification to be written, but it is intended and will be appreciated that embodiments can be variously combined or separated without parting from the disclosure. It is intended that the present disclosure be limited only to the extent required by the appended claims and the applicable rules of law.

It is also to be understood that the following claims are to cover all generic and specific features of the disclosure described herein, and all statements of the scope of the disclosure which, as a matter of language, might be said to fall therebetween.

What is claimed is:

1. A method of treating pulsatile tinnitus (PT) in a subject which comprises:

providing a stent that is braided and self-expanding,

the stent having a proximal end, a distal end, and a tubular flexible body between the proximal end and the distal end, with the same diameter at the proximal and distal end, the tubular flexible body comprising a wire arrayed in a cellular pattern,

wherein the tubular flexible body has a higher degree of stiffness in a first section of the tubular flexible body than in a second section of the tubular flexible body,

wherein the tubular flexible body has different zones of outward force, a length of between about 40 mm and about 80 mm, is configured to expand to conform to an ovoid or triangular shape of vessel of a cerebral venous sinus system of the subject, to secure itself to surrounding walls of the vessels, to be retrievable or re-sheathable and to be implanted in a stenosis in a selected vessel of the vessels of the cerebral venous sinus system.

inserting a guide wire and a flexible delivery catheter through an incision in the femoral, basilic, or internal jugular vein, the stent being contained within a lumen of the delivery catheter;

guiding the stent through one or more of the vessels of the cerebral venous sinus system in a collapsed configuration on the guide wire to the stenosis; and

releasing the stent from the guide wire at the stenosis in the selected vessel to allow the stent to self-expand, to alleviate the stenosis by forcing a surrounding nar-

- rowed segment of the selected vessel to expand, and to secure itself to the surrounding narrowed segment of the selected vessel to and maintain the patency of the selected vessel to treat the PT.
- 2. The method of claim 1 wherein the stent is collapsible ⁵ within the delivery catheter.
- 3. The method of claim 1 wherein the selected vessel is a member selected from the group consisting of the superior sagittal sinus, the transverse sinus, the sigmoid sinus and the straight sinus.
- **4**. The method of claim **1** wherein the stent comprises cells having different sizes in different sections of the stent.
- 5. The method of claim 1 further comprising collapsing the stent within the delivery catheter and repositioning the $_{15}$ stent within the selected vessel.
- **6**. The method of claim **1** wherein the stent comprises a plurality of wires interbraided in a closed cell pattern.
- 7. The method of claim 1 wherein the stent is delivered over the guide wire having a tip at the distal end of the guide wire. 20
- $\pmb{8}$. The method of claim $\pmb{7}$ wherein the tip has a tapered end.
- 9. The method of claim 7 wherein the tip is between 10 and 25 mm in length.
- 10. The method of claim 1 wherein the stent comprises a web structure that allows the stent to self-expand and contract repeatedly until the stent reaches a correct location and can be deployed and secured.
- 11. The method of claim 1 wherein the cellular pattern is $_{\rm 30}$ a closed cell pattern.
- 12. The method of claim 1 wherein the wire is in a braided configuration.
- 13. A method of alleviating a stenosis in a cerebral venous sinus of a patient, wherein the stenosis causes pulsatile $_{35}$ tinnitus (PT), the method comprising

implanting a braided self-expanding stent in a vein of the cerebral venous sinus at a site of the stenosis,

10

- the braided self-expanding stent having a proximal end, a distal end, the same diameter of between about 6 mm and about 10 mm at each of the proximal and distal ends, a length of between about 40 mm and about 80 mm and a tubular flexible body between the proximal end and the distal end,
- the tubular flexible body comprising a plurality of wires arrayed in a closed cell pattern,
- wherein the tubular flexible body has a higher degree of stiffness in a first section of the stent than in a second section of the stent and is arranged to expand with chronic outward force to secure itself to a surrounding narrowed segment of the cerebral venous sinus such that the tubular flexible body conforms to the anatomy of the cerebral venous sinus to alleviate the stenosis by forcing the narrowed segment of the cerebral venous sinus to expand, and to alleviate the PT.
- 14. The method of claim 13 wherein the tubular flexible body has a higher degree of stiffness in a first section of the tubular flexible body than in a second section of the tubular flexible body and expands with chronic outward force to conform to an ovoid or triangular shape of the cerebral venous sinus.
- 15. The method of claim 13 wherein the wires are laser cut.
- 16. The method of claim 13 wherein the length of the stent is between 75 mm and 80 mm.
- 17. The method of claim 13 wherein the stent is delivered over a guidewire having a tip at a distal end.
- 18. The method of claim 17 wherein the diameter of the tip gradually increases from one end to the other.
- 19. The method of claim 13 wherein the stent is resheathable.
- 20. The method of claim 13 wherein the braided self-expanding stent comprises different spacings between cells in different sections of the stent to conform the stent to the shape of the cerebral venous sinus.

* * * * *