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(12) **United States Patent**
Riina et al.

(10) **Patent No.: US 9,486,224 B2**
(45) **Date of Patent: Nov. 8, 2016**

(54) **METHOD AND APPARATUS FOR RESTRICTING FLOW THROUGH AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE STILL MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN**

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(73) Assignee: **Cornell University**, Ithaca, NY (US)

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 13/437,777, filed on Apr. 2, 2012, now Pat. No. 8,956,475, which is a continuation-in-part of application No. 12/657,598, filed on Jan. 22, 2010, now Pat. No. 8,663,301, which

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A61B 17/12 (2006.01)

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(52) **U.S. Cl.**

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(58) **Field of Classification Search**

CPC A61B 17/12172; A61B 17/12131; A61B 17/12118; A61B 17/12022; A61B 2017/12054; A61B 2017/00867; C22F 1/006; A61N 5/0616; A61H 23/00; A61F 2/86; A61F 2230/0095; A61F 2230/005; A61F 2230/0091; A61F 2002/823; A61F 2/95; A61F 2230/0071; A61F 2/91; A61F 2002/30242

USPC 606/200, 191, 127–128; 623/1.11–1.35

See application file for complete search history.

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Primary Examiner — Amy R Weisberg

(74) *Attorney, Agent, or Firm* — Pandiscio & Pandiscio

(57) **ABSTRACT**

A method for making a device for causing thrombosis of an aneurysm, wherein said device comprises a single elastic filament configurable between (i) an elongated, substantially linear configuration, and (ii) a longitudinally-contracted, substantially three-dimensional configuration, said method comprising:

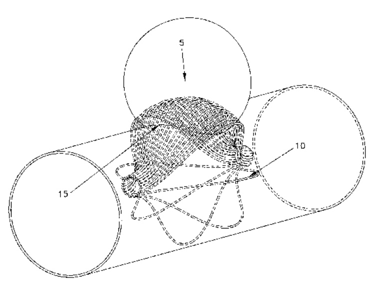
providing a sheet of shape memory material;

producing a single filament, two-dimensional interim structure from said sheet of shape memory material;

mounting said single filament, two-dimensional interim structure to a fixture so that said single filament, two-dimensional interim structure is transformed into said longitudinally-contracted, substantially three-dimensional configuration; and

heat treating said single filament, two-dimensional interim structure while it is mounted to said fixture so as to produce said device in its longitudinally-contracted, substantially three-dimensional configuration.

5 Claims, 77 Drawing Sheets



Related U.S. Application Data

is a continuation-in-part of application No. 12/332,727, filed on Dec. 11, 2008, now Pat. No. 8,728,141.

(60) Provisional application No. 61/007,189, filed on Dec. 11, 2007, provisional application No. 61/205,683, filed on Jan. 22, 2009, provisional application No. 61/277,415, filed on Sep. 24, 2009, provisional application No. 61/470,733, filed on Apr. 1, 2011.

(51) **Int. Cl.**

C22F 1/00	(2006.01)
A61F 2/86	(2013.01)
A61H 23/00	(2006.01)
A61N 5/06	(2006.01)
A61B 17/00	(2006.01)
A61F 2/82	(2013.01)
A61F 2/91	(2013.01)
A61F 2/95	(2013.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B17/12131*** (2013.01); ***A61F 2/86*** (2013.01); ***A61H 23/00*** (2013.01); ***A61N 5/0616*** (2013.01); ***C22F 1/006*** (2013.01); *A61B 2017/00867* (2013.01); *A61B 2017/12054* (2013.01); *A61F 2/82* (2013.01); *A61F 2/91* (2013.01); *A61F 2/95* (2013.01); *A61F 2002/30242* (2013.01); *A61F 2002/823* (2013.01); *A61F 2230/005* (2013.01); *A61F 2230/0071* (2013.01); *A61F 2230/0091* (2013.01); *A61F 2230/0095* (2013.01)

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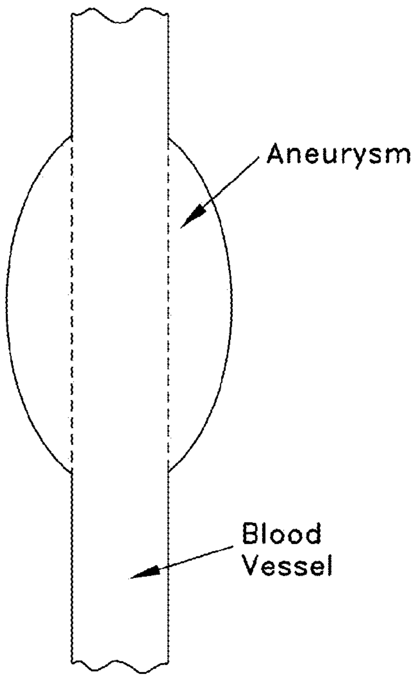
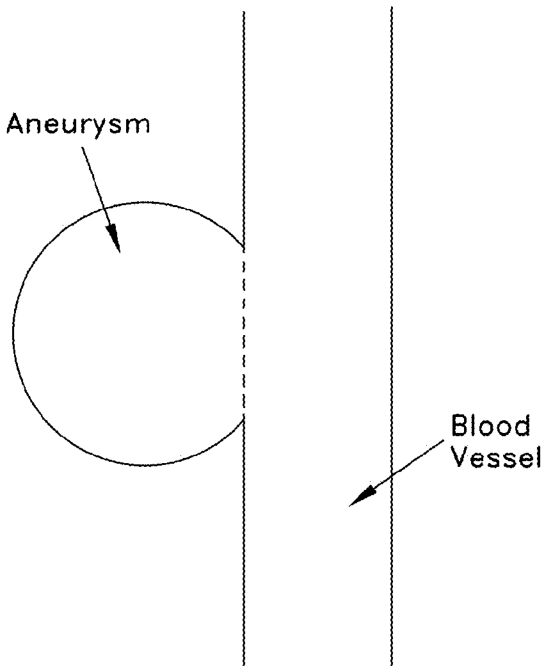


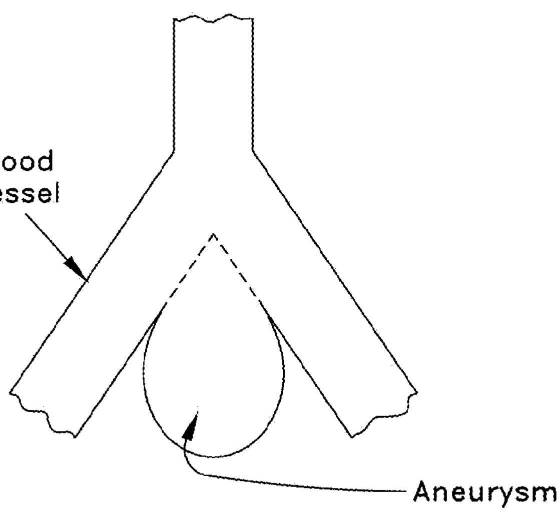
Fusiform Aneurysm

FIG. 1



Lateral Aneurysm

FIG. 2



Bifurcation Aneurysm

FIG. 3

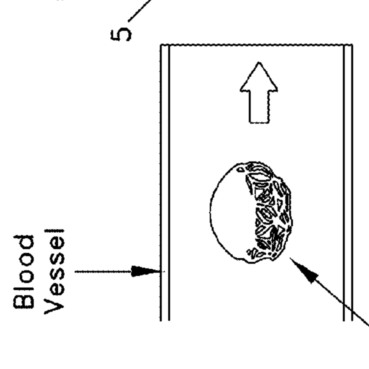


FIG. 4

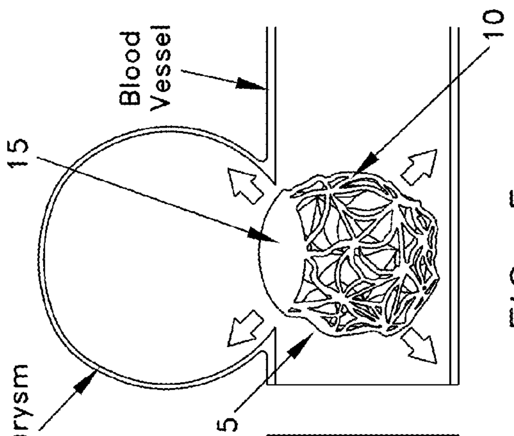


FIG. 5

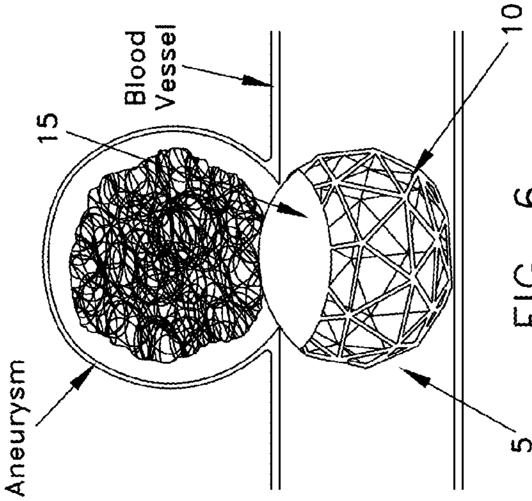


FIG. 6

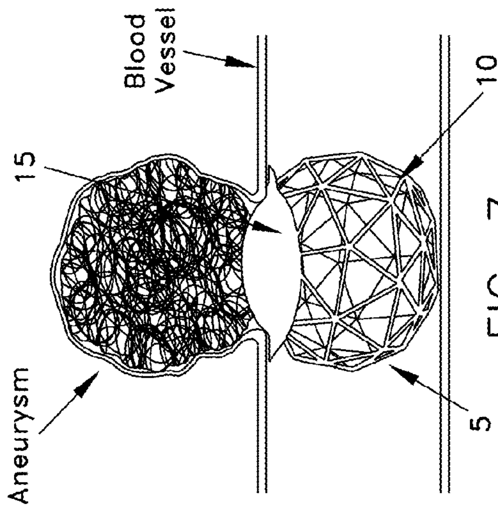


FIG. 7

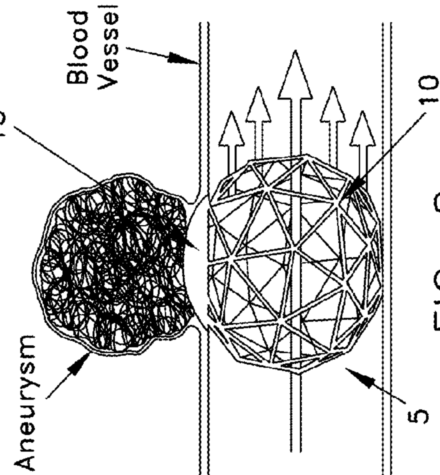


FIG. 8

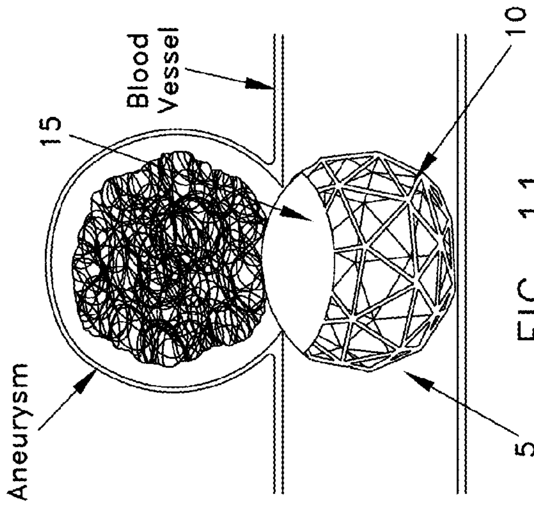


FIG. 11

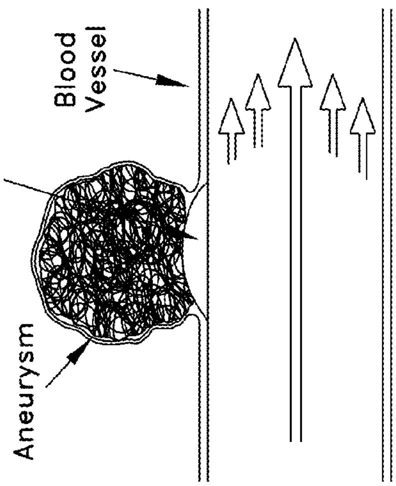


FIG. 13

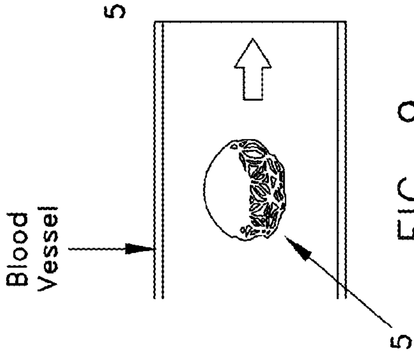


FIG. 9

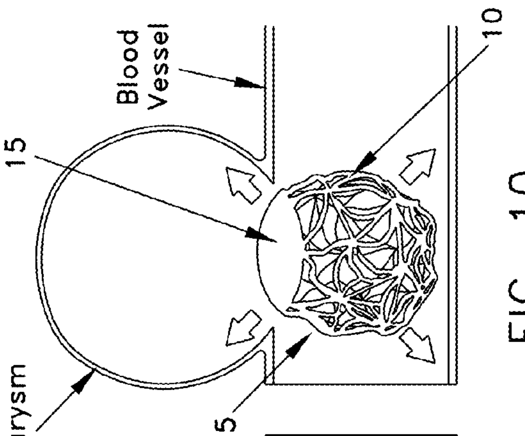


FIG. 10

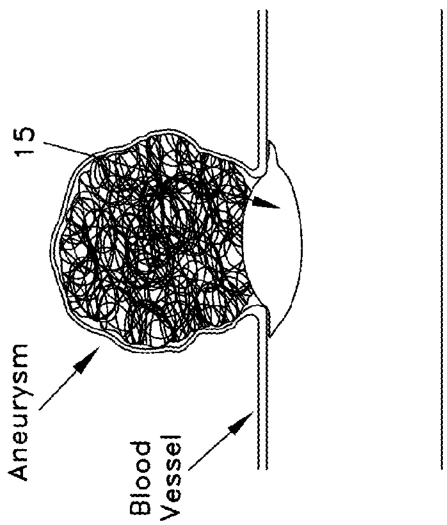


FIG. 12

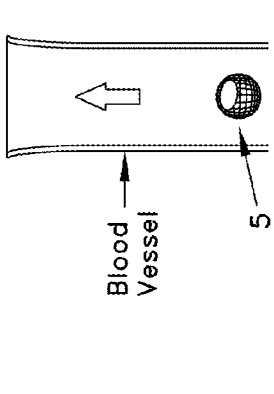


FIG. 14

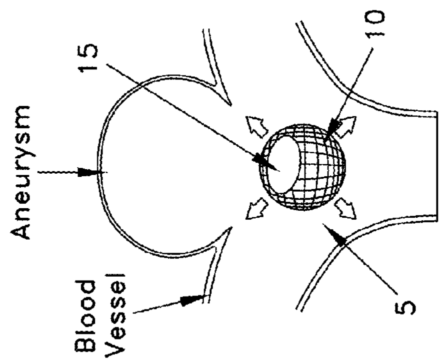


FIG. 15

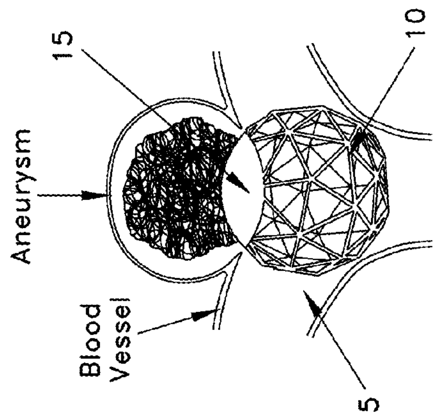


FIG. 16

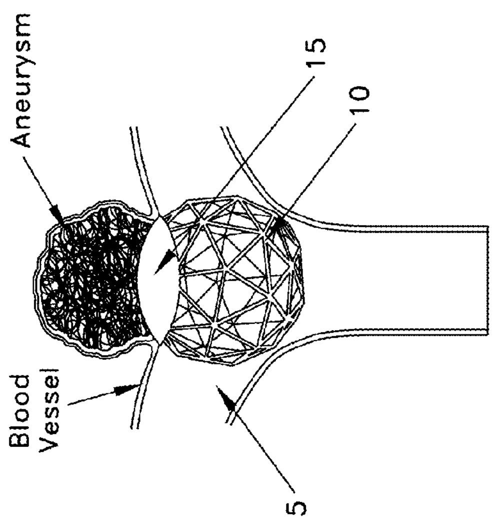


FIG. 17

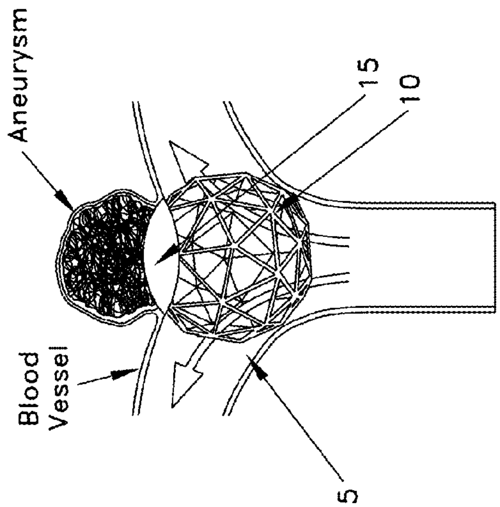


FIG. 18

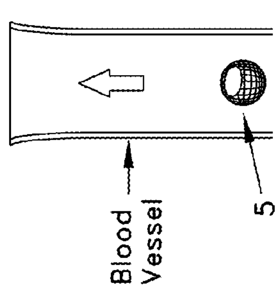


FIG. 19

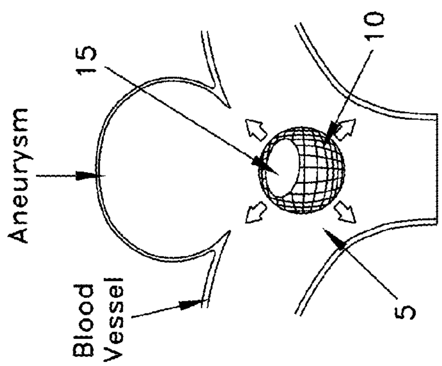


FIG. 20

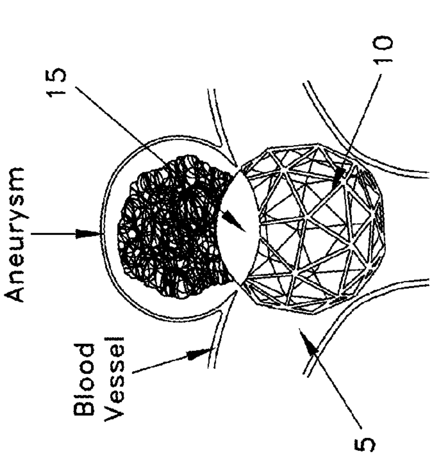


FIG. 21

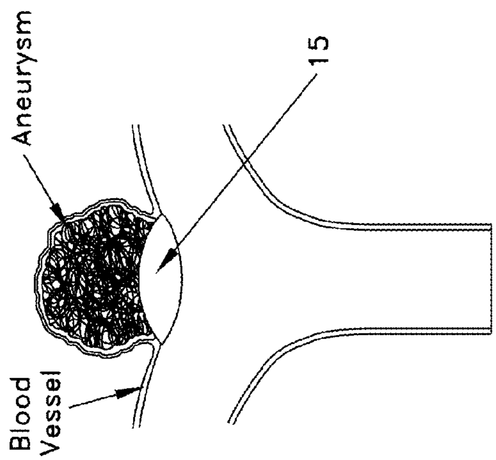


FIG. 22

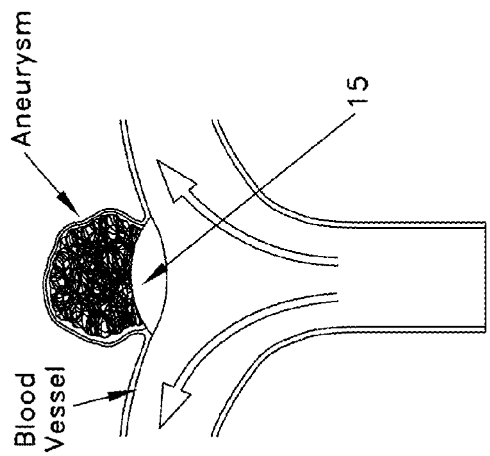


FIG. 23

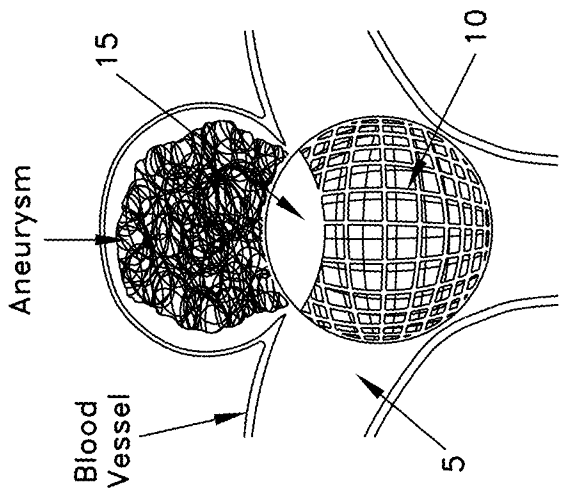


FIG. 24

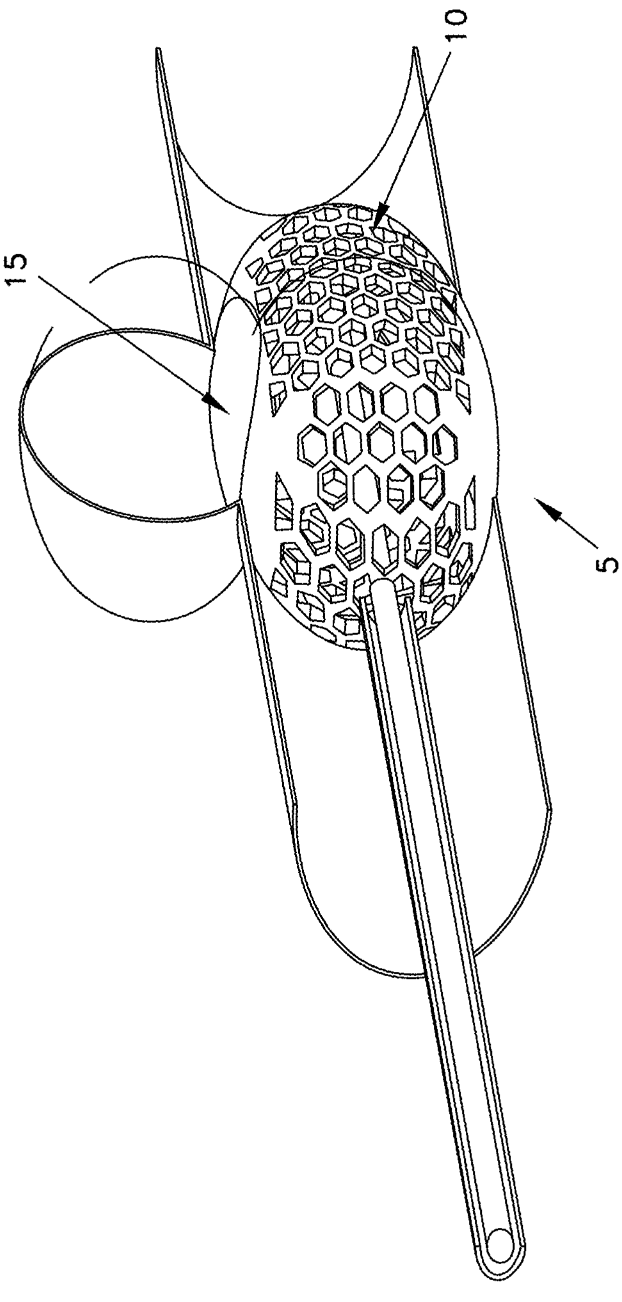


FIG. 25

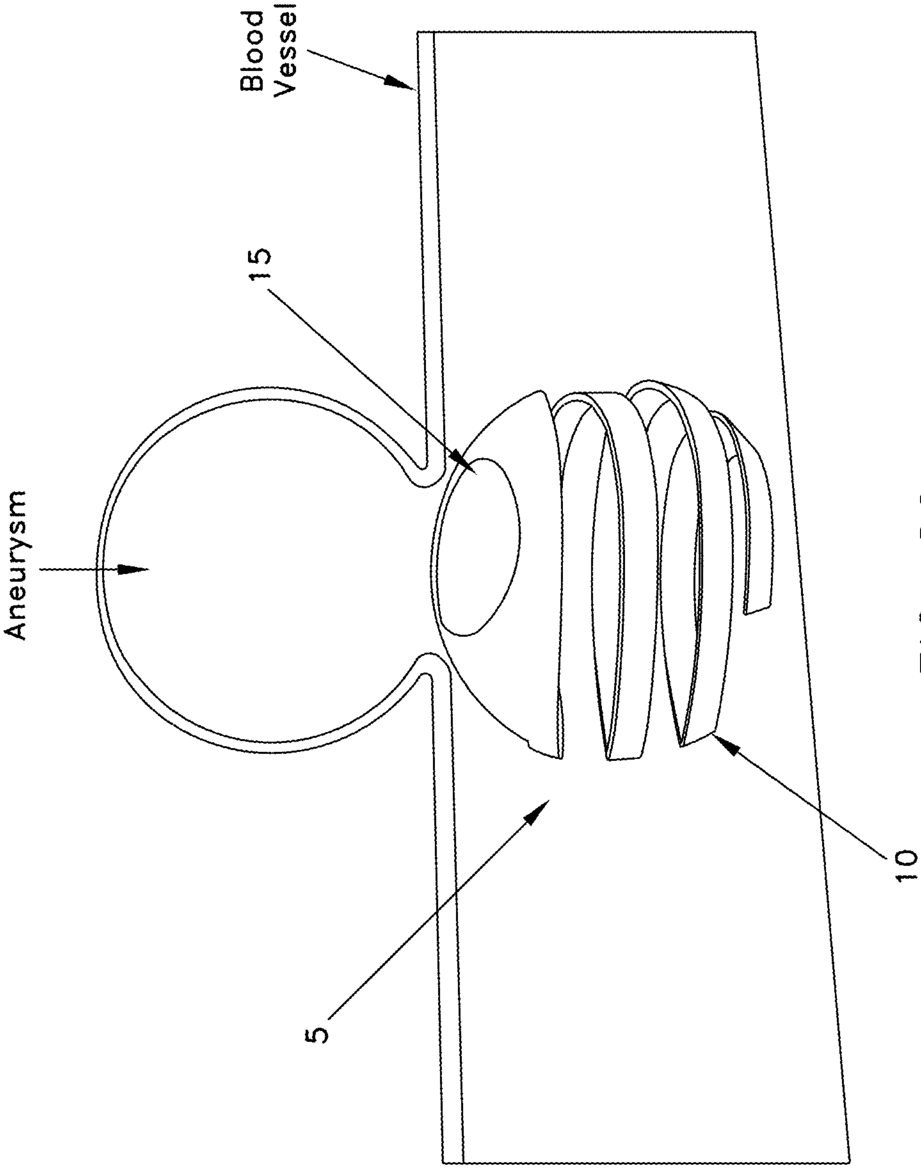


FIG. 26

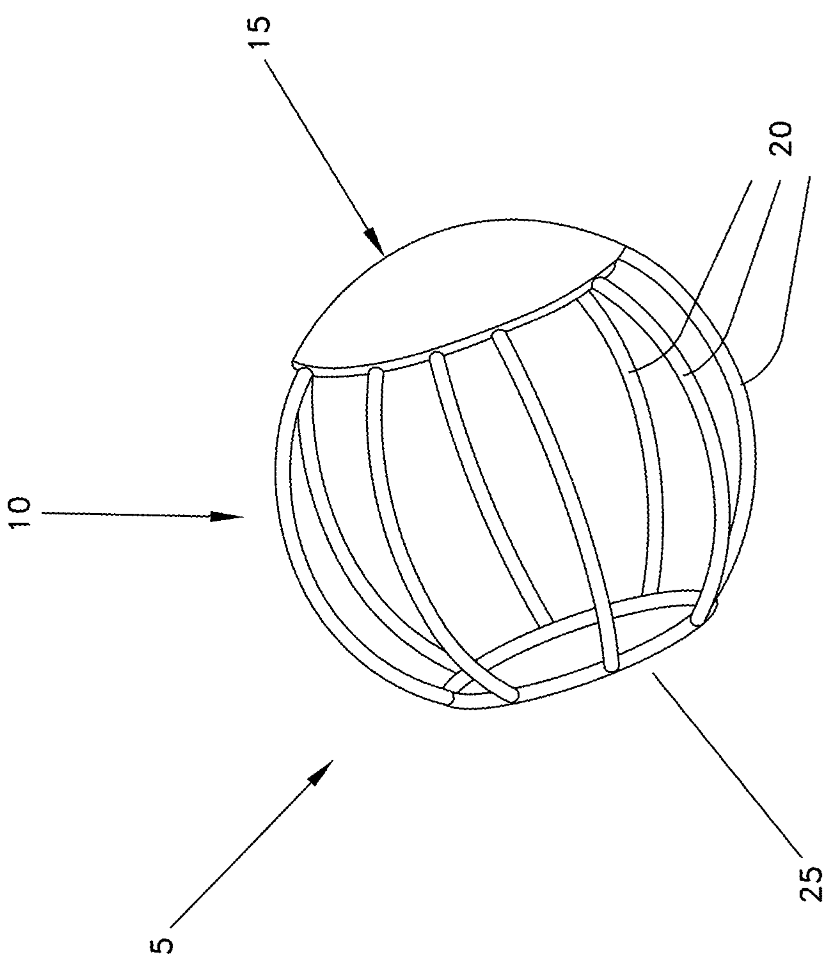


FIG. 27

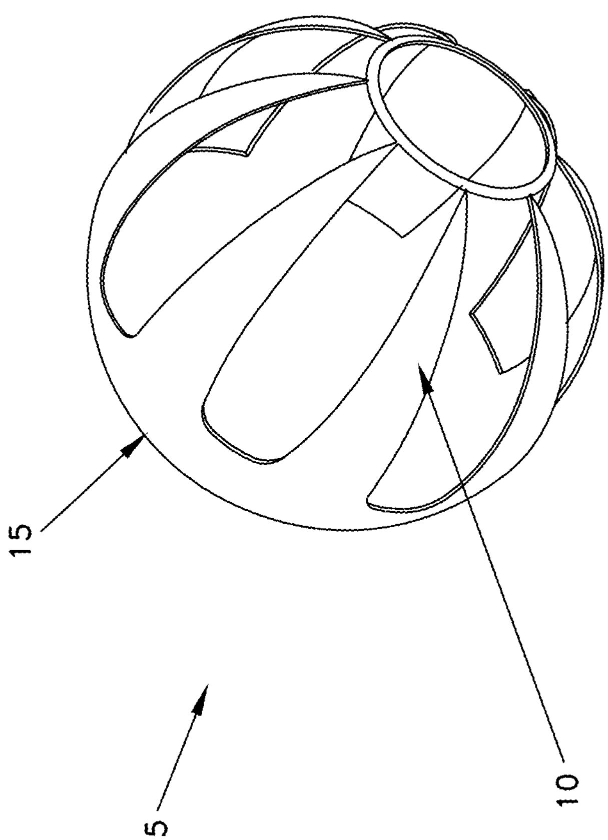


FIG. 28

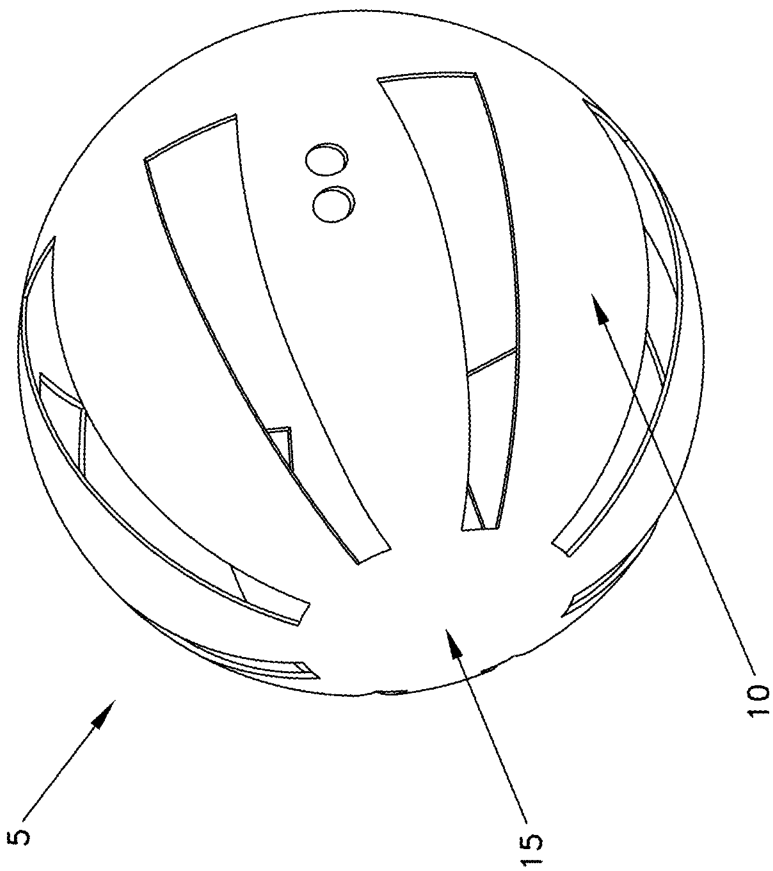


FIG. 29

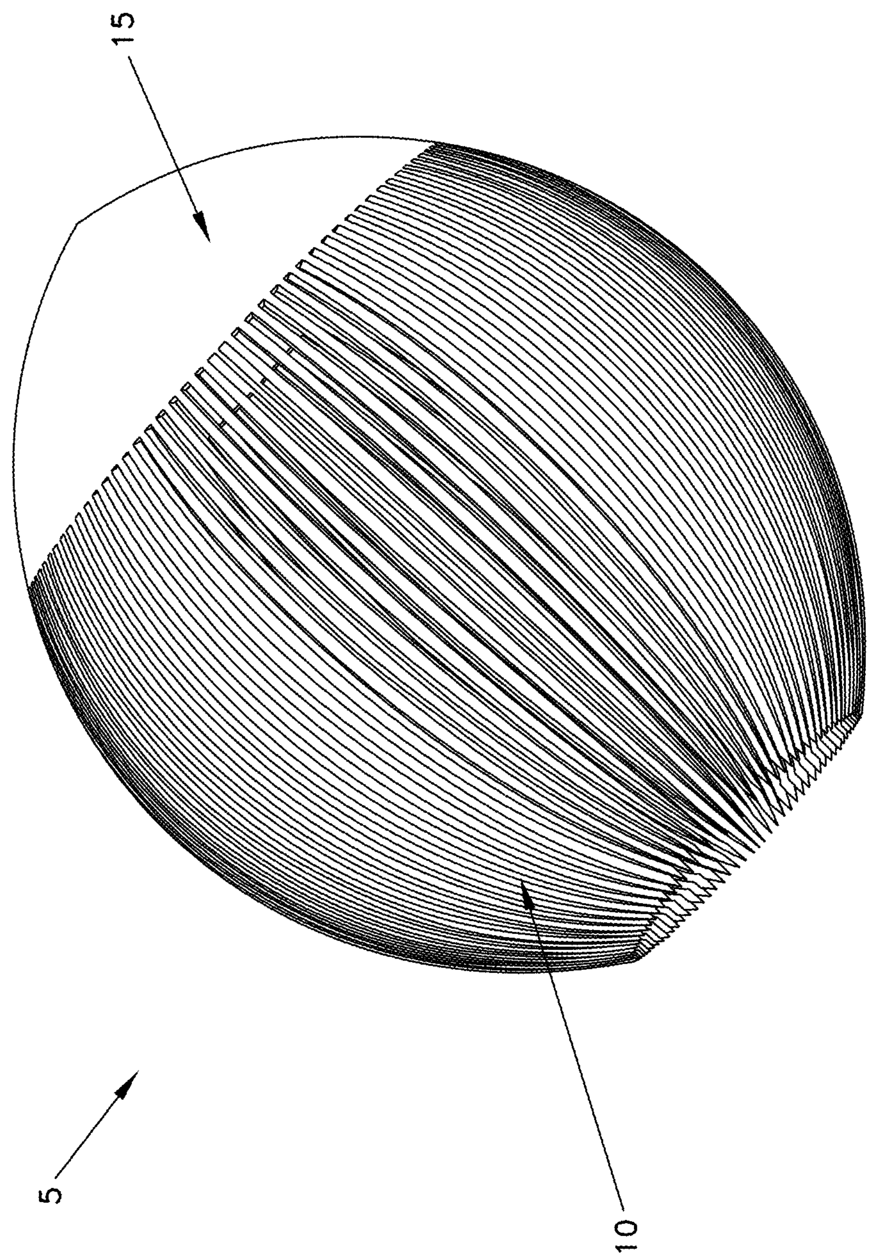


FIG. 30

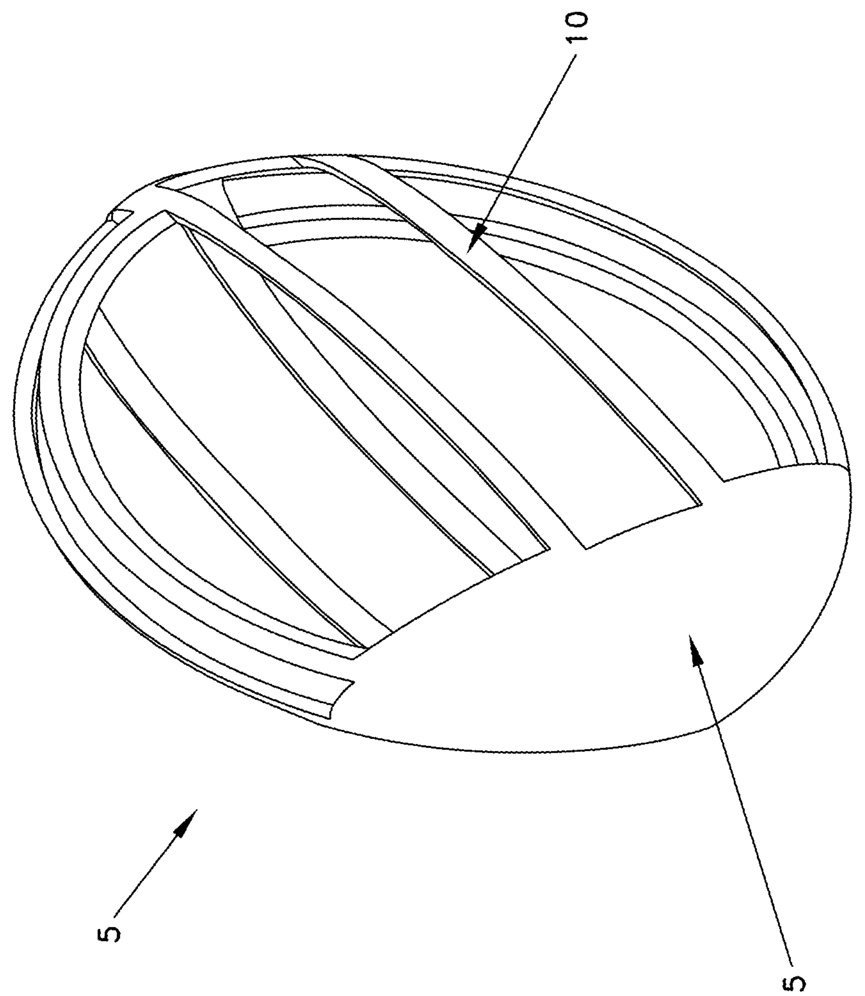


FIG. 31

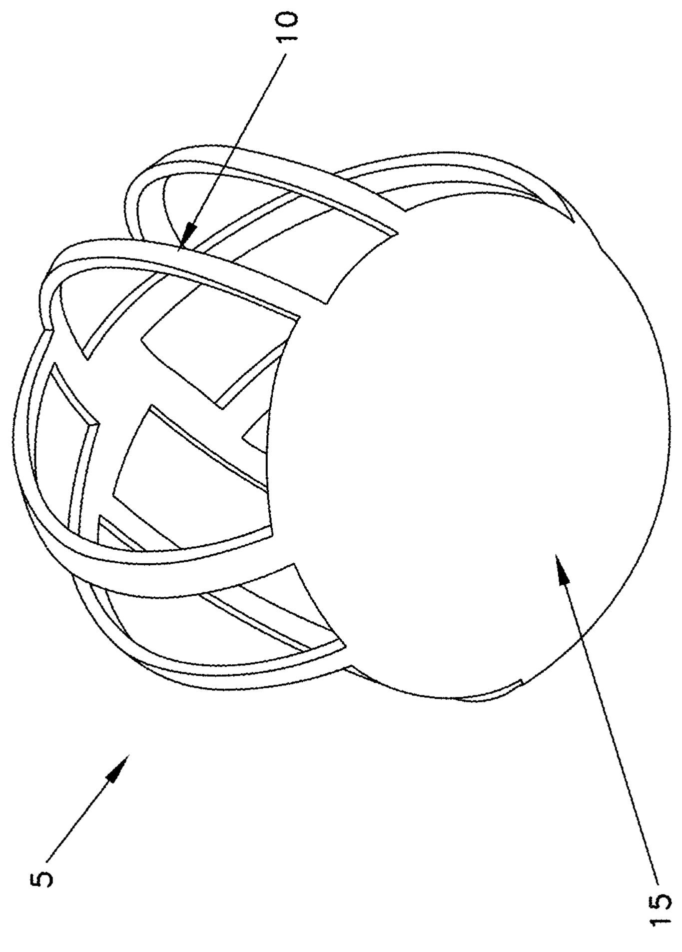


FIG. 32

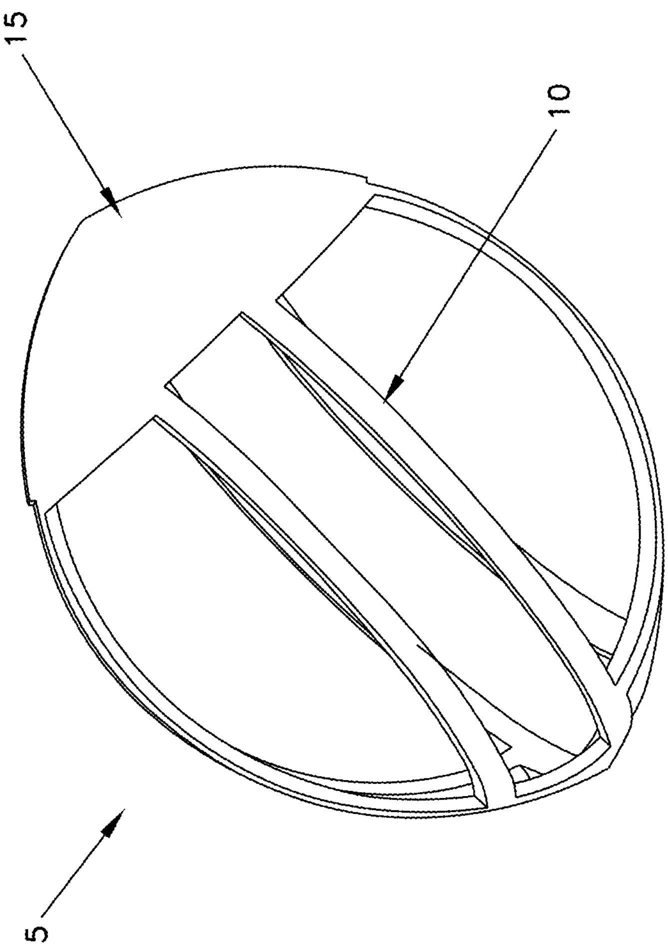


FIG. 33

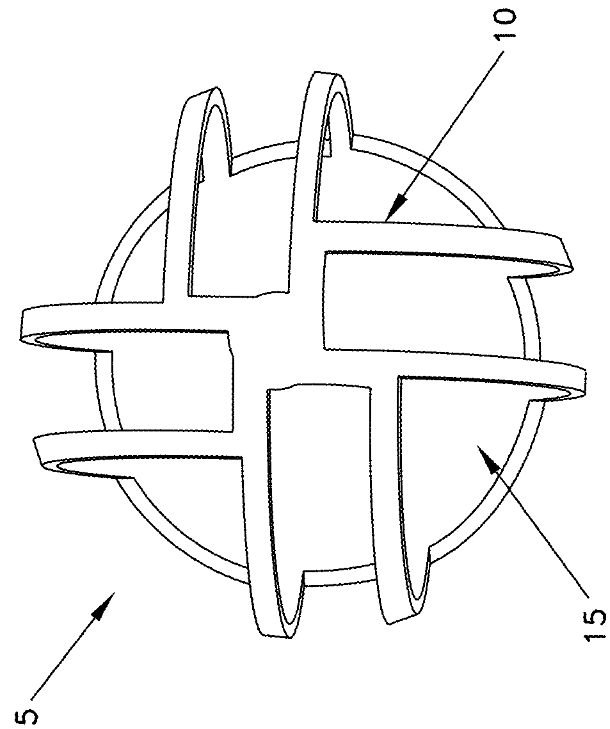


FIG. 34

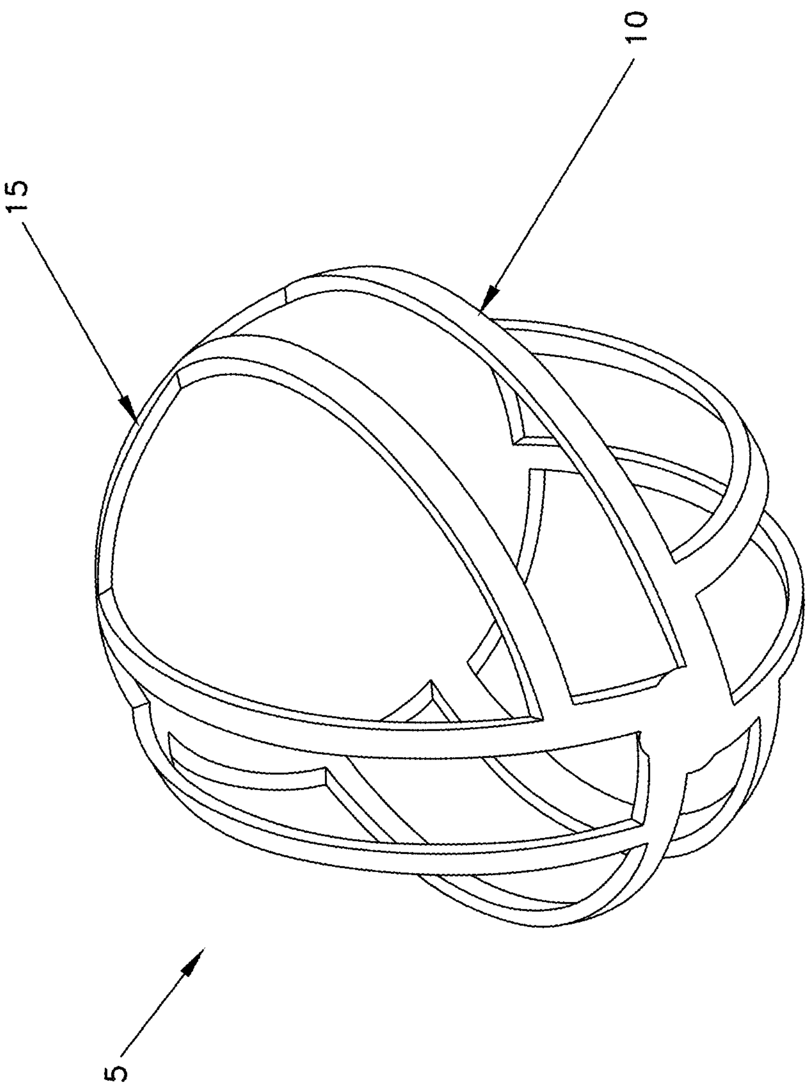


FIG. 35

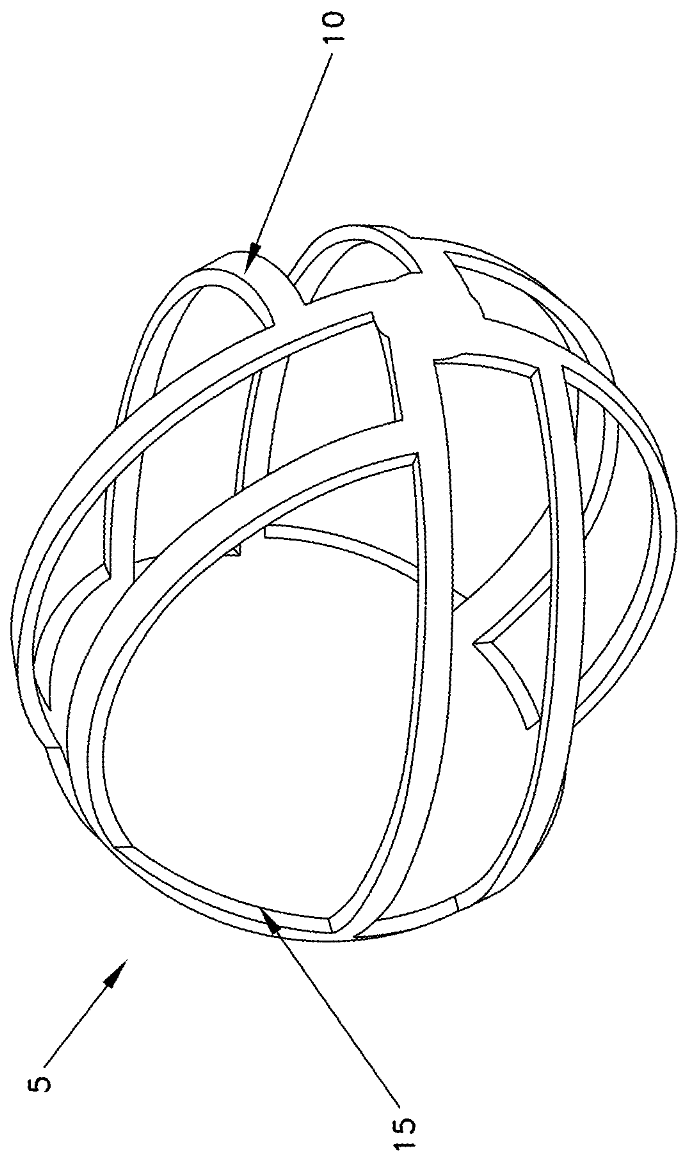


FIG. 36

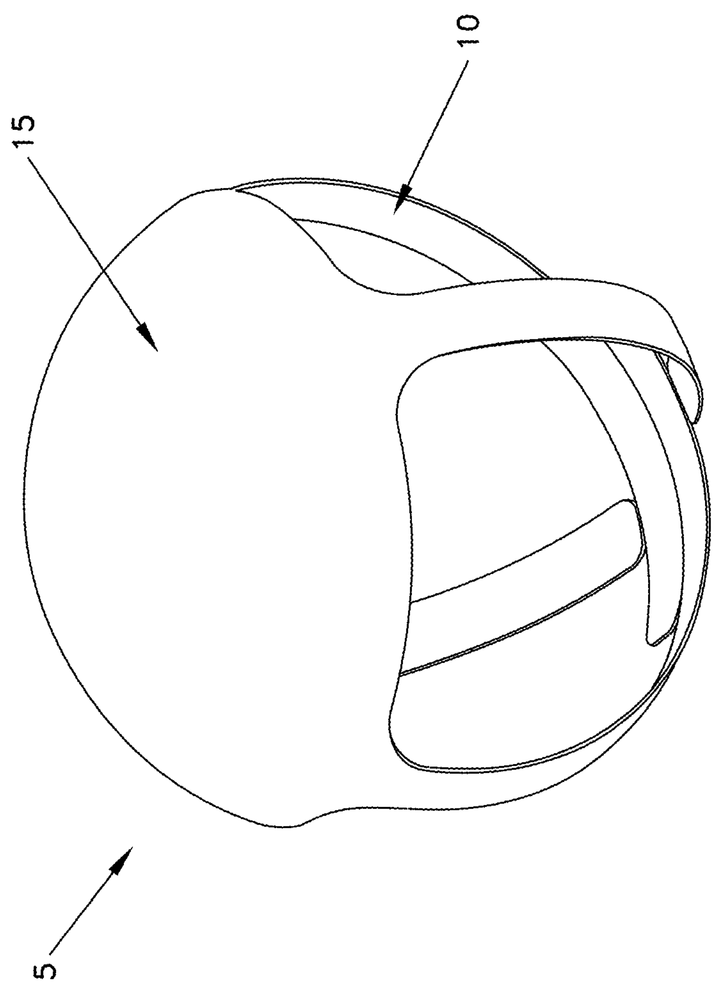


FIG. 37

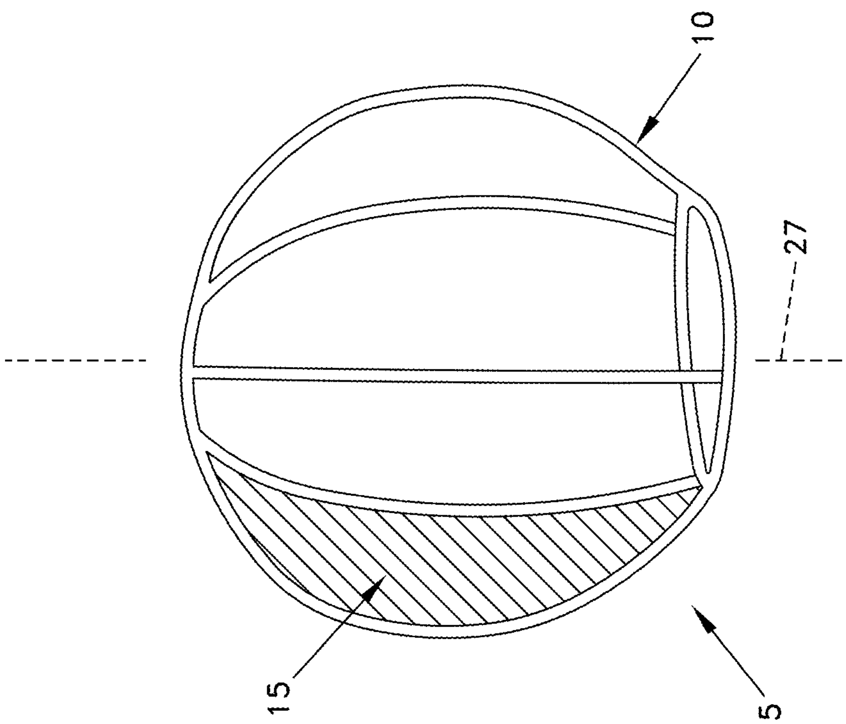
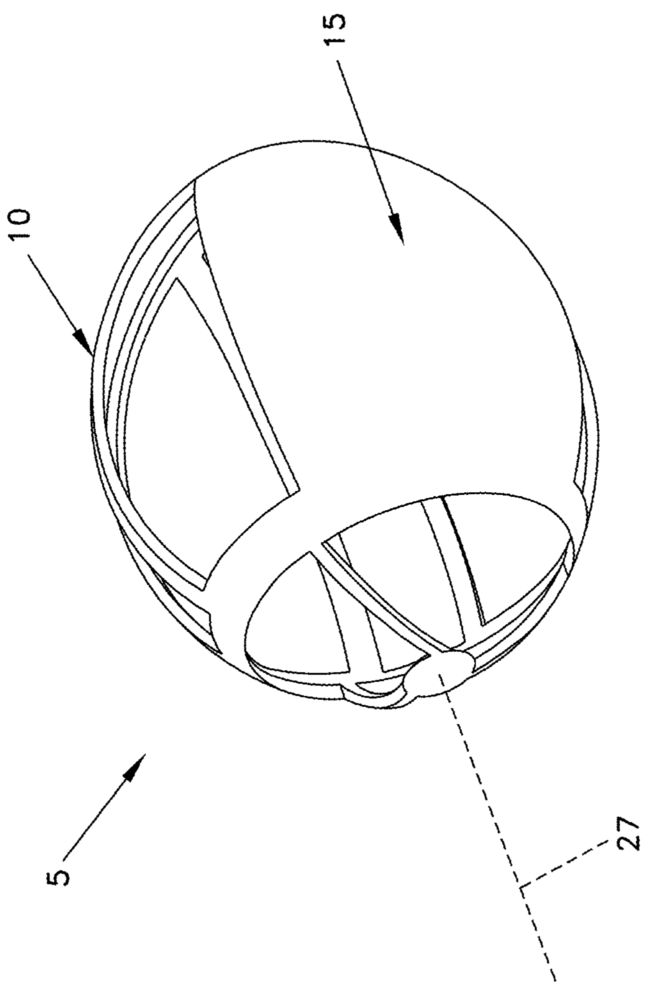


FIG. 38



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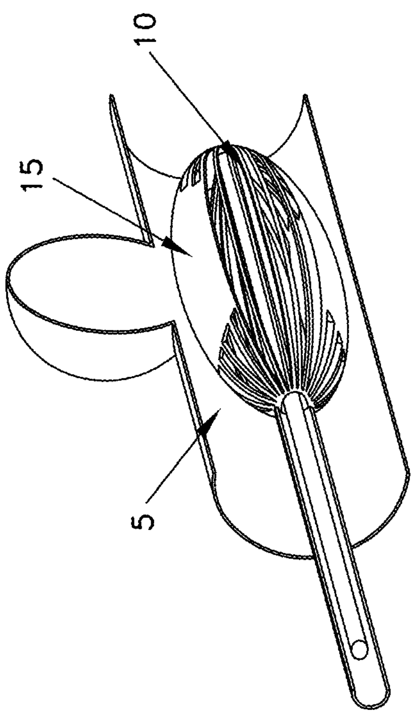

FIG. 40

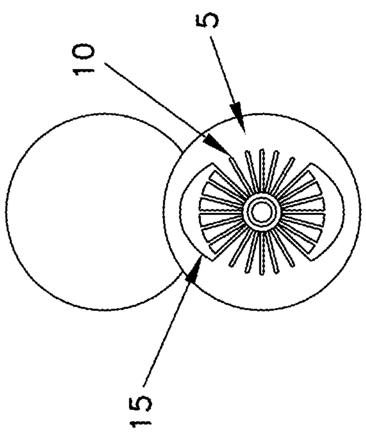

FIG. 41

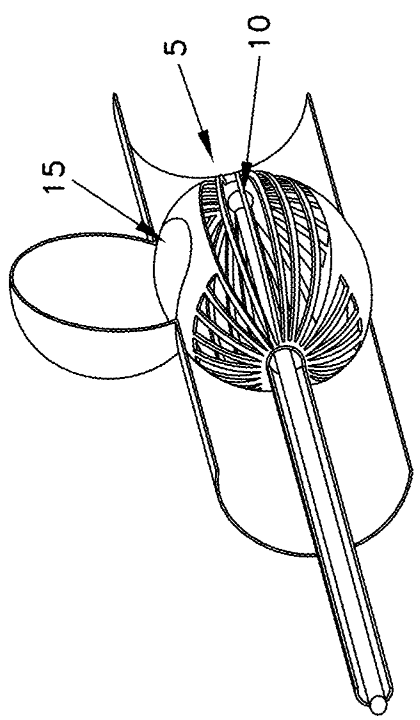

FIG. 42

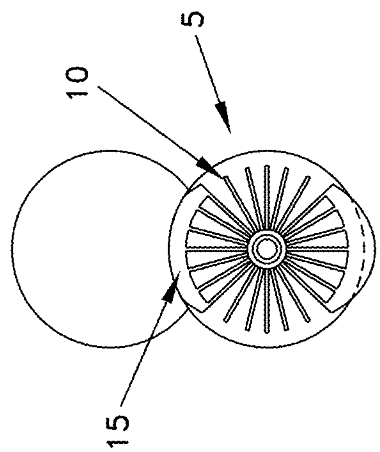

FIG. 43

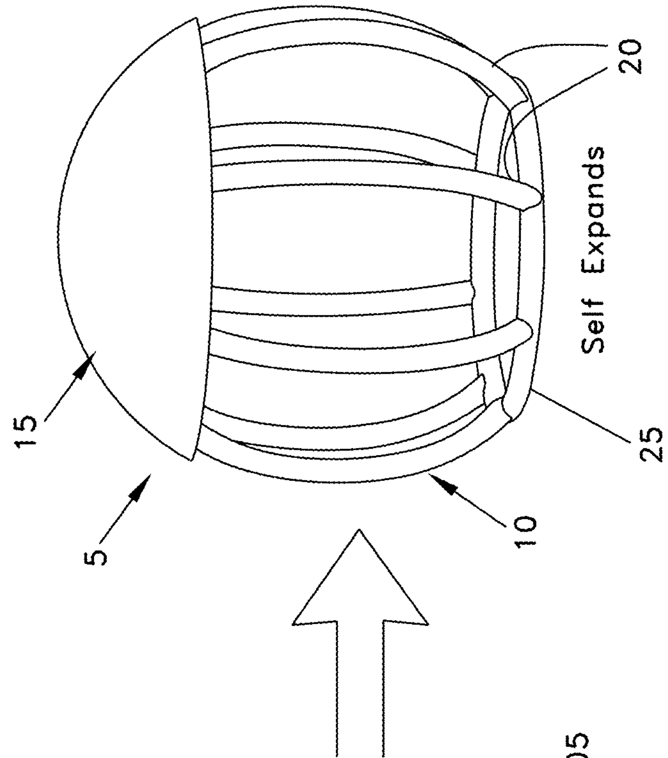

FIG. 45

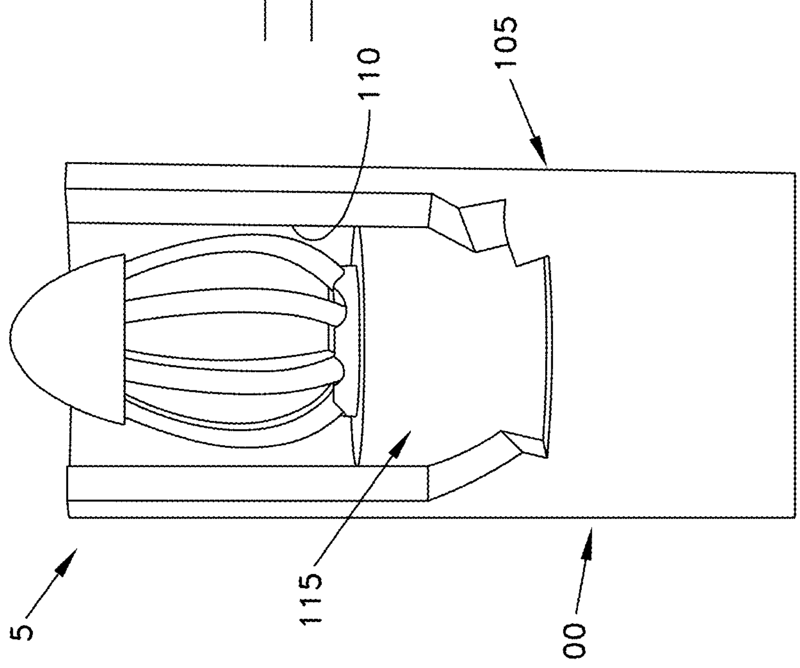

FIG. 44

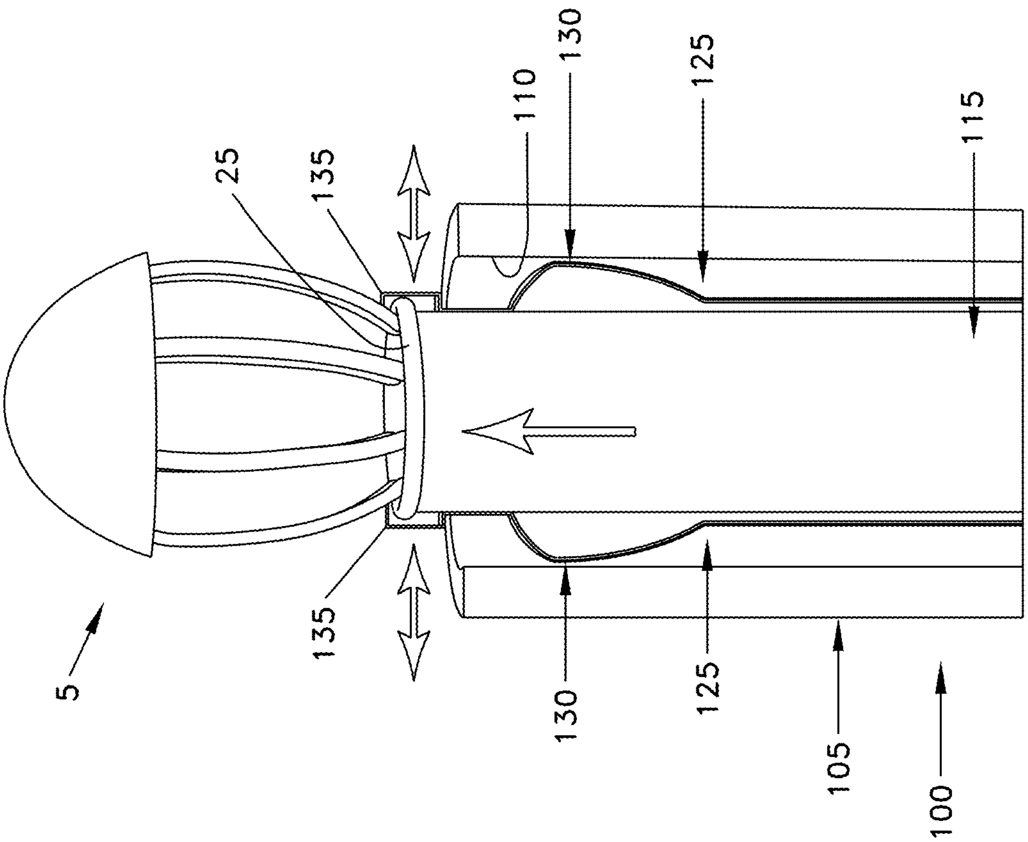

FIG. 46

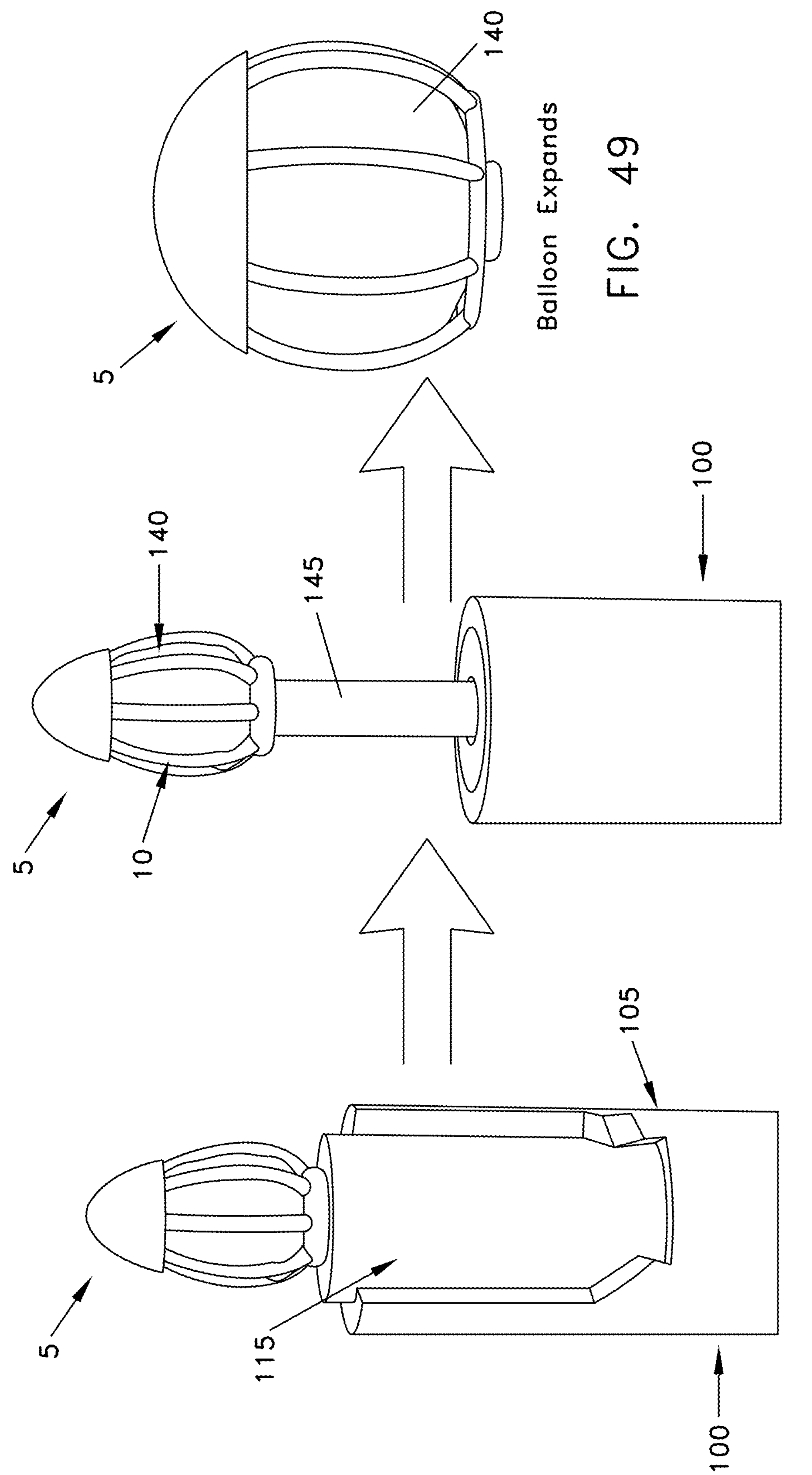

FIG. 47

FIG. 48

FIG. 49

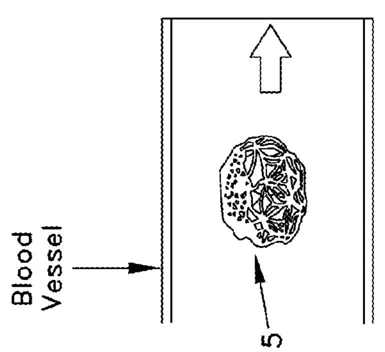

FIG. 50

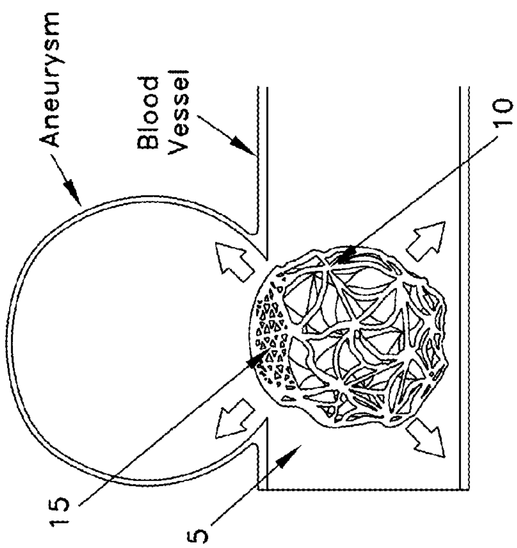

FIG. 51

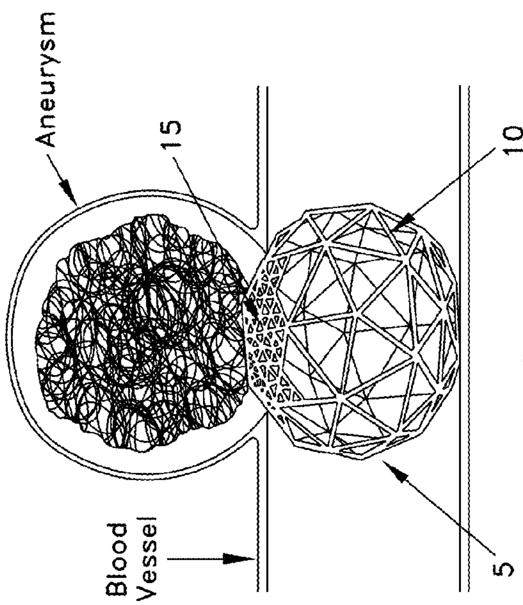

FIG. 52

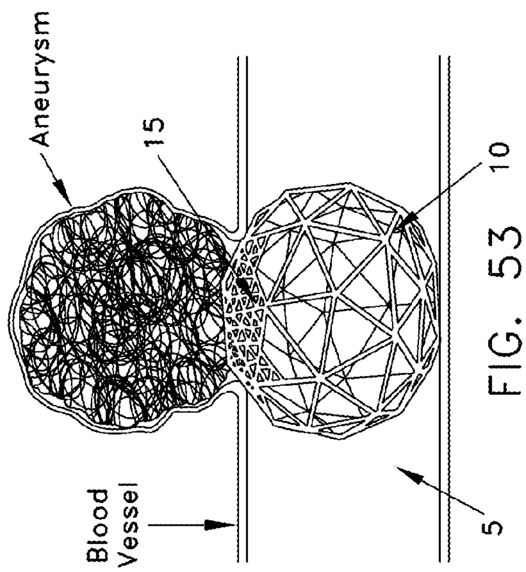

FIG. 53

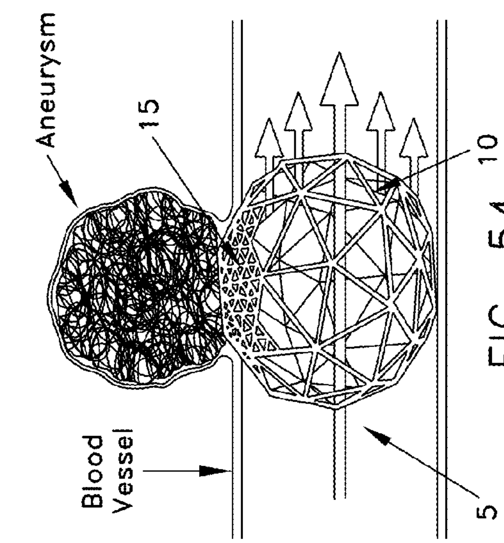

FIG. 54

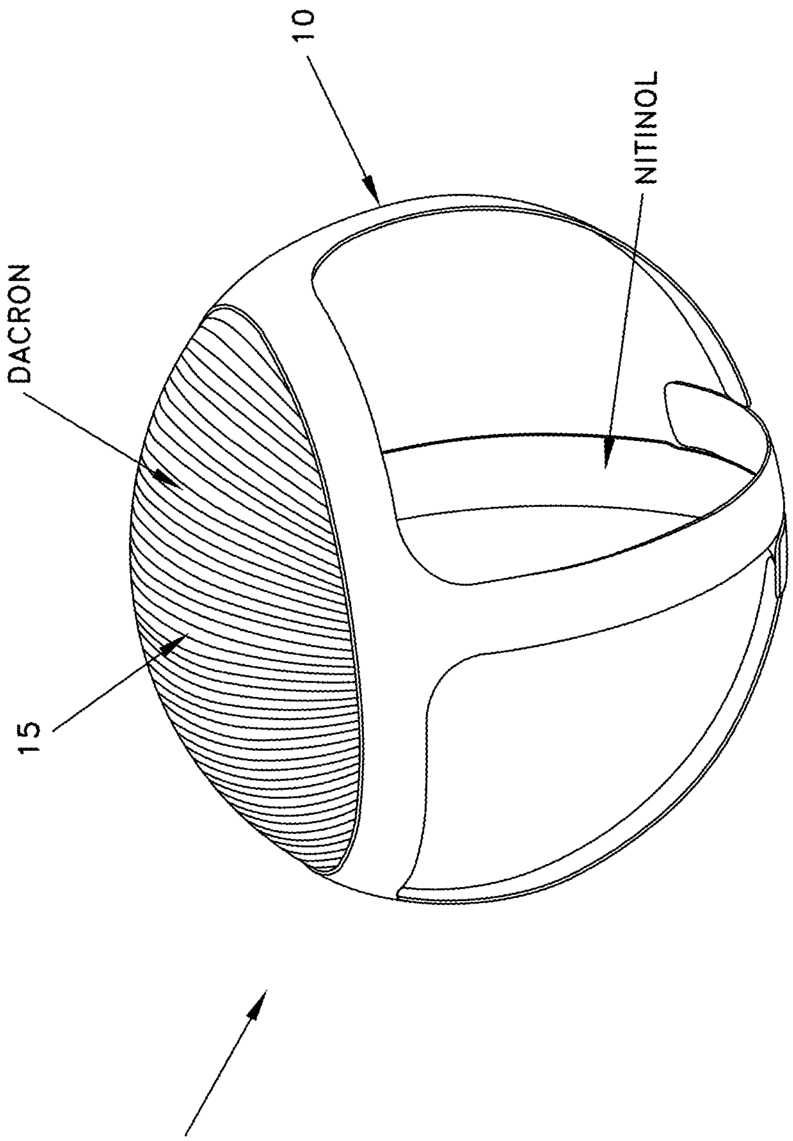

FIG. 55

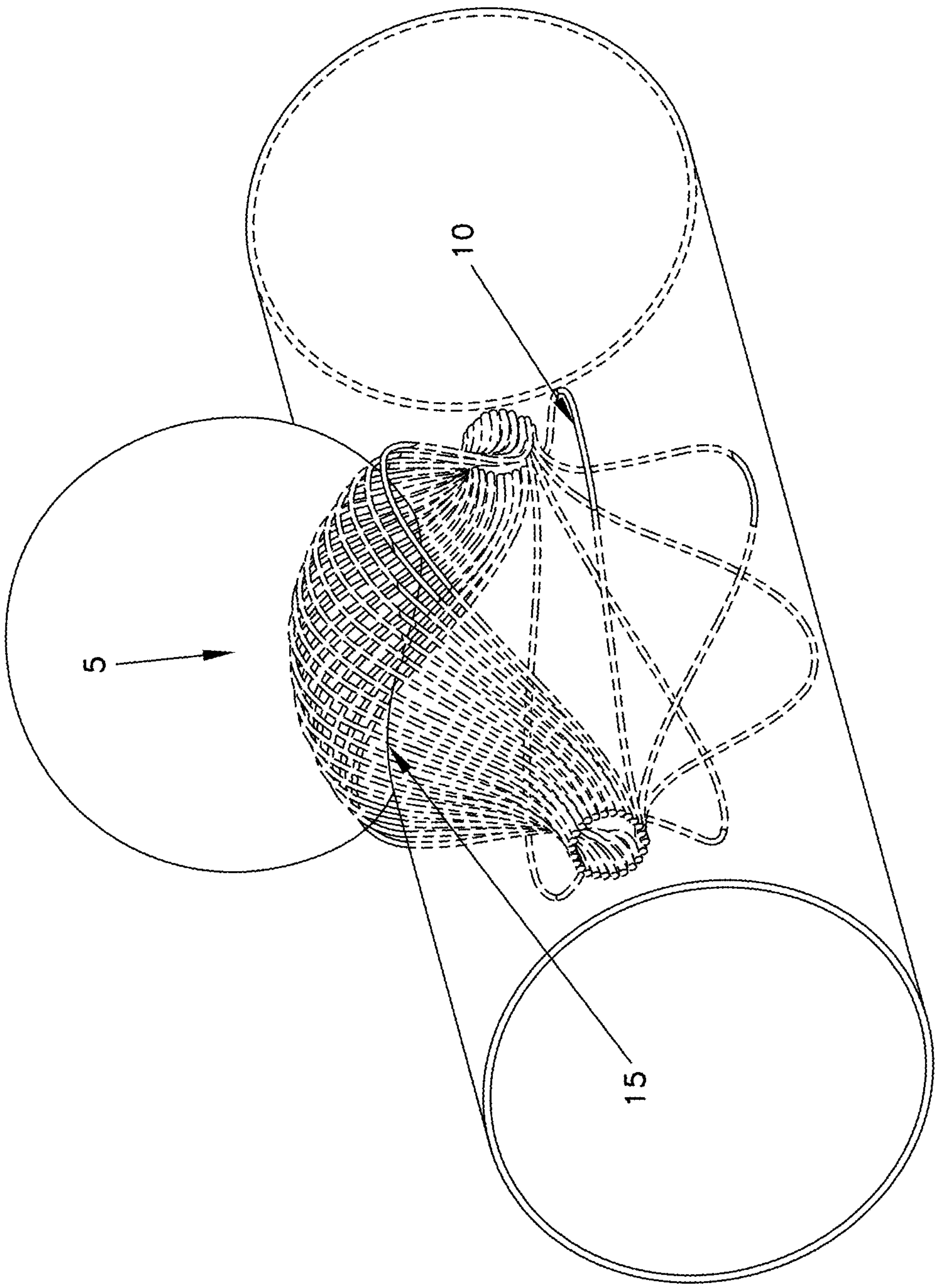

FIG. 56

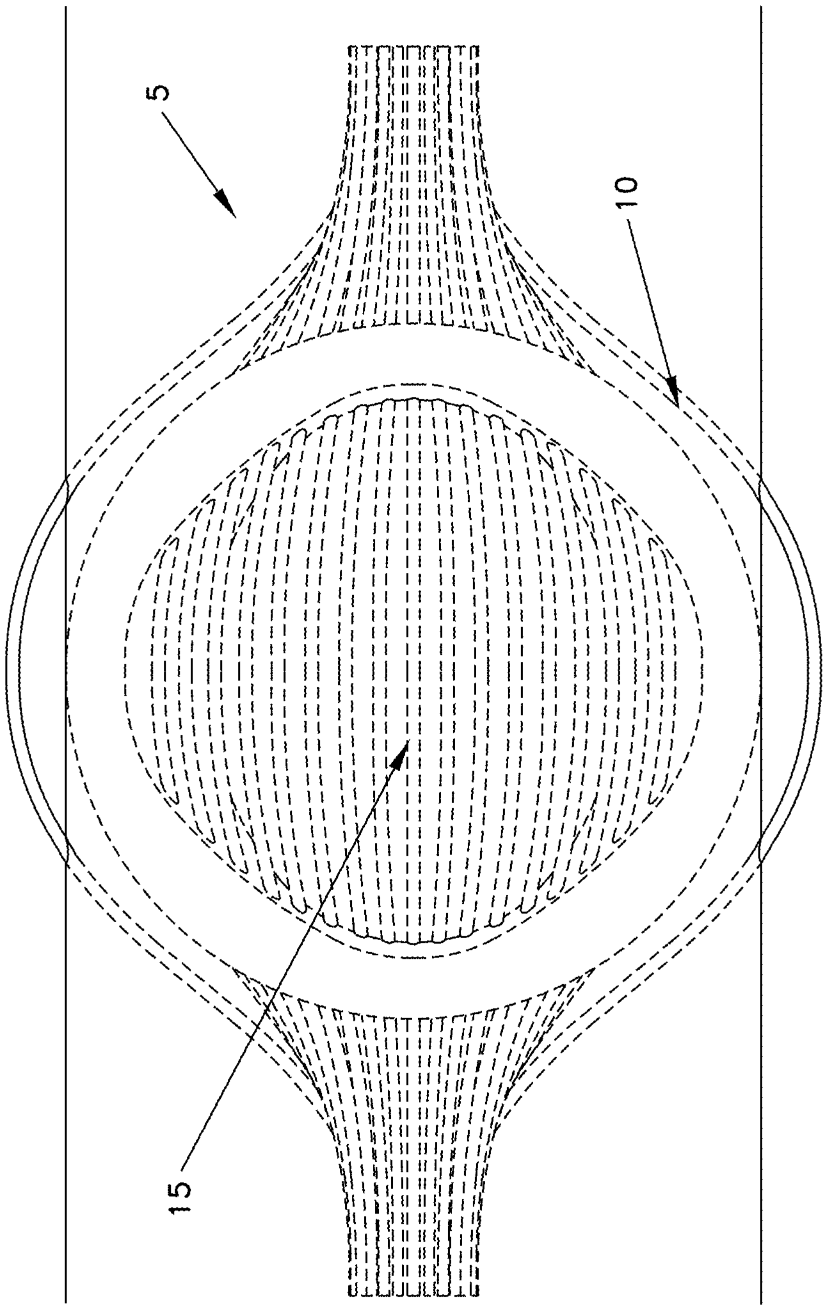

FIG. 57

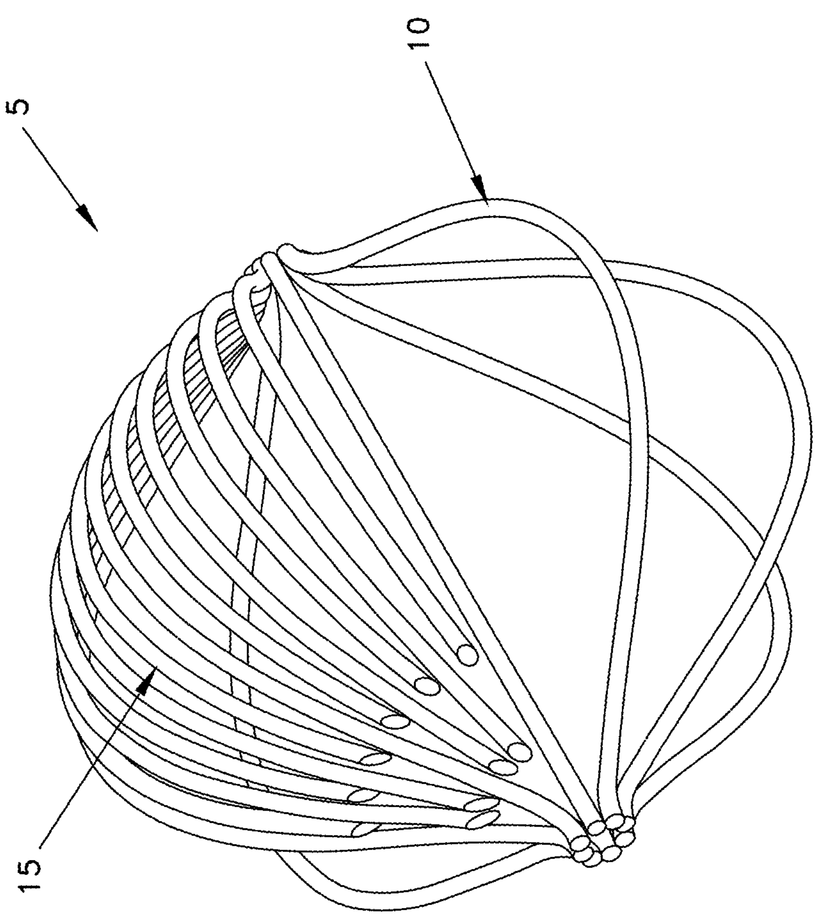

FIG. 58

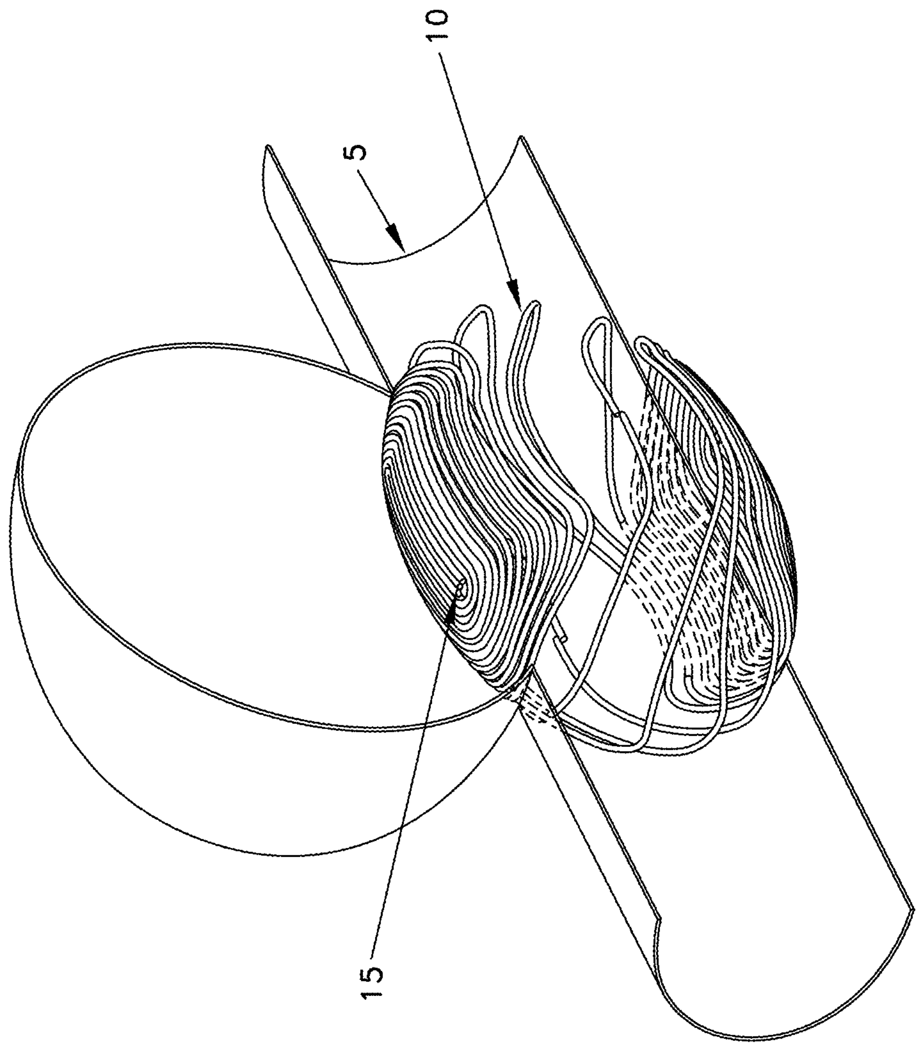

FIG. 59

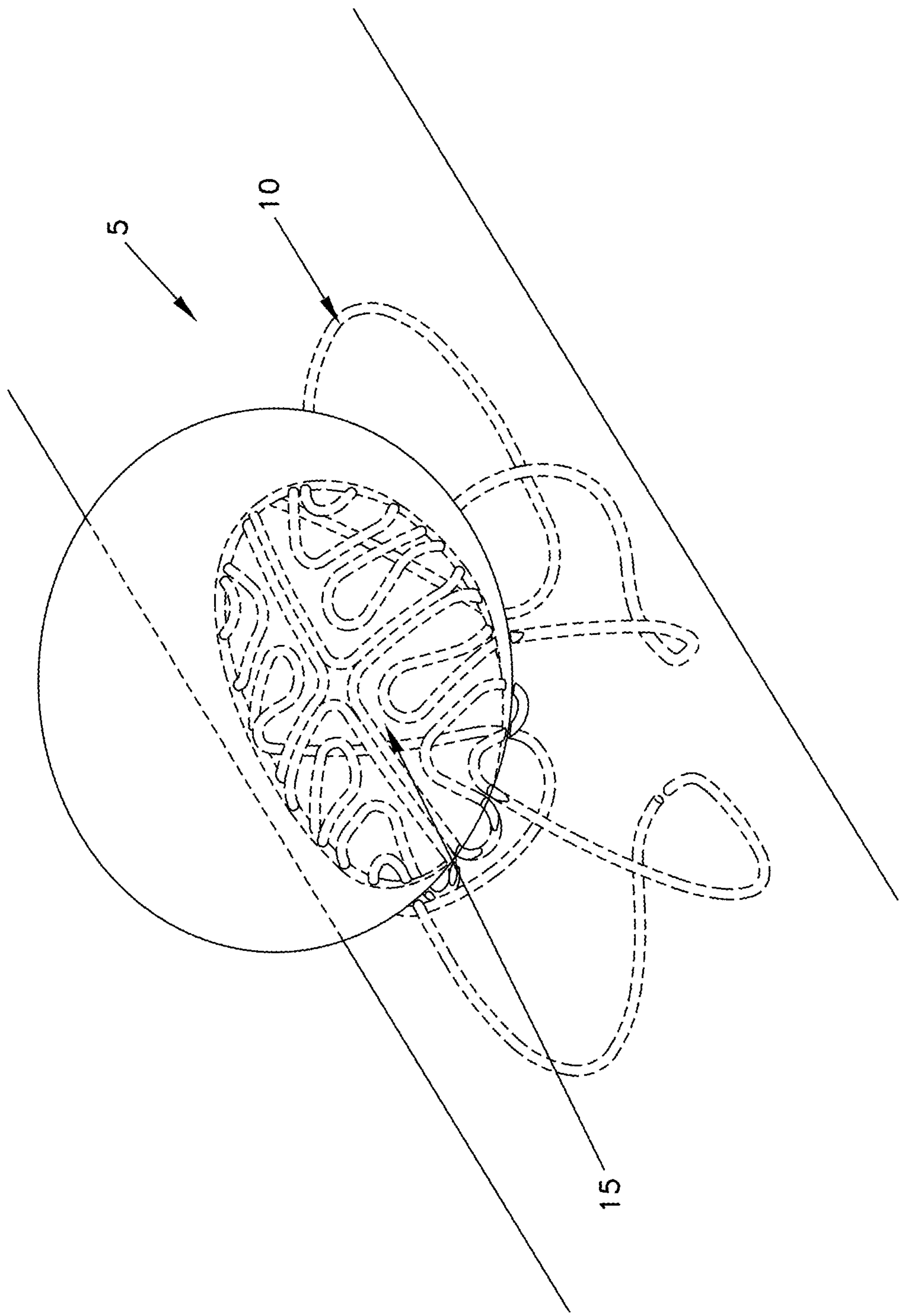

FIG. 60

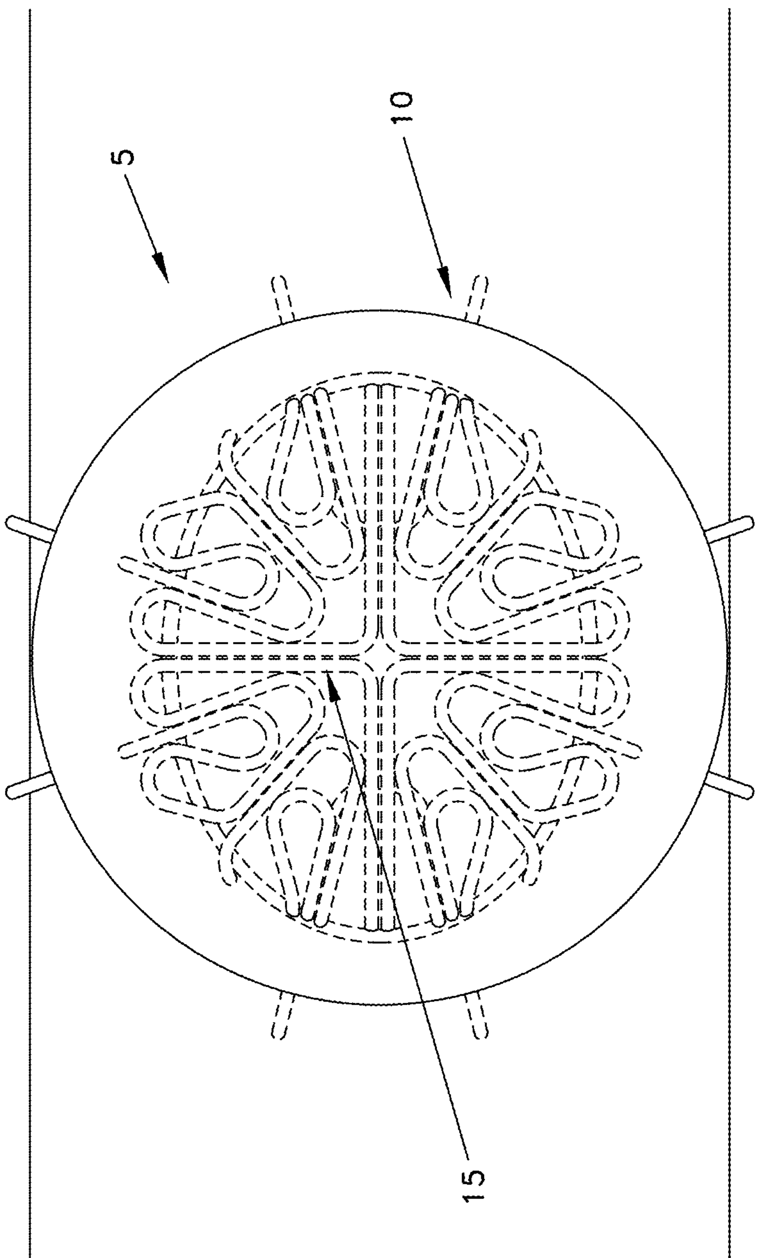

FIG. 61

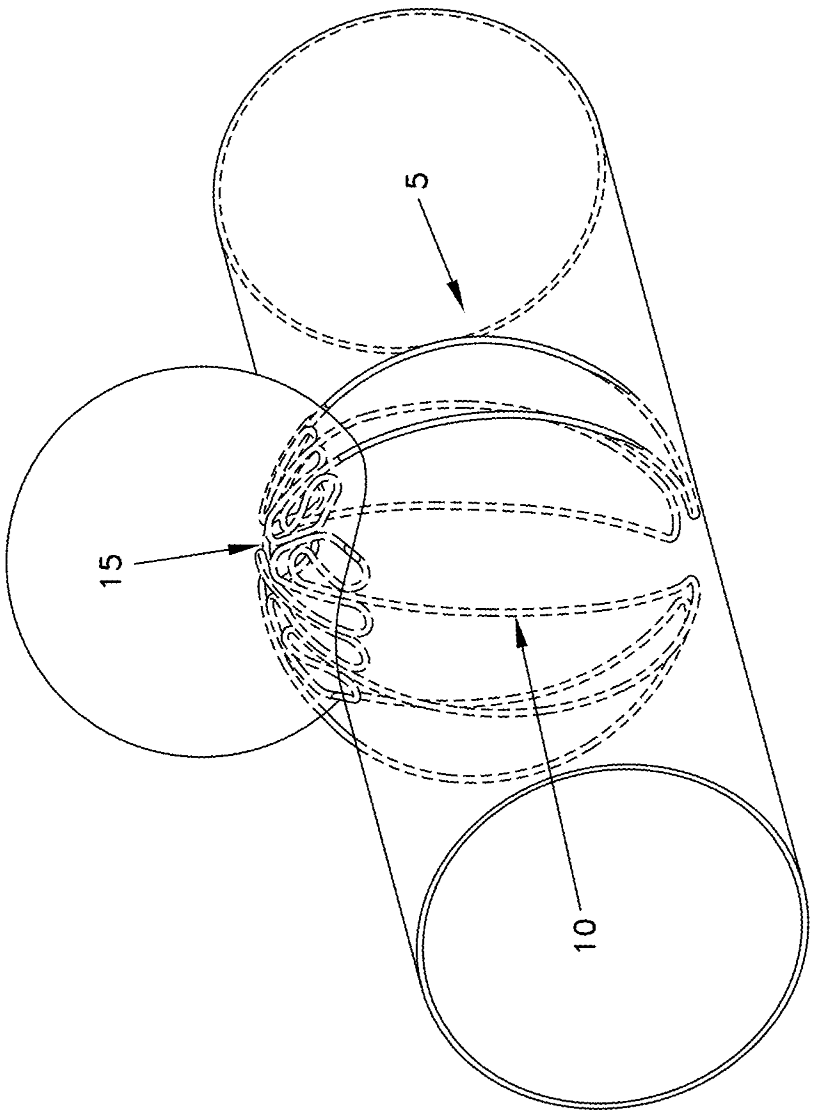

FIG. 62

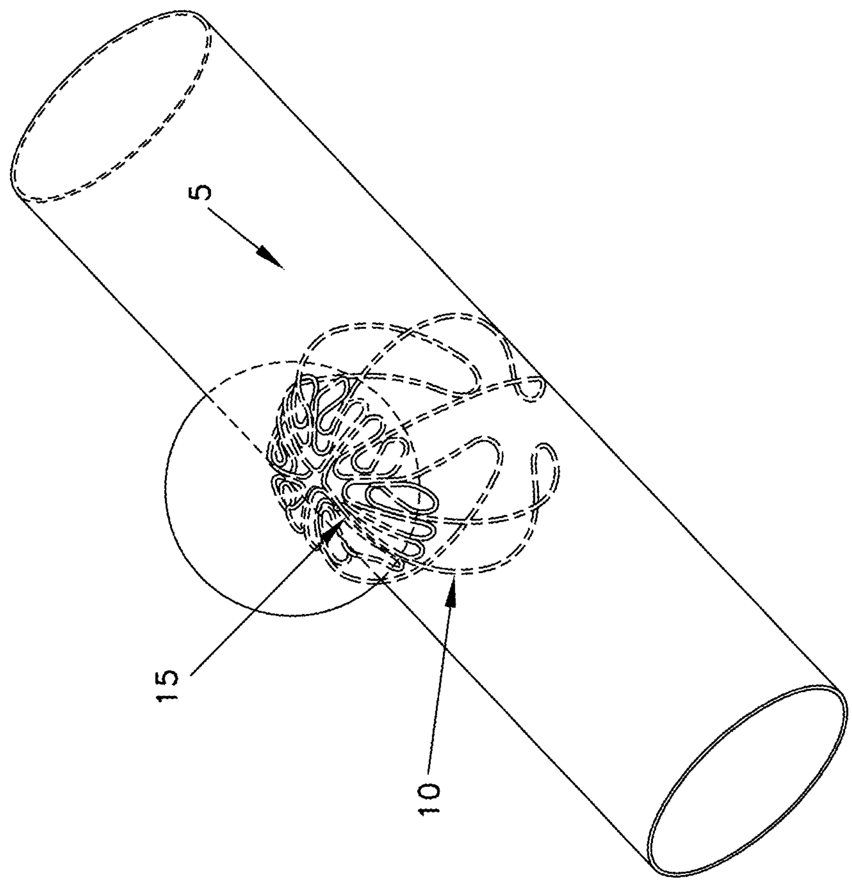

FIG. 63

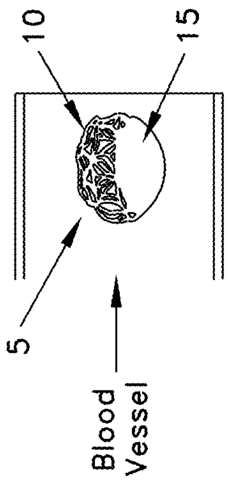

FIG. 64

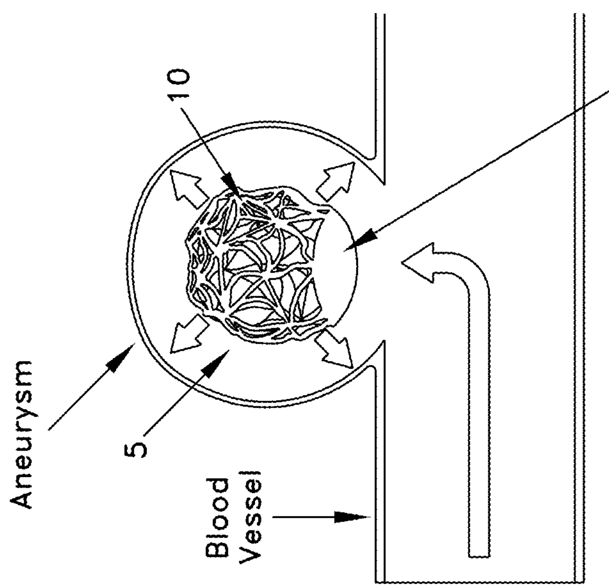

FIG. 65

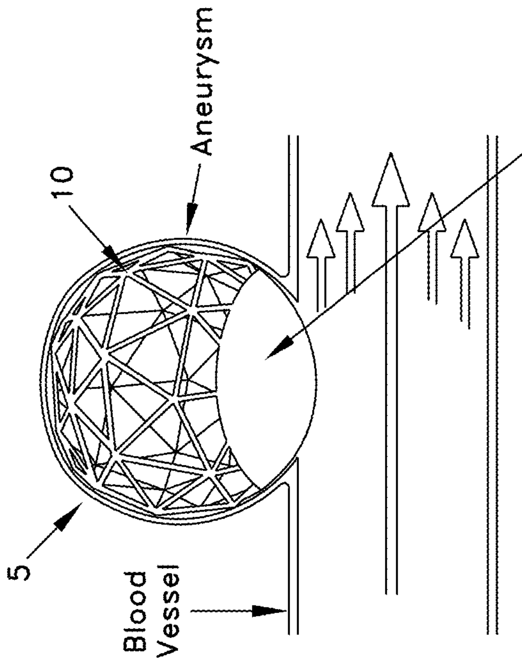

FIG. 66

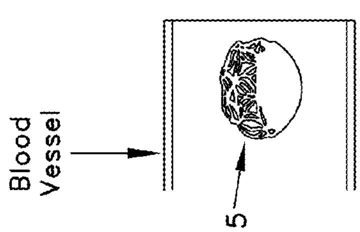

FIG. 67

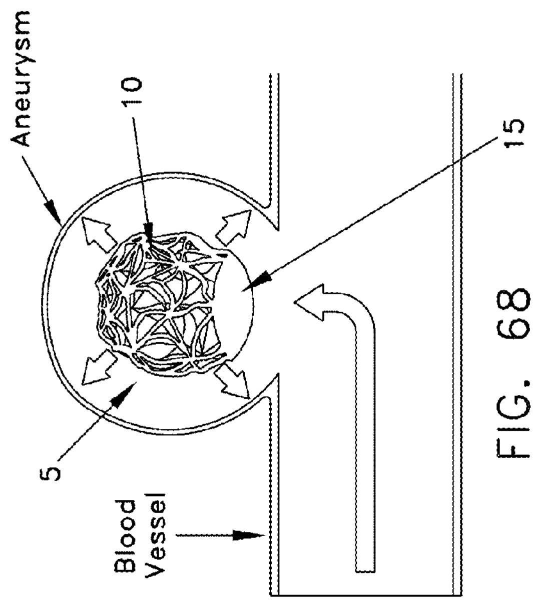

FIG. 68

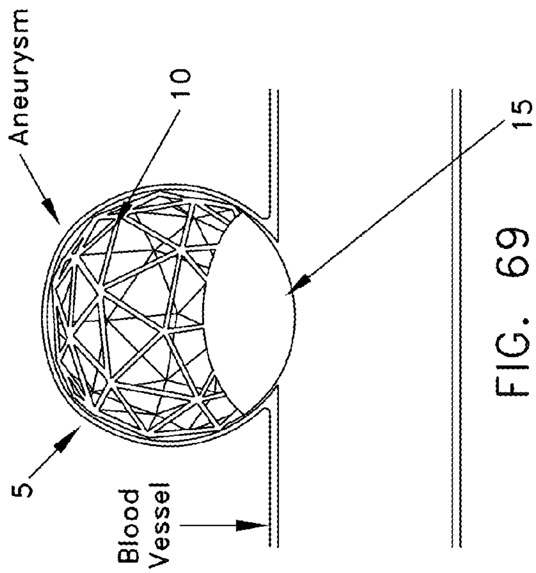

FIG. 69

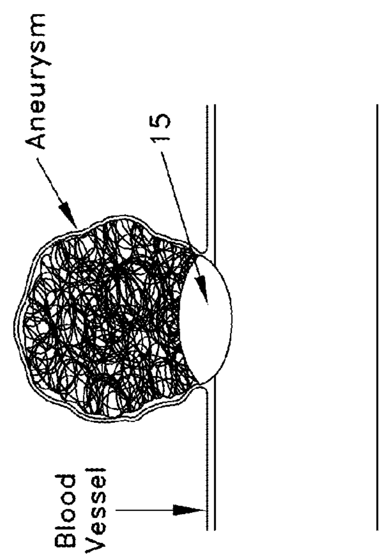

FIG. 70

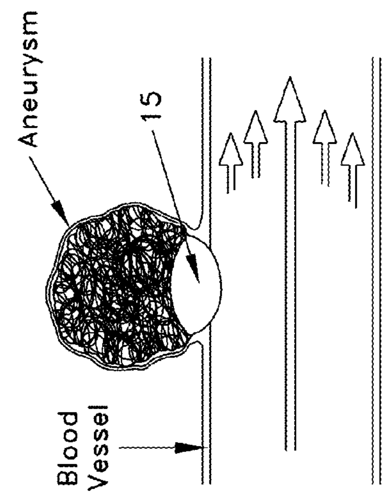

FIG. 71

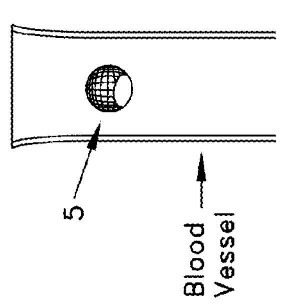

FIG. 72

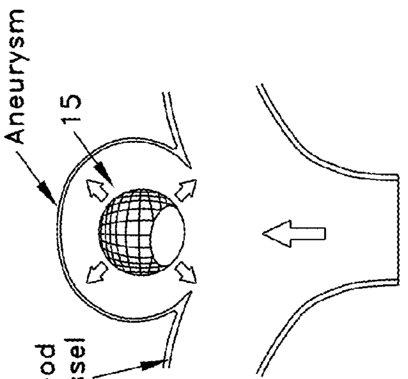

FIG. 73

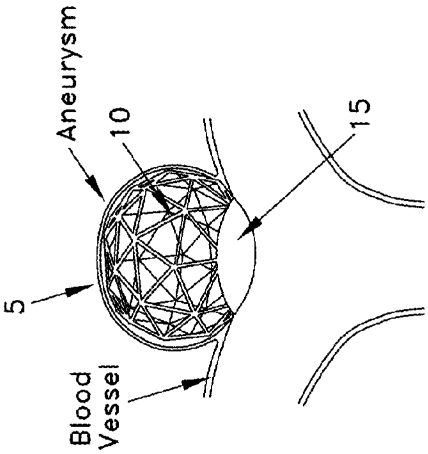

FIG. 74

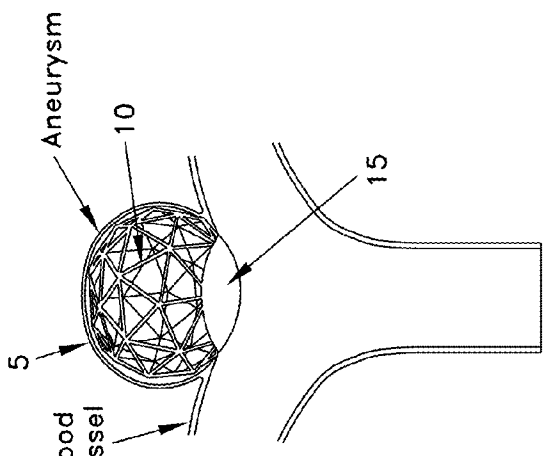

FIG. 75

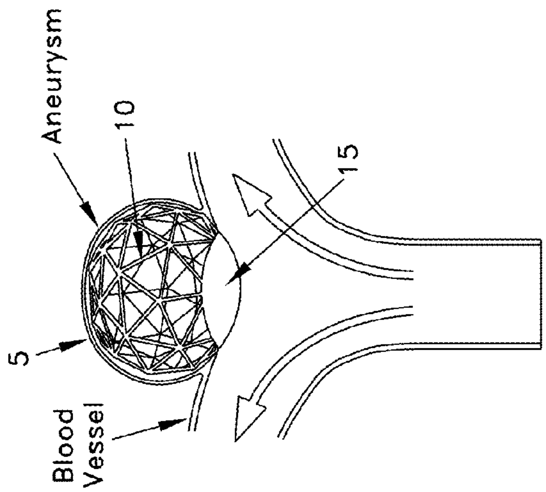

FIG. 76

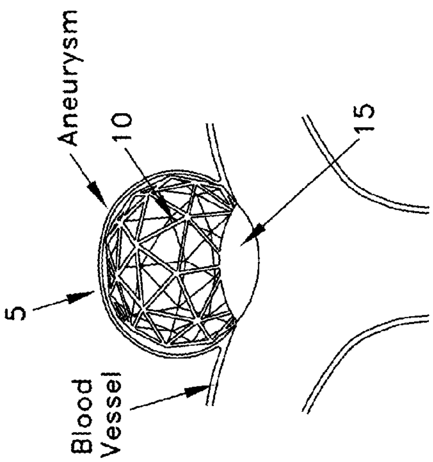

FIG. 79

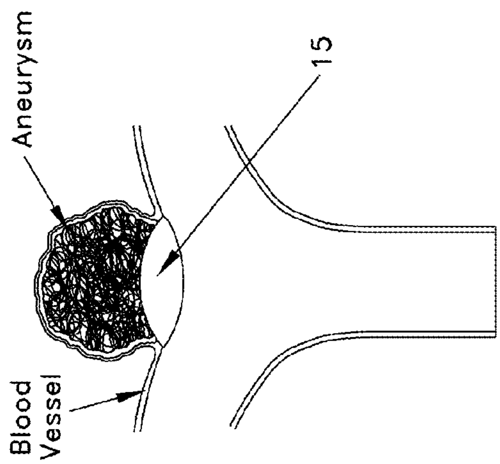

FIG. 81

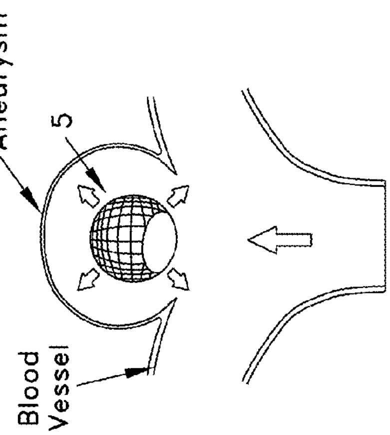

FIG. 78

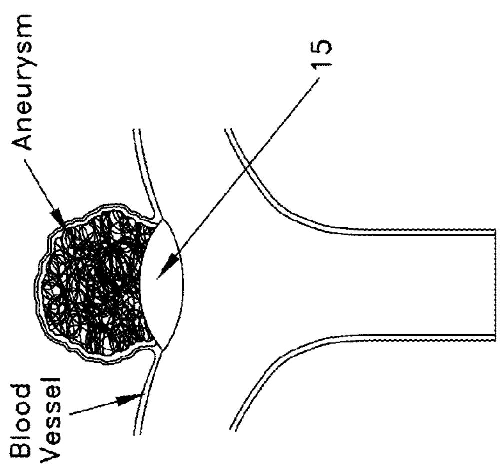

FIG. 80

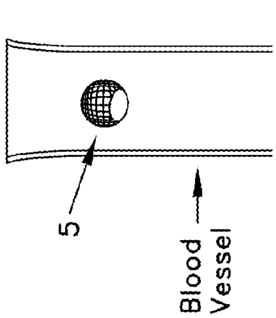

FIG. 77

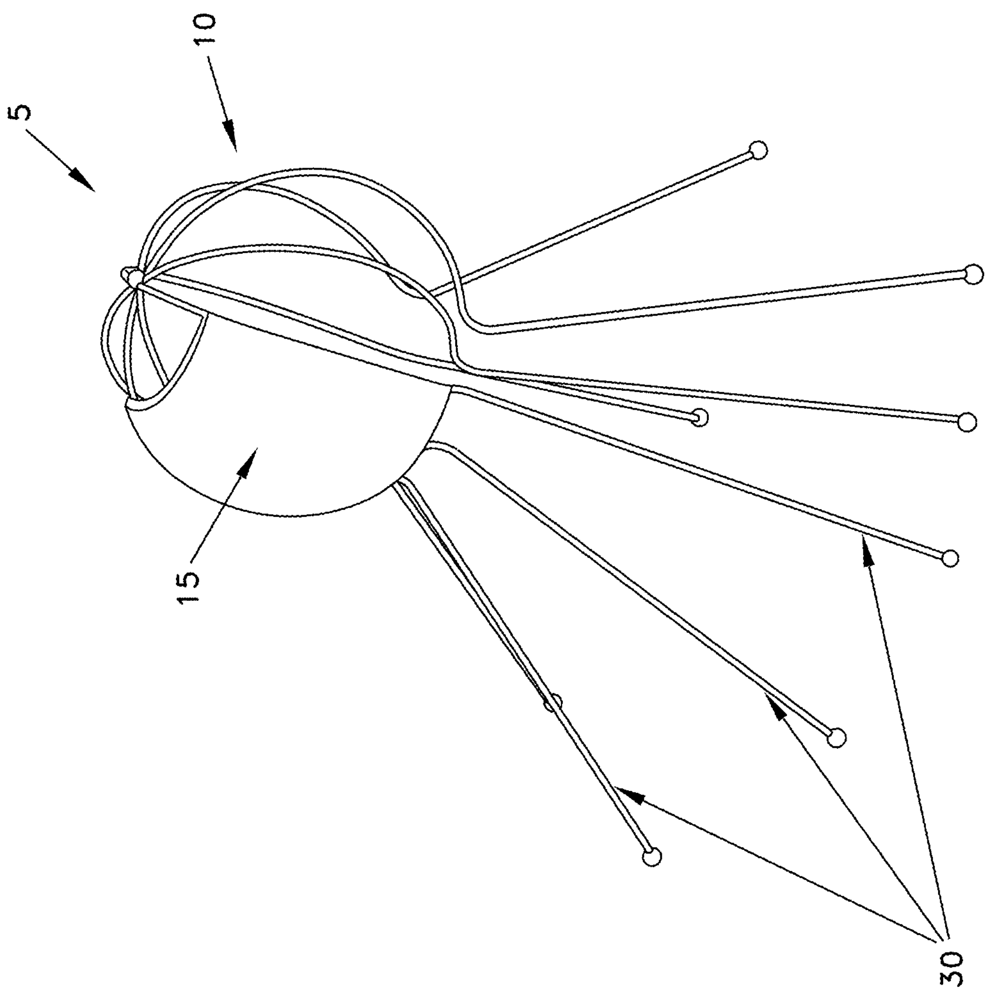

FIG. 82

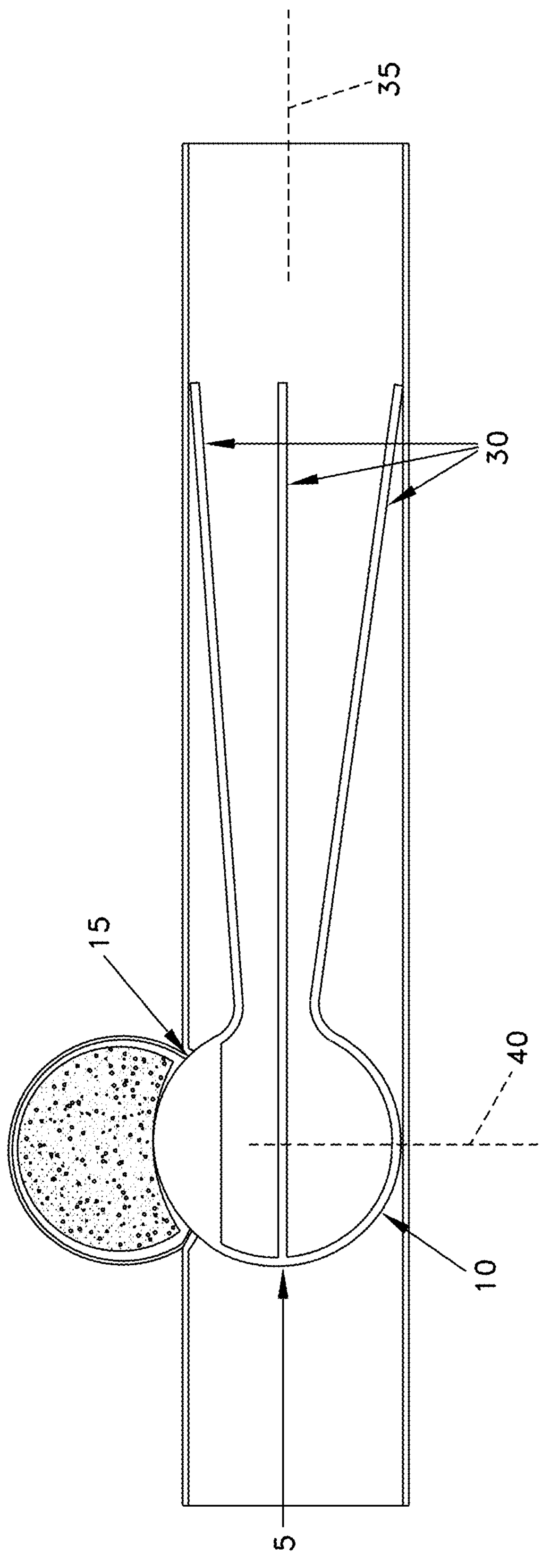

FIG. 83

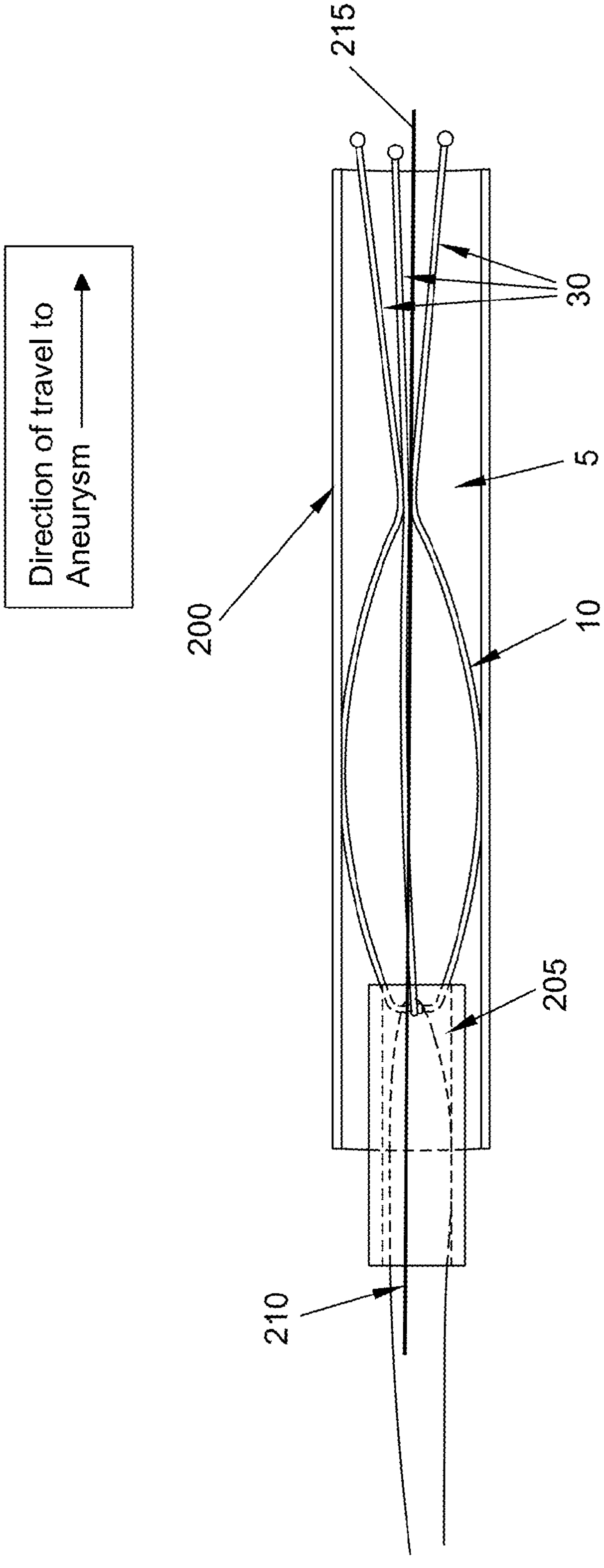

FIG. 84

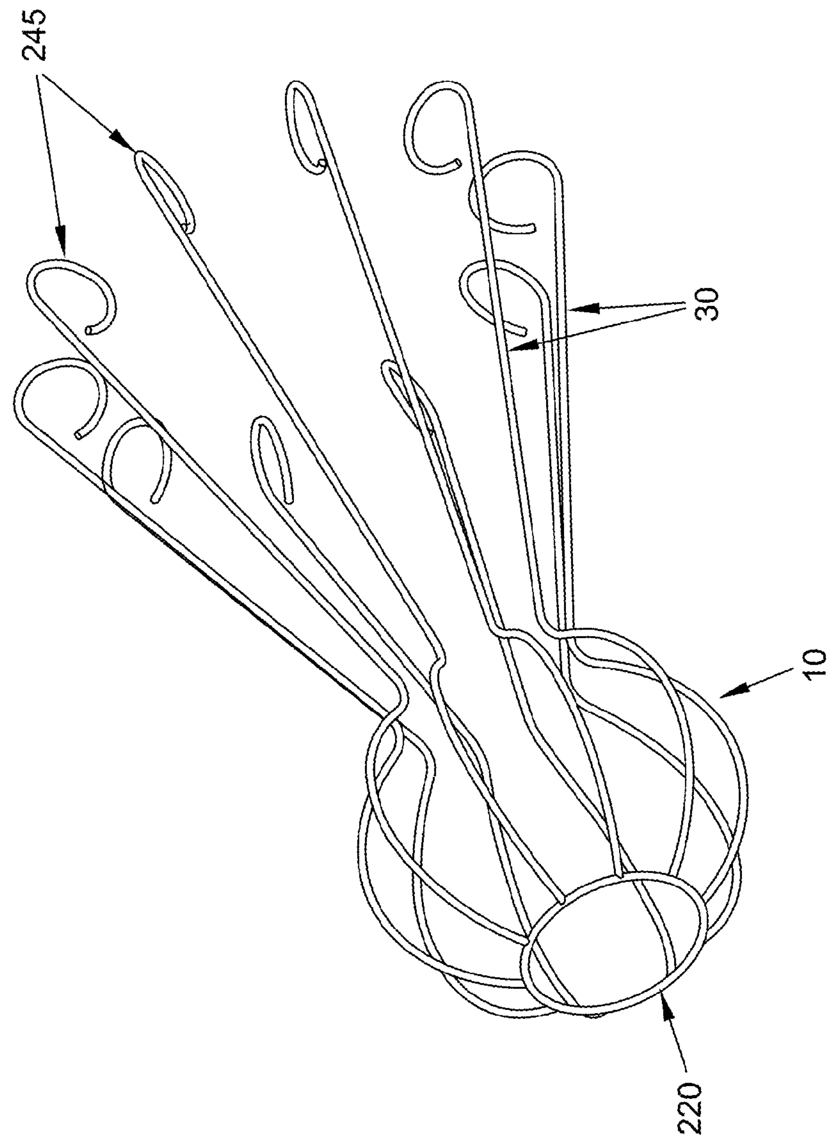

FIG. 85

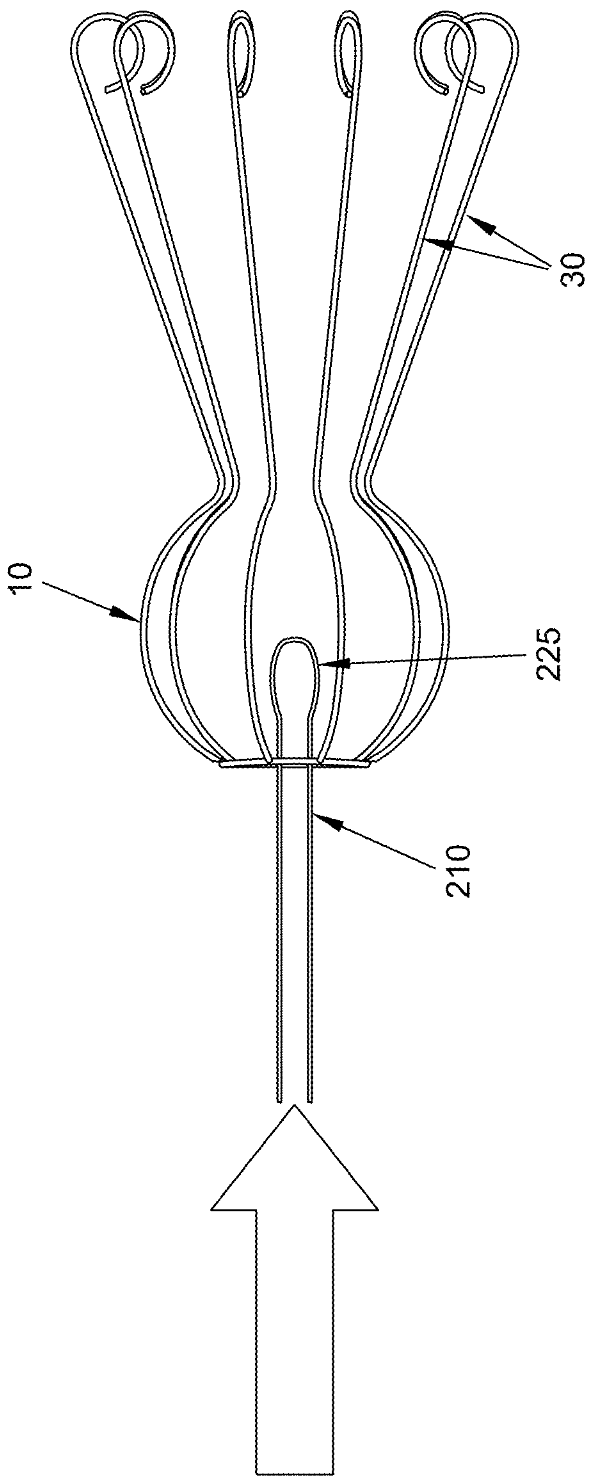

FIG. 86

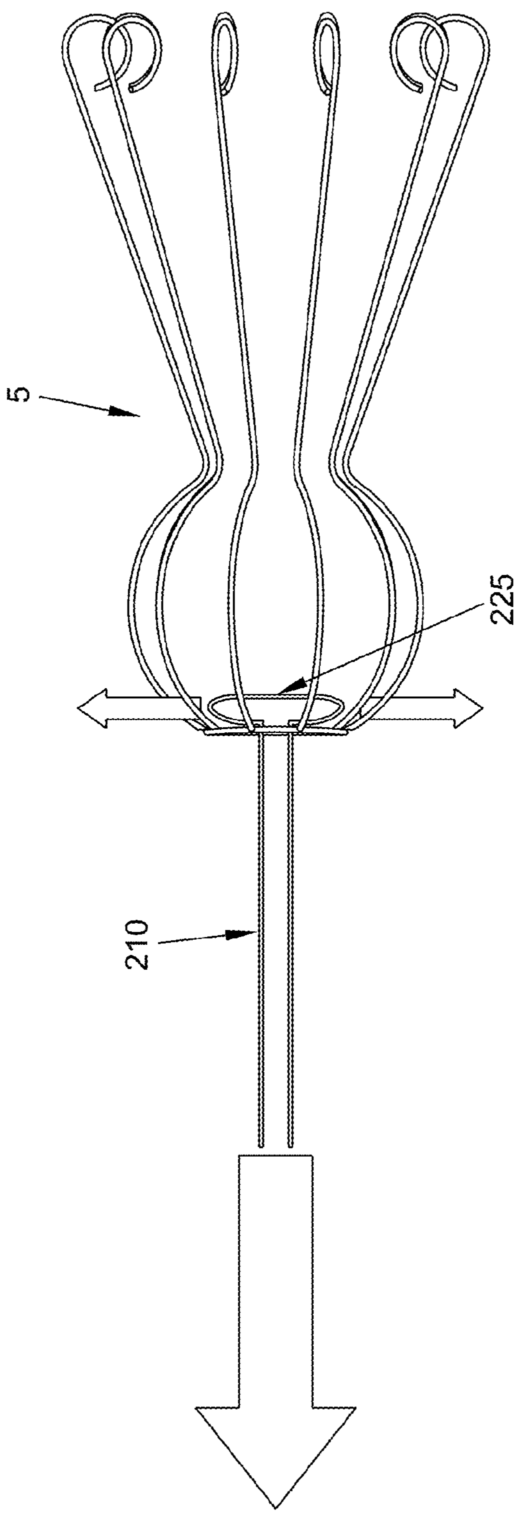

FIG. 87

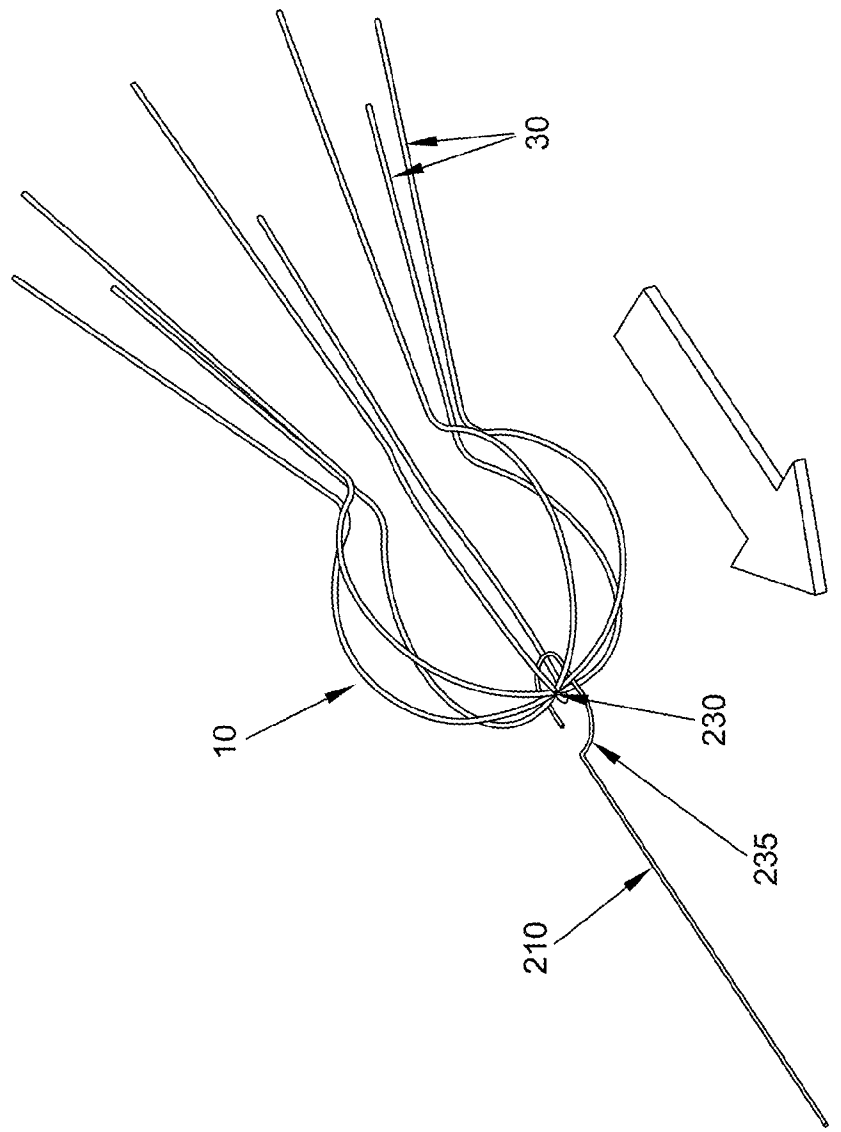

FIG. 88

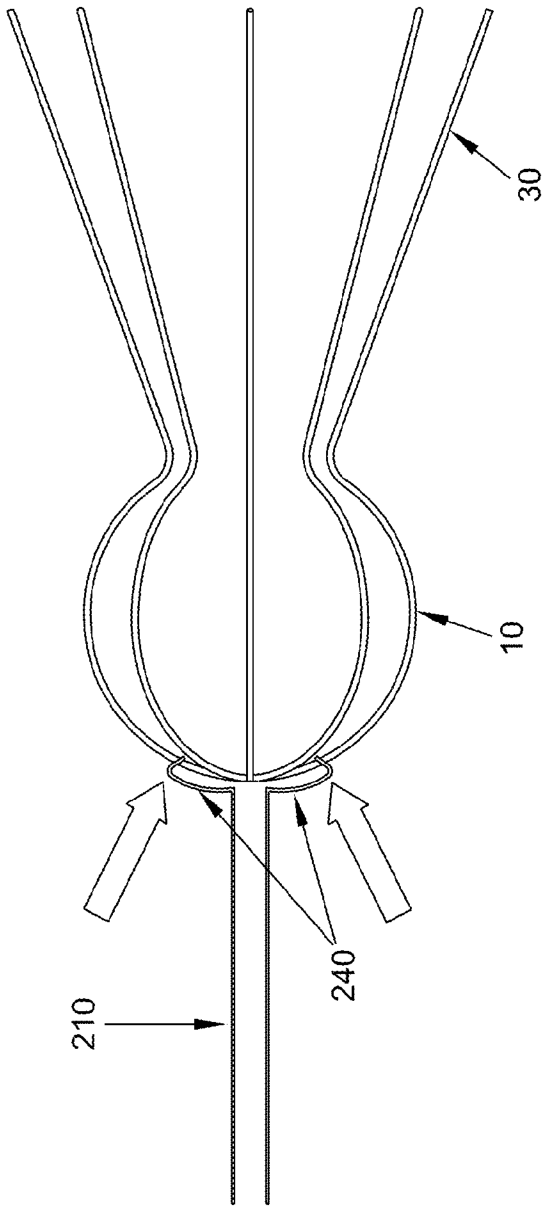

FIG. 89

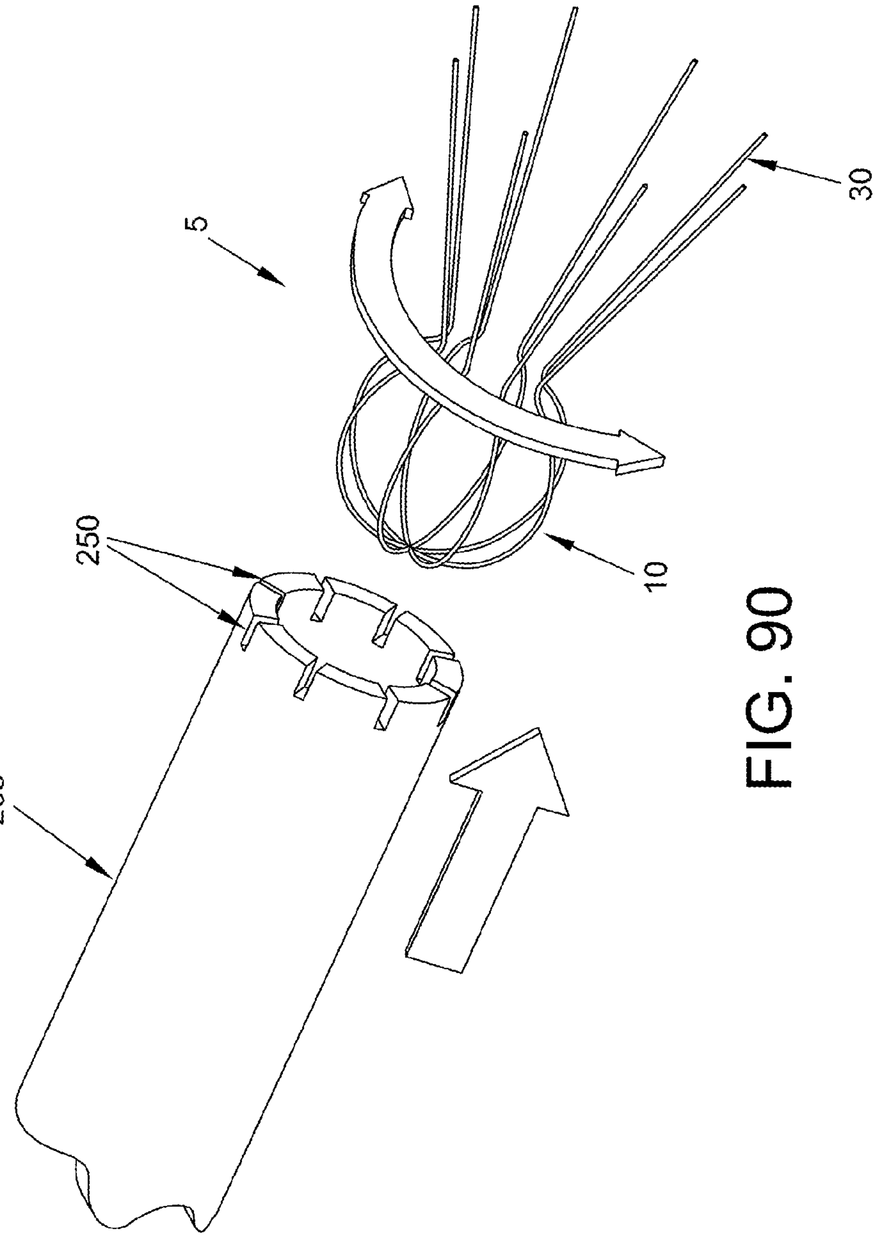

FIG. 90

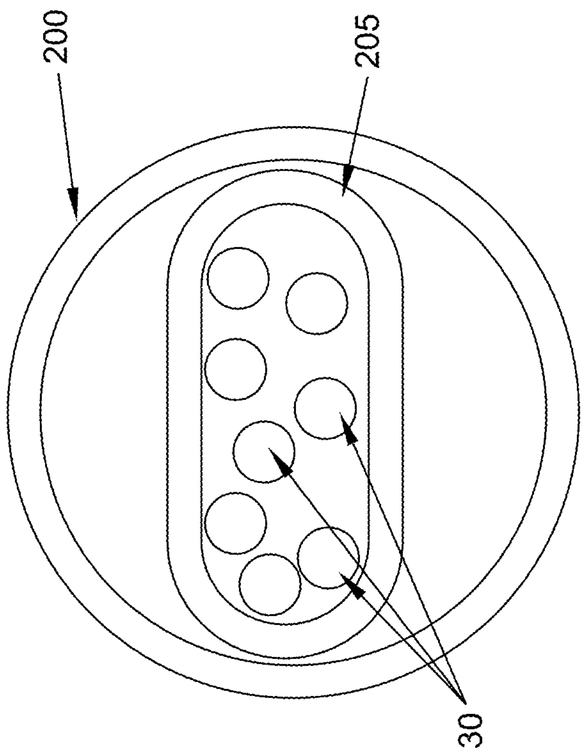

FIG. 91

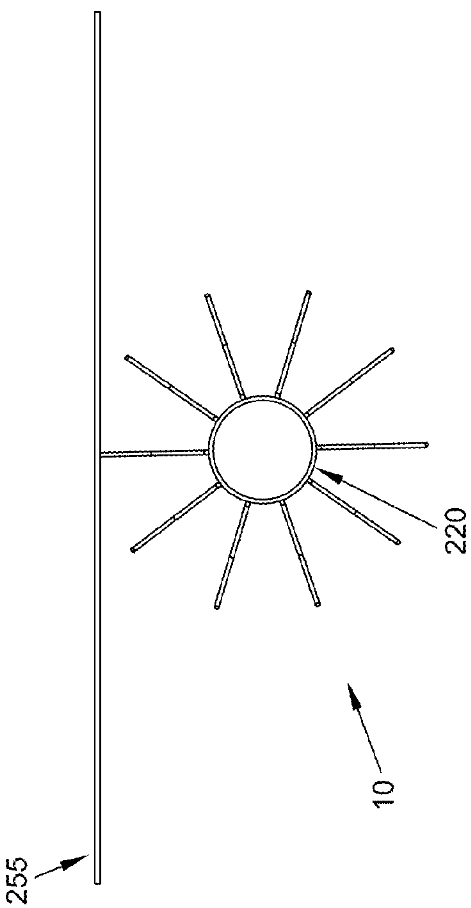

FIG. 92

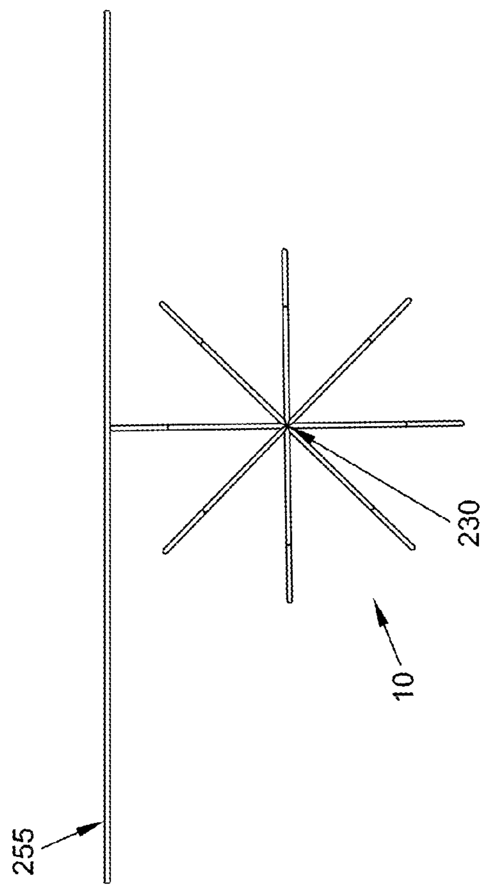

FIG. 93

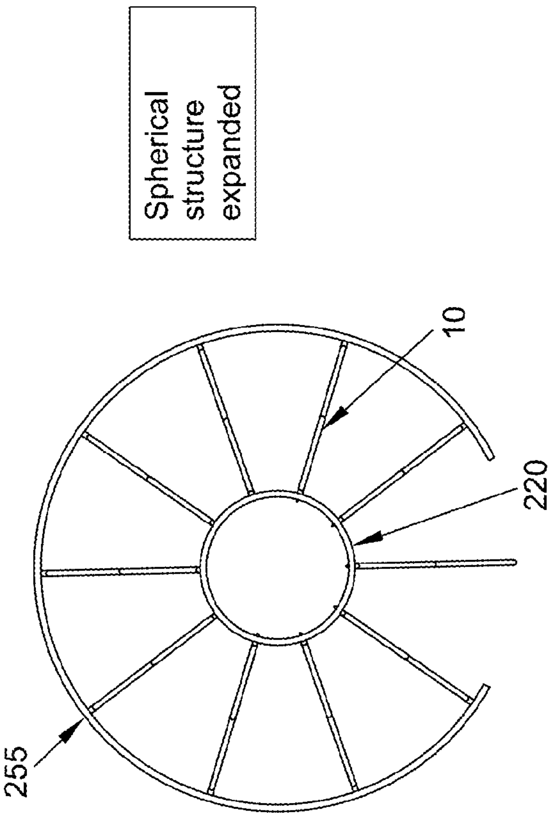

FIG. 94

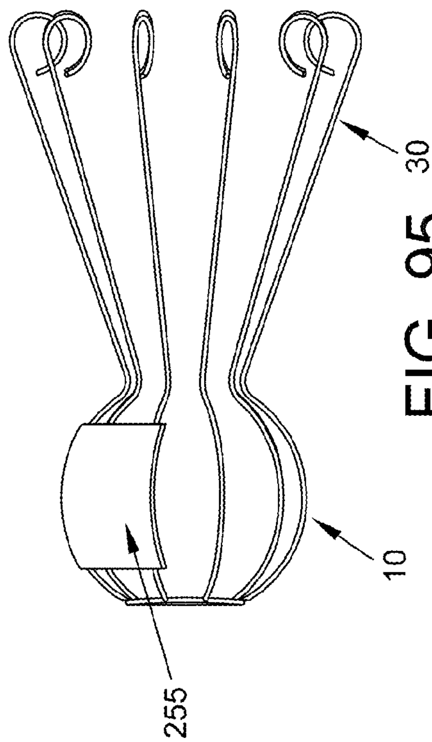

FIG. 95

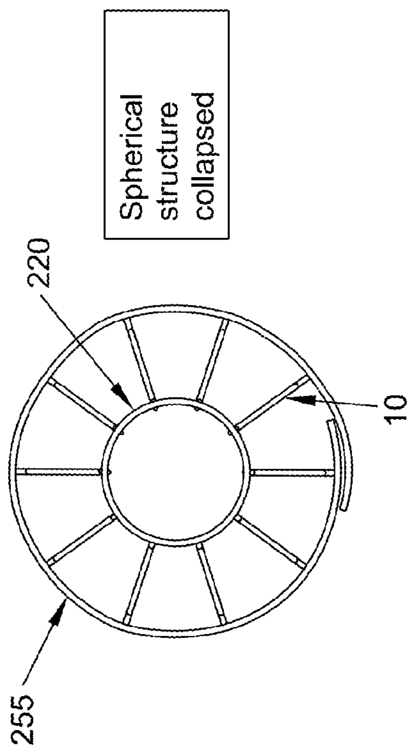

FIG. 96

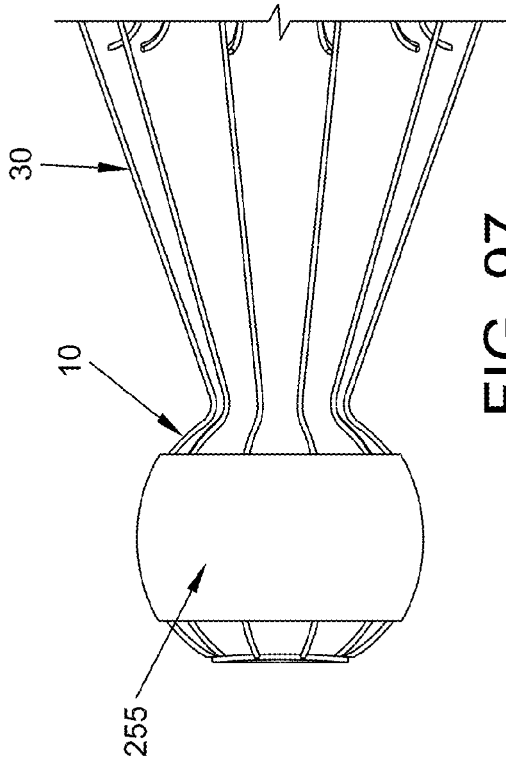

FIG. 97

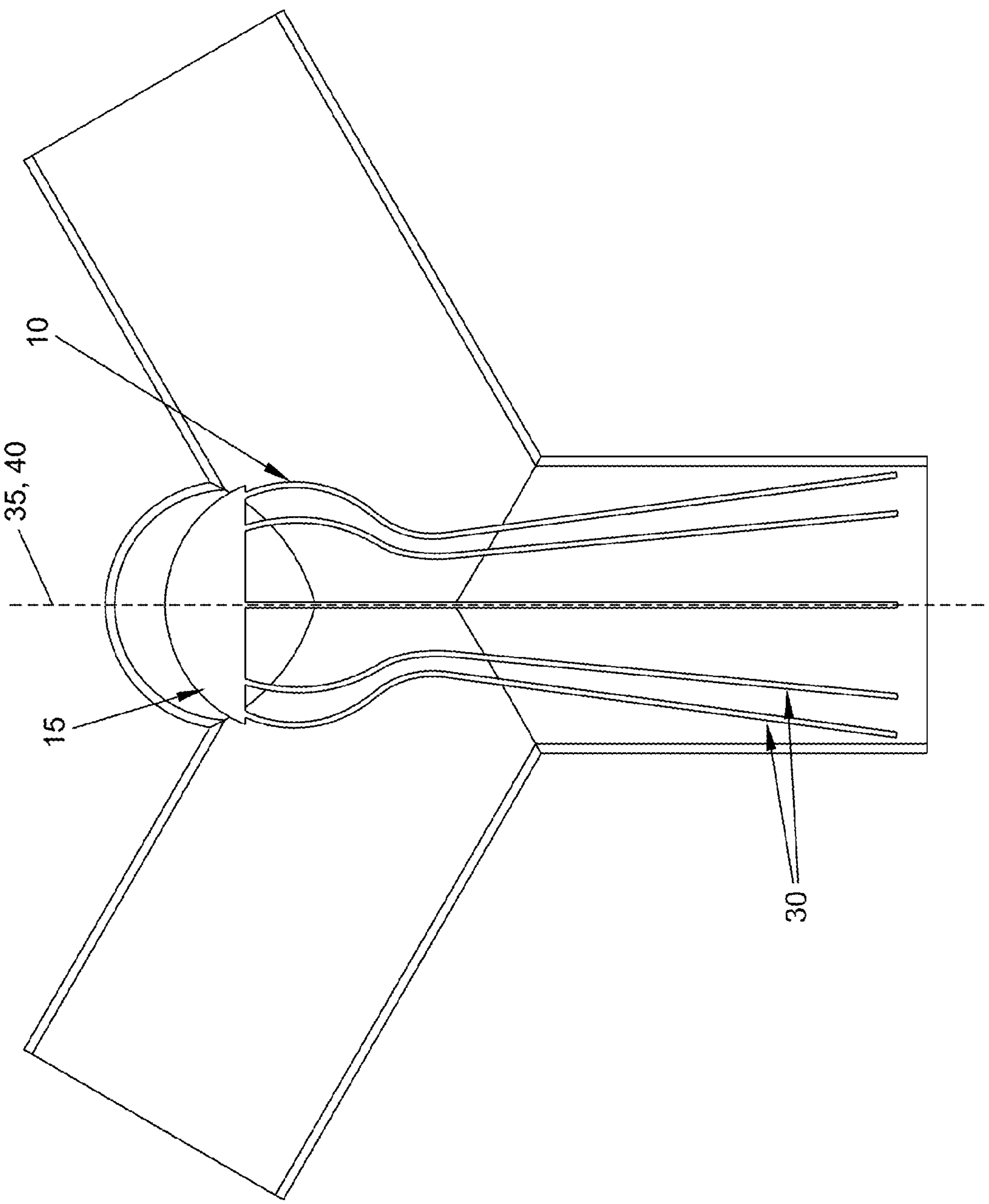

FIG. 98

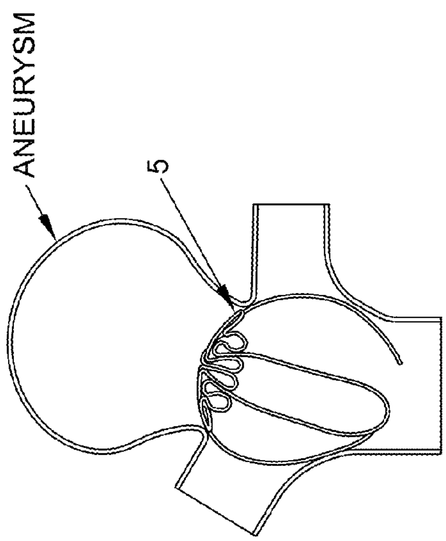

FIG. 99

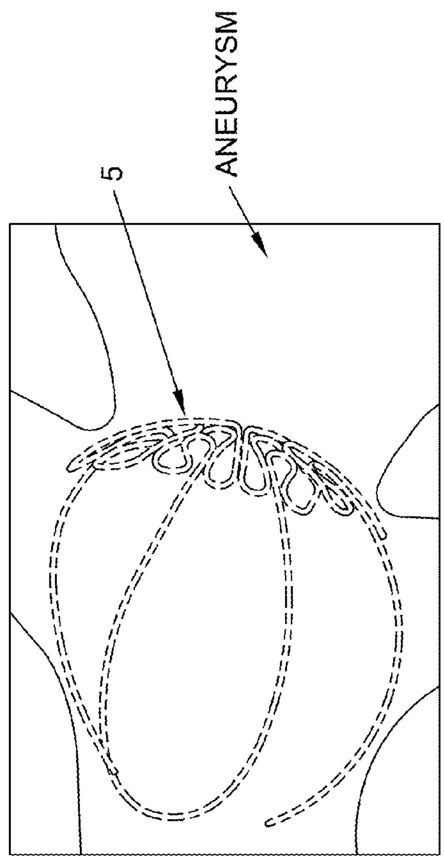

FIG. 100

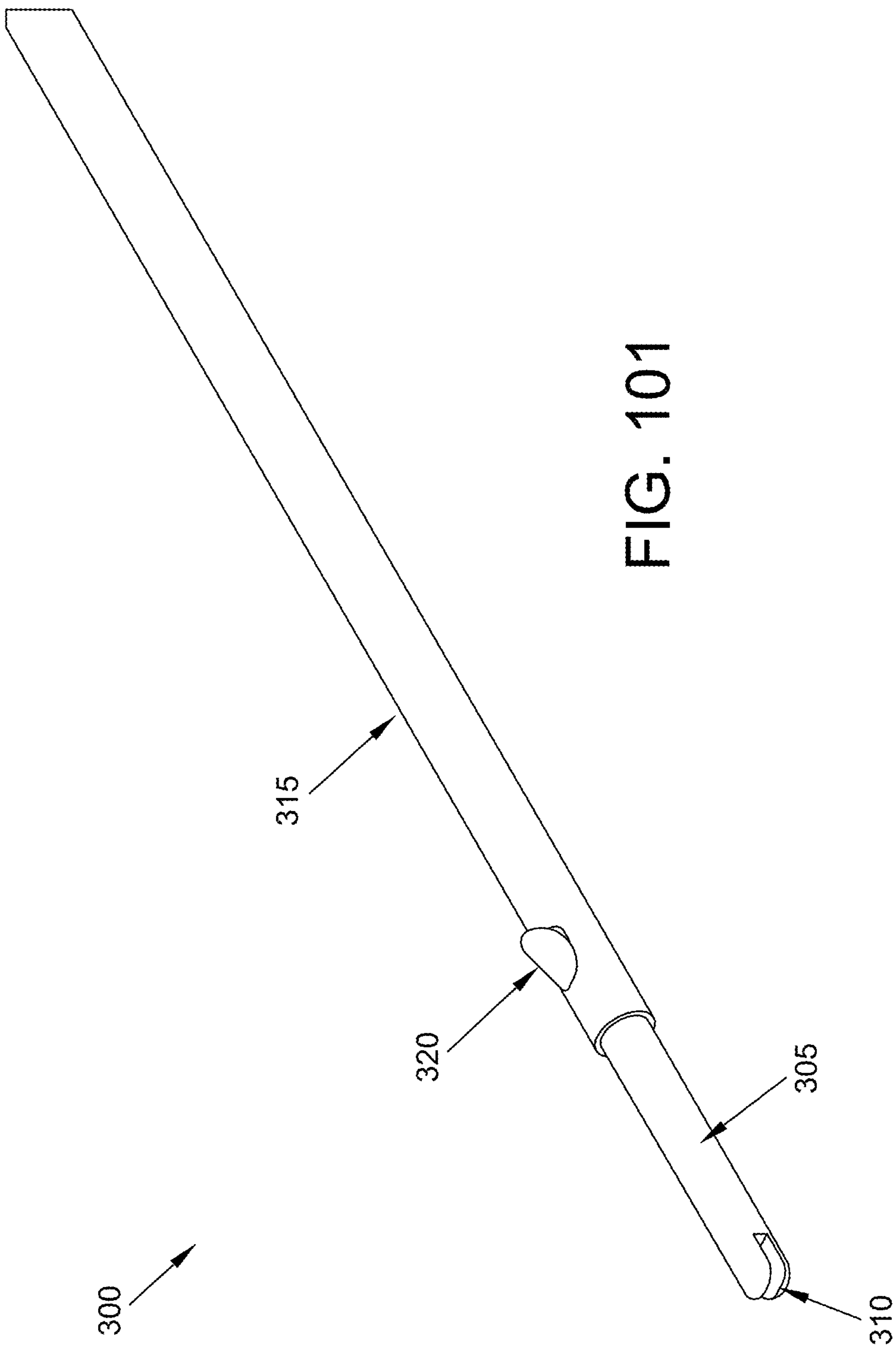

FIG. 101

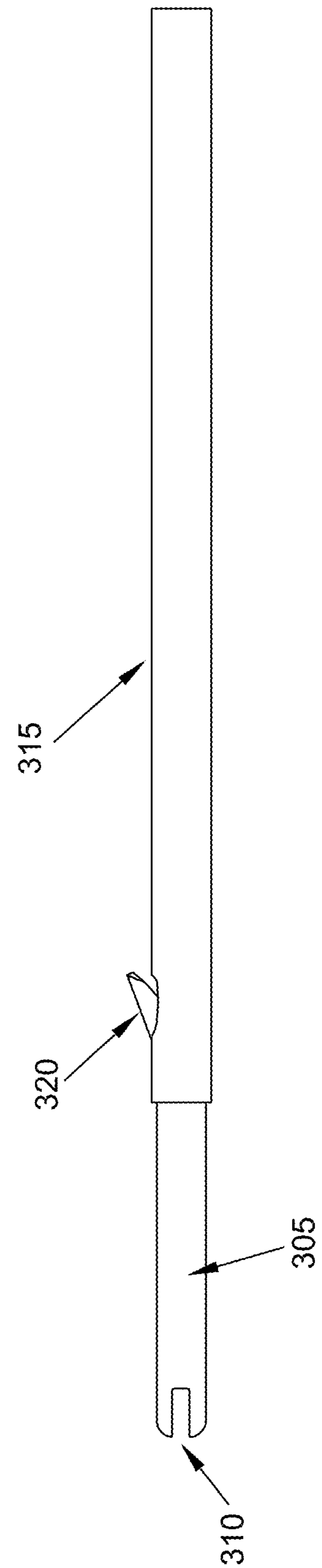

FIG. 102

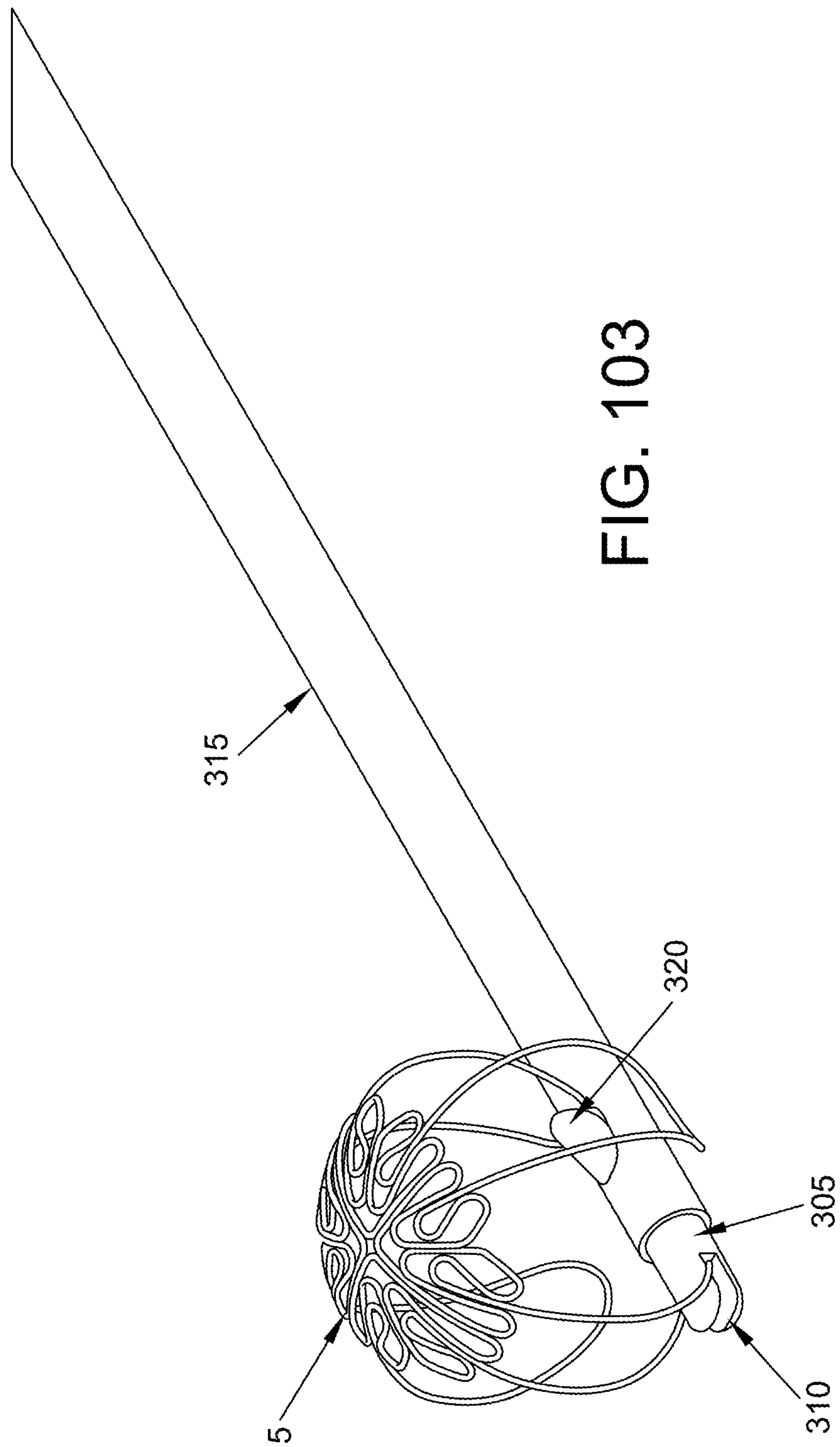

FIG. 103

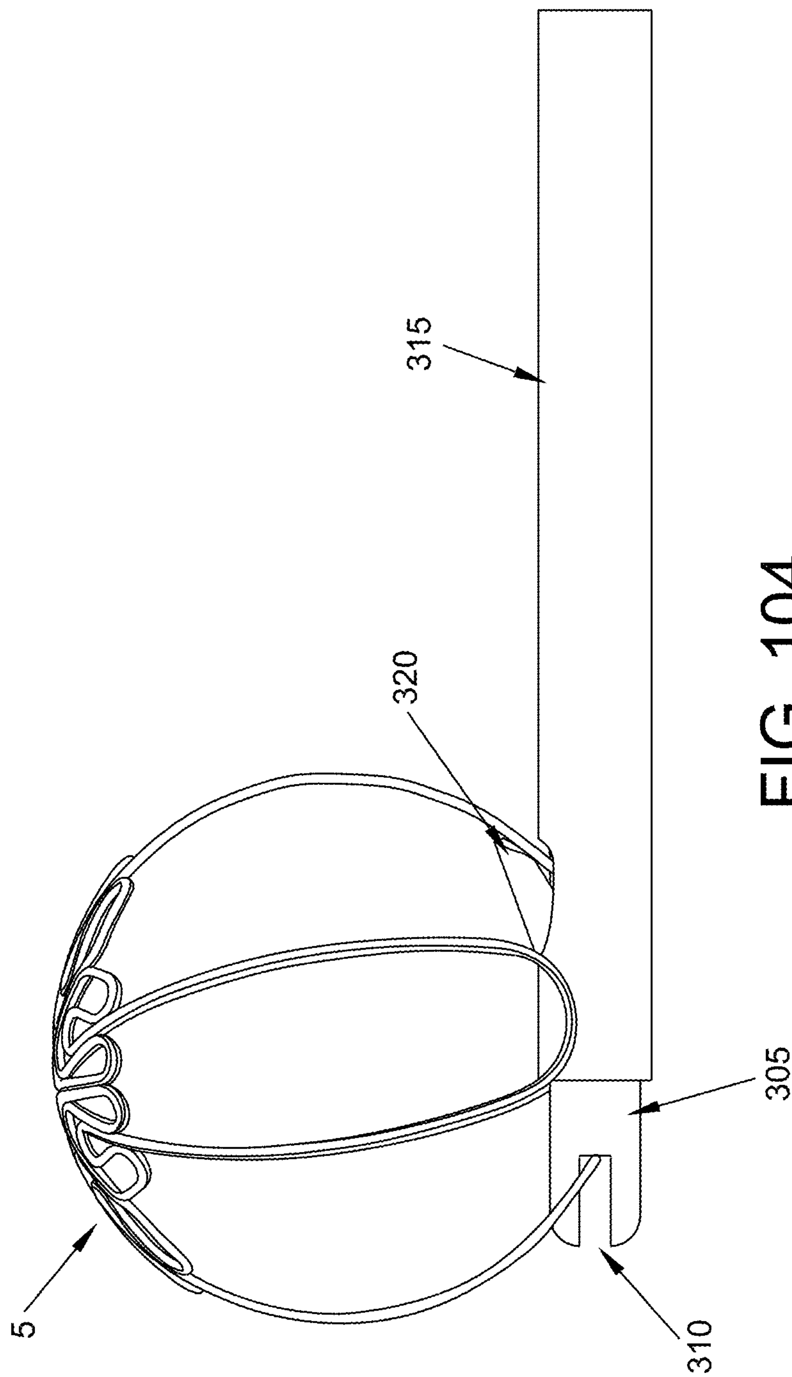

FIG. 104

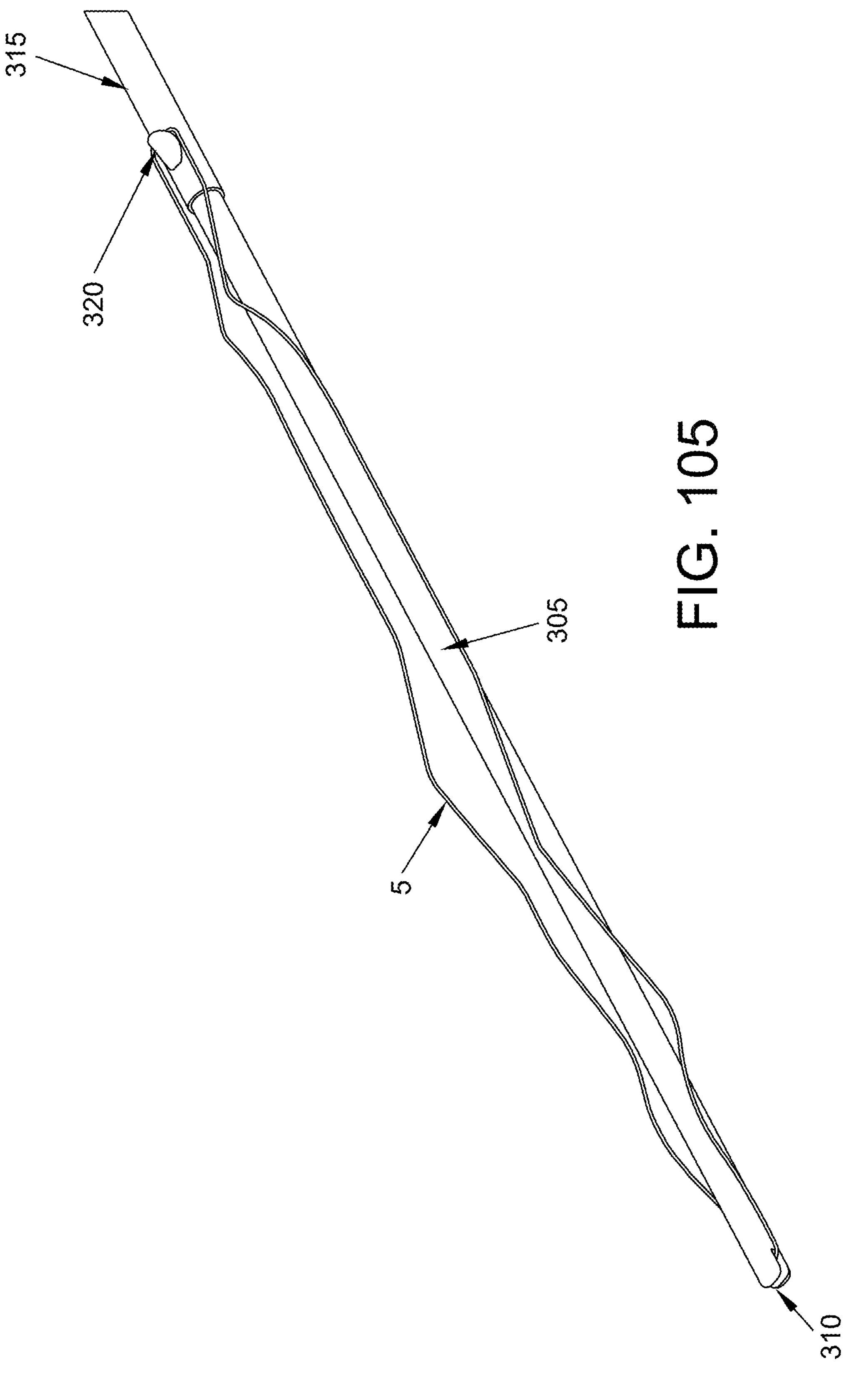

FIG. 105

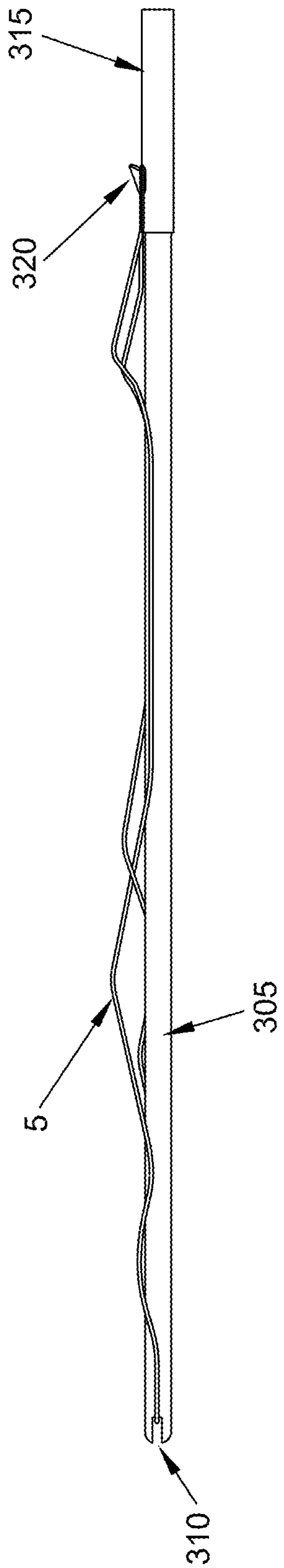

FIG. 106

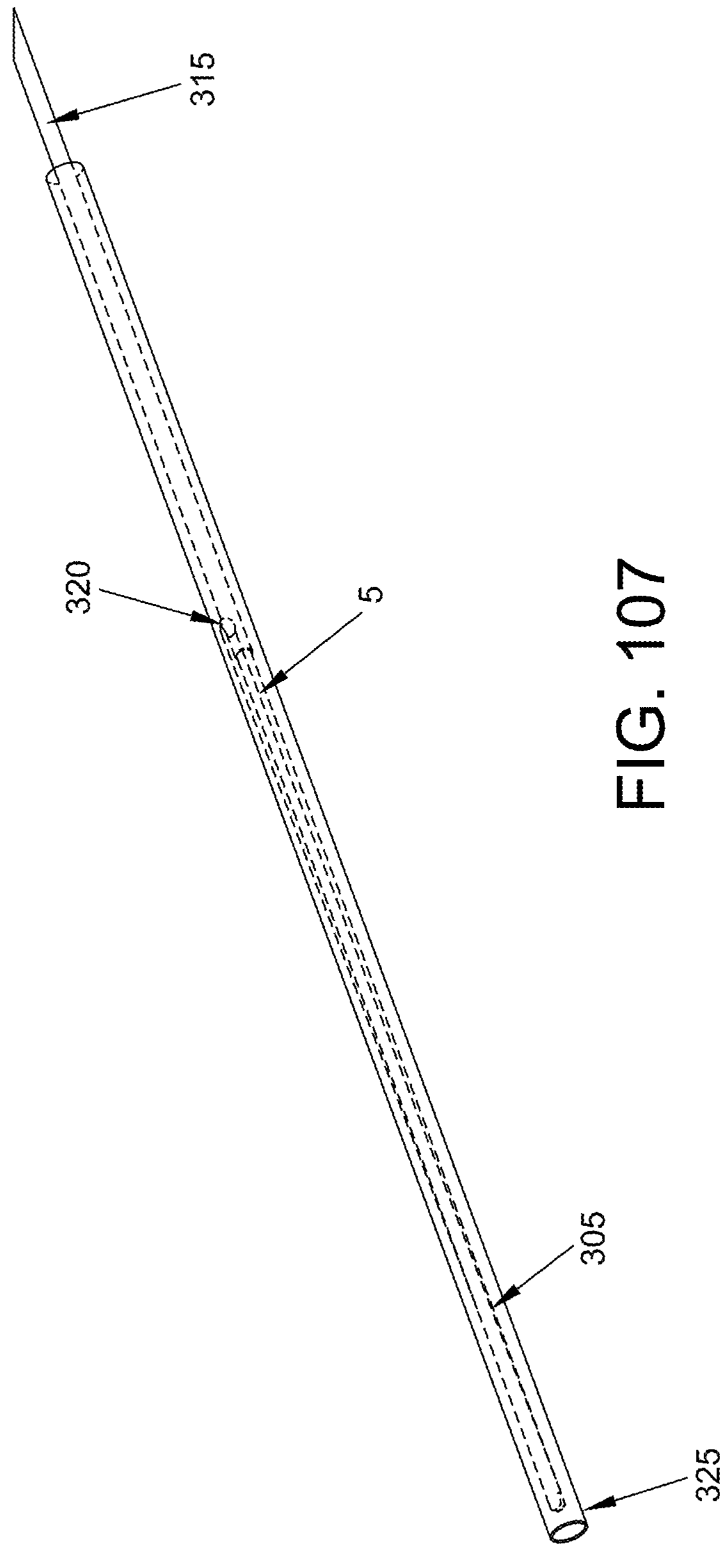

FIG. 107

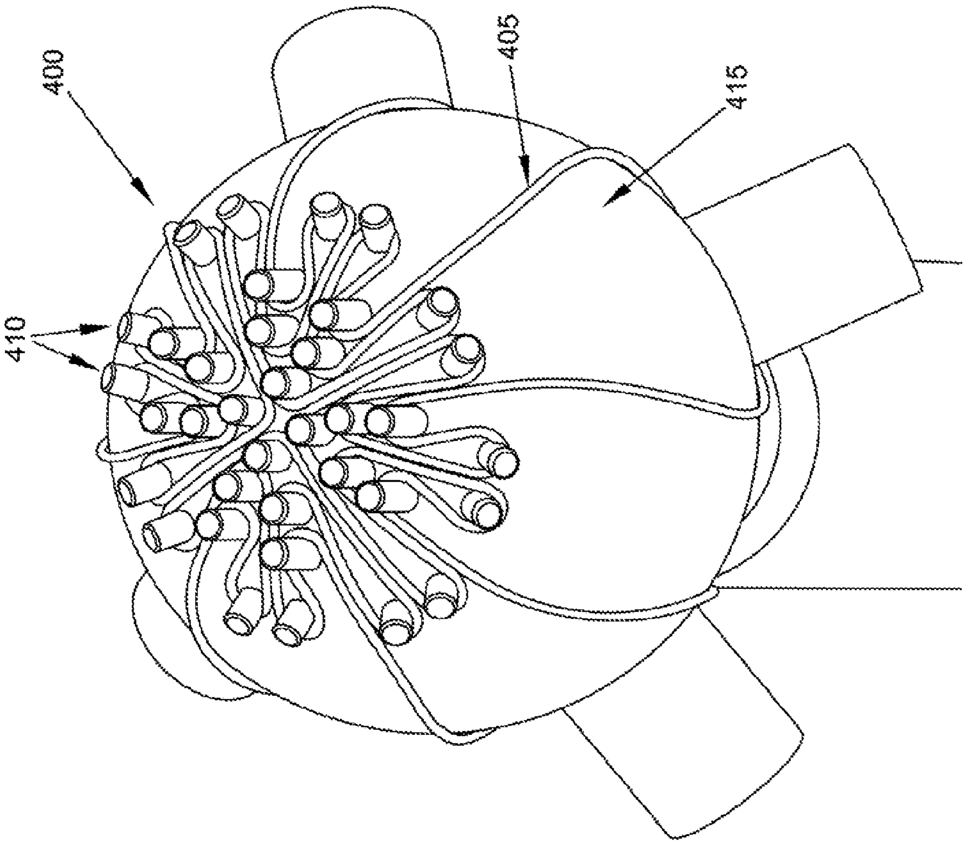

FIG. 108

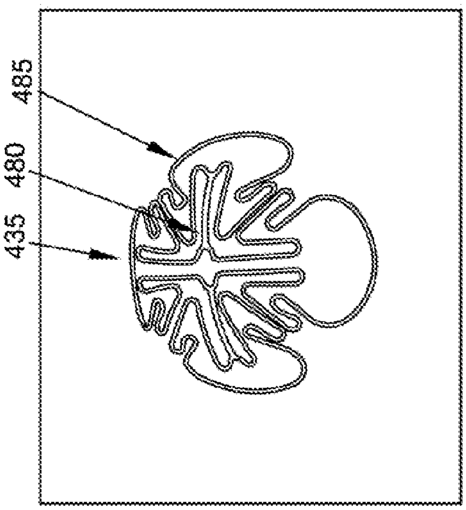

FIG. 111

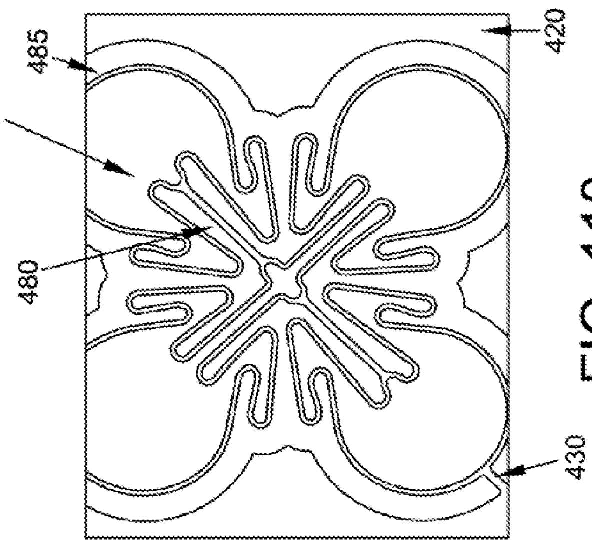

FIG. 110

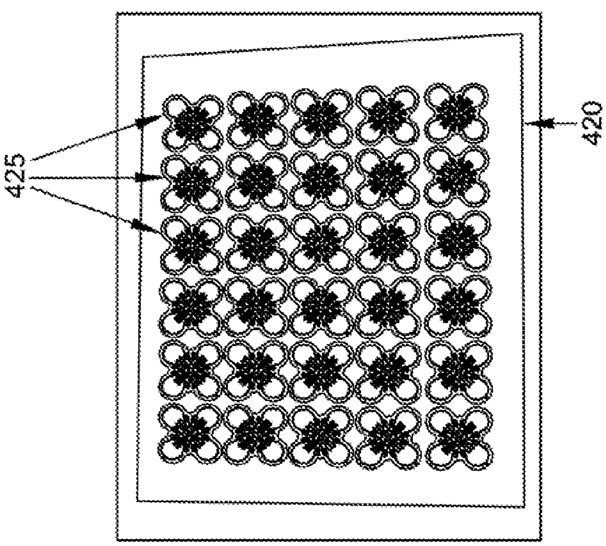

FIG. 109

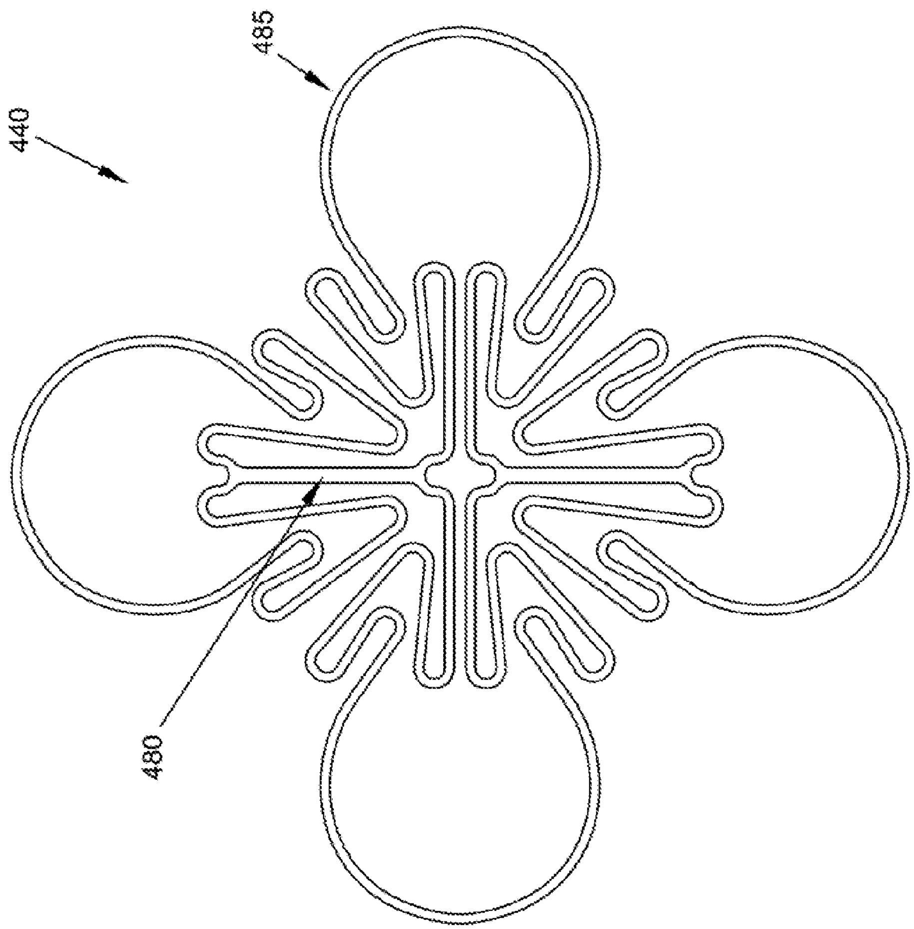

FIG. 112

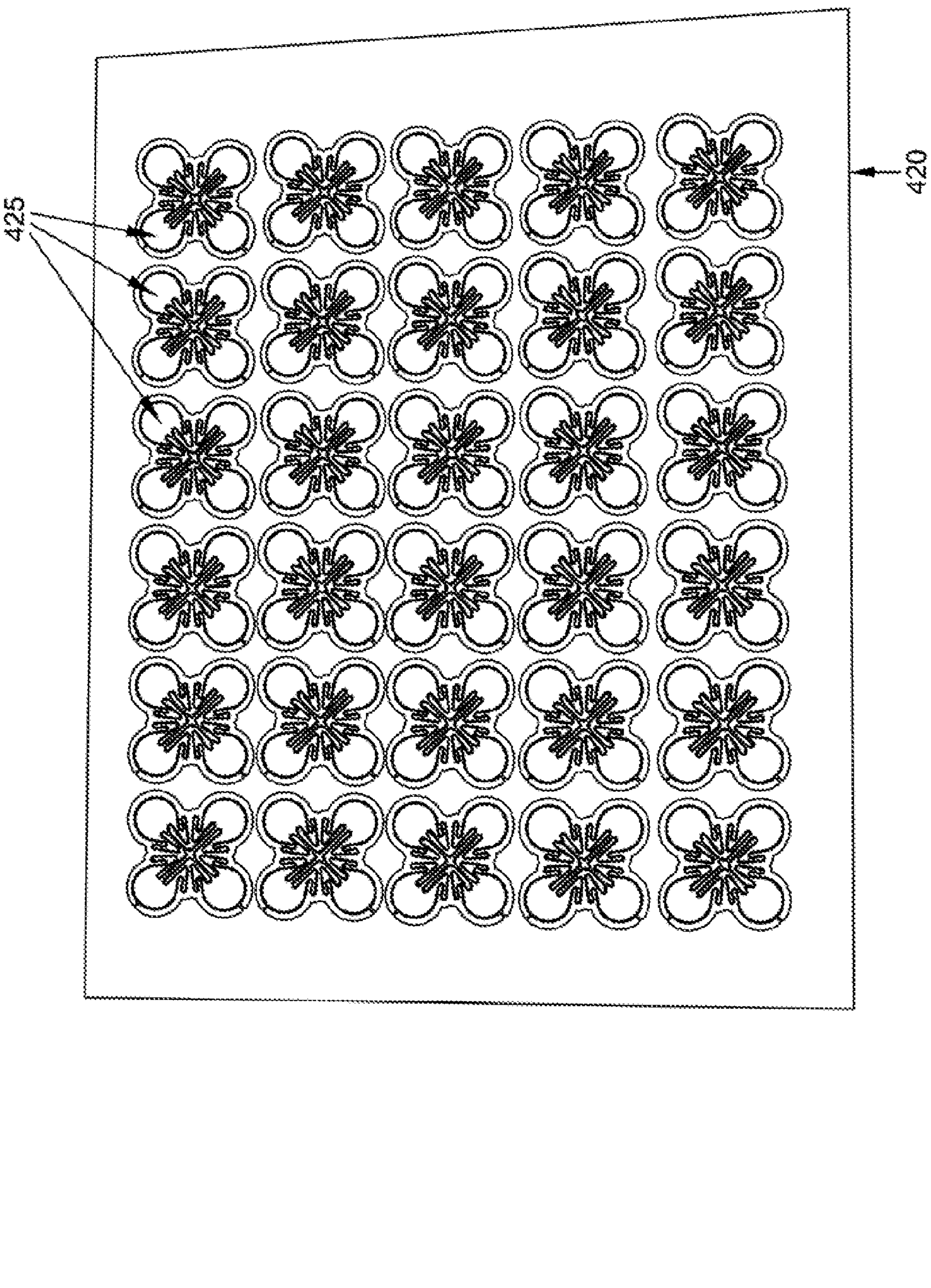

FIG. 113

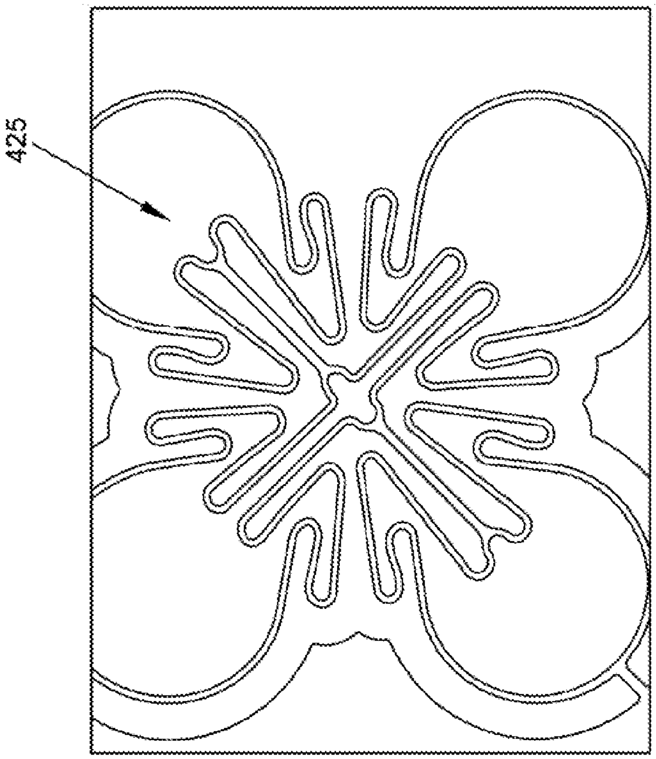

FIG. 115

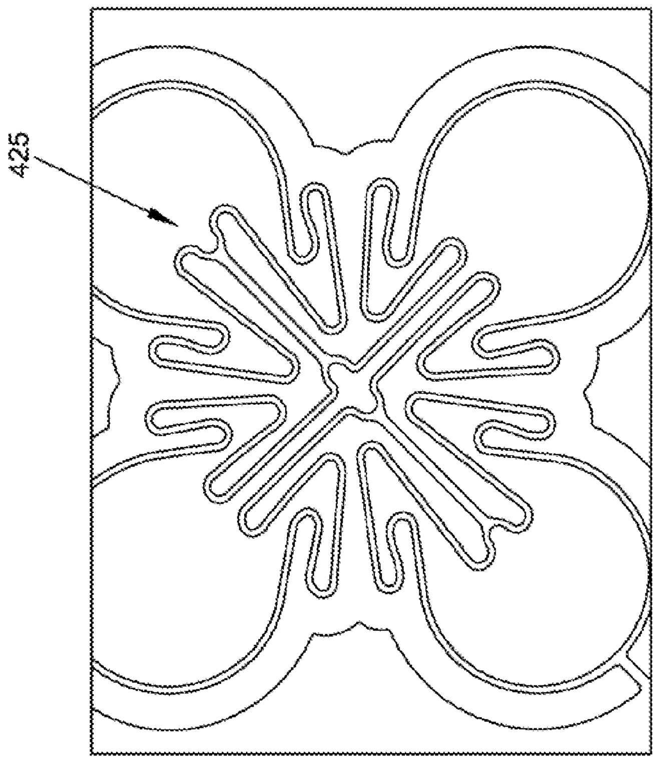

FIG. 114

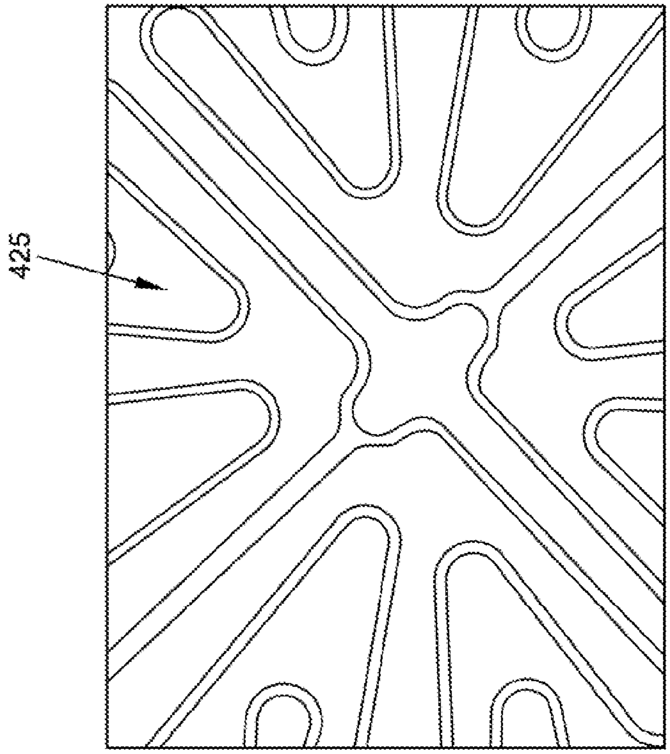

FIG. 117

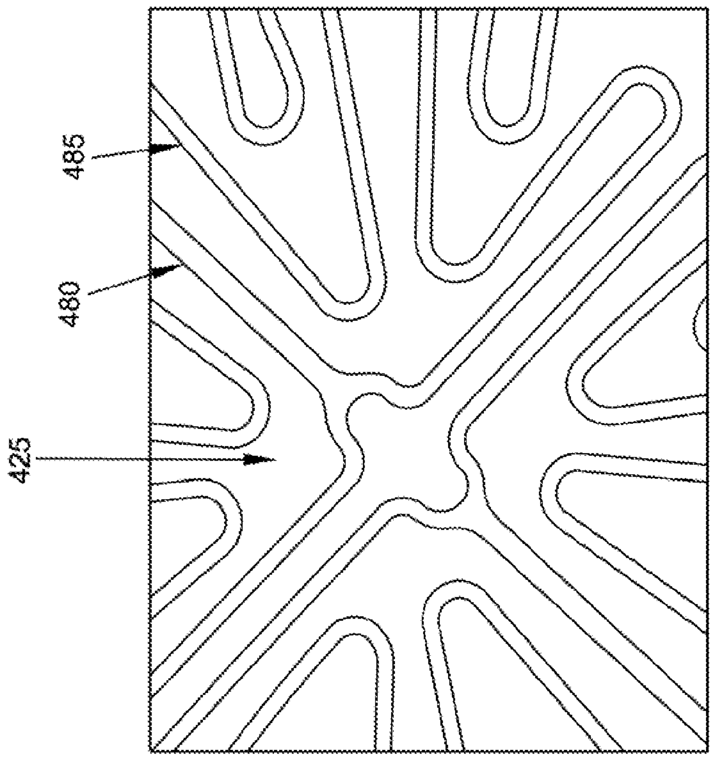

FIG. 116

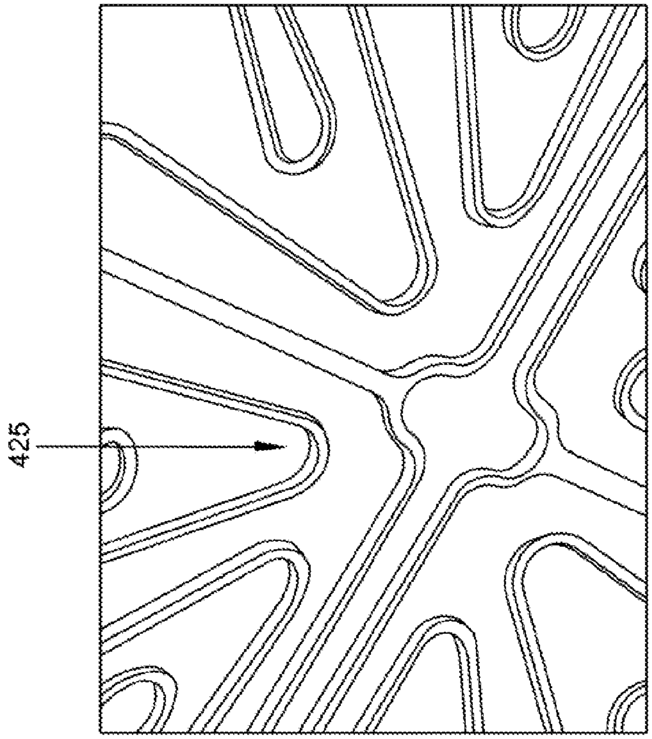

FIG. 119

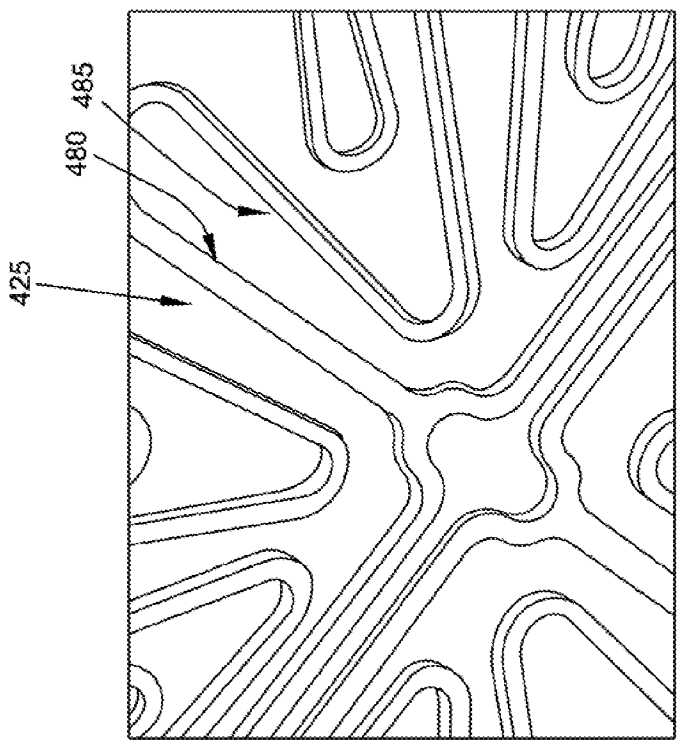

FIG. 118

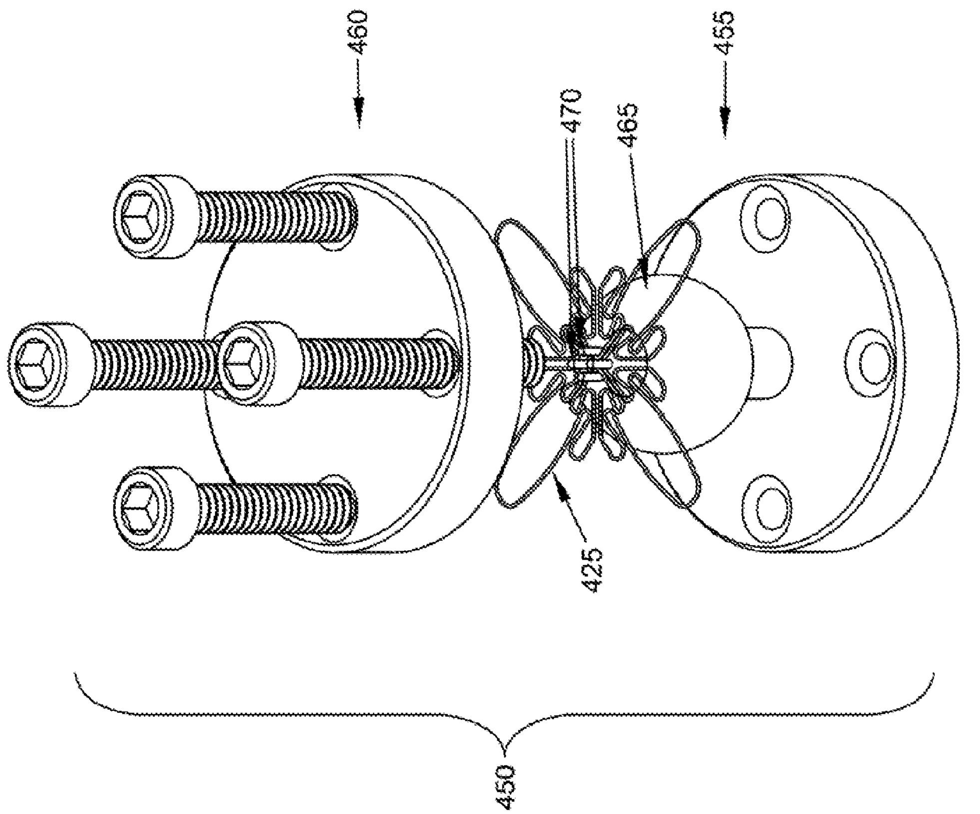

FIG. 120

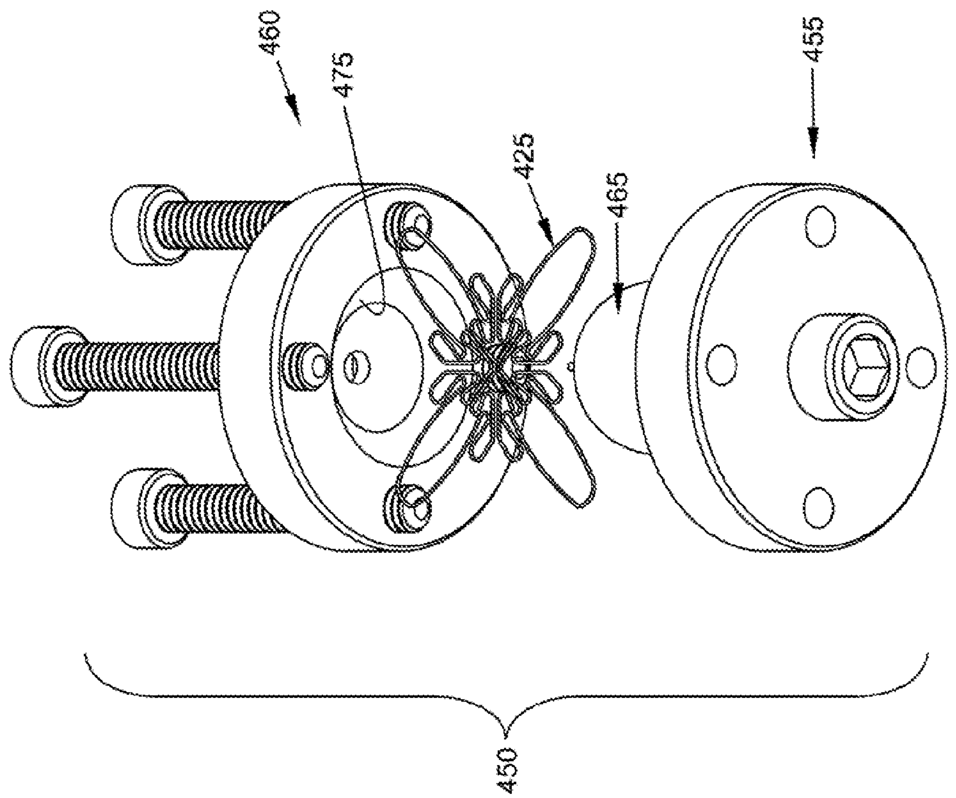

FIG. 121

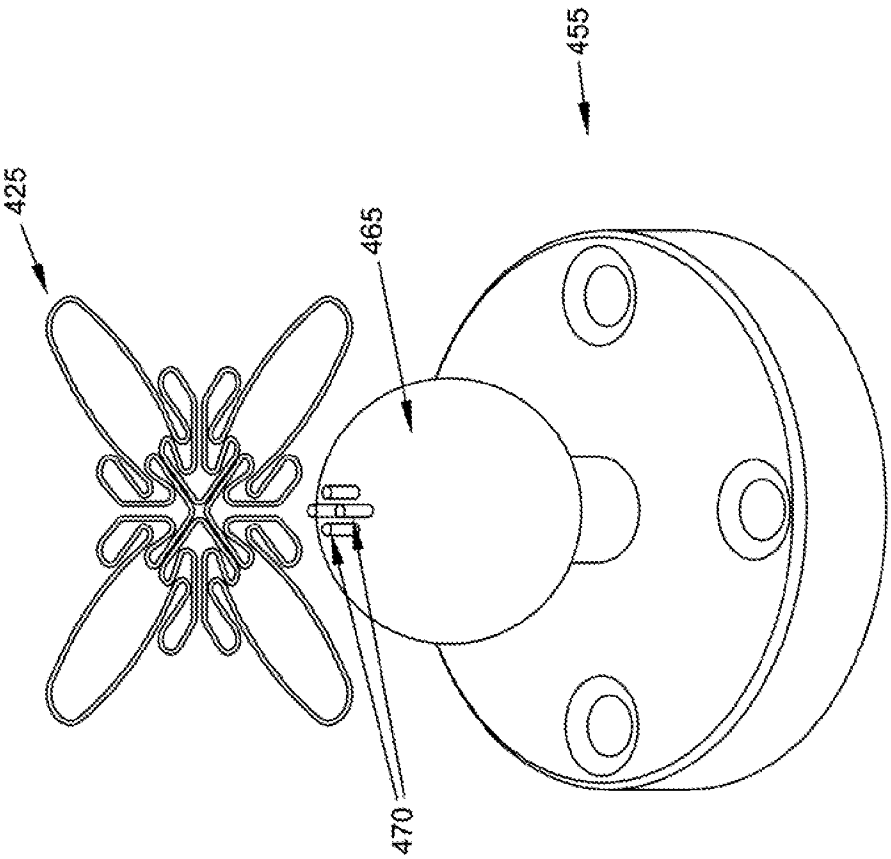

FIG. 122

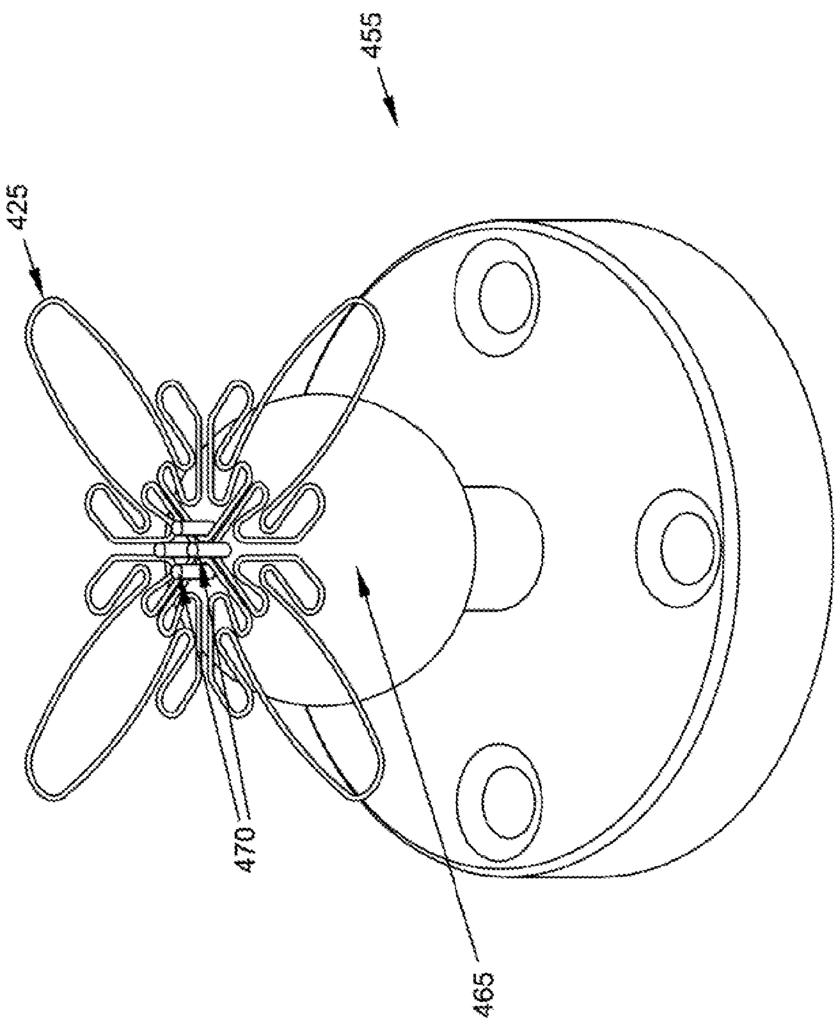

FIG. 123

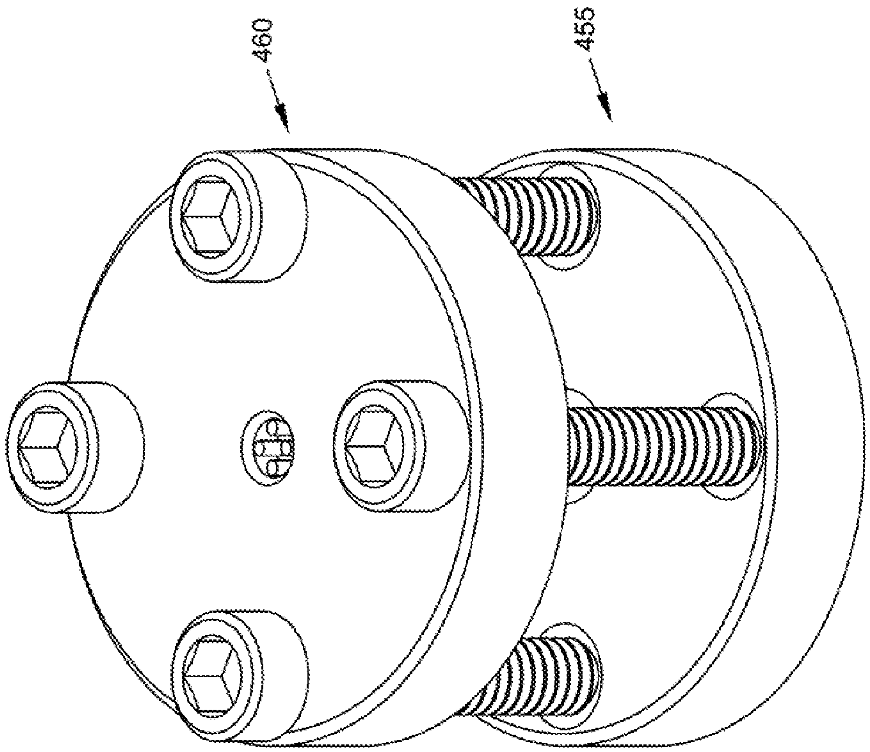

FIG. 124

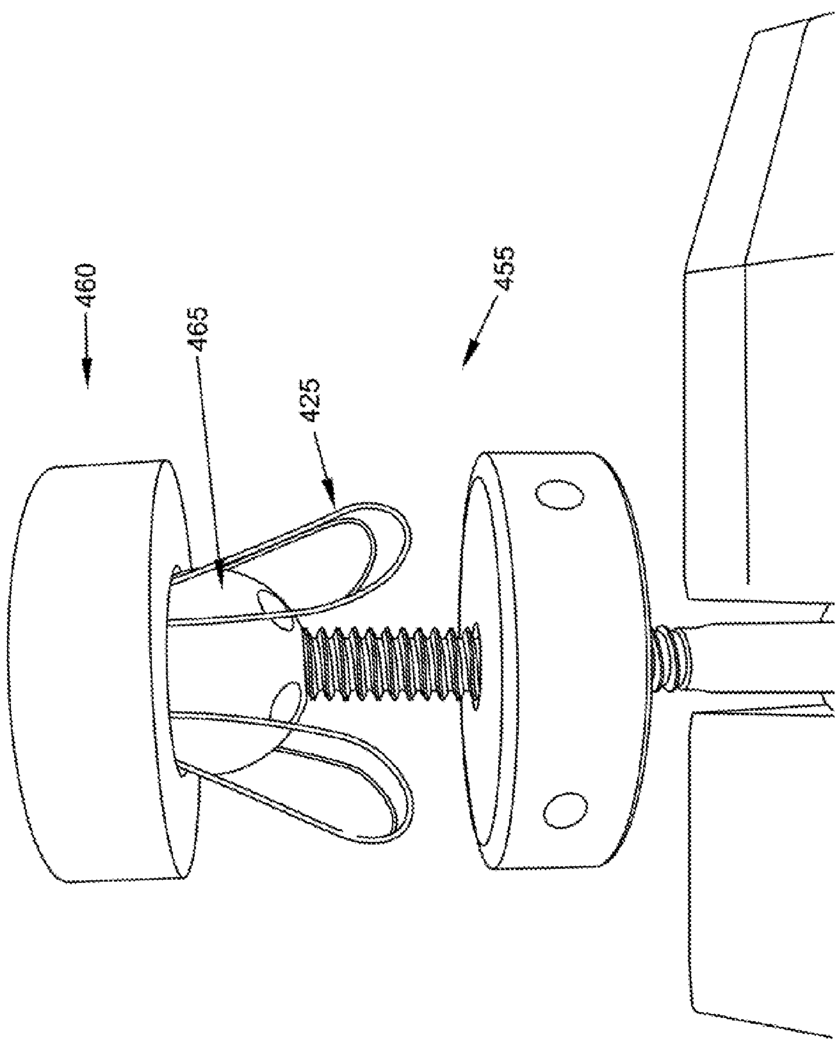

FIG. 125

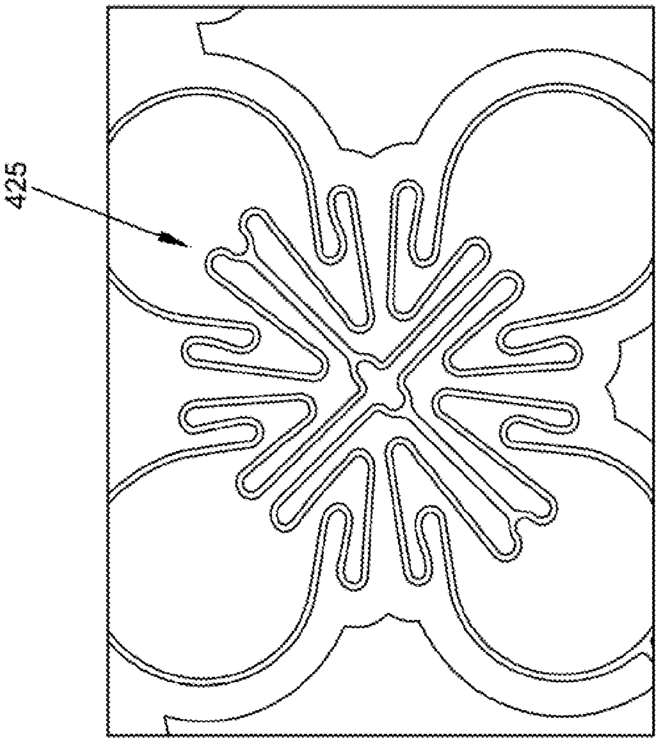

FIG. 127

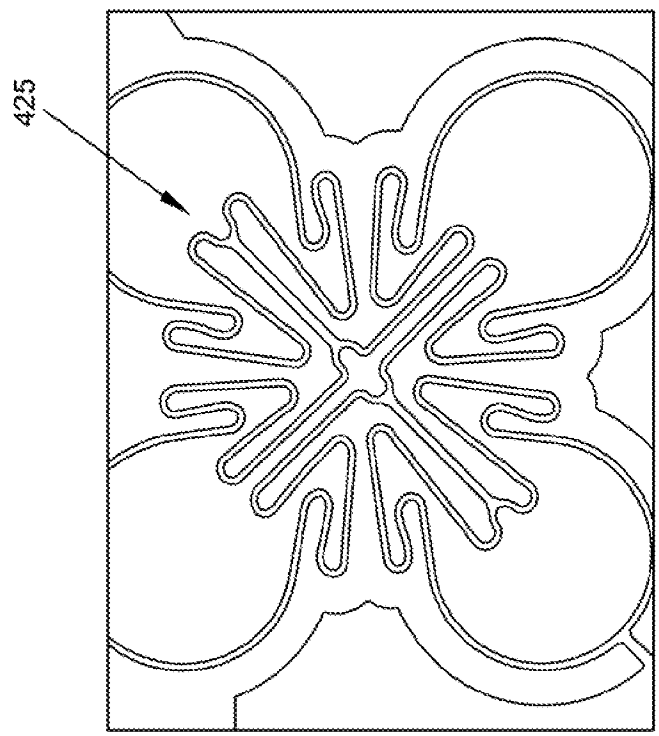

FIG. 126

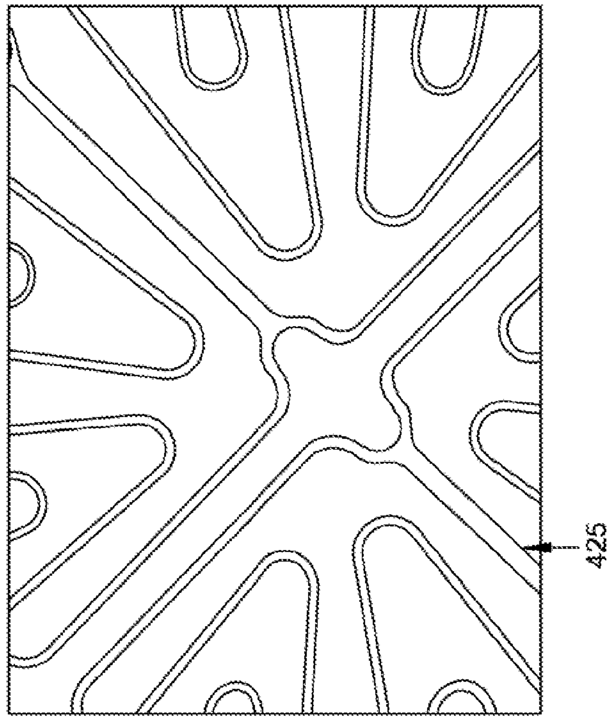

FIG. 129

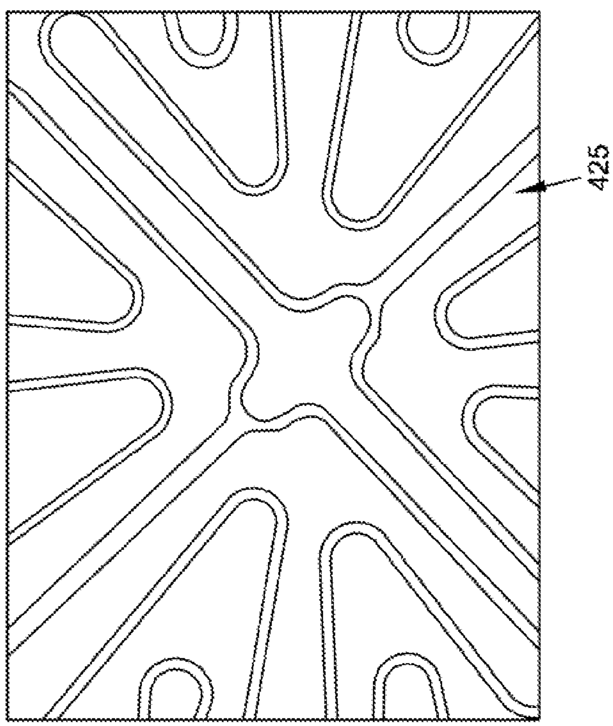

FIG. 128

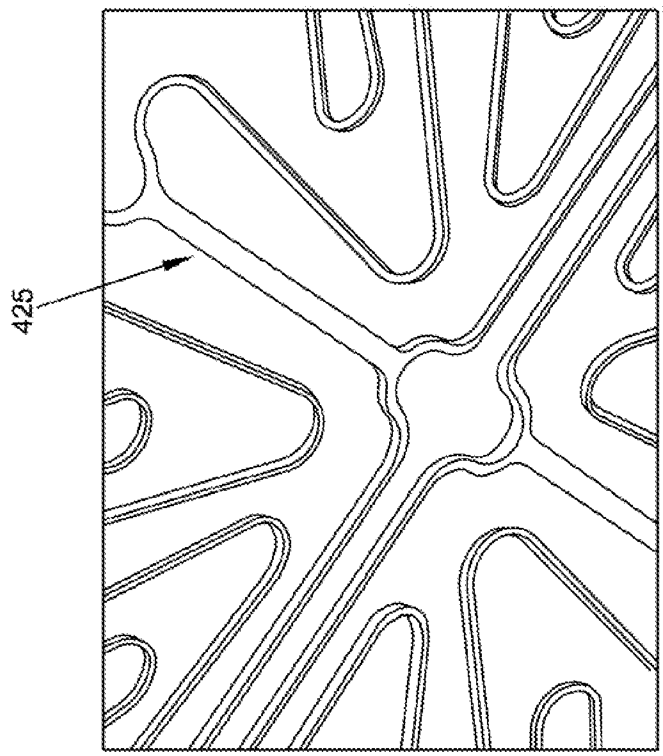

FIG. 131

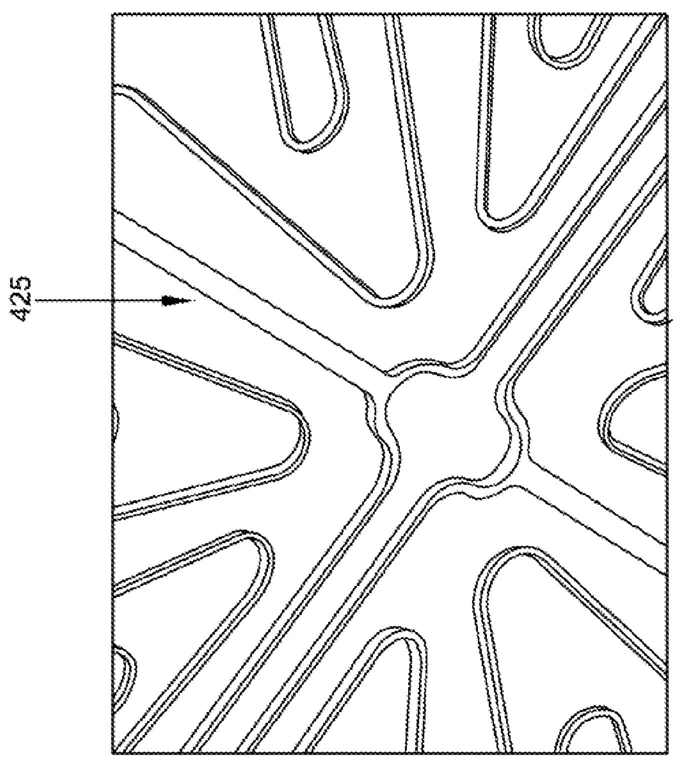

FIG. 130

METHOD AND APPARATUS FOR RESTRICTING FLOW THROUGH AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE STILL MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN

REFERENCE TO PRIOR PATENT APPLICATIONS

This patent application is a continuation of pending prior U.S. patent application Ser. No. 13/437,777, filed Apr. 2, 2012 by Howard Riina et al. for METHOD AND APPARATUS FOR RESTRICTING FLOW THROUGH AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE STILL MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN, which

(i) is a continuation-in-part of prior U.S. patent application Ser. No. 12/657,598, filed Jan. 22, 2010 by Howard Riina et al. for METHOD AND APPARATUS FOR RESTRICTING FLOW THROUGH AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE STILL MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN, which patent application

(a) is in turn a continuation-in-part of prior U.S. patent application Ser. No. 12/332,727, filed Dec. 11, 2008 by Howard Riina et al. for METHOD AND APPARATUS FOR SEALING AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN, which in turn claims benefit of prior U.S. Provisional Patent Application Ser. No. 61/007,189, filed Dec. 11, 2007 by Howard Riina et al. for DEPLOYABLE BLOCKING SPHERE;

(b) claims benefit of prior U.S. Provisional Patent Application Ser. No. 61/205,683, filed Jan. 22, 2009 by Jeffrey Milsom et al. for METHOD AND APPARATUS FOR SEALING AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN; and

(c) claims benefit of prior U.S. Provisional Patent Application Ser. No. 61/277,415, filed Sep. 24, 2009 by Howard Riina et al. for METHOD AND APPARATUS FOR RESTRICTING AN OPENING IN THE SIDE WALL OF A BODY LUMEN, AND/OR FOR REINFORCING A WEAKNESS IN THE SIDE WALL OF A BODY LUMEN, WHILE MAINTAINING SUBSTANTIALLY NORMAL FLOW THROUGH THE BODY LUMEN; and

(ii) claims benefit of prior U.S. Provisional Patent Application Ser. No. 61/470,733, filed Apr. 1, 2011 by Howard Riina et al. for FLOW DIVERTERS.

The above-identified patent applications are hereby incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to medical procedures and apparatus in general, and more particularly to medical procedures and apparatus for restricting flow through an opening in the side wall of a body lumen, and/or for reinforcing a weakness in the side wall of a body lumen, while still maintaining substantially normal flow through the body lumen.

BACKGROUND OF THE INVENTION

The human body consists of many different anatomical structures. Among these anatomical structures are the blood vessels which circulate blood throughout the body, i.e., the arteries which deliver oxygenated blood to the end tissues and the veins which return oxygen-depleted blood from the end tissues.

In some cases, a blood vessel can become weakened, thereby causing the side wall of the blood vessel to balloon outwardly so as to create an aneurysm. See, for example, FIGS. **1**-**3**, which show various types of aneurysms, e.g., a fusiform aneurysm (FIG. **1**), where the aneurysm extends around a substantial portion of the circumference of a blood vessel; a lateral aneurysm (FIG. **2**), where the aneurysm extends out of a limited portion of the side wall of a blood vessel, with a well-defined neck; and a bifurcation aneurysm (FIG. **3**), where the aneurysm extends out of the apex of a bifurcation of a blood vessel. For purposes of the present invention, all of these aneurysms (e.g., fusiform aneurysms, lateral aneurysms and/or bifurcations aneurysms) are considered to extend out of the side wall of a blood vessel.

Aneurysms can present a serious threat to the patient, since they may enlarge to the point of rupture, thereby resulting in a rapid and uncontrolled loss of blood. Depending upon the size and location of the aneurysm, the aneurysm can be life-threatening.

By way of example but not limitation, an intracranial aneurysm can be fatal if rupture occurs. Given the life-threatening nature of such intracranial aneurysms, these aneurysms have traditionally been treated with an open craniotomy and microsurgical clipping. This procedure generally involves placing a small titanium clip across the neck of the aneurysm, thus isolating the aneurysm from blood flow and inhibiting subsequent rupture (or re-rupture). This clipping procedure is typically done under direct visualization, using an operating microscope.

More recently, minimally-invasive techniques have also been used to treat both ruptured and un-ruptured brain aneurysms. These minimally-invasive techniques generally employ interventional neuroradiological procedures utilizing digital fluoroscopy. More particularly, these interventional neuroradiological procedures generally use X-ray visualization to allow the surgeon to place a microcatheter within the dome of the aneurysm. With the microcatheter in place, detachable coils are then deployed within the dome of the aneurysm, thereby reducing blood velocity within the dome of the aneurysm and causing thrombosis of the aneurysm so as to prevent subsequent rupture (or re-rupture). However, this coil-depositing procedure has a number of drawbacks, including the risk of coil herniation into the lumen of the blood vessel; the risk of coil migration out of the aneurysm and into the blood vessel, with subsequent downstream migration; the risk of aneurysm rupture; etc.

As a result, a primary object of the present invention is to provide a new and improved device, adapted for minimally-invasive, endoluminal delivery, which may be used to restrict blood flow to an aneurysm while still maintaining substantially normal blood flow through the blood vessel.

Another object of the present invention is to provide an expandable spherical structure, comprising an open frame with a flow-restricting face (i.e., a closed face or a face having a high strut density), which may be used to restrict flow through an opening in a side wall of a blood vessel while still maintaining substantially normal blood flow through the blood vessel.

Another object of the present invention is to provide an expandable spherical structure, comprising an open frame with a flow-restricting face (i.e., a closed face or a face having a high strut density), which may be used to reinforce a weakness in a side wall of a blood vessel while still maintaining substantially normal blood flow through the blood vessel.

Another object of the present invention is to provide an expandable spherical structure, comprising an open frame with a flow-restricting face (i.e., a closed face or a face having a high strut density), which may be used to restrict flow through an opening in the side wall of a lumen other than a blood vessel, and/or so as to reinforce a weakness in a side wall of a lumen other than a blood vessel, while still maintaining substantially normal flow through the lumen.

Another object of the present invention is to provide an expandable spherical structure which may be used to facilitate the deployment of detachable coils and/or other embolic material into the interior of an aneurysm while still maintaining substantially normal flow through the blood vessel.

And another object of the present invention is to provide a method for manufacturing the novel device of the present invention.

SUMMARY OF THE INVENTION

These and other objects of the present invention are addressed through the provision and use of a novel expandable spherical structure, and a method for making the same.

In one form of the invention, there is provided an expandable substantially spherical structure for deployment in a blood vessel or other body lumen, comprising:

an open frame formed out of a closed loop of filament and configured to assume (i) a collapsed configuration in the form of a substantially two-dimensional elongated loop structure so as to facilitate insertion into the blood vessel or other body lumen, and (ii) an expanded configuration in the form of a three-dimensional substantially spherical structure so as to facilitate retention at a site in the blood vessel or other body lumen; and

a flow-restricting face carried by the open frame;

wherein the open frame is configured so as to permit substantially normal flow therethrough when the open frame is in its expanded configuration, and further wherein the flow-restricting face is configured so as to restrict flow therethrough.

In another form of the invention, there is provided a system for restricting flow to an opening in the side wall of a blood vessel or other body lumen and/or reinforcing a weakness in the side wall or apex of a bifurcation of the blood vessel or other body lumen, while maintaining substantially normal flow through the blood vessel or other body lumen, comprising:

an expandable substantially spherical structure for deployment in the blood vessel or other body lumen, comprising:

an open frame formed out of a closed loop of filament and configured to assume (i) a collapsed configuration in the form of a substantially two-dimensional elongated loop structure so as to facilitate insertion into the blood vessel or other body lumen, and (ii) an expanded configuration in the form of a three-dimensional substantially spherical structure so as to facilitate retention at a site in the blood vessel or other body lumen; and

a flow-restricting face carried by the open frame;

wherein the open frame is configured so as to permit substantially normal flow therethrough when the expandable open frame is in its expanded configuration, and further wherein the flow-restricting face is configured so as to restrict flow therethrough; and

an installation tool for carrying the expandable substantially spherical structure to a deployment site, wherein the installation tool comprises:

an elongated structure having a first mount for seating a first portion of the closed loop and a second mount for seating a second portion of the closed loop, the first mount and the second mount being movable relative to one another between a first position and a second position so that (i) when the first portion of the closed loop is seated in the first mount and the second portion of the closed loop is seated in the second mount and the first mount and second mount are in their first position, the open frame is in its expanded substantially spherical configuration, and (ii) when the first portion of the closed loop is seated in the first mount and the second portion of the closed loop is seated in the second mount and the first mount and second mount are in their second position, the open frame is in its collapsed and elongated configuration.

In another form of the invention, there is provided a method for restricting flow to an opening in the side wall of a body lumen while maintaining substantially normal flow through the body lumen, comprising:

providing an expandable substantially spherical structure for deployment in the body lumen, comprising:

an open frame formed out of a closed loop of filament and configured to assume (i) a collapsed configuration in the form of a substantially two-dimensional elongated loop structure so as to facilitate insertion into the blood vessel or other body lumen, and (ii) an expanded configuration in the form of a three-dimensional substantially spherical structure so as to facilitate retention at a site in the blood vessel or other body lumen; and

a flow-restricting face carried by the open frame;

wherein the open frame is configured so as to permit flow therethrough when the open frame is in its expanded configuration, and further wherein the flow-restricting face is configured so as to restrict flow therethrough;

delivering the expandable substantially spherical structure to a therapy site within the body lumen while the open frame is in its collapsed configuration; and

transforming the expandable substantially spherical structure from its collapsed configuration to its expanded configuration so that the expandable substantially spherical structure is securely lodged in the body lumen, with the flow-restricting face of the expandable substantially spherical structure positioned so as to restrict flow to the opening in the side wall of the body lumen and with the open frame permitting flow through the body lumen.

In another form of the invention there is provided an expandable substantially spherical structure for deployment in a blood vessel or other body lumen, comprising:

an open frame configured to assume a collapsed configuration and an expanded configuration;

a flow-restricting face carried by the open frame; and

a plurality of stabilizing legs attached to, and extending away from, the open frame;

wherein the open frame and the plurality of stabilizing legs are configured so as to permit substantially normal flow therethrough when the open frame is in its expanded configuration, and further wherein the flow-restricting face is configured so as to restrict flow therethrough.

In another form of the invention, there is provided a method for restricting flow through an opening in the side wall of a body lumen while maintaining substantially normal flow through the body lumen, comprising:

providing an expandable substantially spherical structure for deployment in the body lumen, comprising:

an open frame configured to assume a collapsed configuration and an expanded configuration;

a flow-restricting face carried by the open frame; and

a plurality of stabilizing legs attached to, and extending away from, the open frame;

wherein the open frame and the plurality of stabilizing legs are configured so as to permit flow therethrough when the open frame is in its expanded configuration, and further wherein the flow-restricting face is configured so as to restrict flow therethrough;

delivering the expandable substantially spherical structure to a therapy site within the body lumen while the open frame is in its collapsed configuration and the plurality of stabilizing legs are in a collapsed configuration; and

transforming the expandable substantially spherical structure from its collapsed configuration to its expanded configuration, and transforming the plurality of stabilizing legs from their collapsed configuration to an expanded configuration, so that the expandable substantially spherical structure is securely lodged in the body lumen, with the flow-restricting face of the expandable substantially spherical structure positioned so as to restrict flow to the opening in the side wall of the body lumen and with the open frame and the plurality of stabilizing legs permitting flow through the body lumen.

In another form of the invention, there is provided a method for making a device for causing thrombosis of an aneurysm, wherein said device comprises a single elastic filament configurable between (i) an elongated, substantially linear configuration, and (ii) a longitudinally-contracted, substantially three-dimensional configuration, said method comprising:

providing a sheet of shape memory material;

producing a single filament, two-dimensional interim structure from said sheet of shape memory material;

mounting said single filament, two-dimensional interim structure to a fixture so that said single filament, two-dimensional interim structure is transformed into said longitudinally-contracted, substantially three-dimensional configuration; and

heat treating said single filament, two-dimensional interim structure while it is mounted to said fixture so as to produce said device in its longitudinally-contracted, substantially three-dimensional configuration.

In another form of the invention, there is provided a device for positioning in a blood vessel adjacent to an aneurysm for causing thrombosis of the aneurysm while maintaining substantially normal flow through the blood vessel, said device comprising:

a single elastic filament configurable between:

(i) an elongated, substantially linear configuration, whereby to facilitate movement along a blood vessel; and

(ii) a longitudinally-contracted, substantially three-dimensional configuration for lodging within the blood vessel, said longitudinally-contracted, substantially three-dimensional configuration providing (a) a face for positioning adjacent the aneurysm, said face comprising a plurality of lengths of said elastic filament in close proximity to one another so as to restrict blood flow to the aneurysm and thereby cause thrombosis of the aneurysm, and (b) a substantially open frame for holding said face adjacent the aneurysm, said substantially open frame configured so as to maintain substantially normal flow through the blood vessel;

wherein said single elastic filament has a width which varies along its length.

In another form of the invention, there is provided a method for making a device for causing thrombosis of an aneurysm, wherein said device comprises a single elastic filament configurable between (i) an elongated, substantially linear configuration, and (ii) a longitudinally-contracted, substantially three-dimensional configuration, said method comprising:

providing a filament of shape memory material;

mounting said filament of shape memory material to a fixture so that said filament is transformed into said longitudinally-contracted, substantially three-dimensional configuration; and

heat treating said filament so as to produce said device in its longitudinally-contracted, substantially three-dimensional configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts, and further wherein:

FIGS. **1-3** are schematic views showing various types of aneurysms;

FIGS. **4-8** are schematic views showing a novel expandable spherical structure formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a closed face in this particular embodiment), and wherein the expandable spherical structure is shown being used to close off a lateral aneurysm in a blood vessel;

FIGS. **9-13** are schematic views showing another novel expandable spherical structure formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a closed face in this particular embodiment), wherein the open frame is formed out of an absorbable material and the closed face is formed out of a non-absorbable material, and wherein the expandable spherical structure is shown being used to close off a lateral aneurysm in a blood vessel;

FIGS. **14-18** are schematic views showing the expandable spherical structure of FIGS. **4-8** being used to close off a bifurcation aneurysm;

FIGS. **19-23** are schematic views showing the expandable spherical structure of FIGS. **9-13** being used to close off a bifurcation aneurysm;

FIG. **24** is a schematic view showing another novel expandable spherical structure formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a closed face in this particular embodiment), and wherein the open frame of the expandable spherical structure comprises a plurality of struts arranged in a rectangular pattern;

FIG. **25** is a schematic view showing another novel expandable spherical structure formed in accordance with the present invention, wherein the open frame comprises a plurality of struts arranged in a hexagonal pattern;

FIG. **26** is a schematic view showing another novel expandable spherical structure formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a closed face in this particular embodiment), and wherein the open frame of the expandable spherical structure comprises a spherical spiral;

FIG. **27** is a schematic view showing another novel expandable spherical structure formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a closed face in this particular embodiment), and wherein the open frame of the expandable spherical structure comprises a spherical cage;

FIGS. **28-37** are schematic views showing other novel expandable spherical structures formed in accordance with the present invention, wherein the expandable spherical structures comprise spherical cages;

FIGS. **38-43** are schematic views showing other novel expandable spherical structures formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a closed face in this particular embodiment), and wherein the flow-restricting face is disposed to one side of the axis of approach;

FIGS. **44** and **45** are schematic views showing the expandable spherical structure of FIG. **27** being deployed with a syringe-type (e.g., an outer sleeve with an internal pusher) installation tool;

FIG. **46** is a schematic view showing the expandable spherical structure of FIG. **27** being deployed with a syringe-type installation tool equipped with a gripper mechanism;

FIGS. **47-49** are schematic views showing the expandable spherical structure of FIG. **27** being deployed with a syringe-type installation tool equipped with an expansion balloon;

FIGS. **50-54** are schematic views showing another novel expandable spherical structure formed in accordance with the present invention, wherein the expandable spherical structure comprises an open frame with a flow-restricting face (i.e., a face having a high strut density in this particular embodiment), and wherein the expandable spherical structure is shown being used to restrict flow to a lateral aneurysm in a blood vessel;

FIGS. **55-63** are schematic views showing other expandable spherical structures formed in accordance with the present invention, wherein the expandable spherical structures comprise open frames with flow-restricting faces (i.e., faces having high strut densities in these particular embodiments);

FIGS. **64-66** are schematic views showing the expandable spherical structure of FIGS. **4-8** being deployed within the interior of a lateral aneurysm so as to close off the aneurysm;

FIGS. **67-71** are schematic views showing the expandable spherical structure of FIGS. **9-13** being deployed within the interior of a lateral aneurysm so as to close off the aneurysm;

FIGS. **72-76** are schematic views showing the expandable spherical structure of FIGS. **4-8** being deployed within the interior of a bifurcation aneurysm so as to close off the aneurysm;

FIGS. **77-81** are schematic views showing the expandable spherical structure of FIGS. **9-13** being deployed within the interior of a bifurcation aneurysm so as to close off the aneurysm;

FIGS. **82** and **83** are schematic views showing an expandable spherical structure having stabilizing legs extending therefrom so as to form a "comet-shaped" structure, with the structure being configured to restrict flow to a lateral aneurysm in a blood vessel;

FIGS. **84-97** are schematic views showing various constructions for the "comet-shaped" structure of FIGS. **82** and **83**, but with the flow-restricting face of the expandable spherical structure being omitted in FIGS. **84-91** for clarity of viewing;

FIG. **98** is a schematic view showing another comet-shaped structure, but with this structure being configured to restrict flow to a bifurcation aneurysm;

FIGS. **99** and **100** show an expandable spherical structure restricting flow into a bifurcation aneurysm, where the expandable spherical structure is formed out of a "closed loop" of filament, and where the expandable spherical structure is deployed in the patient so that the face having a high strut density is positioned over the mouth/neck of the aneurysm in order to restrict flow into the aneurysm;

FIGS. **101** and **102** are schematic views of an inserter which may be used with an expandable spherical structure formed out of a "closed loop" of filament;

FIGS. **103-107** are schematic views showing how an expandable spherical structure formed out of a "closed loop" of filament may be deployed using the inserter of FIGS. **101** and **102**;

FIG. **108** is a schematic view showing one preferred method for forming a device in accordance with the present invention; and

FIGS. **109-131** are schematic views showing another preferred method for forming a device in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The Novel Expandable Spherical Structure in General

Looking now at FIGS. **4-8**, there is shown a novel expandable spherical structure **5** formed in accordance with the present invention. Expandable spherical structure **5** is adapted for minimally-invasive, endoluminal delivery into a blood vessel or other body lumen, for restricting flow through an opening in the side wall of the blood vessel or other body lumen, and/or for reinforcing a weakness in the side wall of the blood vessel or other body lumen, while still maintaining substantially normal flow through the blood vessel or other body lumen.

Expandable spherical structure **5** generally comprises a spherical body comprising an open frame **10** with a flow-restricting face **15** (i.e., a closed face or a face having a high strut density). Preferably open frame **10** and flow-restricting face **15** together define the entire exterior shape of the spherical body, with open frame **10** making up the majority of the exterior shape of the spherical body.

In one preferred form of the invention, open frame **10** defines approximately 90% of the exterior shape of the spherical body and flow-restricting face **15** defines approximately 10% of the exterior shape of the spherical body. In another preferred form of the invention, open frame **10** defines approximately 80% of the exterior shape of the spherical body and flow-restricting face **15** defines approximately 20% of the exterior shape of the spherical body. In yet another preferred form of the invention, open frame **10** comprises approximately 70% of the exterior shape of the spherical body and flow-restricting face **15** defines approximately 30% of the exterior shape of the spherical body. And in yet another preferred form of the invention, open frame **10** comprises approximately 60% of the exterior shape of the spherical body and flow-restricting face **15** comprises approximately 40% of the exterior shape of the spherical body.

Expandable spherical structure **5** is constructed so that it may be deployed in a blood vessel or other body lumen, by (i) collapsing the expandable spherical structure into a configuration of reduced dimension, (ii) moving the collapsed structure through the blood vessel or other body lumen to a therapy site, and (iii) expanding the collapsed structure to an enlarged dimension at the therapy site, whereby to secure the expandable spherical structure in the blood vessel or body lumen so that its flow-restricting face **15** is presented to a side wall of the blood vessel or other body lumen, whereby to restrict flow to an aneurysm or other opening in the side wall of the blood vessel or other body lumen, or to otherwise reinforce a weakness in the side wall of the blood vessel or other body lumen, without significantly impeding normal flow through the blood vessel or other body lumen.

Significantly, by forming expandable spherical structure **5** in the shape of a spherical body, the endoluminal device is readily centered on the neck of an aneurysm or other opening in a body lumen, with flow-restricting face **15** projecting into the neck of the aneurysm or other opening in a body lumen and reliably restricting flow into the aneurysm or other opening in a body lumen.

Furthermore, by forming expandable spherical structure **5** so that it can expand at the therapy site and lodge itself in the blood vessel or other body lumen with its flow-restricting face **15** presented to a side wall of the blood vessel or other body lumen, expandable spherical structure **5** is effectively self-sizing, since it can be expanded to the degree necessary to span the blood vessel or other body lumen.

More particularly, expandable spherical structure **5** generally comprises an open frame **10** which has a flow restricting face **15** (i.e., a closed face or a face having a high strut density) carried thereon. Open frame **10** is formed so that it can assume a first, collapsed configuration of reduced dimension (FIG. **4**) so as to facilitate moving expandable spherical structure **5** endoluminally through the blood vessel or other body lumen to the therapy site. Open frame **10** is also formed so that it can thereafter be reconfigured to a second, expanded configuration of enlarged dimension (FIGS. **5** and **6**), whereby expandable spherical structure **5** can be lodged in the blood vessel or other body lumen at the therapy site, with its flow-restricting face **15** pressed securely against a side wall of the blood vessel or other body lumen. In this position, flow-restricting face **15** of expandable spherical structure **5** can restrict flow to an aneurysm in the blood vessel (such as the lateral aneurysm shown in FIGS. **4-8**, or a bifurcation aneurysm as will hereinafter be discussed below), or restrict flow to an opening in the side wall of the blood vessel or other body lumen, or reinforce a weakness in the side wall of the blood vessel or other body lumen, etc.

Significantly, by forming the endoluminal device as an expandable spherical structure, the device can be collapsed to a reduced dimension for minimally-invasive, endoluminal delivery into a blood vessel or other body lumen, yet can thereafter be expanded to the required dimension for secure lodgement at the therapy site, whereby to restrict flow to an opening in a body lumen and/or to reinforce a weakness in the side wall of the body lumen. Furthermore, by forming expandable spherical structure **5** in the shape of a spherical body, the endoluminal device is readily centered on the neck of an aneurysm or other opening in a body lumen, with flow-restricting face **15** projecting into the neck of the aneurysm or other opening in a body lumen and reliably restricting flow into the aneurysm or other opening in a body lumen. And by forming expandable spherical structure **5** so that it can expand at the therapy site and lodge itself in the blood vessel or other body lumen with its flow-restricting face **15** presented to a side wall of the blood vessel or other body lumen, expandable spherical structure **5** is effectively self-sizing, since it expands to the degree necessary to span the blood vessel or other body lumen. Additionally, by forming open frame **10** as an open structure, expandable spherical structure **5** can be disposed in the blood vessel or body lumen without significantly impeding normal flow through the blood vessel or other body lumen (FIGS. **6-8**).

Expandable Open Frame 10

As noted above, (i) expandable spherical structure **5** generally comprises a spherical body comprising an open frame **10** with a flow-restricting face **15** (i.e., a closed face or a face having a high strut density); (ii) open frame **10** and flow-restricting face **15** together preferably define the entire exterior shape of the spherical body, with open frame **10** making up the majority of the exterior shape of the spherical body; (iii) open frame **10** is capable of being collapsed in dimension for easy delivery of expandable spherical structure **5** to the therapy site and thereafter expanded in dimension at the therapy site so as to hold flow-restricting face **15** against a side wall of a blood vessel or other body lumen; and (iv) open frame **10** is configured so that it does not significantly impede normal flow through the blood vessel or lumen within which it is deployed.

To this end, open frame **10** is preferably formed with an expandable strut construction, so that it can (i) first assume a configuration of reduced dimension, so that expandable spherical body **5** can move easily through the body to the therapy site, and (ii) thereafter assume a configuration of expanded dimension, so that it can be securely retained at the desired location in the blood vessel or other body lumen and press flow-restricting face **15** securely against the side wall of the blood vessel or body lumen, whereby to restrict flow to an aneurysm or other opening in the blood vessel or other body lumen, or to otherwise reinforce the side wall of the blood vessel or other body lumen. And by forming open frame **10** with an expandable strut construction, open frame **10** is effectively self-sizing, since it expands to the degree necessary to span the blood vessel or other body lumen.

Significantly, by forming open frame **10** with an expandable strut construction, open frame **10** does not significantly impede normal flow through the blood vessel or other body lumen when open frame **10** is in its expanded configuration within the blood vessel or other body lumen.

Thus, for example, in the configuration shown in FIGS. **4-8**, open frame **10** comprises a plurality of struts arranged in a polygonal configuration, with the struts being sized so that the struts present minimal obstruction to normal flow through the lumen.

In one preferred construction, open frame **10** may be formed out of a shape memory alloy (SMA) such as Nitinol, and a temperature transition may be used to change the configuration of open frame **10**. By way of example but not limitation, open frame **10** can be formed so that when it is cooled to a temperature below body temperature, the open frame assumes a collapsed configuration (FIG. **4**), and when it is thereafter warmed to body temperature, the open frame assumes an expanded configuration (FIG. **6**). If desired, open frame **10** can be warmed to body temperature simply by deploying expandable spherical structure **5** in the body. Alternatively, an electrical current may be applied to open frame **10** so as to heat open frame **10** to its expansion temperature, e.g., via resistance heating. Or, a warm or cold saline solution can be flushed through open frame **10** so as to appropriately modulate the temperature of the open frame, whereby to cause the open frame to assume a desired configuration.

Alternatively, open frame **10** can be formed out of a resilient material which can be forcibly compressed into a collapsed configuration, restrained in this collapsed configuration, and thereafter released so that it elastically returns to its expanded configuration. By way of example but not limitation, in this form of the invention, expandable spherical structure **5** might be compressed into a configuration of a reduced dimension, restrained within a sleeve, delivered to the therapy site within the sleeve, and then released from the sleeve so that it elastically returns to an expanded configuration at the therapy site, whereby to lodge itself in the blood vessel or other body lumen, with its flow-restricting face pressed against the side wall of the blood vessel or other body lumen. By way of further example but not limitation, open frame **10** can be formed out of a shape memory alloy (SMA) engineered to form stress-induced martensite (SIM) and thereby exhibit superelastic properties, whereby to permit large shape deformations with elastic return. By way of still further example but not limitation, open frame **10** can be formed out of a suitable polymer which exhibits the desired elastic properties.

In another preferred form of the present invention, open frame **10** is formed with a structure which can be collapsed for delivery to the deployment site and thereafter enlarged to an expanded configuration through the use of an expansion device, e.g., an internal balloon, where the balloon is inflated at the therapy site so as to reconfigure open frame **10** to an expanded condition. This arrangement can be advantageous, since it does not require the open frame to rely on temperature transition or elasticity to expand to its fully expanded configuration (or to any desired expanded configuration less than its fully expanded configuration). Thus, a wide range of well known biocompatible materials (e.g., medical grade stainless steel) may be used to form open frame **10**.

Flow-Restricting Face **15**

Flow-restricting face **15** is carried by (e.g., mounted on, formed integral with, or otherwise connected to) open frame **10** so that flow-restricting face **15** can be pressed securely against the side wall of the blood vessel or other body lumen within which expandable spherical structure **5** is deployed.

Flow-restricting face **15** may comprise a closed face, in the sense that it comprises a substantially complete surface or barrier which is capable of closing off an aneurysm or other opening in side wall of a blood vessel or other body lumen, and/or for reinforcing a weakness in the side wall of the blood vessel or other body lumen. See FIGS. **4-8**, where flow-restricting face **15** is depicted as a closed face.

Alternatively, and as will be discussed in detail below, flow-restricting face **15** may comprise a face having a high strut density which is capable of restricting flow to an aneurysm or other opening in a side wall of a blood vessel or other body lumen, and/or for reinforcing a weakness in the side wall of the blood vessel or other body lumen. In this case, flow-restricting face **15** may not constitute a substantially complete surface, or flow-restricting face **15** may not constitute a substantially fluid-impervious surface, but flow-restricting face **15** will have a strut density sufficiently high to restrict flow through that face, e.g., so as to cause an aneurysm to thrombose.

Flow-restricting face **15** may be formed so as to be substantially rigid or it may be formed so as to be flexible.

Flow-restricting face **15** preferably has the convex configuration shown in FIGS. **4-8**, so that it can form a regular portion of the spherical body of expandable structure **5**. However it should be appreciated that flow-restricting face **15** may also be formed with a planar configuration, or some other configuration, if desired.

Use of Absorbable Materials

If desired, expandable spherical structure **5** can have some or all of its elements formed out of an absorbable material, so that some or all of the elements are removed from the therapy site after some period of time has elapsed.

By way of example but not limitation, open frame **10** can be formed out of an absorbable material, and flow-restricting face **15** can be formed out of a non-absorbable material, so that only flow-restricting face **15** is retained at the therapy site after some period of time has passed. See FIGS. **9-13**. This type of construction can be advantageous where flow-restricting face **15** integrates into the side wall of the blood vessel or other body lumen after some period of time has elapsed, so that a supporting frame is no longer necessary to hold flow-restricting face **15** in position against the side wall of the blood vessel or other body lumen.

It is also possible for the entire expandable spherical structure **5** to be formed out of absorbable material(s), i.e., with both open frame **10** and flow-restricting face **15** being formed out of absorbable materials. This type of construction can be advantageous where flow-restricting face **15** only needs to be held against the side wall of the blood vessel or other body lumen for a limited period of time, e.g., until aneurysm thrombosis/scarring is complete, or to reinforce the side wall of the blood vessel or other body lumen while healing occurs, etc.

It should also be appreciated that, where both open frame **10** and flow-restricting face **15** are absorbable, they may be engineered so as to have different absorption rates, so that they are removed from the therapy site at different times. This may be done by making the various elements out of different materials, or by making the various elements out of different blends of the same materials, etc.

Application to Different Types of Aneurysms

As noted above, expandable spherical structure **5** can be used to restrict flow to various types of aneurysms.

Thus, for example, FIGS. **4-8** and **9-13** show expandable spherical structure **5** being used to restrict flow to a lateral aneurysm (i.e., in these particular embodiments, to close off the lateral aneurysm).

However, it should also be appreciated that expandable spherical structure **5** may be used to restrict flow to a bifurcation aneurysm as well. Thus, for example, FIGS. **14-18** show the expandable spherical structure **5** of FIGS. **4-8** being used restrict flow to a bifurcation aneurysm, and FIGS. **19-23** show the expandable spherical structure **5** of FIGS. **9-13** being used to restrict flow to a bifurcation aneurysm (i.e., in these particular embodiments, to close off the bifurcation aneurysm). In this respect it should be appreciated that the spherical shape of expandable spherical structure **5** is particularly well suited for use in treating bifurcation aneurysms, since it may be seated securely at the bifurcation, pressing flow-restricting face **15** securely against the bifurcation aneurysm, while still allowing blood to flow substantially unobstructed through the blood vessels.

It is also anticipated that expandable spherical structure **5** may be used to restrict flow to other types of aneurysms as well, e.g., certain forms of fusiform aneurysms. Where expandable spherical structure **5** is to be used to restrict flow to a fusiform aneurysm, flow-restricting face **15** may comprise a significantly enlarged surface area, or flow-restricting face **15** may comprise two or more separated segments disposed about the lateral portions of open frame **10**, etc.

Structure of Open Frame 10

It should be appreciated that open frame **10** can be formed with a variety of different configurations without departing from the scope of the present invention.

In one form of the invention, open frame **10** may be formed out of a plurality of struts arranged in a polygonal array. See, for example, FIGS. **4-8**, **9-13**, **14-18** and **19-23**, where open frame **10** is shown formed out of a plurality of struts arranged as triangular polygons. See also FIG. **24**, where open frame **10** is formed out of a plurality of struts arranged as rectangular polygons, and FIG. **25**, where open frame **10** is formed out of a plurality of struts arranged as hexagons.

It is also possible to form open frame **10** with a non-polygonal structure.

Thus, for example, open frame **10** may be formed with a spherical spiral structure, e.g., such as is shown in FIG. **26**, where a spiral strut forms the open frame **10**.

FIG. **27** shows an open frame **10** having a spherical cage structure. More particularly, in this construction, open frame **10** comprises a plurality of axially-aligned struts **20** which extend between flow-restricting face **15** and an annular ring **25**. Struts **20** preferably bow outwardly when open frame **10** is in its expanded configuration, but may be bent inwardly (e.g., to a straight or inwardly-bowed configuration) or otherwise deformed so as to permit open frame **10** to assume a reduced configuration. By way of example but not limitation, struts **20** may be bent inwardly (e.g., so as to extend substantially parallel to one another) when open frame **10** is in its reduced configuration.

FIGS. **28-37** show other spherical cage constructions wherein various struts **20** form open frame **10**.

It will be appreciated that, with the construction shown in FIG. **27**, flow-restricting face **15** sits at one end of the plurality of axially-aligned struts **20** and annular ring **25** sits at the opposing end of the plurality of axially-aligned struts **20**. Since struts **20** are intended to be bowed inwardly so that the expandable spherical structure can assume a reduced configuration, the spherical cage structure of FIG. **27** is generally intended to be delivered axially, with flow-restricting face **15** leading. Thus, this construction is particularly well suited for use with bifurcation aneurysms, where the neck of the aneurysm is typically axially-aligned with the direction of approach (see, for example, FIGS. **14-18** and **19-23**). Accordingly, where the spherical cage structure is intended to be used with lateral aneurysms, it may be desirable to use the spherical cage configuration shown in FIG. **38**, where flow-restricting face **15** is disposed to one side of the axis of approach, i.e., to one side of the axis **27** shown in FIG. **38**. In other words, where the spherical cage structure is intended to be used with a bifurcation aneurysm, flow-restricting face **15** is intended to be aligned with the axis of approach, and where the spherical cage structure is intended to be used with a lateral aneurysm, flow-restricting face **15** is intended to be disposed to one side of the axis of approach. In this way, expandable spherical structure **5** can be endoluminally advanced to the therapy site and flow-restricting face **15** properly positioned relative to the anatomy.

FIGS. **39-43** show other spherical cage constructions wherein various struts **20** form open frame **10** and flow-restricting face **15** is disposed to one side of the axis of approach.

Installation Tools

Various installation tools may be provided to deploy expandable spherical structure **5** within a blood vessel or other body lumen.

Thus, for example, in FIG. **44**, there is shown a syringe-type (e.g., an outer sleeve with an internal pusher) installation tool **100** for deploying the expandable spherical structure **5** shown in FIG. **45**. Installation tool **100** generally comprises a hollow sleeve **105** having a lumen **110** therein, and a pusher **115** slidably disposed within lumen **110**. Lumen **110** is sized so that it can accommodate expandable spherical structure **5** when the expandable spherical structure is in its reduced configuration (FIG. **44**), but not when it is in its enlarged configuration (FIG. **45**). As a result of this construction, expandable spherical structure **5** may be positioned within lumen **110** (distal to pusher **115**) when expandable spherical structure **5** is in its reduced configuration, advanced to the therapy site while within sleeve **105**, and then installed at the therapy site by advancing pusher **115** so that expandable spherical structure **5** is ejected from the interior of sleeve **105**. Once expandable spherical structure **5** has been ejected from sleeve **105**, expandable spherical structure **5** can return to an expanded configuration (FIG. **45**) so as to be securely engaged in the blood vessel or other body lumen in the manner previously described, with flow-restricting face **15** pressed against a side wall of the blood vessel or other body lumen. It will be appreciated that the syringe-type installation tool **100** is particularly advantageous where expandable spherical structure **5** is elastically deformable, such that sleeve **105** can serve to mechanically restrain the expandable spherical structure in its reduced configuration while the expandable spherical structure is within sleeve **105**, and release that mechanical constraint when the expandable spherical structure is ejected from sleeve **105**.

As noted above, expandable spherical structure **5** of FIGS. **27**, **44** and **45** is well suited for use with bifurcation aneurysms, where the neck of the aneurysm is typically axially-aligned with the direction of approach (see, for example, FIGS. **14-18** and **19-23**). Where the spherical cage structure is intended to be used with lateral aneurysms, it may be desirable to use the spherical cage configuration shown in FIG. **38**, where flow-restricting face **15** is disposed to one side of the axis of approach.

If desired, installation tool **100** can be provided with a gripper mechanism to releasably secure expandable spherical structure **5** to installation tool **100**, e.g., so as to releasably secure expandable spherical structure **5** to installation tool **100** until after expandable spherical structure **5** has been advanced to the therapy site and has returned to its enlarged configuration, so that it is ready to be left at the therapy site. This gripper mechanism ensures complete control of expandable spherical structure **5** as it is moved out of the installation tool and erected within the body, and also facilitates more precise positioning (e.g., with proper rotation, etc.) of the expandable structure against the side wall of the body lumen.

More particularly, and looking now at FIG. **46**, installation tool **100** may be provided with a plurality of spring grippers **125**. Spring grippers **125** are disposed within lumen **110** of sleeve **105**, exterior to pusher **115**. Each spring gripper **125** is formed so that when a bowed portion **130** of the spring gripper is restrained within lumen **110**, a hook portion **135** of that spring gripper holds annular ring **25** of expandable spherical structure **5** to the distal end of pusher **115**. However, when pusher **115** is advanced to the point where bowed portion **130** of spring gripper **125** is no longer restrained within lumen **110**, hook portion **135** of spring gripper **125** moves outboard so as to release annular ring **25** of expandable spherical structure **5** from the distal end of pusher **115**. Thus it will be seen that spring grippers may be used to releasably secure expandable spherical structure **5** to installation tool **100** until after the expandable spherical structure has been advanced out of the distal end of the installation tool and returned to its enlarged configuration. This arrangement can provide the clinician with increased control as expandable spherical structure **5** is deployed within the blood vessel.

As noted above, expandable spherical structure **5** of FIGS. **27** and **44-46** is well suited for use with bifurcation aneurysms, where the neck of the aneurysm is typically axially-aligned with the direction of approach (see, for example, FIGS. **14-18** and **19-23**). Where the spherical cage structure is intended to be used with lateral aneurysms, it may be desirable to use the spherical cage configuration shown in FIG. **38**, where closed face **15** is disposed to one side of the axis of approach.

If desired, installation tool **100** can be provided with an expansion balloon for expanding the expandable spherical structure from its reduced configuration to its enlarged configuration. More particularly, and looking now at FIGS. **47-49**, installation tool **100** may be provided with sleeve **105** and pusher **115** as discussed above. In addition, installation tool **100** may be provided with an expansion balloon **140**. Expansion balloon **140** is supported on an inflation rod **145** which is movably disposed within pusher **115**. Expansion balloon **140** is (in its deflated condition) disposed internal to open frame **10** of expandable spherical structure **5**. As a result of this construction, installation tool **100** may receive expandable spherical structure **5** while the expandable spherical structure is in its reduced configuration, carry the expandable spherical structure to the desired therapy site, position the expandable spherical structure at the desired location, and then expand expansion balloon **140** so as to open the expandable spherical structure to its enlarged configuration. Expansion balloon **140** may then be deflated and withdrawn from the interior of expandable spherical structure **5**. It will be appreciated that providing installation tool **100** with an expansion balloon may be advantageous where expandable spherical structure **5** does not self-erect within the body lumen.

Expandable Spherical Structure Having a Flow-Restricting Face Formed with a High Strut Density

In FIGS. **1-50**, flow-restricting face **15** of expandable spherical structure **5** is depicted as a closed face, in the sense that flow-restricting face **15** comprises a substantially complete surface or barrier which is capable of closing off (and/or very significantly reducing flow to) an aneurysm or other opening in the side wall of a blood vessel or other body lumen, and/or for reinforcing a weakness in the side wall of the blood vessel or other body lumen. However, it should be appreciated that for many applications, flow-restricting face **15** need not comprise a substantially complete surface or barrier, i.e., flow-restricting face **15** may be formed with a face having a sufficiently high strut density to form an effectively closed face or to otherwise achieve a desired purpose. Thus, for example, in FIGS. **50-54**, there is shown an expandable spherical structure **5** comprising an open frame **10** having a flow-restricting face **15** formed with a high strut density such that blood flow to the aneurysm will be restricted and the aneurysm will thrombose. In this circumstance, flow-restricting face **15** may be considered to be effectively closed. Furthermore, where flow-restricting face **15** is being used to reinforce a weakness in a side wall (as opposed to being used to restrict flow to an opening in a side wall), closed face **15** may have a somewhat lower strut density, since it does not need to significantly restrict the flow of a fluid.

FIGS. **55-63** show other expandable spherical structures **5** wherein flow-restricting face **15** is formed with a sufficiently high strut density to achieve a desired purpose. In this respect it will be appreciated that, as used herein, the term strut is intended to mean substantially any element spaced from an adjacent element or in contact with an adjacent element. Thus, where flow-restricting face **15** is formed by a face having a high strut density, the struts may be in the form of a screen, a mesh, a lattice, a series of parallel or concentric interlaced or otherwise patterned struts, etc.

It should also be appreciated that it is possible to form the entire expandable spherical structure **5** out of a single superelastic wire, e.g., a shape memory alloy constructed so as to form stress-induced martensite at body temperatures. By way of example but not limitation, an appropriately blended and treated Nitinol wire may be used. In this form of the invention, the expandable spherical structure **5** can be (i) deformed into a collapsed configuration wherein a single path of the wire is constrained within a restraining cannula, and (ii) thereafter reformed in situ by simply pushing the wire out of the distal end of the restraining cannula, whereupon expandable spherical structure **5** reforms in the blood vessel or other body lumen. This form of the invention is particularly well suited to constructions where flow-restricting face **15** is formed with a single, patterned strut arranged to have a high strut density, e.g., with a strut density sufficiently high to restrict flow to the mouth of an aneurysm, and/or a strut density sufficiently high to reinforce the side wall of a blood vessel or other body lumen, and/or a strut density sufficiently high to achieve some other desired purpose. See, for example, FIGS. **59-63**, which show flow-restricting face **15** formed out of a single, patterned strut, where the strut pattern may comprise one or more of a variety of configurations, e.g., with parallel paths, concentric paths, switchback paths, serpentine paths, etc.

Utilizing the Expandable Spherical Structure in Conjunction with Thrombosis-Inducing Coils

As noted above, conventional minimally-invasive techniques for treating brain aneurysms generally involve depositing thrombosis-inducing coils within the dome of the aneurysm. If desired, the expandable spherical structure **5** of the present invention may be used in conjunction with thrombosis-inducing coils, i.e., the thrombosis-inducing coils may be deposited within the dome of an aneurysm after positioning the expandable spherical structure against the mouth of the aneurysm so as to restrict flow into the aneurysm, i.e., by introducing the thrombosis-inducing coils through the face having a high strut density and into the dome of the aneurysm. Alternatively, the thrombosis-inducing coils may be deposited within the dome of the aneurysm before positioning the expandable spherical structure against the mouth of the aneurysm so as to restrict flow into the aneurysm. Significantly, it is believed that this approach will both facilitate thrombosis formation and also prevent coil migration out of the aneurysm.

Deploying the Expandable Spherical Structure within an Aneurysm

It should also be appreciated that expandable spherical structure **5** may be deployed within the body of an aneurysm so that its flow-restricting face **15** confronts the lumen, rather than being within the lumen so that its flow-restricting face confronts the body of the aneurysm. See, for example, FIGS. **64-66**, which show the expandable spherical structure **5** of FIGS. **4-8** deployed within the body of the aneurysm. See also, for example, FIGS. **67-71**, which show the expandable spherical structure **5** of FIGS. **9-13** being disposed within the body of the aneurysm.

Again, the expandable spherical structure **5** may be positioned within the interior of a lateral aneurysm (FIGS. **64-66** and **67-71**) or it may be disposed within a bifurcated aneurysm (FIGS. **72-76** and **77-81**).

Expandable Spherical Structure with Stabilizing Legs—"Comet-Shaped Structure"

It is also possible to provide expandable spherical structure **5** with stabilizing legs. Such a construction may be adapted for use with both lateral aneurysms and with bifurcation aneurysms.

More particularly, and looking now at FIGS. **82** and **83**, there is shown an expandable spherical structure **5** which comprises an open frame **10** with a flow-restricting face **15**. Extending out of open frame **10** are one or more stabilizing legs **30**. Stabilizing legs **30** are formed so that, when flow-restricting face **15** is positioned against the side wall of a blood vessel or other body lumen, stabilizing legs **30** extend endoluminally through the blood vessel or other body lumen. Thus it will be appreciated that the expandable spherical structure **5** shown in FIGS. **82** and **83** is generally intended to be used with a lateral aneurysm, since the center axis **35** of stabilizing legs **30** is set at a right angle to the center axis **40** of flow-restricting face **15** (see FIG. **83**).

Preferably, and as seen in FIGS. **82** and **83**, stabilizing legs **30** together form a somewhat cone-shaped structure, so that the overall shape of open frame **10** (with flow-restricting face **15**) and stabilizing legs **30** is a generally comet-shaped structure.

As seen in FIG. **84**, this comet-shaped structure may be compressed within a containment sheath **200**, with stabilizing legs **30** leading and with open frame **10** (with flow-restricting face **15**) trailing, and with a push catheter **205** and tension wire **210** engaging open frame **10** of expandable spherical structure **5**. At the aneurysm site, push catheter **205** ejects the comet-shaped structure, "legs first", so that closed face **15** restricts access to the mouth of the aneurysm while stabilizing legs **30** help maintain the position of open frame **10** (and flow-restricting face **15**) within the blood vessel. This deployment procedure is preferably conducted over a guidewire **215**.

If the comet-shaped structure subsequently needs to be repositioned or removed from a deployment site, tension wire **210** may be used to pull the comet-shaped structure retrograde, e.g., within the blood vessel or all the way back into containment sheath **200**. To this end, and looking now at FIGS. **85-87**, open frame **10** of expandable spherical structure **5** may comprise a proximal end ring **220**, and tension wire **210** may comprise an expandable head **225** adapted to extend through proximal end ring **220** and then expand, whereupon the comet-shaped structure may be moved retrograde. Alternatively, open frame **10** of expandable spherical structure **5** may comprise an apex **230** of converging wires which can be gripped by a J-hook **235** formed on the distal end of tension wire **210** (FIG. **88**) or by C-fingers **240** formed on the distal end of tension wire **210** (FIG. **89**).

If desired, and looking now at FIGS. **85-87**, the distal ends of stabilizing legs **30** may be turned into eyelets **245**, so as to minimize trauma (during both placement and repositioning) to the side wall of the body lumen (e.g., blood vessel) in which they are disposed.

It will be appreciated that, where flow-restricting face **15** covers only a portion of the circumference of open frame **10**, it can be important for the clinician to ensure the rotational disposition of the comet-shaped structure so that flow-restricting face **15** is properly aligned with the mouth of the lateral aneurysm. For this reason, and looking now at FIG. **90**, push catheter **205** may include a plurality of slits **250** on its distal end which receive the constituent wires of open frame **10**, whereby to permit the clinician to adjust the rotational disposition of the comet-shaped structure (and hence the rotational disposition of flow-restricting face **15** of open frame **10**). Alternatively, and looking now at FIG. **91**, push catheter **205** may be formed with an obround shape (or any other appropriate non-circular shape) so as to permit the clinician to specify the rotational disposition of the comet-shaped structure (and hence the rotational disposition of flow-restricting face **15** of open frame **10**).

Looking now at FIGS. **92** and **93**, flow-restricting face **15** of open frame **10** can be formed by wrapping a membrane **255** over the wire skeleton making up open frame **10** and securing it in position. Thus, FIGS. **94** and **95** show membrane **255** covering only a portion of the circumference of frame **10**, and FIGS. **96** and **97** show membrane **255** covering the complete circumference of frame **10**.

In the foregoing description, the expandable spherical structure **5** of FIGS. **82** and **83** is discussed in the context of a "legs-first" deployment into the blood vessel or other body lumen. However, it should also be appreciated that the expandable spherical structure **5** of FIGS. **82** and **83** may be deployed "head-first" into the blood vessel or other body lumen (i.e., with stabilizing legs **30** trailing open frame **10**).

Looking next at FIG. **98**, it is also possible to provide a comet-shaped structure which can be used with a bifurcation aneurysm. More particularly, in this form of the invention, expandable spherical structure **5** is formed so that center axis **40** of flow-restricting face **15** is aligned with center axis **35** of stabilizing legs **30**. It will be appreciated that where the comet-shaped structure is to be used with to treat a bifurcation aneurysm, it is generally desirable that the "head" of the comet (which comprises flow-restricting face **15**) be ejected out of containment sheath **200** first, with stabilizing legs **30** trailing, whereby to easily place flow-restricting face **15** against the mouth of the aneurysm.

Expandable Spherical Structure Formed Out of a "Closed Loop" of Filament

In the preceding description, expandable spherical structure **5** is described as comprising an open frame **10** having a flow-restricting face **15** carried thereon. More particularly, in some embodiments of the invention, flow-restricting face **15** comprises a substantially complete surface or barrier. See, for example, FIGS. **4-49**. However, in other embodiments of the invention, flow-restricting face **15** need not comprise a substantially complete surface or barrier, i.e., flow-restricting face **15** may be formed with a face having a sufficiently high strut density to form an effectively closed face or to otherwise achieve a desired purpose. Thus, for example, in FIGS. **50-58**, there is shown an expandable spherical structure **5** comprising an open frame **10** having a flow-restricting face **15** formed with a high strut density such that blood flow to the aneurysm will be restricted and the aneurysm will thrombose. In this circumstance, flow-restricting face **15** may be considered to be effectively closed, in the sense that flow-restricting face **15** is sufficiently closed to decrease flow velocity in the aneurysm and result in thrombosis within the aneurysm. Furthermore, where flow-restricting face **15** is being used to reinforce a weakness in a side wall (as opposed to being used to close off an opening in a side wall or to otherwise restrict flow through that opening), flow-restricting face **15** may have a somewhat lower strut density. In any case, however, flow-restricting face **15** will still have a significantly higher strut density than that of open frame **10**.

In the preceding description, it was noted that it is possible to form the entire expandable spherical structure **5** out of a single superelastic wire, e.g., a shape-memory alloy constructed so as to form stress-induced martensite at body temperatures. It was also noted that, in this form of the invention, the expandable spherical structure **5** can be (i) deformed into a collapsed configuration wherein a single path of the wire is constrained within a constraining cannula, and (ii) thereafter reformed in situ by simply pushing the wire out of the distal end of the restraining cannula, whereupon expandable spherical structure **5** reforms in the blood vessel or other body lumen. It was further noted that this form of the invention is particularly well suited to constructions wherein closed face **15** is formed with a single, patterned strut arranged to have a high strut density, e.g., with a strut density sufficiently high to restrict the flow of blood through the mouth of an aneurysm (i.e., to cause thrombosis of the aneurysm), and/or a strut density sufficiently high to reinforce the side wall of a blood vessel or other body lumen, and/or a strut density sufficiently high to achieve some other desired purpose. Again, however, flow-restricting face **15** will still have a significantly higher strut density than that of open frame **10**. See, for example, FIGS. **59-63**, which show flow-restricting face **15** formed out of a single, patterned strut, where the strut pattern may comprise one or more of a variety of configurations, e.g., with parallel paths, concentric paths, switchback patterns, serpentine paths, etc.

In accordance with the present invention, there is now disclosed a further construction wherein expandable spherical structure **5** is formed out of a closed loop of filament such as highly flexible wire (e.g., Nitinol) which has been worked (e.g., on a mandrel) so that its numerous turns approximate the shape of a sphere or ellipsoid when the loop is in its relaxed condition. One face of the sphere (i.e., flow-restricting face **15**) has a higher turn density than the remainder of the sphere (i.e., open frame **10**) so that the high density face can restrict blood flow while the remainder of the sphere easily passes blood flow. The closed loop of filament may be transformed from its spherical shape into another shape by applying physical forces (e.g., tension) to the closed loop of filament. Thus, the closed loop of filament may be transformed from its three-dimensional substantially spherical configuration into a substantially two-dimensional "elongated loop" configuration (e.g., by applying two opposing forces to the interior of the loop) in order that the closed loop of filament may be advanced endoluminally to the site of an aneurysm. Once at the site of the aneurysm, the tension on the elongated loop may be released so that the closed loop of filament returns to its spherical shape, whereby to lodge in the blood vessel with the high density face (i.e., flow-restricting face **15**) diverting the flow of blood away from the aneurysm (i.e., to cause thrombosis within the aneurysm) while the remainder of the sphere (i.e., open frame **10**) easily passes blood flowing through the parent vessel. If the sphere subsequently needs to be re-positioned within the blood vessel, the tension is re-applied to the sphere so as to transform it part or all the way back to its elongated loop configuration, the position of the device is adjusted, and then the foregoing process repeated so as to set the sphere at a new position within the blood vessel. Furthermore, if the sphere needs to be removed from the blood vessel, the tension is re-applied to the sphere so as to transform it back to its elongated loop configuration, and then the loop is removed from the patient. Significantly, this construction has the advantages of (i) ease of positioning, (ii) reliably maintaining its deployed position within the vessel, (iii) ease of re-positioning within the body, and (iv) where necessary, removal from the body.

By way of example but not limitation, FIG. **63** shows a expandable spherical structure **5** which is formed out of a closed loop of highly flexible wire. As can be seen in FIG. **63**, expandable spherical structure **5** approximates the shape of a sphere or ellipsoid when the loop is in its relaxed condition. FIG. **63** shows expandable spherical structure **5** being used to restrict blood flow to a lateral aneurysm. FIGS. **99** and **100** show expandable spherical structure **5** being used to restrict blood flow to a bifurcation aneurysm.

FIGS. **101** and **102** shows an inserter **300** which can be used to reconfigure such a "closed loop" expandable spherical structure **5** from its relaxed spherical (or elliptical) configuration into an elongated loop configuration. To this end, inserter **300** preferably comprises an inner catheter **305** which includes a bifurcated distal end **310** which can seat a segment of the closed loop. Inserter **300** preferably also comprises an outer catheter **315** which includes a mount **320** which can seat another segment of the closed loop.

In use, and as shown in FIGS. **103-107**, inserter **300** is set so that its outer catheter **315** is adjacent to bifurcated distal end **310**, and then a segment of the closed loop expandable spherical structure **5** is seated in bifurcated distal end **310** and another segment of the closed loop expandable spherical structure is seated in mount **320** of outer catheter **315**. Then outer catheter **315** is moved proximally so that the closed loop expandable spherical structure **5** is reconfigured from its relaxed spherical (or elliptical) configuration into an elongated loop configuration, e.g., in the manner of a tensioned elastic band. With the closed loop expandable spherical structure **5** held in this elongated condition on inserter **300**, a transport sheath **325** is (optionally) be placed over the assembly. Inserter **300** (with its passenger closed loop expandable spherical structure **5** and with its overlying transport sheath **325**) is moved through the patient's anatomy until spherical structure **5** is located at the surgical site. Then transport sheath **325** is removed and outer catheter **315** is moved distally on inner catheter **305**. As outer catheter **315** is moved distally on inner catheter **305**, tension on expandable spherical structure **5** is released so that expandable spherical structure **5** can re-assume its spherical or elliptical shape and engage the adjacent anatomy. Then expandable spherical structure **5** is disengaged from inserter **300**, and inserter **300** is removed from the surgical site.

If, after deployment, the closed loop expandable spherical structure needs to be re-positioned within the blood vessel, inserter **300** is used to re-apply tension to the sphere so as to transform the sphere part or all the way back to its loop configuration, the position of the device is adjusted, and then the foregoing process is repeated so as to set the sphere at a new position within the blood vessel.

Furthermore, if, after deployment, the closed loop expandable spherical structure **5** needs to be removed from the blood vessel, inserter **300** is used to re-apply tension to the sphere so as to transform it back to its loop configuration, and then the loop is removed from the patient.

Significantly, this construction has the advantages of (i) ease of positioning, (ii) reliably maintaining its deployed position within the vessel, (iii) ease of re-positioning within the body, and (iv) where necessary, removal from the body.

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In the foregoing disclosure, expandable spherical structure **5** is described as comprising a spherical body. In this regard, it should be appreciated that the term "spherical" is intended to mean a true spherical shape, and/or a substantially spherical shape, and/or a near spherical shape (including but not limited to an ellipsoid shape or a substantially ellipsoid shape or a near ellipsoid shape), and/or an effectively spherical shape, and/or a generally spherical shape, and/or a polyhedron which approximates a sphere, and/or a shape which approximates a sphere, and/or a structure comprising a substantial portion of any of the foregoing, and/or a structure comprising a combination of any of the foregoing, etc.

Thus, for example, expandable spherical structure **5** may include a first section that constitutes a portion of a sphere and a second section which roughly approximates the remaining portion of a sphere.

Method for Manufacturing the Novel Device from a Single Elastic Filament

In the foregoing disclosure, there is disclosed a novel device for, among other things, positioning in a blood vessel (or vessels) adjacent to the mouth of an aneurysm and for causing thrombosis of the aneurysm by restricting blood flow to the aneurysm while maintaining substantially normal blood flow through the blood vessel (or vessels) which receive(s) the device, wherein the device comprises a single elastic filament configurable between: (i) a longitudinally-expanded, substantially linear configuration, whereby to facilitate movement of the device along the vascular system of the patient to the site of the aneurysm; and (ii) a longitudinally-contracted, substantially three-dimensional configuration for lodging within the central lumen of the blood vessel (or vessels) adjacent to the mouth of the aneurysm, the longitudinally-contracted, substantially three-dimensional configuration providing (a) a flow-restricting face for positioning at the mouth of the aneurysm, the flow-restricting face comprising a plurality of lengths of the single elastic filament disposed in close proximity to one another so as to significantly restrict blood flow to the aneurysm and thereby cause thrombosis of the aneurysm, and (b) a substantially open frame for holding the flow-restricting face adjacent to the mouth of the aneurysm, the substantially open frame being configured so as to maintain substantially normal blood flow through the central lumen of the blood vessel (or vessels) which receive(s) the device.

In one preferred form of the present invention, the novel device is formed out of a single elastic filament having distinct first and second ends, and the longitudinally-expanded, substantially linear configuration is formed by disposing the first and second ends oppositely away from one another. In another preferred form of the present invention, the device is formed out of a single elastic filament having its first and second ends unified with one another (e.g., by welding, by banding, etc.) so as to effectively form a continuous, closed loop of elastic filament, and the longitudinally-expanded, substantially linear configuration is formed by disposing the continuous, closed loop of elastic filament so that it essentially consists of two parallel lengths of the single elastic filament.

And in one preferred form of the present invention, the longitudinally-contracted, substantially three-dimensional configuration is substantially spherical, or substantially ellipsoid, or some other three-dimensional shape appropriate for holding the flow-restricting face of the device against the mouth of the aneurysm while maintaining substantially normal blood flow through the central lumen of the blood vessel (or vessels) which receive(s) the device.

And in one preferred form of the present invention, the single elastic filament comprises a shape memory material, e.g., Nitinol, with the elastic filament transforming between its longitudinally-expanded, substantially linear configuration and its longitudinally-contracted, substantially three-dimensional configuration by temperature transition or by superelasticity.

And in one preferred form of the present invention, the shape memory material may comprise an appropriate nickel titanium alloy (e.g., Nitinol), an appropriate copper-based alloy (e.g., Cu—Zn—Al, Cu—Al—Ni, Cu—Al—Mn, Cu—Al—Be, etc.), and an appropriate iron-based alloy (e.g., Fe—Mn—Si, Fe—Cr—Ni—Mn—Si—Co, Fe—Ni—Mn, Fe—Ni—C, Fe—Pt, Fe—Pd, etc.), etc. Additionally, the shape memory material may comprise a shape memory polymer.

In order for a shape memory material to be capable of automatically transforming between a "first shape" and a "second shape" by temperature transition or by superelasticity, it is necessary to first process the shape memory material in a particular manner. More particularly, the shape memory material is initially formed with the "first shape", then it is mechanically transformed to the desired "second shape" and then, while mechanically held in the desired "second shape" (e.g., by a fixture), the shape memory material is heat treated, i.e., it is brought to an elevated temperature for a controlled length of time and then rapidly quenched so as to return the shape memory material to ambient temperature. This processing causes the shape memory material to retain its aforementioned "second shape", even after the device is released from the fixture. Thereafter, the shape memory material may be transformed from its "second shape" to its "first shape" (e.g., by temperature transition or by mechanical deformation) and then, when desired, automatically returned to its "second shape" (e.g., by a different temperature transition or by releasing the mechanical deformation).

Thus it will be seen that, in connection with the present invention, when the novel device is to be formed out of a shape memory material, with the "second shape" being the aforementioned longitudinally-contracted, substantially three-dimensional configuration and the "first shape" being the aforementioned longitudinally-expanded, substantially linear configuration, the device must be held in its "second shape" on a fixture while the shape memory material is appropriately heat treated (e.g., heated and then rapidly quenched) so that the device will thereafter retain its "second shape" when it is released from the fixture.

In one preferred form of the present invention, the elastic filament comprises shape memory material wire (e.g., Nitinol wire), and the novel device is formed by first winding the elastic filament around a plurality of surface features (e.g., posts) disposed on (or in) a three-dimensional body (i.e., "the fixture"), and then appropriately heat treating the elastic filament while it is retained on the fixture so that the elastic filament will retain the desired "second shape" (i.e., the aforementioned longitudinally-contracted, substantially three-dimensional configuration) when the device is released from the fixture. See, for example, FIG. **108**, which shows a novel device **400** comprising a single elastic filament **405**, wherein the elastic filament **405** is wound around a plurality of posts **410** which are mounted on a three-dimensional (e.g., spherical) body **415** (i.e., "the fixture") for appropriate heat treatment. It will be appreciated that this approach may be used regardless of whether the single elastic filament has distinct first and second ends or has its first and second ends unified with one another (e.g., by welding, by banding, etc.) so as to effectively form a continuous, closed loop.

The foregoing manufacturing approach, which may sometimes be referred to herein as the "winding" approach, is highly advantageous since it allows the elastic filament to be formed out of shape memory material wire (e.g., Nitinol wire), which is well known in the art. As a result, it is possible to take advantage of the substantial body of general knowledge which already exists with respect fabricating, handling and heat treating shape memory material wire (e.g., Nitinol wire).

However, as noted above, this "winding" approach requires that the elastic filament be wound around surface features (e.g., posts) disposed on (or in) a three-dimensional body (i.e., "the fixture").

In another preferred form of the present invention, there is provided an alternative manufacturing approach, which may sometimes be referred to herein as the "flat-to-3D" approach. Generally described, with this "flat-to-3D" approach, and looking now at FIGS. **109**-**111**, a flat sheet **420** of shape memory material (e.g., Nitinol) is patterned so as to create at least one, and preferably a plurality of, single filament, two-dimensional interim structures **425** (FIGS. **109** and **110**). These single filament, two-dimensional interim structures **425** are thereafter released (i.e., separated) from the flat sheet **420** (e.g., by severing an attachment tab **430** connecting the single filament, two-dimensional interim structure **425** to the flat sheet **420** of shape memory material), and then mounted onto an appropriate three-dimensional body (i.e., "the fixture") for heat treating (i.e., heating and rapidly quenching), so that the single filament, two dimensional interim structure **425** will thereafter assume the desired "second shape" (i.e., the aforementioned longitudinally-contracted, substantially three-dimensional configuration) **435** (FIG. **111**) when the device is thereafter released from the fixture, whereby to provide the desired shape for the device.

More particularly, the aforementioned longitudinally-contracted, substantially three-dimensional configuration **435** of the device (FIG. **111**) is projected into a corresponding two-dimensional configuration **440** (FIG. **112**) for the device. This two-dimensional projection **440** of the device (FIG. **112**) corresponds to the single filament, two-dimensional interim structure **425** referred to above. This two-dimensional projection **440** of the device (FIG. **112**) is then used to fabricate the single filament, two-dimensional interim structure **425** from a flat sheet **420** of shape memory material.

In one preferred form of the invention, and looking now at FIG. **113**, a plurality of these single filament, two-dimensional interim structures **425** are produced from one flat sheet **420** of shape memory material. This may be effected using a number of different fabrication techniques, including chemical etching, laser cutting, etc. Chemical etching is currently generally preferred, and may yield the single filament, two-dimensional interim structures **425** shown in FIGS. **114**, **116** and **118**, with each individual single filament, two-dimensional interim structure **425** being attached to the flat sheet **420** of shape memory material by at least one attachment tab **430**. Preferably the single filament, two-dimensional interim structure **425** carried by the flat sheet **420** of shape memory material is then electro-polished, which is a "reverse plating" process that electrochemically removes additional material. This occurs preferentially at sharp corners, where the electrical fields are the strongest, thereby advantageously rounding off sharp corners. See, for example, FIGS. **115**, **117** and **119**, which show the etched structures of FIGS. **114**, **116** and **118**, respectively, after electro-polishing.

Thereafter, the single filament, two-dimensional interim structure **425** is dismounted from the flat sheet **420** of shape memory material (e.g., by severing the one or more attachment tabs **430** holding the single filament, two-dimensional interim structure **425** to the flat sheet **420** of shape memory material), and then the freed single filament, two-dimensional interim structure **425** is mounted on an appropriate three-dimensional fixture so that the single filament, two-dimensional interim structure **425** assumes the desired "second shape", i.e., the aforementioned longitudinally-contracted, substantially three-dimensional configuration.

See, for example, FIGS. **120**-**125**, which show a two-part fixture **450** comprising a male half **455** and a female half **460**. Male half **455** comprises a three-dimensional (e.g., spherical) body **465** having a plurality of posts **470** mounted thereon. Female half **460** comprises a three-dimensional (e.g., spherical) cavity **475** which is the substantial inverse of at least a portion of three-dimensional body **465**. The single filament, two-dimensional interim structure **425** is set on the three-dimensional body **465** using posts **470** to stabilize the single filament, two-dimensional interim structure, and then the two halves **455**, **460** are brought together so as to force the single filament, two-dimensional interim structure **425** to assume the desired "second" shape (i.e., the aforementioned longitudinally-contracted, substantially three-dimensional configuration).

With the single filament, two-dimensional interim structure **425** restrained in the desired "second shape" (i.e., the aforementioned longitudinally-contracted, substantially three-dimensional configuration), the device is heat treated (i.e., it is appropriately heated and then rapidly quenched to ambient temperature) so as to "train" the device to assume the desired "second shape" (i.e., the longitudinally-contracted, substantially three-dimensional configuration). The device may thereafter be dismounted from the three-dimensional fixture, whereby to provide the structure **435** shown in FIG. **111**, and thereafter used in the manner previously discussed.

In connection with the foregoing, the following additional points should be appreciated.

Device Design.

In certain circumstances, it may be desirable to form certain portions of the novel device with a stiffer characteristic than other portions of the device, which may require a more flexible characteristic. By way of example but not limitation, by forming certain portions of the device with a stiffer characteristic, the ability of the device to return to its longitudinally-contracted, substantially three-dimensional configuration **435** (FIG. **111**) may be enhanced. This can be extremely useful where the device is made with a relatively thin elastic filament in order to fabricate a relatively small device, since a relatively thin elastic filament may not generate adequate return forces to restore the device to its longitudinally-contracted, substantially three-dimensional configuration **435** (FIG. **111**) when the device is disposed in a blood vessel (or vessels).

One way of providing regions of greater or lesser stiffness is by forming the elastic filament with regions of thicker or thinner dimensions. This is relatively easy to do with the "flat-to-3D" approach of the present invention, where the single filament, two-dimensional interim structure **425** is being formed out of a large flat sheet **420** of shape memory material. In this case, the regions of greater stiffness are formed thicker (e.g., wider) and the regions of lesser stiffness are formed thinner (e.g., narrower).

By way of example but not limitation, where etching is used to fabricate the single filament, two-dimensional interim structure **425** from a flat sheet **420** of shape memory material, the process is essentially a substractive process where material is etched away. As a result, different thicknesses (e.g., widths) may be provided for the elastic filament by etching away more or less material from flat sheet **420**. See, for example, FIG. **110**, where portions **480** of single filament, two-dimensional interim structure **425** have a greater thickness (e.g., width) than portions **485** of single filament, two-dimensional interim structure **425**. This construction is retained in the longitudinally-contracted, substantially three-dimensional configuration **435** (FIG. **111**) which is produced from the single filament, two-dimensional interim structure **425** after appropriate heat treatment on a fixture (e.g., the two-part fixture **450** shown in FIGS. **120-125**).

Another way of forming regions of greater or lesser stiffness is by forming the elastic filament with regions of differing cross-section. By way of example but not limitation, where the device has a round cross-section, the device will tend to bend equally well in all directions when the bend occurs at that cross-section, but where the device has a rectangular cross-section, the device will tend to bend preferentially in certain directions when the bend occurs at that cross-section. Accordingly, it is possible to form regions of greater or lesser stiffness by intentionally varying the cross-section of the device along its length, whereby to provide the device with the mechanical properties desired for various segments of the device. Again, this is relatively easy to do with the "flat-to-3D" approach of the present invention, where the single filament, two-dimensional interim structure **425** is being formed out of a large flat sheet **420** of shape memory material via a subtractive process, since the subtractive process can be used to provide various cross-sections at different points along the device.

Furthermore, the material (e.g., metallurgical) properties of the flat sheet **420** of shape memory material are not necessarily the same in all directions. By way of example but not limitation, the shape memory material may be stronger in one direction than in another direction, e.g., the shape memory material may be stronger in the direction in which it is rolled during the manufacturing process than in the opposing direction. By taking such factors into account when forming the single filament, two-dimensional interim structure **425** from the flat sheet **420** of shape memory material, it is possible to take advantage of varying material properties, e.g., so as to construct devices which can be better stretched or compressed in selected directions.

Etching.

Etching may be conducted from one side of flat sheet **420** or from both sides of flat sheet **420**, either concurrently or serially. Where etching is effected from both sides of flat sheet **420**, the resulting cross-sectional shape of the elastic filament may somewhat resemble a hexagon.

As a general rule, the etching process requires the provision of a space between the "solid" portions (i.e., the filament runs) of the device, where this space is approximately equal to the thickness of the flat sheet **420**.

In one preferred form of the invention, flat sheet **420** is approximately 0.004 inch thick. In another form of the invention, flat sheet **420** is approximately 0.0053 inch thick.

Electro-Polishing.

As noted above, electro-polishing is a "reverse plating" process which electrochemically removes material. It preferentially takes material away from sharp corners, where the electrical fields are the strongest. Rounding sharp corners is believed to be beneficial for the present invention, since it provides a gentle radius where the device touches tissue, and it reduces stress concentrations in the elastic filament. In addition, the rounding of corners will tend to bring the cross-section of the elastic filament to a near-circular shape, which will tend to increase ease of bending in any direction.

Electro-polishing removes material thickness as well. As a simple rule of thumb, electro-polishing creates about a 2× corner radius for a 1× decrease in material thickness. As a result, a 0.0005 inch thickness decrease results in a 0.001 inch radius on an outside corner.

FIGS. **126**, **128** and **130** are views showing electro-polishing to 0.00415 inch thick, and FIGS. **127**, **129** and **131** are views showing electro-polishing to 0.0039 inch thick.

Electro-polishing can also change the surface properties of the shape memory material. By way of example but not limitation, flat sheet **420** typically has machining marks and other marks from the Nitinol sheet fabrication process. These marks may be minimized or diminished in the electro-polishing process.

Electro-polishing can also change the surface finish of the device. Generally, the electro-polishing smooths the surface and makes it more corrosion resistant.

Tailoring the Cross-Section of the Device.

It should be appreciated that the cross-section of the device can affect the mechanical properties of the device when the device is subjected to various forces. By way of example but not limitation, where the device has a round cross-section, the device will tend to bend equally well in all directions when the bend occurs at that cross-section. By way of further example but not limitation, where the device has a rectangular cross-section, the device will tend to bend preferentially in certain directions when the bend occurs at that cross-section. Accordingly, in one form of the present invention, the device has a cross-section which is intentionally varied along its length in accordance with the mechanical properties desired for various segments of the device.

It will be appreciated that a desired cross-section can be achieved by appropriately selecting and implementing a specific manufacturing process, e.g., where etching is used to form the device, various etching parameters (including masking) can be adjusted so as to form a desired cross-section, and/or where electro-polishing is used to form the device, various electro-polishing parameters (including masking) can be adjusted so as to form a desired cross-section, etc.

Forming the Final Three-Dimensional Structure from the Two-Dimensional Interim Structure.

As noted above, the present invention comprises transforming the two-dimensional interim structure **425** (FIG. **110**) into the final three-dimensional structure **435** (FIG. **111**). As this transformation occurs, the spacing between the filament lengths (i.e., runs) of the two-dimensional structure **425** is reduced in the three-dimensional structure **420**. This is because the filament lengths move closer together as the device transforms from a two-dimensional structure to a three-dimensional structure (e.g., as the filament lengths move from a planar arrangement to a spherical arrangement). As result, the design must provide adequate space between the filament lengths in the two-dimensional structure so as to permit appropriate spacing of the filament lengths in the three-dimensional structure.

Modifications

It will be appreciated that still further embodiments of the present invention will be apparent to those skilled in the art in view of the present disclosure. It is to be understood that the present invention is by no means limited to the particular constructions herein disclosed and/or shown in the drawings, but also comprises any modifications or equivalents within the scope of the invention.

What is claimed is:

1. A device for positioning in a blood vessel adjacent to an aneurysm for causing thrombosis of the aneurysm while maintaining substantially normal flow through the blood vessel, said device comprising:

a single elastic filament configurable between:

(i) an elongated, substantially linear configuration, whereby to facilitate movement along a blood vessel; and

(ii) a longitudinally-contracted, substantially three-dimensional configuration for lodging within the blood vessel, said longitudinally-contracted, substantially three-dimensional configuration providing (a) a face for positioning adjacent the aneurysm, said face comprising a plurality of lengths of said elastic filament in close proximity to one another so as to restrict blood flow to the aneurysm and thereby cause thrombosis of the aneurysm, and (b) a substantially open frame for holding said face adjacent the aneurysm, said substantially open frame configured so as to maintain substantially normal flow through the blood vessel;

wherein said single elastic filament is formed from a sheet of shape memory material;

wherein said single elastic filament is formed from the sheet of shape memory material so as to provide the single elastic filament with has a width which varies along its length a cross-section which varies along its length;

wherein said single elastic filament comprises a continuous closed loop.

2. A device according to claim **1** wherein the single elastic filament comprises two distinct ends which are unified so as to form a continuous closed loop.

3. A device according to claim **2** wherein the two distinct ends are unified by welding.

4. A device according to claim **2** wherein the two distinct ends are unified by banding.

5. A device according to claim **1** wherein the single elastic filament has a rectangular cross-section along at least a portion of its length.

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