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(54) **SHAPE-MEMORY POLYMER FOAM DEVICE FOR TREATING ANEURYSMS**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,095,877 A * 7/1963 Rowan A61F 13/36
604/93.01
5,392,787 A * 2/1995 Yoon A61B 17/3462
128/898

(Continued)

FOREIGN PATENT DOCUMENTS

WO 2003082128 10/2003
WO 2006111801 10/2006
WO 2007006139 6/2011

OTHER PUBLICATIONS

International Search Report and Written Opinion for PCT/US14/023712, corresponding to U.S. Appl. No. 13/798,740, 10 pages.

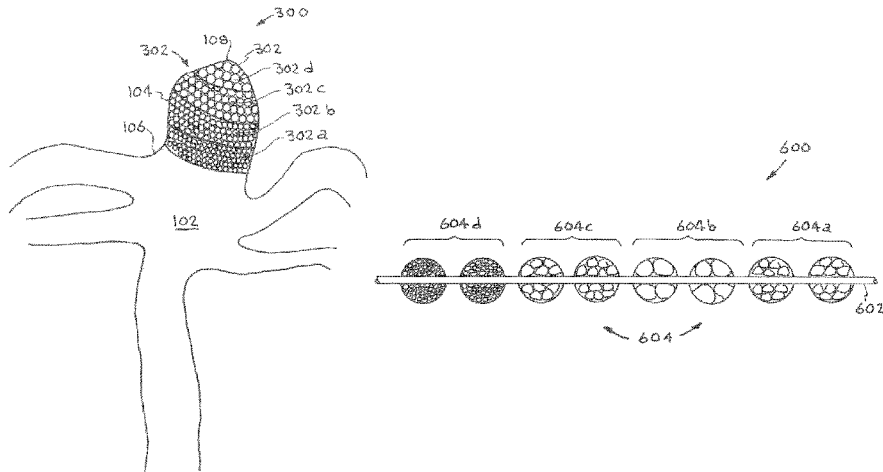
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(57) **ABSTRACT**

A system for treating an aneurysm in a blood vessel or vein, wherein the aneurysm has a dome, an interior, and a neck. The system includes a shape memory polymer foam in the interior of the aneurysm between the dome and the neck. The shape memory polymer foam has pores that include a first multiplicity of pores having a first pore size and a second multiplicity of pores having a second pore size. The second pore size is larger than said first pore size. The first multiplicity of pores are located in the neck of the aneurysm. The second multiplicity of pores are located in the dome of the aneurysm.

19 Claims, 14 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

5,769,884 A * 6/1998 Solovay A61F 2/07
 606/194
 5,891,558 A * 4/1999 Bell A61L 27/46
 424/425
 5,951,599 A * 9/1999 McCrory A61B 17/12022
 606/108
 6,165,193 A * 12/2000 Greene, Jr. A61B 17/12022
 606/191
 6,238,403 B1 * 5/2001 Greene, Jr. A61B 17/12022
 606/108
 6,315,709 B1 * 11/2001 Garibaldi A61B 17/12022
 600/12
 6,346,117 B1 * 2/2002 Greenhalgh A61B 17/12022
 606/200
 6,375,668 B1 * 4/2002 Gifford A61B 17/12022
 606/200
 6,602,261 B2 * 8/2003 Greene, Jr. A61B 17/12022
 606/108
 6,692,510 B2 * 2/2004 West A61B 17/12022
 606/191
 6,723,108 B1 * 4/2004 Jones A61B 17/12022
 606/151
 7,014,645 B2 * 3/2006 Greene, Jr. A61B 17/12022
 606/158
 7,491,214 B2 * 2/2009 Greene, Jr. A61B 17/12022
 606/195
 8,133,256 B2 3/2012 Wilson et al.
 8,771,294 B2 * 7/2014 Sepetka A61B 17/12022
 606/144
 8,870,909 B2 * 10/2014 Cox A61B 17/12022
 606/200
 9,095,342 B2 * 8/2015 Becking A61B 17/12109
 9,155,671 B2 * 10/2015 Fuller A61L 15/22
 9,445,819 B2 * 9/2016 Grace A61B 17/12036
 9,629,636 B2 * 4/2017 Fogarty A61B 17/12022
 10,010,327 B2 * 7/2018 Wilson A61B 17/1214
 2002/0143349 A1 * 10/2002 Gifford, III A61B 17/12022
 606/157

2003/0187473 A1 * 10/2003 Berenstein A61B 17/12022
 606/200
 2003/0195553 A1 * 10/2003 Wallace A61B 17/12022
 606/200
 2003/0199887 A1 * 10/2003 Ferrera A61B 17/12022
 606/151
 2004/0098027 A1 * 5/2004 Teoh A61B 17/12022
 606/200
 2004/0143288 A1 * 7/2004 Searle A61B 17/12022
 606/200
 2005/0015110 A1 * 1/2005 Fogarty A61B 17/12022
 606/200
 2005/0182428 A1 8/2005 Bearinger et al.
 2006/0052816 A1 * 3/2006 Bates A61B 17/12013
 606/200
 2006/0116712 A1 * 6/2006 Sepetka A61B 17/12022
 606/200
 2007/0135907 A1 * 6/2007 Wilson A61F 2/82
 623/1.44
 2008/0097495 A1 * 4/2008 Feller, III A61B 17/12022
 606/157
 2009/0112249 A1 * 4/2009 Miles A61B 17/12122
 606/192
 2009/0112251 A1 * 4/2009 Qian A61B 17/12172
 606/194
 2010/0076463 A1 * 3/2010 Mavani A61B 17/0057
 606/151
 2010/0094335 A1 * 4/2010 Gerberding A61B 17/12022
 606/213
 2010/0228184 A1 * 9/2010 Mavani A61B 17/0057
 604/35
 2011/0022149 A1 * 1/2011 Cox A61B 17/12181
 623/1.11
 2011/0046658 A1 * 2/2011 Connor A61B 17/12022
 606/200
 2011/0144669 A1 * 6/2011 Becking A61B 17/12022
 606/158
 2011/0144686 A1 6/2011 Wilson et al.
 2012/0158034 A1 * 6/2012 Wilson A61B 17/12113
 606/192
 2012/0253369 A1 * 10/2012 Morsi A61B 17/12022
 606/158
 2014/0135812 A1 * 5/2014 Divino A61F 2/95
 606/194

* cited by examiner

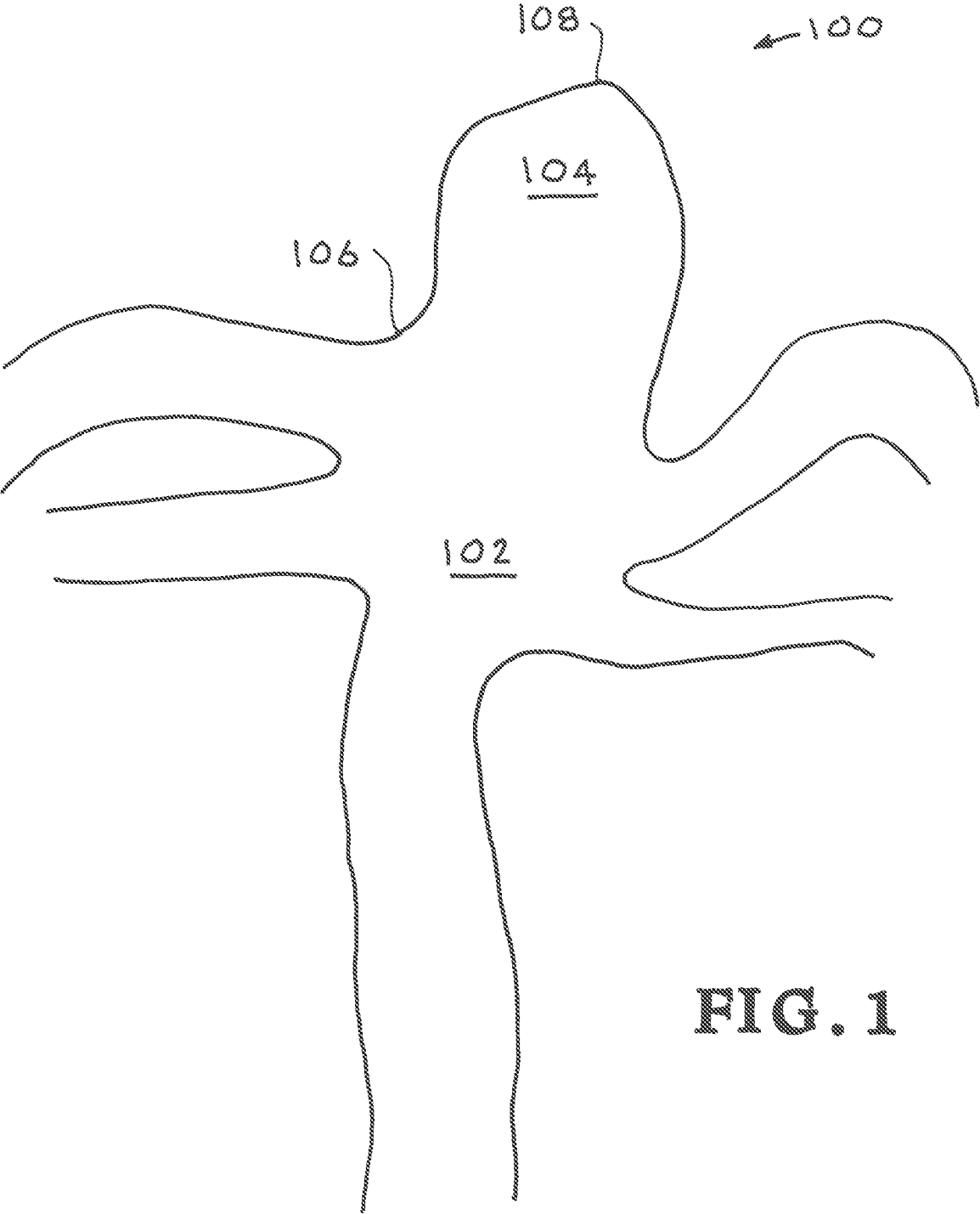


FIG. 1

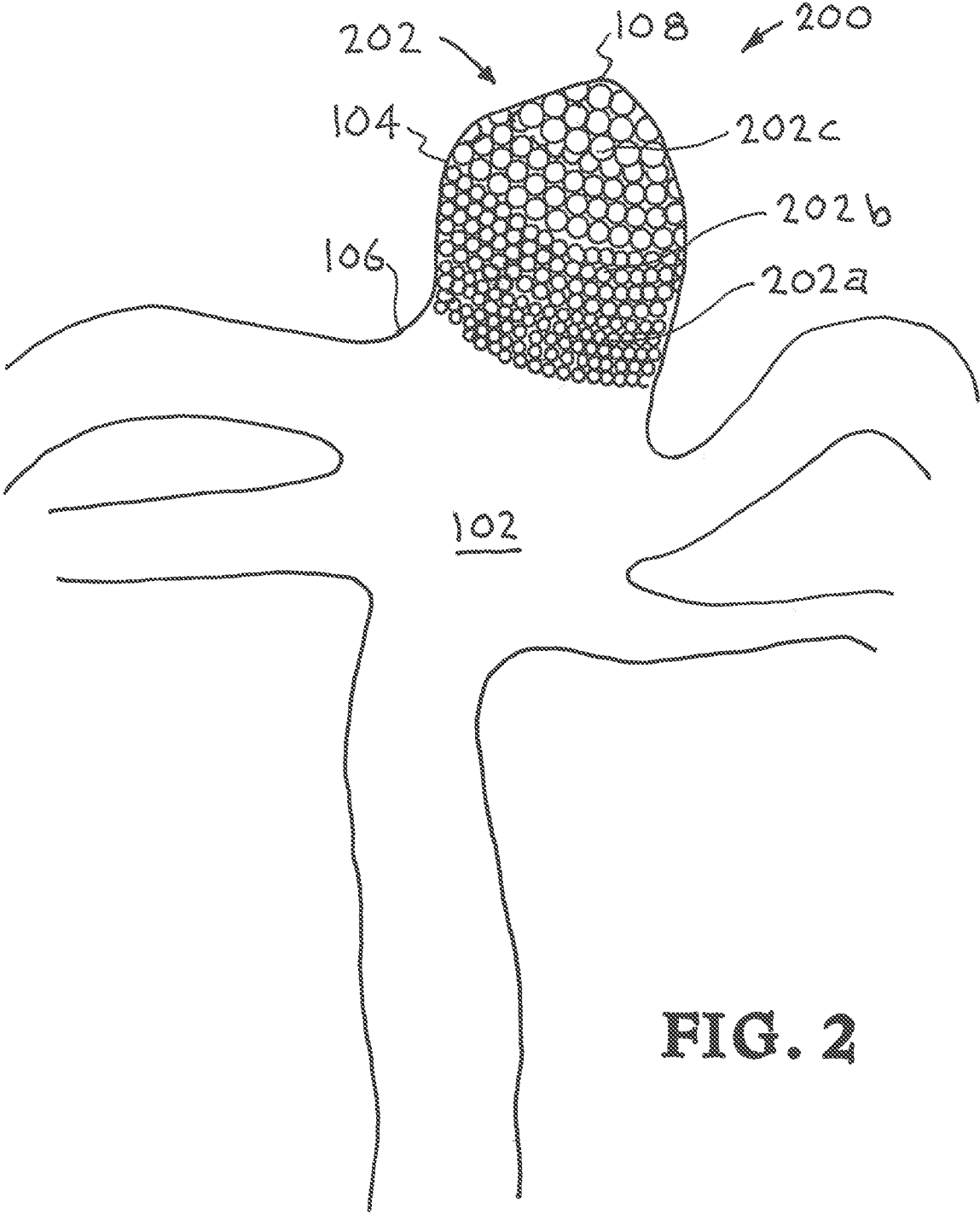


FIG. 2

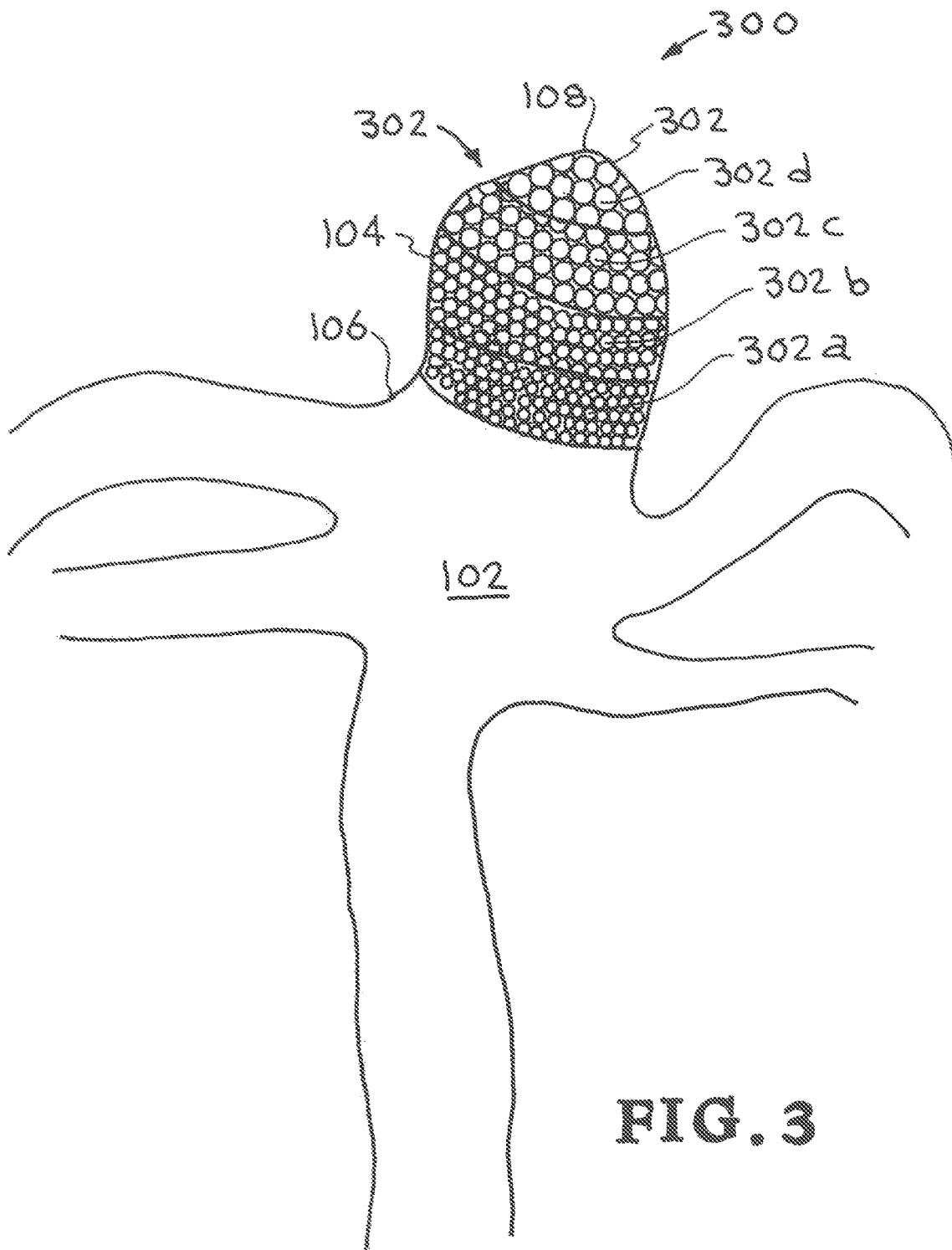


FIG. 3

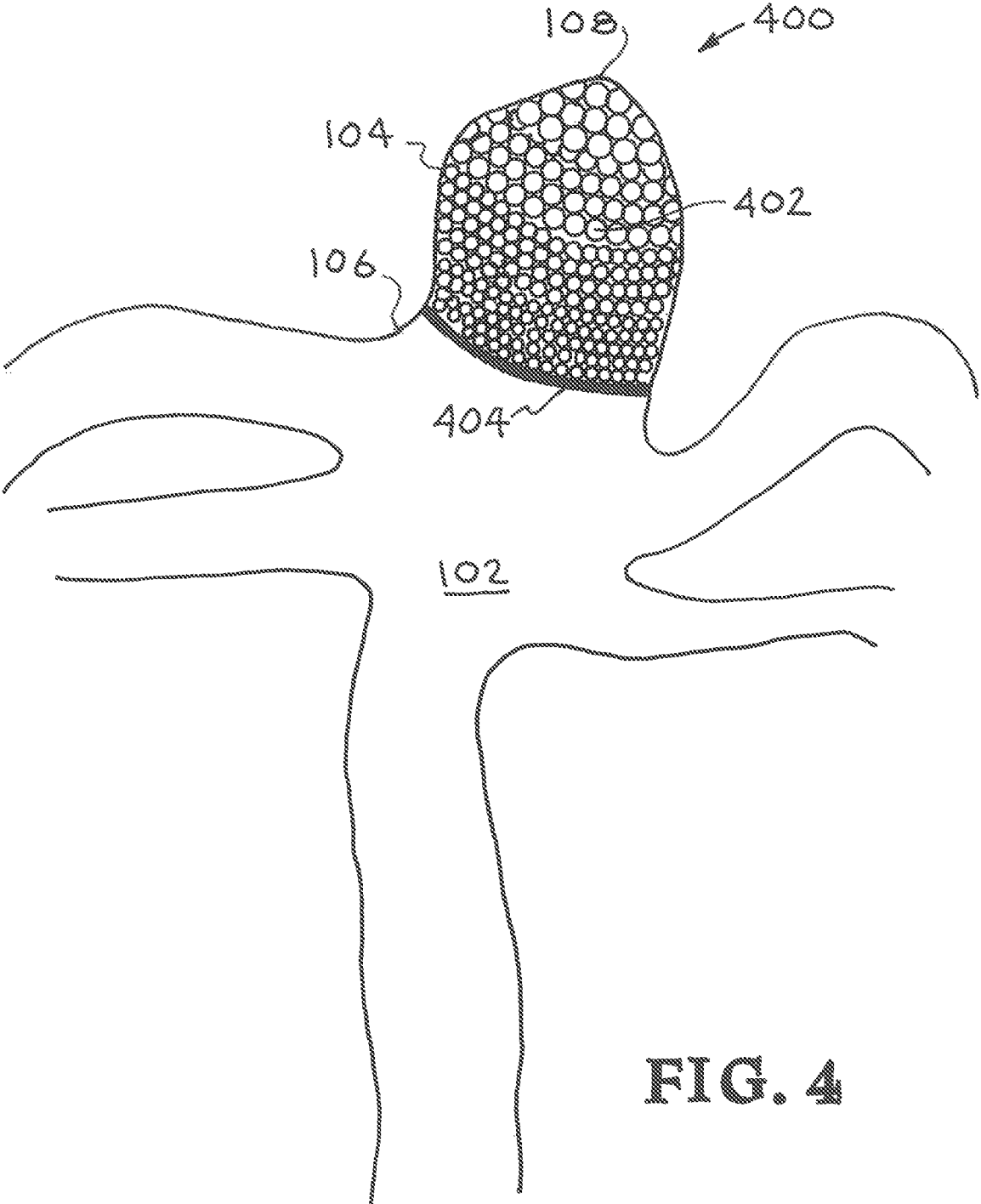


FIG. 4

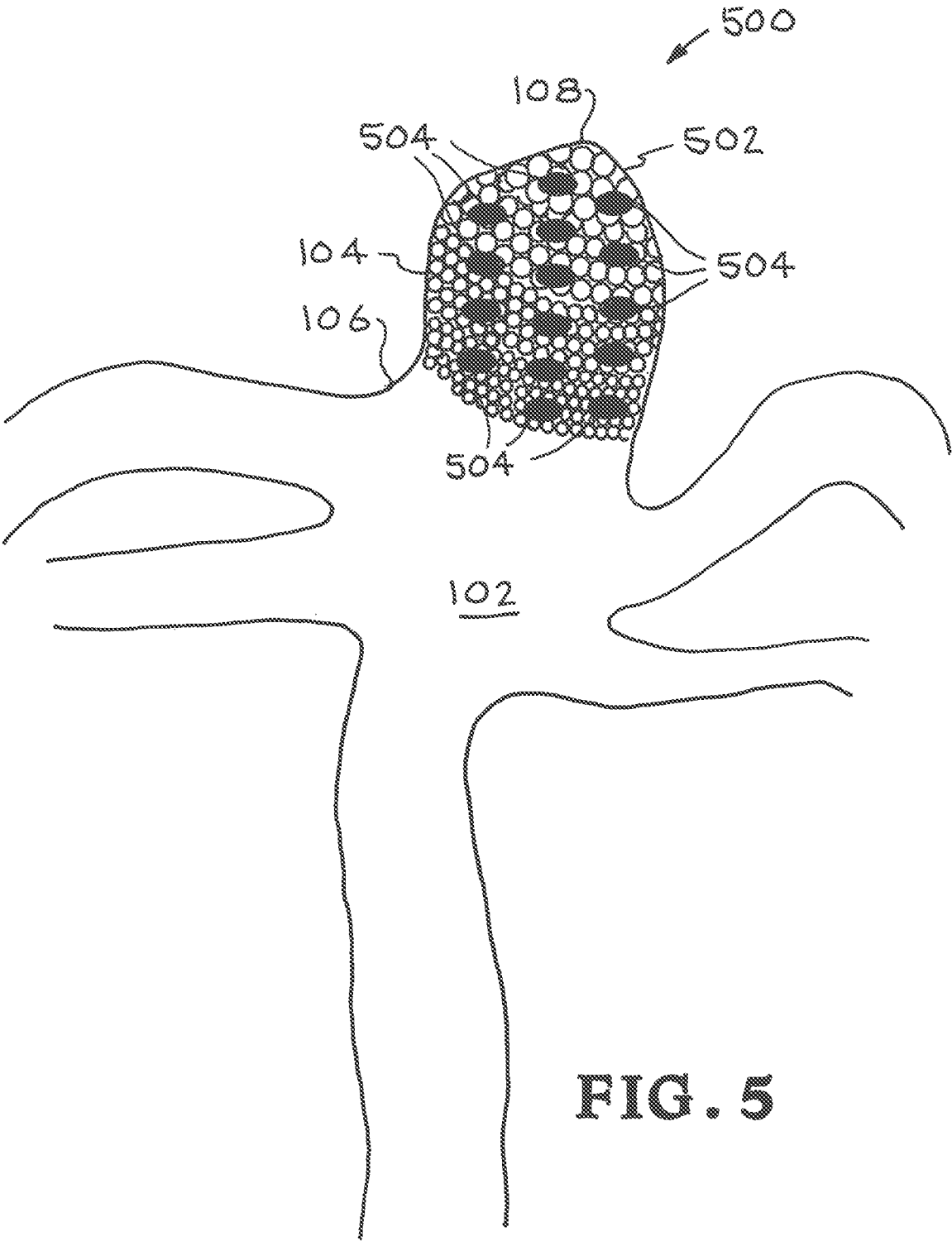


FIG. 5

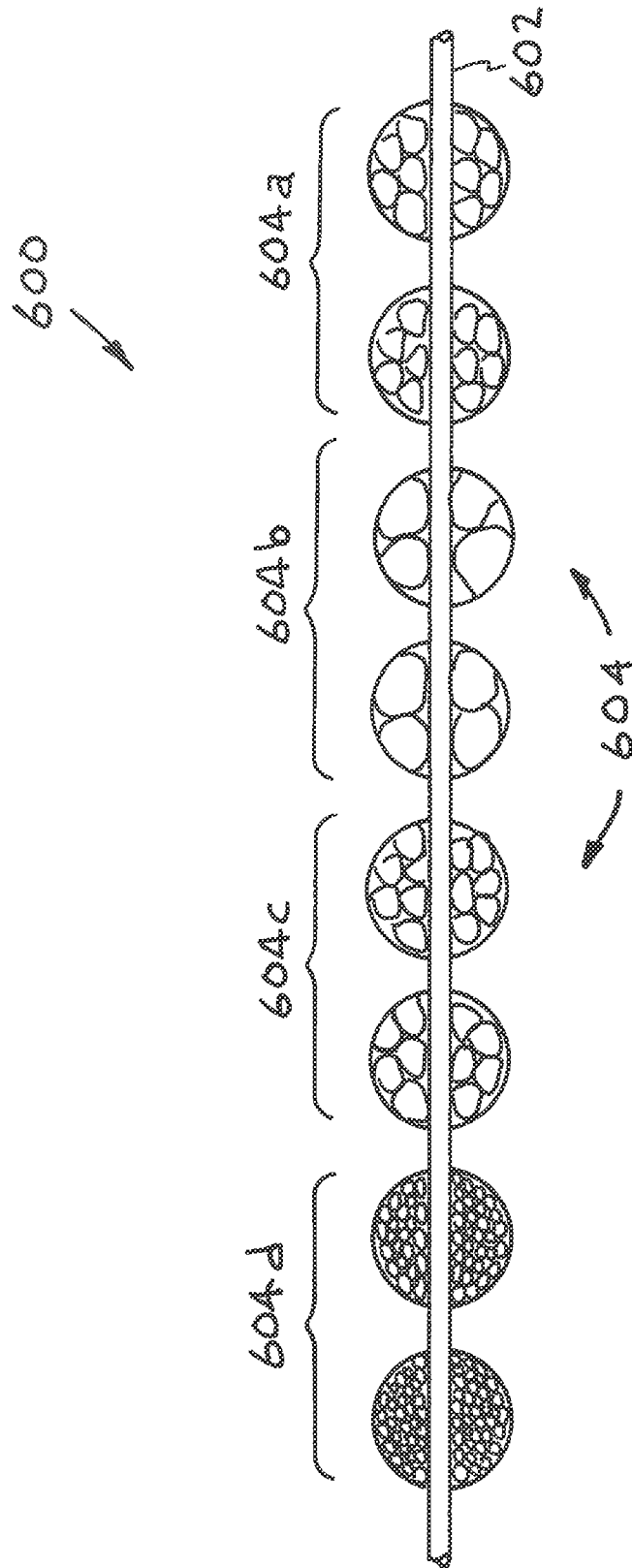


FIG. 6

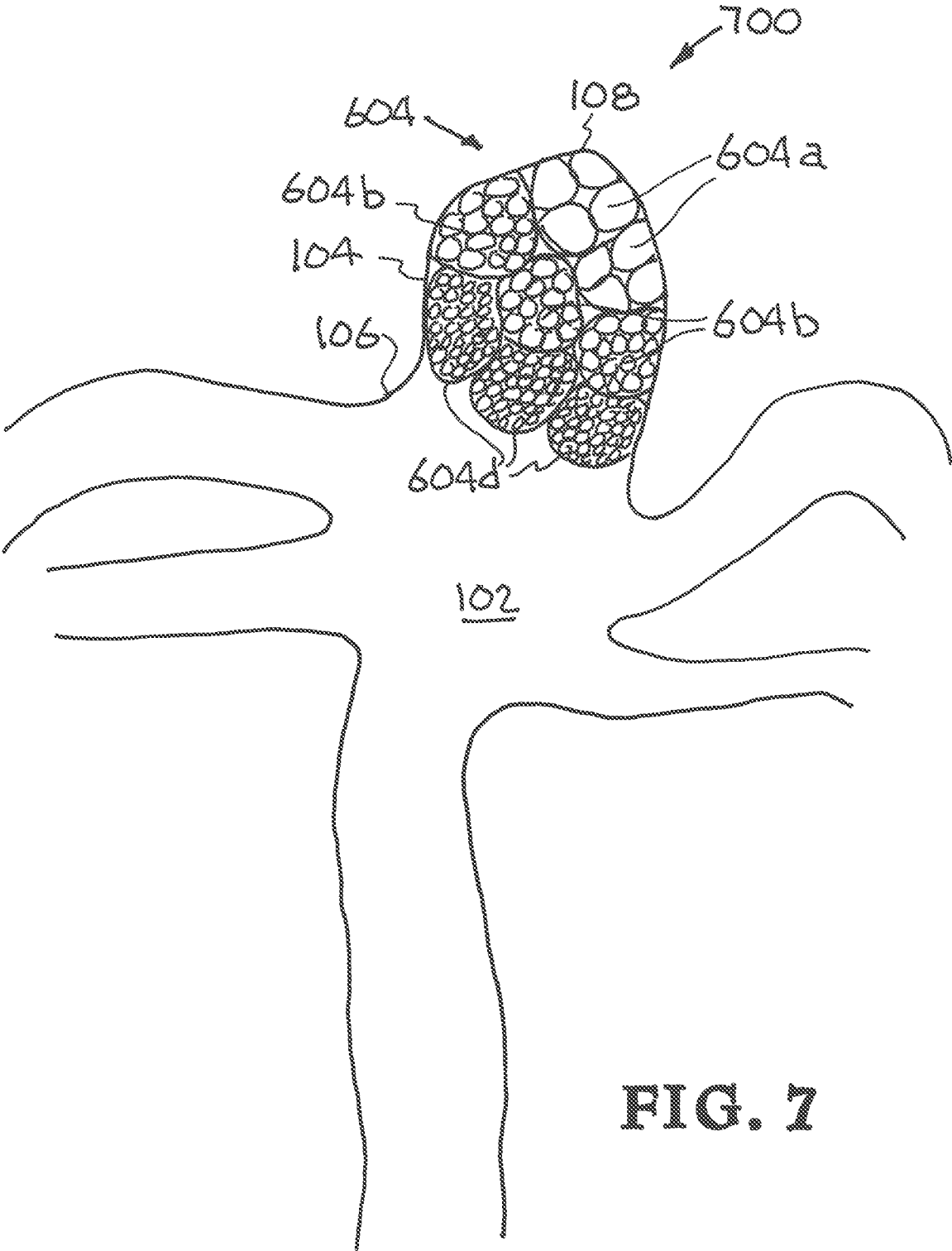


FIG. 7

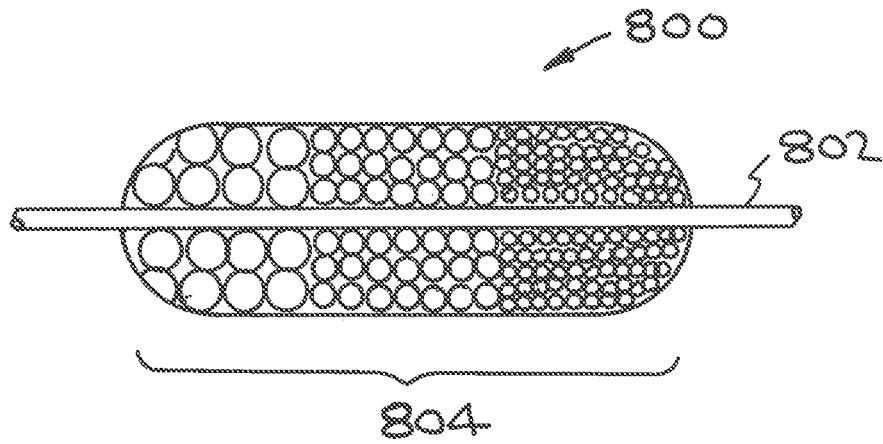


FIG. 8

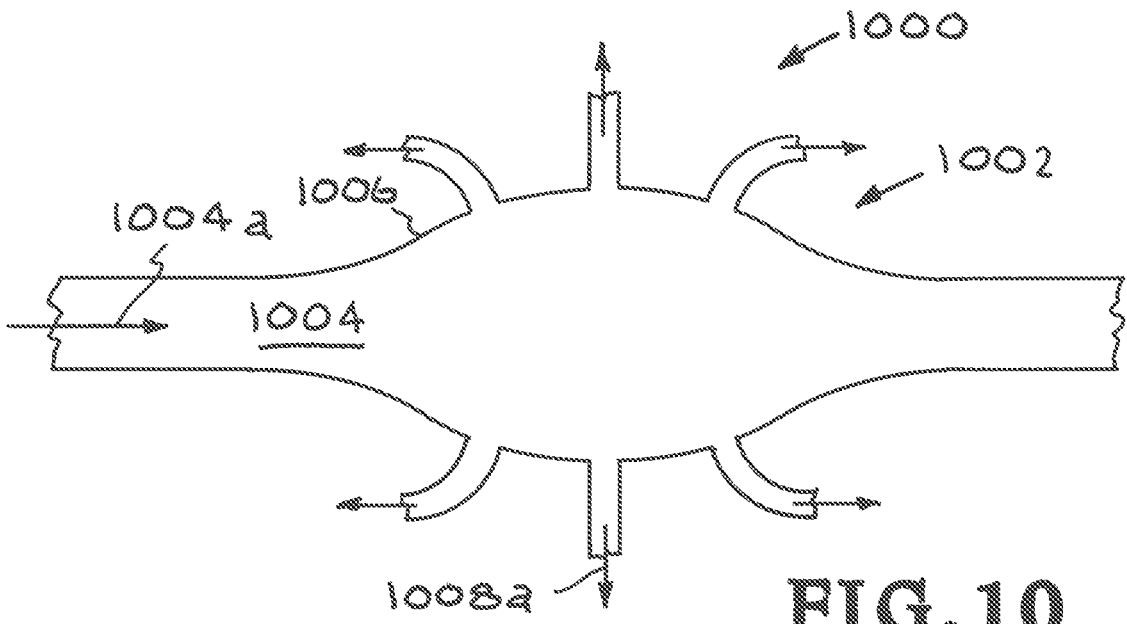


FIG. 10

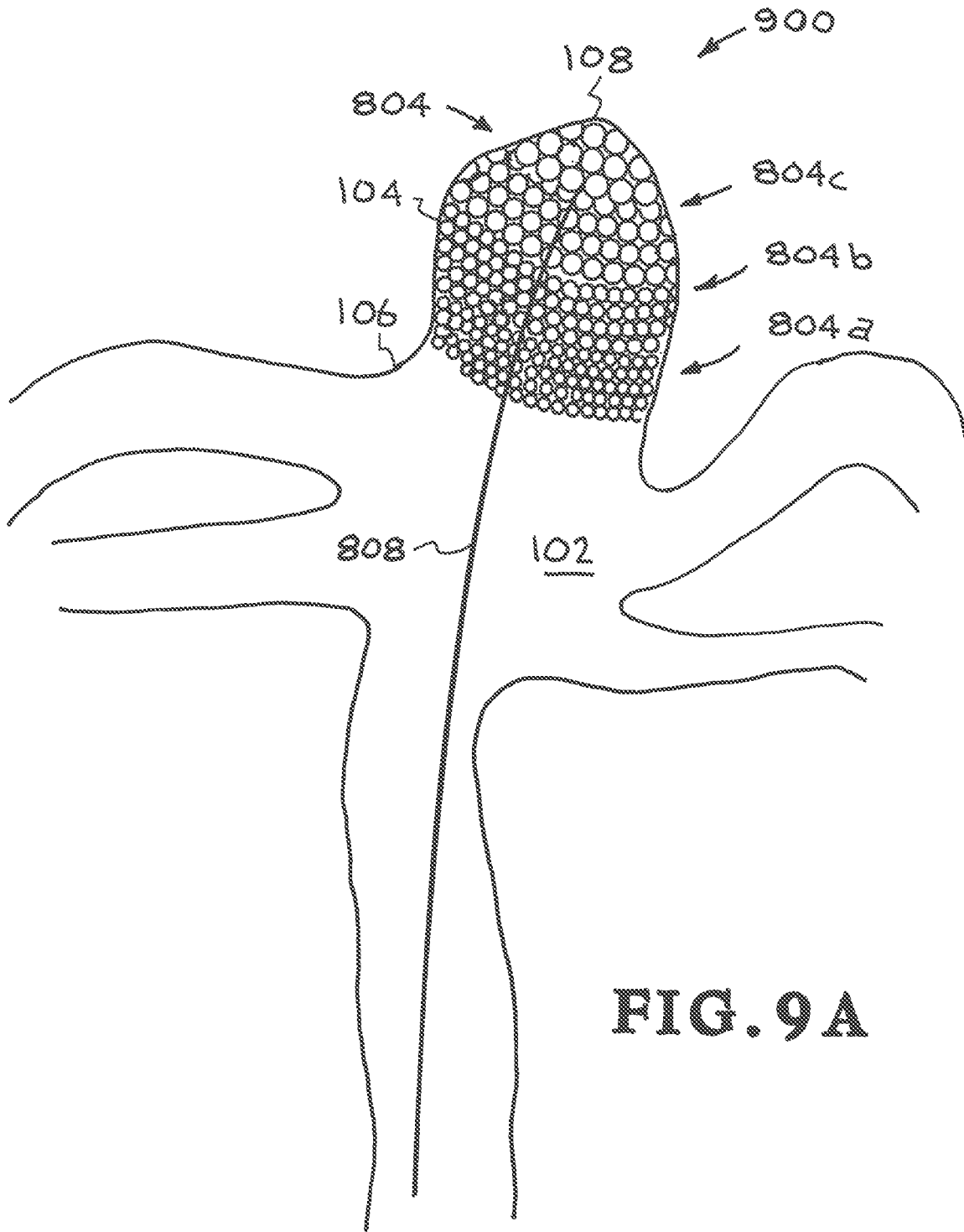


FIG. 9A

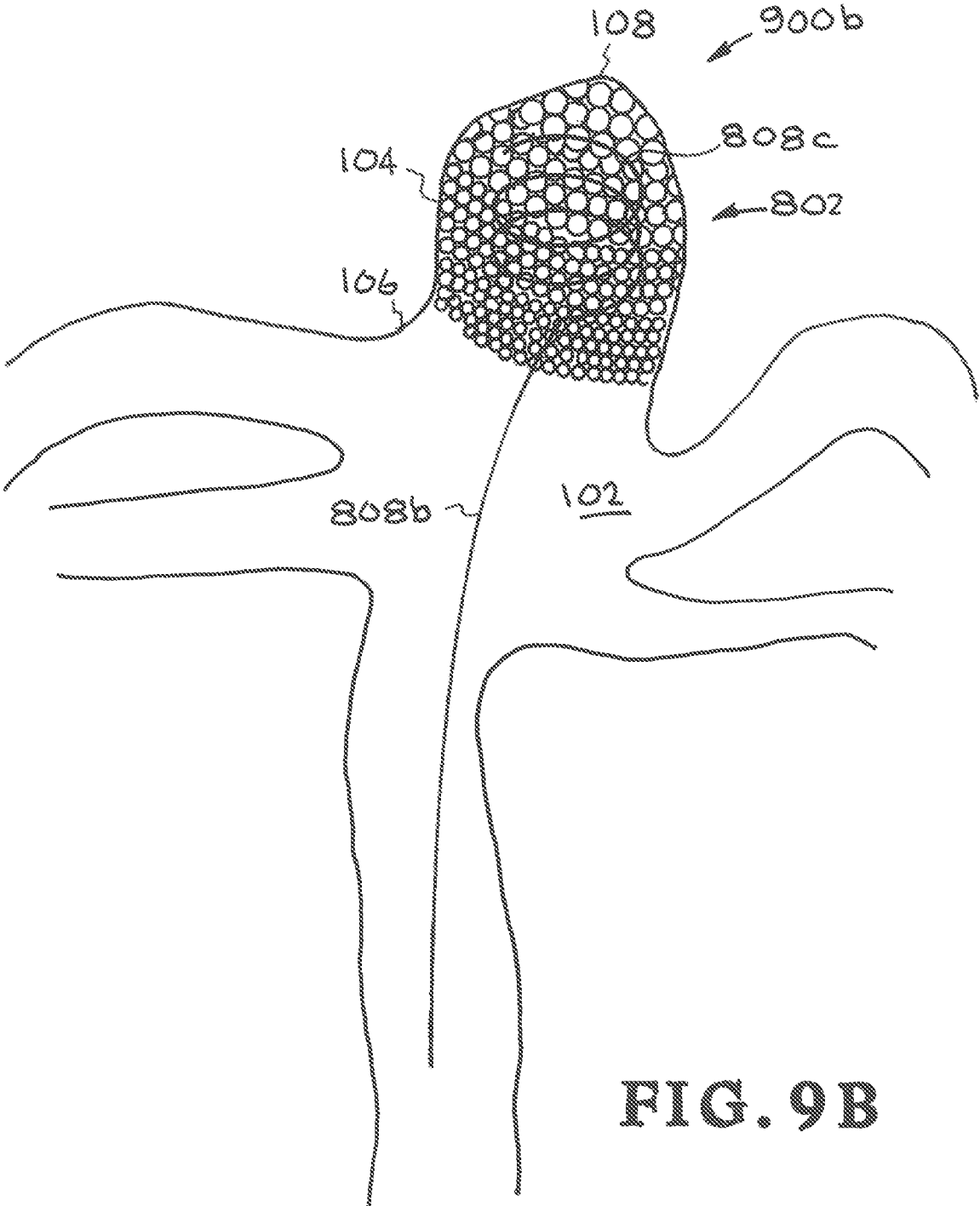


FIG. 9B

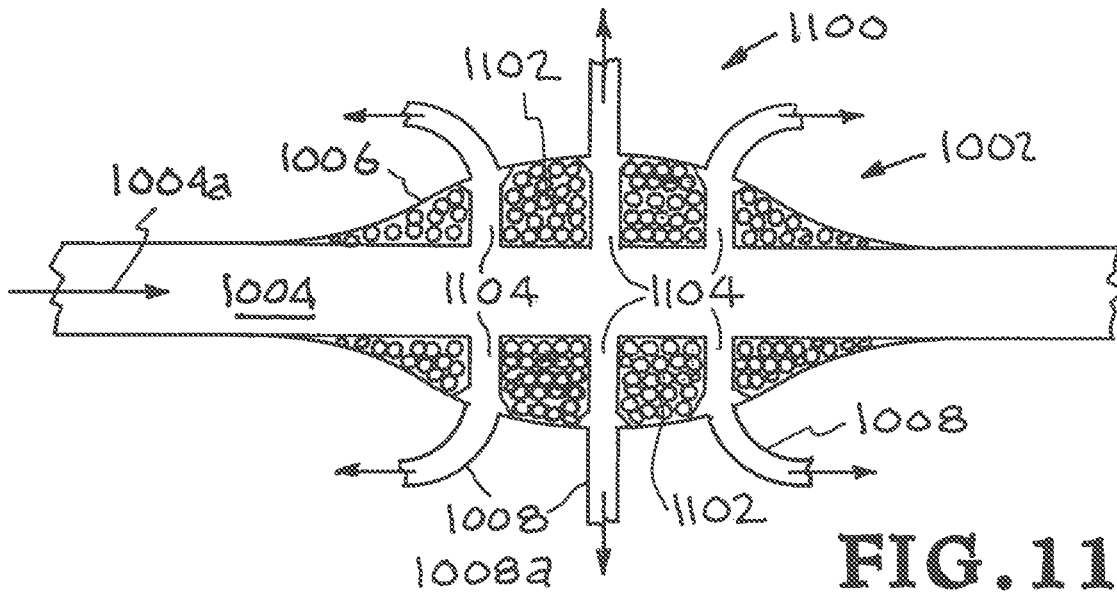


FIG. 11

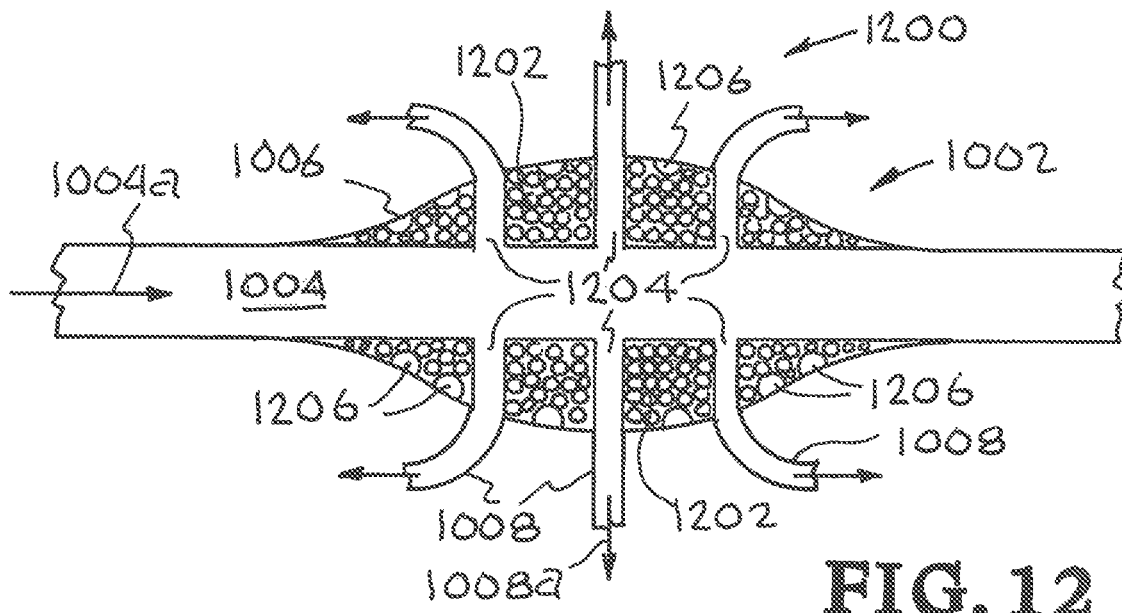


FIG. 12

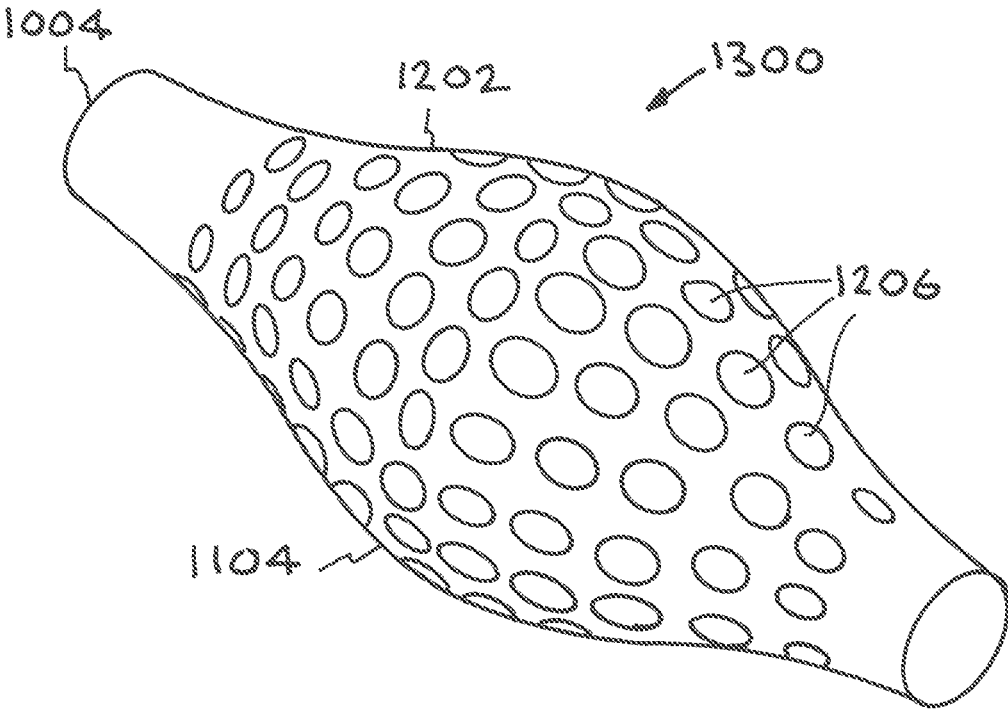


FIG. 13

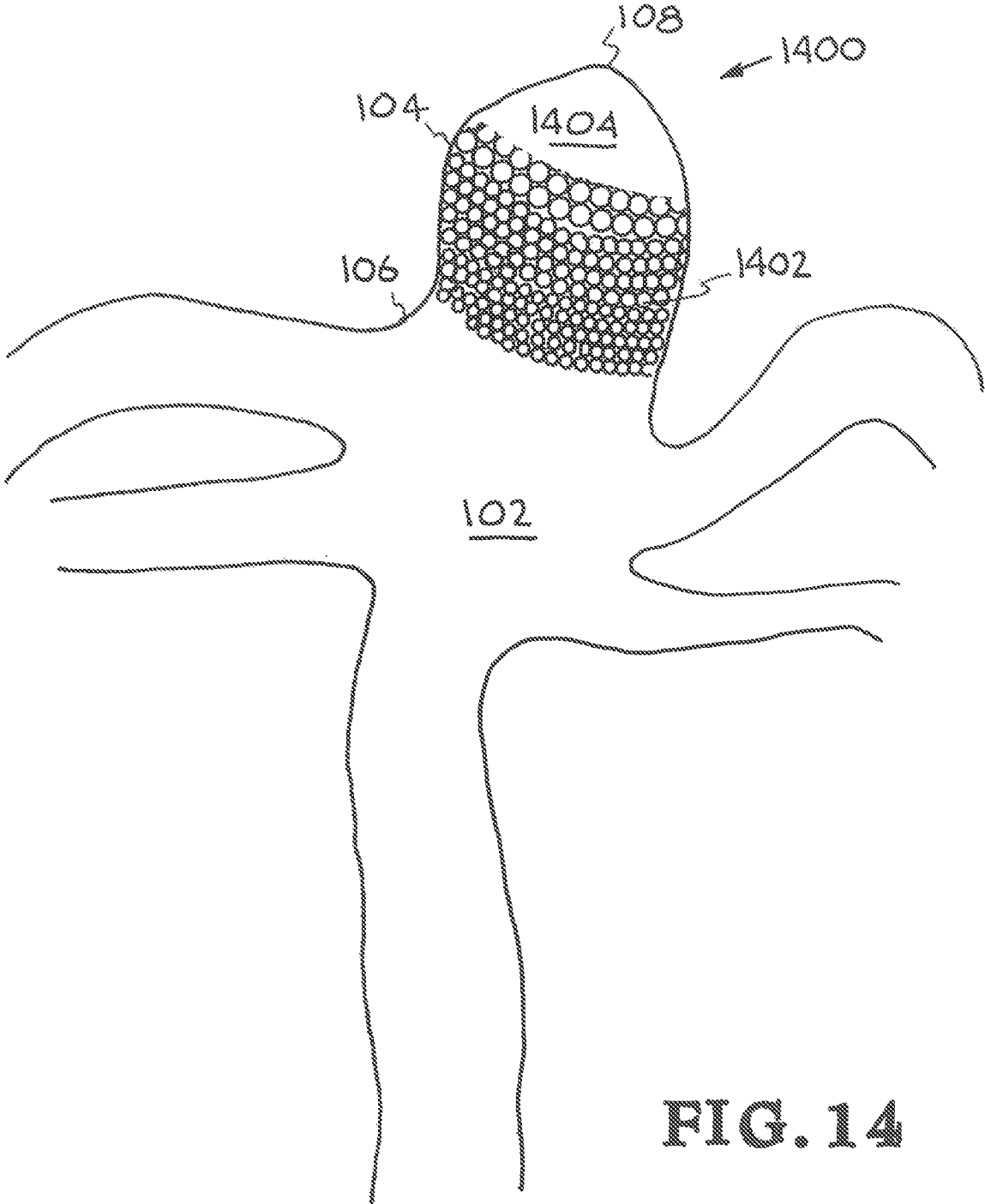


FIG. 14

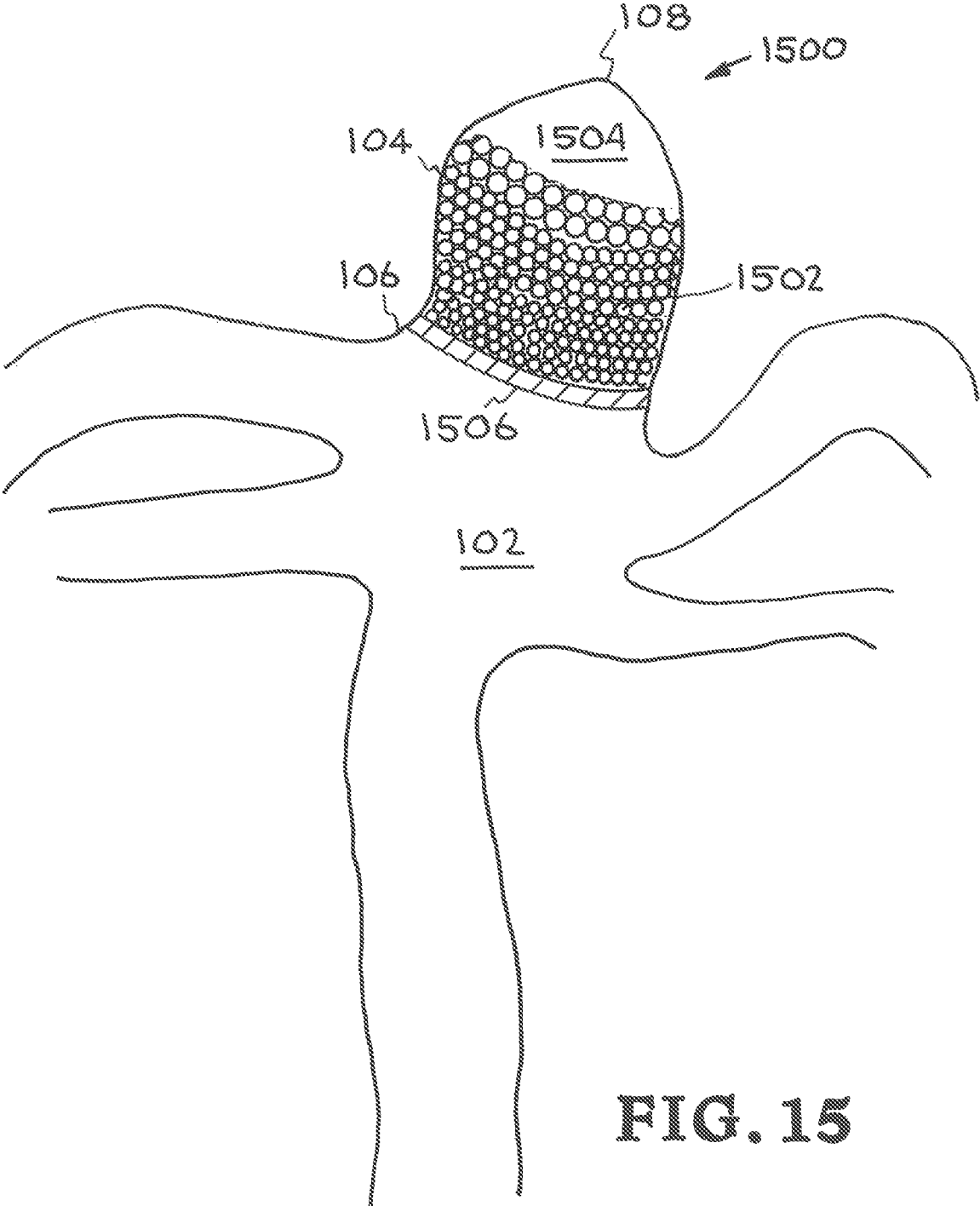


FIG. 15

SHAPE-MEMORY POLYMER FOAM DEVICE FOR TREATING ANEURYSMS

This application is a Continuation of Application Ser. No. 13/798,740 filed Mar. 13, 2013, the disclosure of which is hereby incorporated by reference in its entirety for all purposes.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT

The United States Government has rights in this invention pursuant to Contract No. DE-AC52-07NA27344 between the United States Department of Energy and Lawrence Livermore National Security, LLC for the operation of Lawrence Livermore National Laboratory.

BACKGROUND

Field of Endeavor

The present invention relates to treating aneurysms and more particularly to a shape memory polymer foam device for treating aneurysms.

State of Technology

U.S. Pat. No. 8,133,256 for shape memory polymer foams for endovascular therapies provides the state of technology information quoted below.

“In the general application, a vascular anomaly is treated using the device with the intent of stabilizing the anomaly from further expansion and possible rupture. The device is delivered endovascularly to the site for therapy via a catheter. The catheter may be previously placed using a conventional guidewire or the device may be installed using the guidewire. Once the catheter is placed near the therapeutic site, the device is placed into the anomaly with the guidewire and guided visually by radiology. The device is then held in place and the foam is actuated to expand, filling the anomaly. Once expanded, the foam will stay in place on its own or an additional aid will be used to hold it in place; for example, a diaphragm for the aneurysm or a stent for the AVM. The foam is released from the guidewire or catheter via the expansion process or following actuation by known techniques. The guidewire and/or catheter is then retracted and the therapy is completed. Should there be a misplacement of the foam, retrieval is possible using another shape-memory polymer device or other conventional techniques.”

“Shape-memory materials have the useful ability of being formable into a primary shape, being reformable into a stable secondary shape, and then being controllably actuated to recover their primary shape. Both metal alloys and polymeric materials can have shape memory. In the case of metals, the shape-memory effect arises from thermally induced solid phase transformations in which the lattice structure of the atoms changes, resulting in macroscopic changes in modulus and dimensions. In the case of polymeric materials, the primary shape is obtained after processing and fixed by physical structures or chemical crosslinking. The secondary shape is obtained by deforming the material while in an elastomeric state and that shape is fixed in one of several ways including cooling the polymer below a crystalline, liquid crystalline, or glass transition temperature; by inducing additional covalent or ionic crosslinking, etc.”

“While in the secondary shape some or all of the polymer chains are perturbed from their equilibrium random walk conformation, having a certain degree of bulk orientation.

The oriented chains have a certain potential energy, due to their decreased entropy, which provides the driving force for the shape recovery. However, they do not spontaneously recover due to either kinetic effects (if below their lower T_g) or physical restraints (physical or chemical crosslinks). Actuation then occurs for the recovery to the primary shape by removing that restraint, e.g., heating the polymer above its glass transition or melting temperature, removing ionic or covalent crosslinks, etc. Other types of polymers which undergo shape memory behavior due to photon induced conformational transformations, conformational changes (e.g., rod-coil transition) due to changes in chemical environment (pH, ionic strength, etc.), or structural changes due to imposed fields (e.g., electric, magnetic, . . .) may also be used. Both shape memory alloys (SMAs) and shape memory polymers (SMPs) can be used for the shape memory material of the present invention.”

“A shape memory material therapeutic device has advantages over existing therapeutic devices of being able to be moved more easily through the catheter to the point of placement. A shape memory material therapeutic can be placed more precisely within the geometry of the vascular disorder, and there is a higher degree of control over the expansion process while the device was being held in the desired position. A shape memory material therapeutic can be controllably expanded while being held in precise placement. A shape memory material therapeutic expands to its secondary shape within a few seconds, which is much faster than current expandable hydrogel based devices. The modulus of the devices can be accurately controlled so that expansion forces are low and no damage is done to areas of the vascular lumen.

The shape memory material device is expandable from 100% to 10000% by volume. The shape memory material device is actuated by one of several means including electromagnetic energy delivered optically. The shape memory material device is used to occlude part or all of a lumen, aneurysm, arteriovascular malformation, or other physical anomaly.”

SUMMARY

Features and advantages of the present invention will become apparent from the following description. Applicants are providing this description, which includes drawings and examples of specific embodiments, to give a broad representation of the invention. Various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this description and by practice of the invention. The scope of the invention is not intended to be limited to the particular forms disclosed and the invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims.

The present invention provides a shape memory polymer foam system for treating aneurysms. In one embodiment the present invention provides an apparatus for treating an aneurysm in a blood vessel or vein, wherein the aneurysm has a dome, an interior, and a neck. The apparatus provides a shape memory polymer foam in the interior of the aneurysm between the dome and the neck. The shape memory polymer foam has pores that include a first multiplicity of pores having a first pore size and a second multiplicity of pores having a second pore size. The second pore size is larger than said first pore size. The first multiplicity of pores are located in the neck of the aneurysm. The second multiplicity of pores are located in the dome of the aneurysm.

This provides a shape memory polymer foam system with foam porosity, permeability, and shape to stagnate the blood flow within the aneurysm and to promote thrombus and collagen formation throughout the SMP foam.

The present invention provides a shape memory polymer foam system with a gradation of foam pore size in a continuous fashion from one end of the single piece of foam to the other end. This places the least permeable portion of foam nearest the parent artery, where the blood flow has the highest speed. Consequently, the small pore sizes near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes are larger since it is not necessary to further decelerate the flow in this region.

The present invention has two major advantages. First, it allows for smaller treatment devices since only the necessary amount of foam material required for healing is incorporated into the device. The result is a compact design that can easily reach small intracranial arteries where aneurysms typically form. Second, the present invention preserves essential blood flow to vessels that often line the aneurysm wall.

The invention is susceptible to modifications and alternative forms. Specific embodiments are shown by way of example. It is to be understood that the invention is not limited to the particular forms disclosed. The invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated into and constitute a part of the specification, illustrate specific embodiments of the invention and, together with the general description of the invention given above, and the detailed description of the specific embodiments, serve to explain the principles of the invention.

FIG. 1 is an illustration showing a blood vessel and artery system with an aneurysm.

FIG. 2 is the illustration the blood vessel and artery system with an aneurysm shown in FIG. 1 wherein a single piece of foam fills the aneurysm.

FIG. 3 is the illustration the blood vessel and artery system with an aneurysm shown in FIG. 1 wherein separate pieces of foam with differing pore sizes fill the aneurysm 104.

FIG. 4 is the illustration the blood vessel and artery system with an aneurysm shown in FIG. 1 wherein a foam unit fills the aneurysm and a layer of non-porous SMP coats the base of the foam unit.

FIG. 5 is the illustration the blood vessel and artery system with an aneurysm shown in FIG. 1 wherein a piece of foam fills the aneurysm and an array of non-porous SMP baffles are distributed throughout the foam.

FIG. 6 illustrates a series of SMP foam pieces that are distributed along the wire backbone of a medical device.

FIG. 7 illustrates the placement of the series of SMP foam pieces shown in FIG. 6 in the aneurysm.

FIG. 8 illustrates a single monolithic SMP foam distributed along the wire backbone of a medical device.

FIGS. 9A and 9B illustrate the placement of the single monolithic SMP foam shown in FIG. 8 in the aneurysm.

FIG. 10 is an illustration showing a blood vessel and artery system with a fusiform aneurysm.

FIG. 11 is an illustration showing the fusiform aneurysm that was illustrated in FIG. 10 filled with a SMP foam device.

FIG. 12 is an illustration shows the fusiform aneurysm that was illustrated in FIG. 10 filled with a SMP foam device.

FIG. 13 is an illustration shows the fusiform aneurysm that was illustrated in FIG. 10 and having dimples on the exterior.

FIG. 14 is the illustration the blood vessel and artery system with an aneurysm shown in FIG. 1 wherein a foam unit fills the neck and a portion of the interior of the aneurysm but leaves a void in the dome of the aneurysm.

FIG. 15 is the illustration the blood vessel and artery system with an aneurysm shown in FIG. 1 wherein a foam unit fills the neck and a portion of the interior of the aneurysm but leaves a void in the dome of the aneurysm and including an impermeable layer in the neck.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to the drawings, to the following detailed description, and to incorporated materials, detailed information about the invention is provided including the description of specific embodiments. The detailed description serves to explain the principles of the invention. The invention is susceptible to modifications and alternative forms. The invention is not limited to the particular forms disclosed. The invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims.

The present invention provides systems for treating aneurysms. This invention has particular advantage for treating cranial aneurysms and will be described by various embodiments relating to cranial aneurysms; however it is to be understood that the scope of the invention is not intended to be limited to the particular embodiments and forms disclosed and the invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims.

A cranial aneurysm is a condition that is often asymptomatic until the time of rupture. Subarachnoid hemorrhage associated with aneurysmal rupture is a potentially lethal event with a mortality rate as high as 50 percent. Many patients who survive the initial hemorrhage have permanent disability. A cranial aneurysm, also called cerebral or brain aneurysm, is a disorder in the veins or vascular system of the brain. Cerebral veins or arteries become weak and cause the blood vessels to balloon or dilate. Aneurysms are often found in the Circle of Willis, which is a group of arteries found at the base of the brain. The majority, about 85%, occur in the anterior part of this area. They often happen in the parts of cerebrovascular system that provide blood to the anterior and middle sections of the brain, usually with the internal carotid arteries and their main branches. There are different kinds of aneurysms based on size and shape. Those less than 15 mm are considered small. A size of 15 to 25 mm means the aneurysms are large while those found over 50 mm are considered super giants. The most common shape of aneurysms is saccular; this means it has some saccular outpouching. Some of these saccular aneurysms also have a stem or neck; these are called berry aneurysms. Those without stems are called fusiform aneurysms. Congenital defects or head trauma can lead to aneurysms. The more common cause is high blood pressure and atherosclerosis or the buildup of fatty deposits in the arteries. This is a greater

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cause for concern in the midst of the obesity problem in developed countries. This disorder does not adhere to any age range, but occurs more often in adults. It also favors women with a ratio of 3 to 2.

The present invention provides systems for treating these intracranial aneurysms through the endovascular delivery of a shape memory polymer foam (SMP) device. The systems function by producing flow conditions within the post-treatment aneurysm that optimize the body's healing response to the treatment procedure. This invention includes systems for customizing the SMP foam structure of the device to obtain flow conditions within the post-treatment aneurysm that optimize the body's healing response to the treatment procedure. In various embodiments the present invention provides systems for designing the SMP foam porosity, permeability, and shape to stagnate the blood flow within the aneurysm and to promote thrombus and collagen formation throughout the SMP foam.

The system of the present invention provides a number of advantages. For example, it allows for smaller treatment devices since only the necessary amount of SMP foam material required for healing is incorporated into the device. The result is a compact design that can easily reach small intracranial arteries where aneurysms typically form. Also, the system of the present invention preserves essential blood flow to vessels that often line the aneurysm wall by including channels that deliver blood from the parent artery to these vessels. Such transport will not only maintain the health of tissue downstream of these vessels, but will also provide a robust means of promoting the body's healing response to the treatment procedure. The current FDA-approved technique of treating aneurysms with detachable metal coils and/or an endoluminal stent do not provide this advantage since the coils randomly fill the aneurysm, thereby occluding these vessels.

The present invention is further described and illustrated by a number of examples of systems constructed in accordance with the present invention. Various changes and modifications of these examples will be apparent to those skilled in the art from the description of the examples and by practice of the invention. The scope of the invention is not intended to be limited to the particular examples disclosed and the invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims.

Referring now to the drawings and in particular to FIG. 1, an illustration shows a blood vessel and artery system with an aneurysm. The illustration is designated generally by the reference numeral 100. The illustration 100 represents cerebral arteries and blood vessels 102. An aneurysm 104 is shown as a bulging or ballooning in the wall. It is caused when a portion of the wall weakens. As the aneurysm 104 expands, there is an increased likelihood that the aneurysm will burst. The aneurysm 104 is shown with a dome 108 and a neck 106.

EXAMPLE 1

Single Piece of SMP Foam

Referring now to FIG. 2, an illustration shows the blood vessel and artery system and the aneurysm that were illustrated in FIG. 1. The illustration is designated generally by the reference numeral 200. The illustration 200 shows the cerebral arteries and blood vessels 102 and the aneurysm 104. The aneurysm 104 is shown with a dome 108 and a

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neck 106. The aneurysm 104 is shown with a single piece of SMP foam 202 in the aneurysm 104.

As illustrated in FIG. 2, the single piece of SMP foam 202 fills the aneurysm 104. The single piece of SMP foam 202 has a gradation of SMP foam pore size 202a, 202b, and 202c in a continuous fashion from one end of the single piece of SMP foam to the other end. This places the least permeable portion 202a of the SMP foam nearest the parent artery, where the blood flow has the highest speed. Consequently, the small pore sizes 202a near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes 202c are larger since it is not necessary to further decelerate the flow in this region. Through this gradation of pore sizes 202a, 202b, and 202c, the total amount of polymer material comprising the device can be reduced. In general, the cranial aneurysm 104 is treated using a device for stabilizing the aneurysm from further expansion and possible rupture. The device is delivered endovascularly to the site for treatment via a catheter. The catheter may be previously placed using a conventional guidewire or the device may be installed using a guidewire. Once the catheter is placed near the treatment site, the device is placed into the anomaly with the guidewire and guided visually by radiology.

The device is then held in place and the SMP foam is actuated to expand, filling the aneurysm. Once expanded, the SMP foam will stay in place on its own or an additional aid can be used to hold it in place. The SMP foam is released from the guidewire or catheter via the expansion process or following actuation by known techniques. The guidewire and/or catheter is then retracted and the treatment is completed.

EXAMPLE 2

Separate Pieces of SMP Foam

Referring now to FIG. 3, another embodiment of the present invention is illustrated. This embodiment is designated generally by the reference numeral 300. The illustration shows the blood vessel and artery system 102 and the aneurysm 104 that were shown in FIG. 1. The aneurysm 104 is shown with a dome 108 and a neck 106. As illustrated in FIG. 3, separate pieces of SMP foam unit 302 with differing pore sizes fill the aneurysm 104. The separate pieces of SMP foam unit 302 with differing pore sizes have a gradation of SMP foam pore size 302a, 302b, 302c, and 302d in a discrete fashion from one end of the SMP foam unit 302 to the other end. This places the least permeable portion 302a of the SMP foam nearest the parent artery, where the blood flow has the highest speed. Consequently, the small pore sizes 302a near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes 302d are larger since it is not necessary to further decelerate the flow in this region. Through this gradation of pore sizes 302a, 302b, 302c, and 302d the total amount of polymer material comprising the device can be reduced.

EXAMPLE 3

Coating Base of the SMP Foam

Referring now to FIG. 4, another embodiment of the present invention is illustrated. This embodiment is designated generally by the reference numeral 400. The illustra-

tion shows the blood vessel and artery system **102** and the aneurysm **104** that were shown in FIG. 1. The aneurysm **104** is shown with a dome **108** and a neck **106**. As illustrated in FIG. 4, a SMP foam unit **402** fills the aneurysm **104**. A layer of non-porous SMP **404** coats the base of the SMP foam unit **402**. This provides an impermeable layer that provides further enhancement of the hemodynamic conditions to promote thrombus formation. Consequently, the high speed parent artery flow cannot penetrate as deeply into the SMP foam and a greater portion of the blood within the treated aneurysm travels at a slower speed.

As illustrated in FIG. 4, the single piece of SMP foam **402** has a gradation of foam pore size in a continuous fashion from one end of the single piece of SMP foam to the other end. This places the least permeable portion of the SMP foam nearest the parent artery, where the blood flow has the highest speed. Consequently, the small pore sizes near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes are larger since it is not necessary to further decelerate the flow in this region. Through this gradation of pore sizes, the total amount of polymer material comprising the device can be reduced.

EXAMPLE 4

SMP Baffles Within SMP Foam

Referring now to FIG. 5, another embodiment of the present invention is illustrated. This embodiment is designated generally by the reference numeral **500**. The illustration shows the blood vessel and artery system **102** and the aneurysm **104** that were shown in FIG. 1. The aneurysm **104** is shown with a dome **108** and a neck **106**. As illustrated in FIG. 5, a SMP foam unit **502** fills the aneurysm **104**. An array **504** of non-porous SMP baffles are distributed throughout the SMP foam unit **502**. This provides impermeable baffles that provide further enhancement of the hemodynamic conditions that promote thrombus formation. Consequently, the high speed parent artery flow cannot penetrate as deeply into the SMP foam unit **502** and a greater portion of the blood within the treated aneurysm travels at a slower speed.

The SMP foam unit **502** has a gradation of foam pore size in a continuous fashion from one end of the single piece of SMP foam to the other end. This places the least permeable portion of the SMP foam nearest the parent artery, where the blood flow has the highest speed. Consequently, the small pore sizes near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes are larger since it is not necessary to decelerate the flow in this region. Through this gradation of pore sizes, the total amount of polymer material comprising the device can be reduced.

EXAMPLE 5

SMP Foam Pieces on Wire Backbone

Referring now to FIG. 6, another embodiment of the present invention is illustrated. This embodiment is designated generally by the reference numeral **600**. In the embodiment **600**, gradation of pore sizes is achieved through a series of SMP foam pieces **604** that are distributed along the wire backbone **602** of the medical device. The separate pieces of SMP foam have differing pore sizes **604a**,

604b, **604c**, and **604d** in a discrete fashion from one end of the wire backbone **602** to the other end. The wire backbone **602** assumes a three-dimensional shape inside the aneurysm.

Referring now to FIG. 7, the placement of the series of SMP foam pieces **604** in the aneurysm **104** is illustrated. The wire backbone **602** assumes a three-dimensional shape inside the aneurysm. As the wire backbone **602** with SMP foam pieces **604** is delivered to the aneurysm **104**, the coiling action of the wire positions the various SMP foam pieces **604a**, **604b**, **604c**, and **604d** in such a manner as to place the pieces with the smallest pore sizes closest to the aneurysm neck **106**. Consequently, the small pore sizes **604a** near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes **604b** are larger since it is not necessary to decelerate the flow in this region. Through this gradation of pore sizes **604a**, **604b**, **604c**, and **604d** the total amount of polymer material comprising the device can be reduced.

EXAMPLE 6

Single Monolithic SMP Foam on Wire Backbone

Referring now to FIG. 8, another embodiment of the present invention is illustrated. This embodiment is designated generally by the reference numeral **800**. In the embodiment **800**, gradation of pore sizes is achieved through a single monolithic SMP foam **804** on wire backbone **802** of the medical device. The sections of the monolithic SMP foam have differing pore sizes **804** in a continuous fashion from one end of the wire backbone **802** to the other end. The wire backbone **802** assumes a three-dimensional shape inside the aneurysm.

Referring now to FIGS. 9A and 9B, the placement of the single monolithic SMP foam **804** in the aneurysm **104** is illustrated. The single monolithic SMP foam **804** and the wire backbone **802** are positioned with a guidewire **808**. The guidewire **808** shown in FIG. 9A is removed. The guidewire **808b** shown in FIG. 9B is also removed; however, the wire **808c** remains in the aneurysm **104**. The wire backbone **802** assumes a three-dimensional shape inside the aneurysm. As the wire backbone **802** with single monolithic SMP foam **804** is delivered to the aneurysm **104**, the coiling action of the wire **808c** positions the monolithic SMP foam sections **804a**, **804b**, and **804c** in such a manner as to place the section with the smallest pore sizes closest to the aneurysm neck **106**. Consequently, the small pore sizes **804a** near the aneurysm neck rapidly decelerate the flow as it enters the aneurysm. Near the aneurysm fundus, where the blood flow has a much smaller speed, the pore sizes **804c** are larger since it is not necessary to decelerate the flow in this region. Through this gradation of pore sizes **804a**, **804b**, and **804c** the total amount of polymer material comprising the device can be reduced.

EXAMPLE 7

Fusiform Aneurysm

Referring now to FIG. 10, an illustration of a fusiform aneurysm is provided. The illustration is designated generally by the reference numeral **1000**. The illustration **1000** shows a fusiform aneurysm **1002** that is a bulging or ballooning in the wall **1006** of the parent artery **1004**. Parent artery flow is represented by the arrow **1004a**. Blood vessels

1008 extend from the parent artery **1004**. Blood vessel flow is represented by the arrow **1008a**.

Referring now to FIG. **11**, an illustration shows the fusiform aneurysm **1002** that was illustrated in FIG. **10** filled with a SMP foam device **1102**. The illustration of the fusiform aneurysm **1002** filled with a SMP foam device **1102** is designated generally by the reference numeral **1100**. The illustration **1100** shows the fusiform aneurysm **1002** filled with the SMP foam device **1102** with internal channels **1104** to transfer blood flow from the parent artery **1004** to the blood vessels **1008** arising from the aneurysm wall **1006**. The SMP foam **1102** fills the bulging portion of the fusiform aneurysm **1002**.

EXAMPLE 8

Fusiform Aneurysm SMP Foam Device with Dimples

Referring now to FIG. **12**, an illustration shows the fusiform aneurysm **1002** that was illustrated in FIG. **10** filled with a SMP foam device **1202**. The illustration of the fusiform aneurysm **1002** filled with a SMP foam device **1202** is designated generally by the reference numeral **1200**. The illustration **1200** shows the fusiform aneurysm **1002** filled with the SMP foam device **1202** with internal channels **1204** to transfer blood flow from the parent artery **1004** to the blood vessels **1008** arising from the aneurysm wall **1006**. The SMP foam **1202** fills the bulging portion of the aneurysm **1002**. The external dimples **1206** promote a healing response to the treatment procedure.

Referring now to FIG. **13**, an illustration shows the SMP foam device **1002** having the internal channels to transfer blood flow from the parent artery to the blood vessels. The SMP foam fills the bulging portion **1300** of the aneurysm **1002**. The external dimples **1206** promote a healing response to the treatment procedure.

EXAMPLE 9

Void at Dome

Referring now to FIG. **14**, an illustration shows the blood vessel and artery system and the aneurysm that were illustrated in FIG. **1** with an embodiment of the invention including a void at the dome. The illustration is designated generally by the reference numeral **1400**. The illustration **1400** shows the cerebral arteries and blood vessels **102** and the aneurysm **104**. The aneurysm **104** is shown with a dome **108** and a neck **106**. The aneurysm **104** is shown with a piece of SMP foam **1402** in the aneurysm **104** partially filling the aneurysm **104**. The upper portion of the aneurysm **104** is a void **1404**. The SMP foam may not be necessary in the void **1404** in the upper portion of the aneurysm **104**.

EXAMPLE 10

Void at Dome and Impermeable Layer at Neck

Referring now to FIG. **15**, an illustration shows the blood vessel and artery system and the aneurysm that were illustrated in FIG. **1** with an embodiment of the invention including a void at the dome and an impermeable layer at the neck. The illustration is designated generally by the reference numeral **1500**. The illustration **1500** shows the cerebral arteries and blood vessels **102** and the aneurysm **104**. The aneurysm **104** is shown with a dome **108** and a neck **106**.

The aneurysm **104** is shown with a piece of SMP foam **1502** in the aneurysm **104** partially filling the aneurysm **104**. The upper portion of the aneurysm **104** is a void **1504**. The SMP foam may not be necessary in the void **1504** in the upper portion of the aneurysm **104**. A layer of non-porous SMP **1506** coats the base of the SMP foam unit **1502**. This provides an impermeable layer that provides further enhancement of the hemodynamic conditions that promote thrombus formation and subsequent healing. Consequently, the high speed parent artery flow cannot penetrate as deeply into the SMP foam and a greater portion of the blood within the treated aneurysm travels at a slower speed.

While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

The invention claimed is:

1. An apparatus to treat an aneurysm comprising:

a shape memory polymer (SMP) foam to be located in the aneurysm interior;

a delivery conduit;

a wire backbone configured to permanently remain in the aneurysm after implantation of the SMP foam into the aneurysm; and

a means for advancing the backbone through vasculature, the means for advancing the backbone being coupled to a proximal end portion of the backbone;

wherein the SMP foam has pores that include a first multiplicity of pores having a first pore size and a second multiplicity of pores having a second pore size, the second pore size being larger than the first pore size; wherein the SMP foam comprises first and second individual separate pieces of SMP foam that (a) are not permanently directly connected to each other, and (b) are distributed along the backbone;

wherein the first individual separate piece of SMP foam includes the first multiplicity of pores and the second individual separate piece of SMP foam includes the second multiplicity of pores;

wherein the first individual separate piece of SMP foam is between the means for advancing the backbone and the second individual separate piece of SMP foam;

wherein the first and second individual separate pieces of SMP foam are arranged to deploy from the delivery conduit and into the vasculature in serial fashion with the second individual piece of SMP foam deploying from the delivery conduit before the first individual piece of SMP foam deploys from the delivery conduit.

2. The apparatus of claim **1** wherein the second multiplicity of pores are configured to be located in a dome of the aneurysm.

3. The apparatus of claim **1** comprising additional multiplicities of pores in the SMP foam; wherein the additional multiplicities of pores have pore sizes larger than the first pore size but smaller than the second pore size.

4. The apparatus of claim **3** wherein pores with the smallest pore size are configured to be in a neck of the aneurysm and pores with the largest pore size are configured to be in a dome of the aneurysm.

5. The apparatus of claim **1** comprising a coating of non-porous SMP on the SMP foam.

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6. The apparatus of claim 1 comprising non-porous baffles in the SMP foam; wherein the baffles are located between walls of the SMP foam.

7. The apparatus of claim 1 wherein:

a single axis intersects the second multiplicity of pores, first and second peripheral walls of the SMP foam, and a middle portion of the SMP foam that couples the first and second peripheral walls to each other; and the second multiplicity of pores extends from the first peripheral wall all the way through the middle portion of the SMP foam and all the way to the second peripheral wall.

8. The apparatus of claim 1 wherein the SMP foam has a peripheral wall that includes dimples.

9. An apparatus comprising:

a shape memory polymer (SMP) foam to be located in an interior of an aneurysm;
a delivery conduit;
a backbone wire configured to permanently remain in the aneurysm after implantation of the SMP foam into the aneurysm; and
a delivery wire coupled to a proximal end portion of the backbone wire;

wherein (a) the SMP foam has first pores having a first pore size and second pores having a second pore size that is larger than the first pore size, (b) the SMP foam comprises first and second individual separate SMP foam pieces which are not permanently directly connected to each other and which are distributed along the backbone wire, (c) the first SMP foam piece includes the first pores and the second SMP foam piece includes the second pores, (d) the first SMP foam piece is proximal to the second SMP foam piece and the second SMP foam piece is substantially adjacent a distal end of the backbone wire, (e) the first SMP foam piece is between the delivery wire and the second SMP foam piece, and (f) the first and second SMP foam pieces are arranged to deploy from the delivery conduit and into vasculature in serial fashion with the second SMP foam piece deploying from the delivery conduit before the first SMP foam piece deploys from the delivery conduit.

10. The apparatus of claim 9 wherein the first SMP foam piece is configured to be located in a neck of the aneurysm.

11. The apparatus of claim 9 comprising additional individual separate SMP foam pieces, which are not permanently directly connected to each other and which have pore sizes unequal to the first pore size, distributed along the backbone wire between the first and second SMP foam pieces.

12. The apparatus of claim 9 wherein an exterior portion of the SMP foam is coated with a non-porous SMP.

13. The apparatus of claim 9 wherein the first and second SMP foam pieces are configured to directly contact one another when expanded and deployed in the aneurysm.

14. An apparatus comprising:

a shape memory polymer (SMP) foam to be located in a physical anomaly;
a delivery conduit;
a backbone wire to remain in the anomaly after implantation of the SMP foam into the anomaly; and
a delivery wire coupled to a proximal end portion of the backbone wire;

wherein (a) the SMP foam has first pores having a first pore size and second pores having a second pore size that is larger than the first pore size, (b) the SMP foam comprises first and second individual separate SMP

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foam pieces which are not permanently directly connected to each other and which are distributed along the backbone wire, (c) the first SMP foam piece includes the first pores and the second SMP foam piece includes the second pores, (d) the first SMP foam piece is proximal to the second SMP foam piece, (e) the first SMP foam piece is between the delivery wire and the second foam piece; and (f) the first and second SMP foam pieces are arranged to deploy from the delivery conduit and into vasculature in serial fashion with the second SMP foam piece deploying from the delivery conduit before the first SMP foam piece deploys from the delivery conduit.

15. The apparatus of claim 14 comprising a third individual separate SMP foam piece, which is not permanently directly connected to either of the first and second SMP foam pieces, distributed along the backbone wire between the first and second SMP foam pieces; wherein the third SMP foam piece has third pores having the first pore size.

16. The apparatus of claim 14 comprising a third individual separate SMP foam piece, which is not permanently directly connected to either of the first and second SMP foam pieces, distributed along the backbone wire between the first and second SMP foam pieces; wherein the third SMP foam piece has third pores having a third pore size that is greater than the first pore size but smaller than the second pore size.

17. The apparatus of claim 16 comprising a fourth individual separate SMP foam piece, which is not permanently directly connected to any of the first, second, or third SMP foam pieces, distributed along the backbone wire between the third and second SMP foam pieces; wherein the fourth SMP foam piece has fourth pores having the third pore size.

18. The apparatus of claim 14 comprising third and fourth individual separate SMP foam pieces, wherein:

the third SMP foam piece (a) is not permanently directly connected to any of the first, second, and fourth SMP foam pieces, (b) is on the backbone wire distal to the first SMP foam piece, and (c) has a third pore size;
the fourth SMP foam piece (a) is not permanently directly connected to any of the first, second, and third SMP foam pieces, (b) is on the backbone wire distal to the first SMP foam piece, and (c) has a fourth pore size;
the third pore size is unequal to any of the first, second, and fourth pore sizes; and
the fourth pore size is unequal to any of the first, second, and third pore sizes.

19. The apparatus of claim 18 comprising fifth, sixth, seventh, and eighth individual separate SMP foam pieces, wherein:

the fifth SMP foam piece (a) is not permanently directly connected to any of the first, second, third, fourth, sixth, seventh, and eighth SMP foam pieces, (b) is on the backbone wire distal to the first SMP foam piece, and (c) has a fifth pore size;
the sixth SMP foam piece (a) is not permanently directly connected to any of the first, second, third, fourth, fifth, seventh, and eighth SMP foam pieces, (b) is on the backbone wire distal to the first SMP foam piece, and (c) has a sixth pore size;
the seventh SMP foam piece (a) is not permanently directly connected to any of the first, second, third, fourth, fifth, sixth, and eighth SMP foam pieces, (b) is on the backbone wire distal to the first SMP foam piece, and (c) has a seventh pore size;
the eighth SMP foam piece (a) is not permanently directly connected to any of the first, second, third, fourth, fifth,

sixth, and seventh SMP foam pieces, (b) is on the backbone wire distal to the first SMP foam piece, and (c) has an eighth pore size;

the fifth pore size is equal to the first pore size;

the sixth pore size is equal to the second pore size;

the seventh pore size is equal to the third pore size; and

the eighth pore size is equal to the fourth pore size.

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