(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 June 2011 (16.06.2011)

PCT

(10) International Publication Number
WO 2011/072053 A1

(51) International Patent Classification:
*A61B 17/08* (2006.01)

(21) International Application Number:
PCT/US2010/059530

(22) International Filing Date:
8 December 2010 (08.12.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/285,397 10 December 2009 (10.12.2009) US

(71) Applicant *(for all designated States except US)*: NEUROVASX, INC. [US/US]; 7351 Kirkwood Lane N., Maple Grove, Minnesota 55369 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: LEE, Jeffrey A. [US/US]; 16110 15th Avenue N., Plymouth, Minnesota 55447 (US).

(74) Agents: MADDEN, Robert B., et al.; Schwegman, Lundberg & Woessner, PA, P.O. Box 2938, Minneapolis, Minnesota 55402 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

# (54) Title: ANEURYSM SHIELD

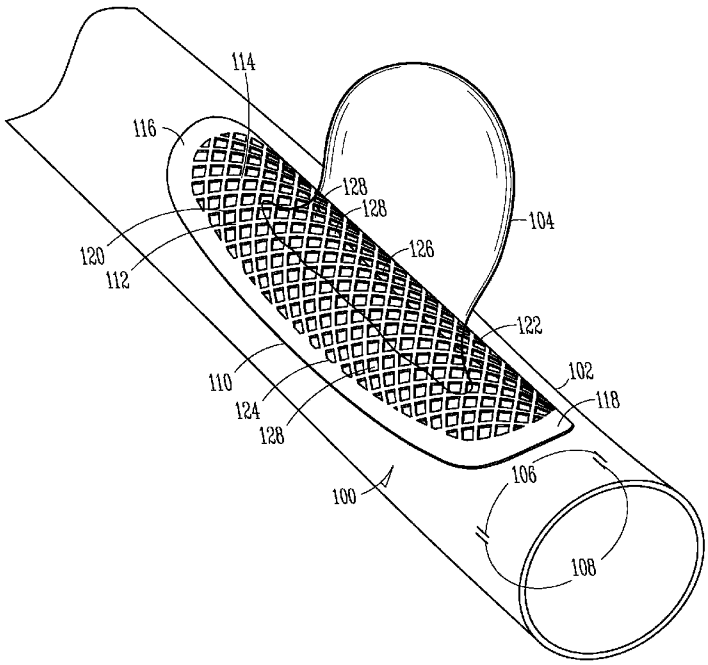



FIG. 1

**(57) Abstract**: An aneurysm shield includes a shield frame having proximal and distal frame ends. First and second draped wings extend between the proximal and distal frame ends with the first draped wing opposing the second draped wing. A first peripheral edge extends along the first draped wing, and a second peripheral edge extends along the second draped wing. The first and second draped wings are separated at the first and second peripheral edges. A shell extends across the shield frame between the first and second draped wings. The first and second draped wings are movable between a closed configuration and an anchoring configuration. In the closed configuration the first draped wing is adjacent to the second draped wing. In the anchoring configuration one or more of the first and second draped wings is spread away from the other wing to engage the aneurysm shield with a vessel wall.

WO 2011/072053 A1

# ANEURYSM SHIELD

## RELATED APPLICATIONS

This patent application claims the benefit of priority to U.S. Provisional Patent Application Serial Number 61/285,397, filed on December 10, 2009, which is incorporated herein by reference in its entirety.

## FIELD

Aneurysm treatment.

## COPYRIGHT



## BACKGROUND

An aneurysm is a balloon-like swelling in a wall of a blood vessel. Aneurysms result weaken the vessel wall and predispose the vessel to tearing or rupture with potentially catastrophic consequences for the individual with the aneurysm. A vascular aneurysm is an abnormal dilation of a blood vessel and usually occurs because of disease or genetic predisposition that weakens an arterial wall and allows it to expand. Aneurysm sites tend to experience mechanical stress concentrations, and fluid flow may be the most likely initiating cause for the formation of these aneurysms.

Aneurysms in cerebral circulation tend to occur in an anterior communicating artery, posterior communicating artery, and a middle cerebral artery. The majority of these aneurysms arise at curves or bends in the vessels or bifurcations of these vessels. Cerebral aneurysms are often diagnosed by the rupture and subarachnoid bleeding of the aneurysm.

Cerebral aneurysms are commonly treated in open surgical procedures where the diseased vessel segment is clipped across the neck of the aneurysm. While considered to be an effective surgical technique, particularly in light of the alternative (e.g., a ruptured or re-bleed of a cerebral aneurysm), neurosurgery suffers from a number of disadvantages. The surgical procedure is complex and expensive, requiring experienced surgeons and well-equipped surgical facilities.

The surgical option has been the long held standard of care for the treatment of aneurysms. Surgical treatment involves a long, delicate operative procedure that has a significant risk and a long period of postoperative rehabilitation and critical care. Successful surgery allows for an endothelial cell to endothelial cell closure of the aneurysm and therefore a cure for the disease. If an aneurysm is present in the brain and bursts a subarachnoid hemorrhage develops with the possibility of death. Moreover, even with successful surgery, recovery takes several weeks and often requires a lengthy hospital stay.

In order to overcome some of these drawbacks, interventional methods and prostheses have been developed to provide an artificial structural support to the vessel region impacted by the aneurysm. The structural support must have an ability to maintain its integrity under blood pressure conditions and impact pressure within an aneurysmal sac and thus prevent or minimize a chance of rupture. In one example, a self-expanding cylindrical tube attempts to span an aneurysm isolate the aneurysm from blood flow.

## IN THE FIGURES

Figure 1 is a perspective view showing one example of a aneurysm shield disposed within a vessel and throttling an aneurysm.

Figure 2A-D are perspective views showing examples of aneurysm shields.

Figures 3A-F are perspective view showing other examples of aneurysm shields.

Figures 3G, H are top views showing still other examples of aneurysm shields with varying porosity.

Figure 4A Shows one example of an aneurysm shield in a closed configuration.

| | |
|---|---|
| Figure 4B | Shows the aneurysm shield shown in Figure 4A in an anchoring configuration. |
| Figure 5 | is a perspective view showing one example of an aneurysm shield including articulation openings. |
| Figure 6 | Shows one example of an aneurysm shield having a perforated shell positioned over an arcuate portion of a vessel including an aneurysm. |
| Figure 7 | is a perspective view showing one example of a shield delivery catheter. |
| Figure 8A | is a side view of one example of a shield delivery catheter with a shield sheath sectioned and an aneurysm shield is in a closed configuration. |
| Figure 8B | is a cross sectional view of the shield delivery catheter of Figure 8A with the aneurysm shield in the closed configuration. |
| Figure 8C | Shows the shield delivery catheter of Figure 8A with the aneurysm shield released and in an anchoring configuration. |
| Figure 9A | is a top view showing one example of an aneurysm shield including a radiopaque targeting reticle in an anchoring configuration. |
| Figure 9B | is a top view showing the aneurysm shield of Figure 9A including a radiopaque targeting reticle in a closed configuration. |
| Figure 10A | is a side view showing the aneurysm shield of Figure 9A retained along a delivery catheter within a vessel. |
| Figure 10B | is a top view showing the aneurysm shield of Figure 9A retained along a delivery catheter within a vessel. |
| Figure 11A | is a side view showing the aneurysm shield of Figure 9A in the anchoring configuration over an arcuate portion of the vessel including the aneurysm. |
| Figure 11B | is a side top view showing the aneurysm shield of Figure 9A in the anchoring configuration over an arcuate portion of the vessel including the aneurysm. |
| Figure 12A | is a top view of one example of aneurysm shield blank. |
| Figure 12B | is a top and side view of one example of an aneurysm shield formed from the blank shown in Figure 12A. |

Figure 12C is a perspective and side view of the aneurysm shield shown in Figure 12B set in an anchoring configuration.

Figure 13 is a block diagram showing one example of a method for using an aneurysm shield.

## DESCRIPTION

Although detailed embodiments of the disclosure are shown herein, it is to be understood that the disclosed embodiments are merely exemplary of the disclosure that may be embodied in various and alternative forms. Specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for teaching one skilled in the art to variously employ the aneurysm filler detacher mechanism embodiments. Throughout the drawings, like elements are given like numerals.

The present disclosure relates generally to aneurysm shields and methods for repairing defects in physiological vessels and lumens including, but not limited to, defects in blood vessels, gas passageways and the like. Further, the present disclosure describes aneurysm shields and methods for obstructing (e.g., occluding) undesirable openings in vessels and passageways with minimally invasive implantation techniques. The aneurysm shields and methods described herein (including the delivery catheters) are used in the repair of aneurysms and may be employed to repair other blood vessel irregularities, other physiological passageway irregularities, septal defects and other tissue defects with minimally invasive surgical techniques.

One example of an aneurysm shield 100 is shown disposed in vessel 102 in Figure 1. Aneurysm shield 100 extends across an aneurysm 104 and prevents flow of bodily fluids including blood into the aneurysm 104. In another example, the aneurysm shield 100 includes a perforated shell area (described below) and the perforated shell area throttles flow into the aneurysm 104, thereby substantially preventing the flow of blood into the aneurysm 104 with velocity capable of expanding the aneurysm 104, retaining the aneurysm 104 at its current size or causing hemorrhaging at the aneurysm.

As shown in Figure 1, the aneurysm shield 100 extends over an arcuate portion of the vessel 106 leaving a bare portion of the vessel 108 clear of the aneurysm shield 100 and thereby free of any engagement with the aneurysm shield 100. As will be described in further detail below, because the aneurysm shield 100 extends only over an arcuate portion of the vessel 106, endothelial cells only graft to the aneurysm shield 100 along the arcuate portion of the vessel 106. Adequate blood flow pas the aneurysm shield 100 is maintained over the lifetime of the aneurysm shield 100 within the vessel 102.

The aneurysm shield 100 includes a shield frame 110 extending around the perimeter of the aneurysm shield 100. The shield frame 110 circumscribes a shell 112 extending across the aneurysm shield 100. In one example, the shield frame 110 and the shell 112 are constructed with the same material and are integral. In still another example, the shield frame 110 is constructed with a different material from the shell 112 and the shell 112 is coupled across the shield frame 110 to form the aneurysm shield 100. Optionally, the shield frame 110 is constructed with the same material as the shell 112 and the shell 112 is a separate piece from the shield frame 110 and coupled across the frame.

As shown in the example in Figure 1, the shell 112 is a perforated shell including interstitial spaces 128 (e.g., perforation openings) that permit blood flow through the aneurysm shield 100 and into the aneurysm 104. While blood flow is permitted through the perforated shell 112, the perforated shell 112 substantially throttles blood flow through the aneurysm shield 100. Throttling of blood flow prevents a stream of blood with high velocity (e.g., velocity close to blood flow velocity in the vessel 102) from entering the aneurysm 104. Because the blood flow into the aneurysm 104 is at a substantially slower rate than the blood flow through the vessel 102, the aneurysm 104 is subject to less stress, minimizing expansion of the aneurysm 104 or hemorrhaging of the aneurysm 104. Additionally, the perforated shell 112 permits some flow of blood into the aneurysm 104 to allow the aneurysm 104 to heal over time after positioning of the aneurysm shield 100 within the vessel 102.

By allowing at least some flow into the aneurysm 104 through the aneurysm shield 100, the aneurysm 104 is substantially prevented from expanding or bursting while the blood flow has access to the tissues of the aneurysm 104. The aneurysm 104 can thereby gradually heal and shrink and may eventually be reabsorbed into the wall of the vessel 102. Further, the aneurysm shield 100 restricts communication between the vessel 102 and the aneurysm 104 and prevents debris from escaping into the bloodstream. Where the shell 112 is perforated, the shield 100 retains debris within the aneurysm 104 while at the same time allowing some blood flow to reach the tissues of the aneurysm for healing.

Additionally, where blood flow is permitted through the perforated shell 112 of the aneurysm shield 100, medicines and other compounds disposed along the aneurysm shield 100 are carried from the aneurysm shield and into the aneurysm 104 by blood flow through the aneurysm shield 100. These medicines and compounds are able to interact with the tissue surrounding the aneurysm 104 and accelerate the healing and treatment of the aneurysm 104 after positioning of the aneurysm shield 100 within the vessel 102.

As will be described in further detail below, the shell 112 includes one or more of a variety of perforation patterns sized and shaped to permit a range of blood flows through the aneurysm shield 100. The degree of perforation to the shell 112 is selected, in one example, according to the vessel 102 in which the aneurysm shield 100 is positioned, the desired blood flow into the aneurysm 104, and a desired blood flow into any branch vessels near the aneurysm 104 that the aneurysm shield 100 extends over. In still another example, the shell 112 is a continuous shell surface without any perforations and thereby blocks any flow into the aneurysm 104. Stated another way, the shell 112 provides a continuous surface across at least a portion of the shield 100 (e.g., from between a shield distal end 116 to a shield proximal end 118) and substantially prevents all flow of blood into the aneurysm 104 thereby starving the aneurysm of any blood.

The aneurysm shield 100 described in Figure 1 includes a number of characteristics common to the other exemplary aneurysm shields described herein. Referring again to Figure 1, the aneurysm shield 100 includes a shield spine 114 extending from the shield distal end 116 to the shield proximal end 118. The shield spine 114 shown in Figure 1 is a portion of the shield frame 114 and the shell 112. Stated another way, in the example shown in Figure 1, the shield spine 114 is not a separate piece of the aneurysm shield 100 and is instead a portion of the materials comprising the shell 112 and the shield frame 110. That is to say, the shield spine 114 provides a point of reference for discussion of other features of the aneurysm shield 100. Optionally, the shield spine 114 is a structural feature of the aneurysm shield 100 and thereby provides a portion of the framework of at least one of the shield frame 110 and the shell 112.

Extending from the shield spine 114 are a first draped wing 120 and a second draped wing 122. Both of the first and second draped wings 120, 122 include a portion of the shell 112 and spread the aneurysm shield 100 across the aneurysm 104 and along an arcuate portion of the vessel 106. The first and second draped wings 120, 122 include a first wing peripheral edge 124 and a second wing peripheral edge 126, respectively. The first and second draped wings 120, 122 extend from the shield spine 114 to the respective wing peripheral edges 124, 126. As described in further detail below, in one example the aneurysm shield 100 is constructed with a shape memory material including a shape memory alloy such as Nitinol. For instance, the aneurysm shield 100 is positioned within the vessel 102 with the first and second draped wings 120, 112 positioned over one another. After positioning of the aneurysm shield 100 at the desired location within the vessel 102, the aneurysm shield 100 is released allowing the first and second draped wings to assume an expanded configuration (e.g., an anchoring configuration) within the vessel 102. For example, where the aneurysm shield 100 is constructed with a shape memory material at least the first and second wing peripheral edges 124, 126 engage against the vessel 102 and position and retain the aneurysm shield 100 at the desired portion of the vessel 102 (e.g., across the aneurysm 104). In still another example, a portion of the first and second draped wings 120, 122 (not just the wing peripheral edges) expand and fit against the arcuate portion 106 of the vessel 102 to retain the aneurysm shield 100 at the desired location within the vessel 102. Stated another way, the first and second draped wings 120, 122, in addition to their first and second wing peripheral edges 124, 126, are engaged with the vessel 102 to retain the aneurysm shield 100 at a desired location within the vessel 102.

The exemplary aneurysm shields described herein are constructed with materials that include one or more of the following: Nitinol (including shape memory Nitinol and superelastic Nitinol having a composition of around 56 percent Nickel and 44 percent Titanium), shape memory polymers, silicone, high molecular weight polyethylene, polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures or copolymers of these; polylactic acid, polyglycolic acid;or a suitable mixture of any of these.

As described above, superelastic Nitinol, shape memory Nitinol and Nitinol alloys are particularly useful for some embodiments described herein. A superelastic material recovers elastic deformations of up to about 10 percent. With shape memory Nitinol, in at least some examples, the shape memory Nitinol retains a first shape when below body temperature and assumes a second (expanded) retaining configuration when at or above body temperature.

Some aneurysm shield embodiments further include one or more coatings. For some embodiments, a portion or all of the aneurysm shield embodiments are coated with a conventional radiopaque coating. The radiopaque coating identifies the location of the aneurysm shield by X-ray or fluoroscopy during or after its introduction into the patient's vascular system and brain. Radiopaque coatings including aneurysm reticle patterns are described in further detail below.

Referring now to Figures 2A-D, examples of aneurysm shields 200A-D including shield frames 202 with continuous shells 204 are shown. As previously described, solid and continuous shells 204 substantially prevent the flow of blood and other bodily fluids into an aneurysm including the aneurysm 104 shown in Figure 1. In at least some respects the aneurysm shields 200A-D shown in Figures 2A-D are similar to the aneurysm shield 100 shown in Figure 1. For instance, the aneurysm shields 200A-D include the shield frame 202 and shell 204. Additionally, the aneurysm shields 200A-D include shield proximal and distal ends 206, 208 and first and second draped wings 210, 212 extending between the shield proximal and distal ends 206, 208.

Referring now to Figure 2C, the aneurysm 200C includes a unitary shield body 214. The unitary shield body 214 includes the shield frame 202 and shell 204. Stated another way, the unitary shield body 214 provides an integral construction of the shield frame 202 and the shell 204. For instance, the unitary shield body 214 is cut from a single piece of material including but not limited to plastics, metals and the like. In one example, the unitary shield body 214 is die-cut from a single piece of material and thereafter formed into the anchoring configuration shown in Figure 1. After forming of the unitary shield body 214 into the anchoring configuration, the shield body is deflected into a closed configuration for deployment into a vessel. After deployment within the vessel the unitary shield body 214 expands to fit within the vessel and retain the shield frame 200C at the vessel location across the aneurysm.

Figures 2A, B, D show another example of a construction of the aneurysm shields 200A, B, D. These aneurysm shields include a shield frame 202 physically separated from the shell 204. After formation of the shield frame 202 the shell 204 is coupled along the shield frame 202 to form the aneurysm shields 200A, B, D. Referring to Figure 2D, in one example the aneurysm shield 200D includes a shield body 216 comprising the shield frame 202 and the shell 204. Coupling features 218 couple the shell 204 with the shield frame 202. In one example, the coupling features include sutures extending through the shell material and extending around the shield frame 202. The sutures provide a mechanical fastening structure extending between the shell 204 and the shield frame 202 and retain the shell 204 along the shield frame 202. The coupling features 218 include in other examples but are not limited to welds, adhesives, fasteners and the like.

In the examples shown in Figures 2A, B, D the shield frame 202 is constructed with a shape memory material. The shape memory material of the shield frame 202 retains the aneurysm shields 200A, B, D in a closed configuration during implantation within the patient. After implantation the shape memory materials of the aneurysm shields 200A, B, D expand the aneurysm shields into an anchoring configuration where the aneurysm shields engage with the vessel 102 as previously described and shown in Figure 1. Stated another way, the shield frame 202 is constructed with the shape memory material and the shell 204 is constructed with a pliable material such as a polymer stretched across the shield frame 202 and coupled there along. After the aneurysm shields 200A, B, D are deployed, the shield frame 202 expands into an anchoring configuration (shown in Figure 1) and as the shield frame 202 expands, the shell 204 correspondingly expands with the shield frame. The shell 204 engages along the vessel wall 102 to substantially throttle or occlude the aneurysm 104. Although Figure 2D has been described with regard to a solid or continuous shell 204, in another example, a perforated shell included a woven shell of polymer fabric is coupled along the shield frame 202. Coupling features 218 including for instance, sutures, extend through the woven polymers of the shell 204 and couple around the shield frame 202 to retain the woven shell 204 on the shield frame 202.

As described above, the aneurysm shield, in one or more examples includes a polymer shell. The polymer shell includes, but it not limited to, biocompatible materials. Optionally, the polymer shell includes one or more of bioabsorbable and biodegradable materials. In another option, the polymer shell includes, but is not limited to, polyethylene, silicone, PTFE, EPTFE, PLA and shape memory polymers.

Figures 3A-F show multiple examples of perforated aneurysm shields 300A-E. At least some of the examples shown in Figures 3A-F include similar features and will be described once and referred to collectively in description of the examples shown in the Figures. Referring first to Figures 3A, B, one example of an aneurysm shield 300A is shown. The aneurysm shield 300A includes a shield frame 302 and shell 304A. The shell 304A is a perforated shell having shell supports 310A extending between the shield proximal end 306 and shield distal end 308. Shell ribs 312A extend across the aneurysm shield 300A between the first and second draped wings 301. The shell supports 310A and shell ribs 312A are patterned across the shell 304A in a grill work configuration forming perforation openings 314A.

As previously described, a perforated shell 304A permits the throttled flow of blood through the aneurysm shield 300A, for instance into an aneurysm while also permitting the flow of blood through the aneurysm shield 300A into a branch vessel otherwise covered by the aneurysm shield 300A. As shown in Figure 3A, the perforated shell 304A extends over substantially the entirety of the aneurysm shield 300A. Optionally, the shell 304A extends over only a portion of the aneurysm shield 300A, for example, the portion of the aneurysm shield 300A positioned over an aneurysm, such as aneurysm 104 shown in Figure 1. In another example, the perforated area of the shell 304A extends only over a portion of the shell 304A positioned over the aneurysm 104 and a branch vessel thereby permitting the throttled flow of blood into the aneurysm 104 and flow of blood into the branch vessel to substantially prevent occlusion of the branch vessel through placement of the aneurysm 300A.

The perforation openings 314A shown in Figure 3A leave open approximately 25 percent of the total shell 304A and permit some flow of blood through the aneurysm 300A. As will be understood and further described below, the shells 304A-E are configured with a variety of perforation patterns to permit a variety of blood flows through the aneurysm shields 300A-E. For instance, where the perforation openings comprise 25 percent or more of the perforated area of the shells 304A-E, sufficient blood flow is permitted through the aneurysm shields 300A-E to maintain flow into branch vessels covered by the aneurysm shields while also throttling flow into aneurysms covered by the shields.

The shells 304A-E with the perforation openings 314A-E are formed in one instance through dye cutting an aneurysm shield blank from a piece of material and thereafter cutting the perforation openings 314A-E into the aneurysm shields 300A-E. The perforation openings 314A-E are formed with methods including, but not limited to, machining, etching and the like. In another option, the perforation openings 314A-E are formed in the aneurysm shields 300A-E through weaving of polymer fibers to form the aneurysm shields. For instance, the aneurysm shields 304A-E are woven in particular patterns to permit a desired amount of blood flow through the aneurysm shields 300A-E.

Figures 3C and 3D show two more examples of aneurysm shields 300C, D. The examples shown in Figures 3C and 3D of the shell supports 310C, D and shell ribs 312 C, D of the corresponding aneurysm shields 300C, D present perforation openings 314C, D therebetween that open about 35 percent of the perforated area of the shells 304C, D. Stated another way, the shells 304C, D have a total surface coverage of around 65 percent of the total area of the shells 304C, D. Because the aneurysm shields 300C, D provide enhanced perforated area relative to the aneurysm shield 300A blood flow through the shields 300C, D is correspondingly enhanced. As described below shells or portions of shells with increased porosity (e.g., greater than 25 percent) are useful to promote blood flow to tissue and branch vessels underlying the aneurysm shields. The specialist may select or specify an aneurysm shield for a procedure according to the type of aneurysm (size, shape and the like) and its location. For instance, the specialist would choose an aneurysm shield with one or more specified porosities according to the blood flow needed (or lack of blood flow needed) for the aneurysm and surrounding tissues and vessels.

Referring to Figure 3C, the shell supports 310C and shell ribs 312C criss-cross the shell 304C to form a crossing grid work pattern with perforation openings 314C formed between the shports and ribs 310C, 312C. The perforation openings 314C, as previously described, open approximately 35 percent of the total area coverage of the shell 304C.

Referring now to Figure 3D, the shell supports 310D and shell ribs 312D extend over the shell 304D to form a spiral pattern with about 65 percent total surface coverage of the shell 304D. The spiral configuration is formed by the shell ribs 312D extending in a spiral shape from one draped wing 301 to a second draped wing 301 on the opposing side of the aneurysm shield 300D. The shell supports 310D extend across the shell 300D substantially perpendicular to the spine of the aneurysm 300D extending between the shell proximal end 306 and shell distal end 308. The shell supports 310D thereby provide structural support to the shell ribs 312D extending in the spiral pattern across the shell 304D of the aneurysm shield 300D.

Referring now to Figures 3E, F, another example of an aneurysm shield 300E is shown. The criss-crossing shell supports 310E and shell ribs 312E form a grid work pattern extending across the shell 304E. For instance, the shell ribs and shell supports 312E, 310E extend from one side of the shield frame 302 to the opposed side of the shield frame 302 (e.g., from the shield proximal end 306 to the shield distal end and from one draped wing 301 to the opposed draped wing 301). Relative to the previously described patterns of the perforated shells 304A-D, the shell 304E covers roughly 55 percent of the total area of the shell 304E. Stated another way, the perforation openings 314E comprise around 45 percent of the total area of the shell 304E thereby providing substantially more open area through the aneurysm shield 304E and corresponding greater flow potential to an aneurysm 104 and branch vessels covered by the aneurysm shield 304E. Optionally, any of the aneurysm shields 300A-E include multiple shell configurations such as shell configurations 304A-E and thereby provide varied flow rates across a single aneurysm shield. Stated another way, the covered area (and conversely the open area) of the perforated portions of the aneurysm shield shell is changed at locations along the shield to adjust flow rates through the shield at the corresponding locations.

Two additional examples of aneurysm shields 300G, H are shown in Figures 3G and 3H, respectively. The aneurysm shields shown in these two figures include shells 304G and 304H and each shell includes varying porosity. Referring first to Figure 3G, the aneurysm shield 3G includes a shield frame 302 extending around the shell 304G. The shell 304G includes a shell first portion 316 and a shell second portion 318. As shown in Figure 3G, the shell first portion 316 includes perforations 320. The shell first portion 316 including the perforations 320 throttles blood flow through the aneurysm shield 300G, for instance, into an aneurysm within the vasculature. The shell second portion 318 includes shell cavities 322 spaced around the aneurysm shield 300G. The shell cavities 322 allow vascular tissue immediately underlying the aneurysm shield 300G to have direct contact with blood flow through the vessel containing the aneurysm shield 300G. Stated another way, the shell first portion 316, where the first portion includes perforation 320, throttles flow into an aneurysm the shell first portion 316 is positioned over, and the shell second portion 318, with the shell cavities 322, permits unrestricted blood flow to the tissue surrounding the aneurysm.

The aneurysm shield 300G including the shield frame 302 and the shell supports 324 of the shell second portion 318 anchor the aneurysm shield in place within the vasculature while positioning the shell first portion 316 with the perforations 320 at the desired location over the aneurysm. That is to say, the aneurysm shield 300G provides a discrete location with the shell first portion 316 for covering of an aneurysm while providing a larger framework in the shell second portion 318 and the shield frame 302 for positioning and anchoring of the aneurysm shield 300G within the vasculature in the shield retaining configuration.

Although the shell first portion 316 is shown near the center portion of the aneurysm shield 300G the shell first portion 316 is positioned, in other examples of the aneurysm shield 300G, anywhere within the aneurysm shield. For instance, the shell first portion 316 is positioned closer to the shield frame 302 (with a first portion 316 center offset from a shield 300G center) while the remainder of the shell second portion 318 includes corresponding shell supports 324 to support the shell first portion at that location within the shield frame 302. While the shell cavities 322 have been described as permitting blood flow to the tissue surrounding the aneurysm it is understood that blood flow is also permitted through the shell second portion 318 (and the shell cavities 322) to branch vessels that the aneurysm shield 300G overlies. Branch vessels are shown later in Figure 6. Referring to Figure 6, where the aneurysm shield 300G is positioned within the vessel 603 the shell cavities 322 of the shell second portion 318 permit substantially unrestricted flow into the branch vessel 604 overlaid by the aneurysm shield 300G. In contrast, the aneurysm 602 is covered by the shell first portion 316. In the example where the shell first portion 316 includes the perforation 320 blood flow into the aneurysm 602 is substantially throttled thereby minimizing the pressure on the aneurysm 602 while correspondingly minimizing the risk of rupture of the aneurysm and facilitating eventual healing and reabsorption of the aneurysm tissue into the surrounding vessel 603.

Referring again to Figure 3G, as described above, in one example, the shell first portion 316 includes perforations 320. In one example, where throttling of blood flow into the aneurysm is desired the shell first portion 316 includes a perforated area less than or equal to around 25% of the total area of the shell first portion 316. Where decreased blood flow into the aneurysm is desired the perforations 320 make up less of the area of the shell first portion 316, for instance, 20 percent, 15 percent, 10 percent, 5 percent or the like. Optionally, where blockage of blood flow into the aneurysm is desired the shell first portion 316 is without perforations 320 and provides a solid continuous surface for positioning over the aneurysm to substantially block all blood flow to the aneurysm.

As described herein in other examples, the aneurysm shield 300G including the shell first portion and shell second portion 316, 318 is formed with methods including, but not limited to, punching of metal or polymer blanks, molding of polymer blanks, and machining or molding of the perforations and shell cavities 320, 322 into the shield blank. The shell supports 324 are constructed with sufficient strength to support the shell first portion 316 while in a closed configuration for delivery and in the retaining configuration after the aneurysm shield 300G is positioned at a desired location within the vasculature. Additionally, the shell supports 324 are constructed with sufficient structural integrity to retain the shell first portion 316 at the desired location (e.g., over the aneurysm) throughout the operating lifetime of the aneurysm shield 300G. While four shell supports 324 are shown in Figure 3G, in other examples, an aneurysm shield similar to aneurysm shield 300G includes one or more shell supports 324 to position the shell first portion 316 at a desired location within the aneurysm shield. The one or more shell supports 324 support the shell first portion 316 with sufficient structural integrity to maintain the shell first portion at that location during delivery and throughout the operating lifetime of the aneurysm shield.

Another example of an aneurysm shield 300H having multiple regions each with different porosities is shown in Figure 3H. As with other aneurysm shields described herein, the aneurysm shield 300H includes a shield frame 302 and a shell 304H. As shown in Figure 3H, the shell 304H includes two components, a shell first portion 326 and a shell second portion 328. In one example, an aneurysm shield similar to the aneurysm shield 300H includes multiple shell portions including two or more shell portions (e.g., first, second, third portions and the like). The shell first portion 326 includes first perforations 330 while the shell second portion 328 includes second perforations 332.

The first perforations 330 of the shell first portion 326 permit throttled blood flow through the shell first portion 326 (e.g., to an aneurysm covered by the shell first portion). As previously described, throttling of blood flow into an aneurysm is advantageous to minimize pressure within the aneurysm and correspondingly minimize the risk of rupture of the aneurysm. Additionally, providing at least some blood flow to the tissues of the aneurysm allows the aneurysm to heal over time. In another example, the second perforations 332 of the shell second portion 328 provide a higher percentage of open area across the shell second portion 328 relative to the shell first portion 326. The blood flow through the shell second portion 328 is thereby less restricted allowing for enhanced passage of blood through the aneurysm shield 300H to tissues and branch vessels underlying the shell second portion 328.

In one example, the first shell portion 326 with the first perforations 330 has around 25 percent or less open area to permit throttled blood flow through the shell first portion to an aneurysm lying underneath. In still another example, the shell second portion 328 with the second perforation 332 has an open area greater than 25% permitting enhanced blood flow through the aneurysm shield 300H into the tissue surrounding the aneurysm and any branch vessels the aneurysm shield lies over. The first and second perforations 330, 332 are tailored in other examples to provide desired flow rates through the corresponding first and second shell portions 326, 328 according to the location of the aneurysm within the vasculature and the type of aneurysm (size, neck opening and the like) the aneurysm shield is placed over. For instance, where enhanced blood flow is needed into the aneurysm the first perforations 330 in shell first portion 326 are a larger percentage of the area of the first shell portion. In another example, where increased throttling of blood flow to the aneurysm is desired the first perforations 330 of the shell first portion 326 are 25 percent or less of the area of the shell first portion 226. In a similar manner, the second perforations 332 of the shell second portion 328 are tailored to the blood flow needs of the tissue surrounding an aneurysm as well as any branched vessels located underneath the shell second portion 328. For instance, where enhanced blood flow is needed to a branch vessel the shell second portion 328 includes second perforations 332 occupying greater than 25 percent of the area of the shell second portion 328 (e.g., 35 percent, 45 percent, or more). This permits relatively unrestricted blood flow into the branch vessels and limited interruption or throttling of blood flow into those branched vessels and the tissues that the branch vessels support.

In still another example, where blockage of blood flow into the aneurysm is desired the first shell portion 326 is without perforations and instead includes a substantially continuous and uninterrupted surface. In yet another example, the shell second portion 328 includes minimal second perforations 332 (e.g., 25 percent or less of the total area of the shell second portion 328) while the shell first portion 326 includes larger or additional first perforations 330 to permit enhanced blood flow through the shell first portion 326. For instance, where the aneurysm shield 300H is positioned with the shell first portion 326 substantially overlaying a branch vessel and the shell second portion overlays an aneurysm or aneurysms the shell second portion 328 with the second perforations 332 throttles blood flow through the shell second portion into the aneurysm or aneurysms.

Figures 4A and 4B show one example of an aneurysm shield 400 in a closed configuration (shown in Figure 4A) and an anchoring configuration (shown in Figure 4B). The aneurysm shield 400 includes features similar to those of the previously described aneurysm shields in Figures 1-3F. For instance, the aneurysm shield 400 includes a first draped wing 402 and a second draped wing 404. The first and second draped wings 402, 404 extend from a shield spine 408 extending across the back of the aneurysm shield 400. As previously described, the shield spine 408 is integral to the shell 412 and shield frame 410. In another example the shield spine 408 is a separate portion of the aneurysm shield 400 coupled with the shield frame 410 and the shell 412. As shown in Figures 4A and 4B, the aneurysm shield 400 includes a shield frame 410 standing around the shell 412. The shell 412 in one example includes a continuous unbroken surface configured to substantially prevent flow through the aneurysm shield 400. In another example, such as the example shown in Figure 4B, the shell 412 is perforated to allow some flow through the aneurysm shield 400. The flow (e.g., blood flow) is throttled through the aneurysm shield 400 including the perforated shell 412 to substantially retard high velocity blood flow into an aneurysm and minimize the risk of hemorrhaging and expansion of the aneurysm. The flow through the perforations in the shell 412 allow for some flow through the aneurysm shield 400, for instance into branch vessels covered by the aneurysm shield. The aneurysm shield is thereby positionable near an aneurysm adjacent to a branch vessel while at the same time allowing flow into the branch vessel.

Referring now to Figure 4A, the aneurysm shield 400 is shown in a closed configuration where the first draped wing 402 is wrapped around the aneurysm shield 400 and positioned adjacent to the second draped wing 404. The wing peripheral edge 405 of the second draped wing 404 is positioned underneath the first draped wing 402. The aneurysm shield 400 in the closed configuration thereby circumscribes a delivery instrument lumen 414. The delivery instrument lumen 414 is useful for receiving delivery instruments including catheters sized and shaped to retain the aneurysm shield 400 in the closed configuration while the aneurysm shield is positioned within the vasculature near an aneurysm. Additionally, by overlapping the first and second draped wings 402, 404, the aneurysm shield 400 is retained in a compact configuration while closed and presents a smaller profile for easier vascular access and delivery.

Optionally, the wing peripheral edges 405 of the aneurysm shield 400 are positioned adjacent to but separated from each other when in the closed configuration. That is to say, the wing peripheral edges 405 overlap in the closed configuration, but are physically separated along the edges (e.g., they don't physically connect at a weld or integral piece of material) by a gap between the first and second draped wings 402, 404. As described in further detail below, because the first and second draped wings 402, 404 are physically separated along their wing peripheral edges 405, the aneurysm shield 400 is movable between the closed configuration and the anchoring configuration shown in Figure 4B. Stated another way, as the aneurysm shield 400 expands into the anchoring configuration, the delivery instrument lumen 414 shown in Figure 4A is eliminated and the delivery instrument is able to freely move out of position from the aneurysm shield 400 and leave the aneurysm shield at the desired location within the vasculature.

Referring now to Figure 4B, the aneurysm shield 400 is shown in an expanded anchoring configuration. As previously described, the aneurysm shield 400 in one example is constructed with a shape memory material that biases the first and second draped wings 402, 404 out of the closed configuration and into the anchoring configuration after the aneurysm shield 400 is released within the vasculature. As shown by arrows 406 in Figure 4B the first and second draped wings 402, 404 expand into the anchoring configuration to engage with an arcuate portion of the vasculature. The first and second draped wings 402, 404 engage with the arcuate portion of the vasculature and hold the aneurysm 400 in a desired location for instance, across an aneurysm neck opening. First and second draped wings 402, 404 in the expanded configuration hereby hold the shell 412 over the aneurysm and substantially throttle or prevent flow into the aneurysm to relieve stresses on the tissues of the aneurysm thereby allowing the aneurysm to heal over time.

In still another example, the aneurysm shield 400 is constructed with a material formed into the anchoring configuration shown in Figure 4B. The aneurysm shield 400 in this configuration is deformed into the closed configuration shown in Figure 4A as it is loaded into the delivery instrument. Upon disengagement from the delivery instrument the natural bias of the aneurysm shield 400 deflects the first and second draped wings 402, 404 outwardly into the anchoring configuration shown in Figure 4B. Stated another way, the spring bias of the aneurysm shield 400 moves the first and second draped wings 402, 404 from the closed configuration shown in Figure 4A to the anchoring configuration shown in Figure 4B.

Figure 5 shows one example of an aneurysm shield 500 including articulation openings 516 positioned within and around the aneurysm shield 500 to provide enhanced flexibility and pliability to the aneurysm shield and allow the aneurysm shield to conform to the nonlinear geometries of a vessel. The aneurysm shield 500 includes a shield frame 502 extending around a shell 504. As previously described, the shield frame 502 and the shell 504 may be constructed integrally or separately and thereafter coupled together. The aneurysm shield 500 further includes first and second draped wings 506, 508 extending from a shield spine 510. As shown in Figure 5 the first and second draped wings 506, 508 optionally extend along the shield spine 510 from the shield proximal end 512 to the shield distal end 514. In another example, the first and second draped wings 506, 508 extend along only a portion of the aneurysm shield 500. For instance, the first and second draped wings 506, 508 extend along a portion of the shield spine 510 between the shield proximal end 512 and shield distal end 514.

Referring again to Figure 5, the articulation openings 516 are shown distributed along the shield frame 502 and through the shell 504. In the example shown in Figure 5, the articulation openings 516 are positioned near the wing peripheral edges 518. For example, some of the articulation openings 516 are formed by recesses in the shield frame 502 that extend into the shell 504. The articulations openings 516 extend around the aneurysm shield 500. Other articulation openings 516 are formed through the shell 504 of the aneurysm shield 500. The articulation openings 516 in one example are formed near the wing peripheral edges 518 to maintain a consistent perforated shell 504 along the shield spine 510 thereby consistently throttling or preventing flow through the aneurysm shield 500 when the aneurysm shield is positioned over an aneurysm.

In still another example, the articulation openings 516 extend between the opposed wing peripheral edges 518 and extend across at least a portion of the shield spine 510 to enhance the pliability of the aneurysm shield 500 within especially torturous vasculature of the body. For example, the articulation openings 516 near the shield proximal end 512 and distal end 524 are near to or extend across the shield spine 510 to providing enhanced deflection capabilities near the shield proximal and distal ends 512, 514.

In still another example, the articulation openings 516 extend across the aneurysm shield 500 between the wing peripheral edges 518 near the shield intermediate portion 515. Stated another way, the articulation openings 516 are positioned along the first and second draped wings 506, 508 near the middle of the aneurysm shield 500. The aneurysm shield 500 is able to more easily deflect at the shield intermediate portion 515. Optionally, articulation openings 516 are absent in other portions of the aneurysm shield 500, such as the shield proximal end and shield distal end 514 to allow positioning of the shield proximal end or shield distal end 512, 514 over the aneurysm without articulation openings at the aneurysm opening. A variety of aneurysm shields with articulation openings at various locations along the shields gives the specialist a plurality of options when choosing a shield for a portion of the vasculature having a particular non-linear shape. The specialist chooses an aneurysm shield with the articulation openings arranged on the shield to properly deflect into a conforming configuration to the vessel shape and at the same time includes a portion of the shell that overlies the aneurysm without articulation openings present.

Where the articulation openings 516 are formed within a continuous aneurysm shield 500, for instance an aneurysm shield having an integral shield frame 502 and shell 504 constructed of a single piece of material without perforations, the articulation openings are formed in a variety of methods. For instance, the articulation openings are etched or machined into the aneurysm shield 500 in a pattern configured to provide a specified flexibility to the aneurysm shield to deflect within a vessel having a nonlinear shape. In another example, where the aneurysm shield 500 includes a perforated shell with a shield frame 502 extending there around, the articulation openings 516 formed along the shield frame 502 in one example may be formed with methods including but not limited to machining, etching and the like. Similarly, the articulation openings 516 within the shell portion 504 of the aneurysm shield 500 may be formed with methods including but not limited to machining, etching, weaving of larger articulation openings into the woven pattern of a perforated shell, mechanical forming of articulation openings within the perforated shell such as by reaming and the like.

The aneurysm shield 500 shown in Figure 5 provides a device capable of throttling or preventing flow into an aneurysm when the aneurysm shield is positioned across an arcuate portion of a vessel containing the aneurysm. Additionally, the articulation openings 516 shown along at least the first and second draped wings 506, 508 allow the aneurysm shield 500 to deflect within the vasculature and assume a similar configuration to the shape of the arcuate portion of the vasculature on which the aneurysm shield 500 is deployed. Stated another way, as the aneurysm shield 500 is deployed at a specified location within the vasculature the articulation openings 516 allow the aneurysm shield to engage and wrap along the natural undulations and non-linear portions of the vasculature to assume a configuration that substantially lays the aneurysm shield 500 along the corresponding vessel surface.

Referring now to Figure 6, another example of an aneurysm shield 600 including a perforated shell 616 surrounded by a shield frame 614 is shown. As previously described above, the aneurysm shield 600 extends across an arc less than 360 degrees. Stated another way, the aneurysm shield 600 extends between a first wing peripheral edge 601 and a second wing peripheral edge 601, in an arc of less than 360 degrees. For instance, the aneurysm shield 600 extends 180 degrees from one wing peripheral edge 601 to the other wing peripheral edge 601. In another example, the aneurysm shield 600 extends less than 180 degrees from the first wing peripheral edge 601 to the second wing peripheral edge 601. In the anchoring configuration the wing peripheral edges 601 of the aneurysm shield (including the aneurysm shield extending less than 180 degrees) engage against the wall of the vessel 603 and hold the aneurysm shield 600 in place at a desired location within the vessel. One specified location within the vessel 603 is shown in Figure 6. As shown, the aneurysm shield 600 extends over an aneurysm 602 and a covered branch vessel 604. The aneurysm shield 600 extends along an arcuate portion of the vessel 618 while a bare portion of the vessel 620 is free of the aneurysm shield 600 to leave an uncovered branch vessel 606 exposed and capable of receiving full blood flow from the vessel 603.

The positioning of the aneurysm shield 600 within the vessel 603 with a perforated shell 616 throttles the aneurysm flow 608 into the aneurysm 602. Because the aneurysm 602 is without an outlet and the perforations of the perforated shell 616 break up the blood flow through the shield, the aneurysm flow 608 into the aneurysm is throttled and substantially minimizes any pressure on the tissues forming aneurysm the 602. In contrast, the covered branch flow

610 through the covered branch vessel 604 passes through the aneurysm shield 600 and is able to continue on through the covered branch vessel 604 because the branch vessel 604 continues away from the vessel 603. Stated another way, because the covered branch flow 610 is able to continue moving through the covered branch vessel 604, the throttled velocity of the covered branch flow 610 is maintained through the covered branch vessel 604 allowing for continued delivery of fluids, including blood, to locations in the body along the covered branch vessel 604.

In contrast to the arcuate portion of the vessel 618 where the aneurysm shield 600 is positioned, the bare portion of the vessel 620 is without any portion of the aneurysm shield 600. The uncovered branch vessel 606 thereby receives an uncovered branch flow 612 that is not throttled by the aneurysm shield 600. Stated another way, because the aneurysm shield 600 does not fully circumscribe the vessel 603 the uncovered branch vessel 606 is able to maintain an uncovered branch flow 612 with substantially the same velocity and flow rate as before the implantation of the aneurysm shield 600.

The specialist using the aneurysm shield 600, including the perforated shell 616, is thereby able to position the aneurysm shield 600 within the vessel 603 to throttle flow into the aneurysm 602 and substantially minimize any stresses incident on the aneurysm 602 to allow the aneurysm to heal over time while receiving a minimal amount of blood flow to support the tissues forming the aneurysm and facilitate the healing of those tissues. Additionally, the specialists can position the aneurysm shield 600 near branch vessels, such as the covered branch vessel 604, and even cover the covered branch vessel 604 with the aneurysm shield while still allowing covered branch flow 610 through the aneurysm shield and down the covered branch vessel 604. Because the velocity is maintained through the covered branch vessel 604, blockage of the perforations adjacent to the covered branch vessel 604 is substantially prevented as any endothelial cell growth at that portion of the aneurysm shield 600 is swept down the covered branch vessel 604. Endothelial cell growth may extend across the portion of the aneurysm shield 600 adjacent to the aneurysm 602 but because of the velocity and flow rates of the covered branch flow 610 such cell growth is substantially prevented, thereby allowing continued delivery of blood and fluid through the covered branch vessel 604 even after positioning of the aneurysm shield 600 over the covered branch vessel.

Further, because the aneurysm shield 600 extends over only an arcuate portion of the vessel 618, the specialist is able to position the aneurysm shield 600 so a vessel, such as the uncovered branch vessel 606 (shown in Figure 6), is free from the aneurysm shield and capable of delivering continuous blood flow at substantially the same original velocity through the uncovered branch vessel. The perforated nature of the shell 616 as well as the limited arcuate span of the aneurysm shield 600 thereby provides enhanced flexibility to the specialist for positioning of the aneurysm shield 600 in a variety of locations within the vasculature capable of sustaining an aneurysm 602 while also including branch vessels in close proximity to the aneurysm 602.

One example of a shield delivery catheter 700 is shown in Figure 7. The shield delivery catheter 700 is configured to deliver an aneurysm shield such as the aneurysm shields shown herein to a desired location within the vasculature and deploy the aneurysm within the vasculature in an orientation to cover an aneurysm within the vessel. The exemplary shield delivery catheter 700 includes a catheter body 702 extending between a catheter proximal portion 704 (the proximal portion extends beyond the draftsman's break) toward a catheter distal portion 706. In one example, a guidewire lumen 708 extends through the catheter body 702. The guidewire lumen is configured to receive a steering device, such as a steerable guidewire, to traverse the vasculature. The shield delivery catheter 700 is tracked along the guidewire and delivered to the desired location within the vasculature.

Referring to Figure 7 again, the catheter distal portion 706 includes a distal retaining ridge 710 and a proximal retaining ridge 712 defining a retaining recess 714. The shield support 716 extends between the distal and proximal retaining ridges 710, 712. The retaining recess 714 is sized and shaped to receive an aneurysm shield in a closed configuration (See Figure 4A) for retention of the aneurysm shield during delivery to a specific location within the vasculature for deployment.

As shown in Figure 7, the shield support 716 extends between the distal and proximal retaining ridges 710, 712. In the closed configuration the aneurysm shield is wrapped around the shield support 716 to retain the aneurysm shield along the shield delivery catheter 700. A recess depth 718, in one example, is greater than or equal to a thickness of the aneurysm shield. When the aneurysm shield is positioned along the shield support 716 in the closed configuration, the shield is substantially disposed within the overall perimeter of the shield delivery catheter 700 (e.g., within the perimeter defined by the distal and proximal retaining ridges 710, 712). Because the aneurysm shield is retained within the retaining recess 714 the catheter body 702 with the aneurysm shield is substantially isodiametric and capable of receiving a shield sheath for passage over the catheter body 702 and retention of the aneurysm shield in the closed configuration.

In one example, the shield delivery catheter 700 is constructed with one or more materials including, but not limited to, plastics, metals and the like. In one example, the shield delivery catheter 700 is constructed with a biocompatible polymer having sufficient elasticity to follow a guidewire through tortuous vasculature and arrive at a desired location within a vessel. In another example, the shield delivery catheter 700 is formed with one or more lumen liners to define the guidewire lumen 708 and a combination of shrink tubing and reflow plastic is used to form the catheter distal portion 706 and catheter proximal portion 704.

Referring now to Figures 8A-C, one method for deploying the aneurysm shield 800 with the shield delivery catheter 700 is shown step-by-step beginning at Figure 8A and culminating at Figure 8C. Referring first to Figure 8A, the aneurysm shield 800 is shown exposed within the retaining recess 714 of the shield delivery catheter 700. The shield sheath 802 extends over the distal retaining ridge 710, the proximal retaining ridge 712 and the retaining recess 714 with the aneurysm shield 800 therein. The shield sheath 802 is, in one example, slidable along the catheter body 702 to selectively cover and expose the aneurysm shield 800 for corresponding containment and deployment of the aneurysm shield from the shield delivery catheter 700.

Referring now to Figure 8B, the aneurysm shield 800 is shown in cross-section in a closed configuration around the shield support 716 of the shield delivery catheter 700. As shown, the aneurysm shield 800 includes a first draped wing 804 and a second draped wing 806. The first and second draped wings 804, 806 are wrapped around the shield support 716 of the catheter body

702. In the closed configuration shown in Figure 8, the aneurysm shield 800 is retained along the shield delivery catheter 700 until it is deployed as further described below. For instance, the first and second draped wings 804, 806 include corresponding first and second wing peripheral edges 808, 810. As shown in Figure 8B, the second wing peripheral edge 810 of the second draped wing 806 is wrapped over top of the first wing peripheral edge 808 of the first draped wing 804.

As previously described above, in one example the aneurysm shield 800 is constructed with a shape memory material including, but not limited, Nitinol or other shape memory plastics and alloys. The aneurysm shield 800 is deformed into the closed configuration around the shield support 716. In still another example, the aneurysm shield 800 is formed in an anchoring configuration such as the anchoring configuration shown previously and thereafter deformed into the closed configuration around the shield support 716. The shield sheath 802 is thereafter slid over the retaining recess 714 to hold the deformed aneurysm shield 800 in the closed configuration along the catheter body 702. In this example the deformation of the aneurysm shield 800 is opposed by the natural spring bias of the aneurysm shield, and the shield sheath 802 acts to retain the aneurysm shield 800 along the shield support 716 within the retaining recess 714.

Referring now to Figure 8C the aneurysm shield 800 is shown in a deployed configuration. For instance, the sheath 802 is slid proximally along the catheter body 702 toward the catheter proximal portion 704. As the shield sheath 802 is slid proximally, the aneurysm shield 800 is exposed, allowing the aneurysm shield to expand from the closed configuration into the anchoring configuration. As the aneurysm shield 800 expands the first and second draped wings 804, 806 extend away from the configuration shown in Figure 8B and into the anchoring configuration shown. As the aneurysm shield 800 expands away from the shield support 716 the aneurysm shield 800 engages with the surrounding vasculature at a specific location within the body (for instance, at a location having an aneurysm). The first and second draped wings 804, 806 engage with the wall of the vessel and retain the aneurysm shield 800 in the anchoring configuration at the desired location within the vessel.

Importantly, while the aneurysm shield 800 is in the closed configuration within the shield delivery catheter 700, the shield delivery catheter is rotated within the vasculature to rotatably position the aneurysm shield 800 at a desired location to cover an aneurysm. Once the aneurysm shield 800 is rotatably positioned, the shield sheath 802 is withdrawn to allow the aneurysm shield 800 to expand into the anchoring configuration to cover the aneurysm and throttle blood flow into the aneurysm (with a perforated shell) or completely prevent blood flow into the aneurysm (with a continuous unperforated shell). After the aneurysm shield 800 has expanded away from the shield support 716 and exited the retaining recess 714, the shield delivery catheter 700 is withdrawn proximally. In one example, the shield delivery catheter 700, particularly the distal retaining ridge 710, includes a bevel sized and shaped to slide the distal retaining ridge 710 over the aneurysm shield 800 where there is incidental contact between the distal retaining ridge and the aneurysm shield as the shield delivery catheter 700 is removed proximally.

As previously described above, the aneurysm shield 800 is constructed with a shape memory material. Where the aneurysm shield 800 is constructed with the shape memory material, upon exposure to the surrounding environment of the vasculature including the heat of the surrounding environment (e.g., blood), the aneurysm shield 800 expands into the anchoring configuration shown in Figure 8C. In another option where the aneurysm shield 800 is constructed with a material deformed into the anchoring configuration but is not otherwise formed of shape memory material, as the shield sheath 802 is withdrawn proximally the natural spring bias of the aneurysm shield 800 expands the first and second draped wings 804, 806 from the shield support 716 and engages the aneurysm shield 800 along the desired location within the vessel.

The shield delivery catheter 700 facilitates the positioning of the aneurysm shield 800 within a desired location within a vessel. For instance, the shield delivery catheter 700 permits proximal and distal movement of the aneurysm shield 800 within the vasculature while the aneurysm shield 800 is retained within the closed configuration. Similarly, because the aneurysm shield 800 is retained within the retaining recess 714 of the shield delivery catheter 700, the catheter body 702 is rotated to position the aneurysm shield 800 at substantially any arcuate portion of the vessel. Through a combination of rotation and longitudinal and proximal movement the aneurysm shield 800 is accurately and reliably positioned over the neck portion of an aneurysm to substantially close or throttle blood flow into the aneurysm. In still another option, where the aneurysm shield 800 is constructed with a shape memory material that does not immediately assume the anchoring configuration upon exposure to the surround environment, the specialist may selectively move the shield sheath 802 distally over the shield to recover the aneurysm shield 800 and then reposition the aneurysm shield as needed according to further observation (e.g., by fluoroscopy) during the implantation procedure.

Referring now to Figures 9A and 9B, one example of an aneurysm shield 900 is shown including one or more positioning markers for positioning of the aneurysm shield at a desired location within the vasculature (e.g., longitudinally and rotationally within the vessel). As described with previous aneurysm shield examples, the aneurysm shield 900 includes shield proximal and distal ends 902, 904 and first and second draped wings 906, 908. A first wing peripheral edge 907 extends around the first draped wing 906 and a second wing peripheral edge 909 extends around the second draped wing 908.

As described above, the aneurysm shield 900 is constructed with an integral construction in one example, where the aneurysm shield 900 is formed from a single piece of material, for instance by the die-cutting of an aneurysm shield blank followed by chemical etching, machining and the like of the blank to form interstitial spaces (e.g., perforations) that throttle blood flow through the aneurysm shield. In another example, the aneurysm shield 900 is constructed with a single piece of material having a continuous surface that prevents blood flow through the aneurysm shield. In still another example, the aneurysm shield 900 is constructed with multiple components including a shield frame separate from the shell extending across the aneurysm shield. The shell in one example, is perforated to permit at least some blood flow through the aneurysm shield 900. In yet another example, the shell is a continuous surface coupled with a shield frame to prevent blood flow through the aneurysm shield 900.

Referring now to Figure 9A, the aneurysm shield 900 is shown in an expanded anchoring configuration for ease of viewing the first and second positioning markers 910, 912. The first positioning marker 910 extends between the shield proximal end 902 and the shield distal end 904. In one example, the first positioning marker 910 extends along the entirety of the aneurysm shield 900. In another example, the first positioning marker 910 extends over only a portion of the aneurysm shield for instance, through the middle portion of the aneurysm shield. The second positioning marker 912 shown in Figures 9A, 9B extends between the first and second draped wings 906, 908. As shown in Figure 9A, the second positioning marker 912 extends from the first wing peripheral edge 907 to the second wing peripheral edge 909. As with the first positioning marker 901, in one example the second positioning marker 912 extends over only a portion of the aneurysm shield 900 for instance, some portion of the shield between the first and second wing peripheral edges 907, 909.

The first and second positioning markers 910, 912 in one example form an aneurysm reticle pattern 914 that includes a center portion crossing near the center portion of the aneurysm shield 900. Optionally, the aneurysm reticle pattern 914, including the first and second positioning markers 910, 912, is positioned at another location on the aneurysm shield 900 spaced from the center portion of the aneurysm shield. The aneurysm reticle pattern 914 including the first and second positioning markers 910, 912 facilitate accurate positioning of the aneurysm shield 900 within a vessel.

As previously shown, for instance in Figure 1, an aneurysm 104 is located on one arcuate portion of a vessel such as vessel 102. Because the aneurysm shield 900 extends in a semi-circular fashion when engaged with the vessel wall, the aneurysm shield 900 is rotated into position across the aneurysm 104 to prevent or throttle blood flow into the aneurysm. By including the first and second positioning markers 910, 912 to form the aneurysm reticle pattern 914, the aneurysm shield 900 when fed through the vasculature is guidable to an aneurysm and thereafter positionable over the neck of the aneurysm to substantially throttle or prevent blood flow into the aneurysm.

In one example, the first and second positioning markers 910, 912 (and the aneurysm reticle pattern 914) are formed with, but not limited to, radiopaque materials, other materials visible through imaging techniques and the like. For instance, the first and second positioning markers 910, 912 are formed with materials viewable through imaging techniques used to observe an aneurysm within a vessel and correspondingly longitudinally position an instrument within the vessel near the aneurysm. In one example the aneurysm shield 900 includes materials within the shield that are radiopaque to form the first and second positioning markers 910, 912. In another example, the first and second positioning markers 910, 912 with radiopaque materials are coated onto the aneurysm shield 900. The coated or integral positioning markers 910, 912 form the aneurysm reticle pattern 914 with these radiopaque materials. Imaging of the aneurysm shield 900 with the markers 910, 912 is easily performed as the aneurysm shield is moved within the vasculature and rotatably positioned at the appropriate portion of the vessel to close or throttle flow into the aneurysm.

Figure 9B shows the aneurysm shield 900 of Figure 9A in a closed configuration. The closed configuration is previously described above with regard to other aneurysm shield examples. In the closed configuration shown in Figure 9B the first and second positioning markers 910, 912 are still visible as the aneurysm reticle pattern 914 between the shield proximal and distal ends 902, 904. Provision of the first and second positioning markers 910, 912 at these locations allows for the aneurysm shield 900 to be longitudinally and rotatably positioned within a vessel while the aneurysm shield is housed within a delivery device such as the shield delivery catheter 700 shown in Figure 7. For instance, the aneurysm reticle pattern 914 is visible along the aneurysm shield 900 whether the aneurysm shield is in the closed configuration (within the delivery catheter 700) or the anchoring configuration (after deployment from the catheter 700) shown in Figure 9A.

Optionally, the aneurysm shield 900 is free of first and second positioning markers 910, 912 and the associated aneurysm reticle pattern 914. Instead, the shield delivery catheter, such as catheter 700 shown in Figure 7, includes first and second positioning markers configured to position the aneurysm shield 900 within the shield delivery catheter for eventual positioning of the shield 900 over an aneurysm. Stated another way, the positioning markers on the shield delivery catheter 700 are aligned with a corresponding portion of the shield 900 and positioning of the markers at the aneurysm also positions the shield 900. In still another example, both the aneurysm shield 900 and the shield delivery catheter 700 include radiopaque markings configured to position the aneurysm shield and the shield delivery catheter within the appropriate portion of the vasculature for deployment of the aneurysm shield at a desired aneurysm site.

Figures 10A and 10B show the aneurysm shield 900 in a closed configuration and position along a shield delivery catheter 1000. Figure 10A shows a side view of the shield delivery catheter 1000 and the aneurysm shield 900. Figure 10B shows a top view of the aneurysm shield 900 and the shield delivery catheter 1000. The dual views of the aneurysm shield 900 are used to accurately position the aneurysm shield 900 within the vessel 102 to extend across the aneurysm 104.

Referring first to Figure 10A, the aneurysm shield 900 is shown in a side view along the shield delivery catheter 1000 and positioned beneath the aneurysm 104. As shown by the directional arrows pointing in the proximal and longitudinal directions as well as in a rotatable direction, the shield delivery catheter 1000 and the aneurysm shield 900 positioned on the shield delivery catheter are movable longitudinally within the vessel 102 and are also rotatable within the vessel. Longitudinal movement of the shield delivery catheter 1000 positions the aneurysm shield 900 below the aneurysm 104. For instance, the second positioning marker at 912 of the aneurysm reticle pattern 914 is shown near a midpoint of the aneurysm 104. Positioning of the second positioning marker 912 near the center portion of the aneurysm 104 longitudinally positions the aneurysm shield 900 at the proper longitudinal location for engagement with the vessel across the aneurysm 104. Additionally, the first positioning marker 910 of the aneurysm reticle pattern 914 is shown in a position adjacent to the aneurysm 104. The position of the first positioning marker 910 notifies the specialist that the aneurysm shield 900 is properly oriented so when the aneurysm shield 900 is in the anchoring configuration the aneurysm shield 900 will be positioned at the upper portion of the vessel 102 adjacent to the aneurysm 104 and not open in an upside-down configuration where the aneurysm shield 900 would be positioned along the bottom portion of the vessel 102.

Referring now to 10B, the aneurysm shield 900 positioned along the shield delivery catheter 1000 is shown in a top view. As previously described, the second positioning marker 912 extends across a center portion of the aneurysm 104. With the view in Figure 10B the specialist is able to rotatably position the aneurysm shield 900 so the first positioning marker 910 also extends through the center portion of the aneurysm 104. Further, the specialist is able to use the shield delivery catheter 1000 to accurately laterally position the shield delivery catheter 1000 and the aneurysm shield 900 at the appropriate portion of the vessel 102 with the aneurysm reticle pattern 914 near a center portion of the aneurysm 104.

As described herein, with the two imaging views shown in Figures 10A and 10B, the specialist is able to accurately position the aneurysm shield 900 extending in a semi-circular fashion around the vessel 102 by positioning the first and second positioning markers 910, 912 of the aneurysm reticle pattern 914 in alignment with the aneurysm 104. Optionally and as previously described above, where the first and second positioning markers 910, 912 are located on the shield delivery catheter 1000, similar positioning of the aneurysm shield 900 is performed. In such an example, the aneurysm shield 900 is appropriately positioned along the shield delivery catheter 1000. For instance, the aneurysm shield 900 is in substantial alignment with the first and second positioning markers 910, 912. Stated another way, the center portion of the aneurysm shield 900 is substantially aligned with the aneurysm reticle pattern 914 shown on the shield delivery catheter 1000.

Figures 11A and 11B show the aneurysm shield 900 in a deployed anchoring configuration within the vessel 102. As previously described and shown in Figures 10A and 10B the aneurysm shield 900 is positioned relative to the aneurysm 104 by aligning the first and second positioning markers 910, 912 with the aneurysm 104. As shown in Figure 11A, the first positioning marker is positioned substantially adjacent to the aneurysm 104 along the wall of the vessel 102. The second positioning marker 912 is positioned beneath the aneurysm shield 104. As shown in Figure 11A, the second positioning marker 912 extends toward the center of the aneurysm 104. Referring now to Figure 11B, the first and second positioning markers 910, 912 are shown substantially in the center of the aneurysm 104 when the aneurysm shield 900 is viewed from the top. The first and second positioning markers 910, 912 included in the aneurysm reticle pattern 914 have been used to align the aneurysm shield 900 with the aneurysm 104 and substantially ensure the aneurysm 900 is positioned to cover the aneurysm 104 and thereby prevent or throttle blood flow into the aneurysm 104 (i.e., where the shield is a continuous solid surface or perforated).

The first and second positioning markers 910, 912 forming the aneurysm reticle pattern 914 provide a reliable and consistent feature on the aneurysm shield 900 or shield delivery catheter 1000 (See Figures 10A, B) for positioning of the aneurysm shield 900 relative to the aneurysm 104. Stated another way, the aneurysm reticle pattern 914 provides a site for the specialist to use as the aneurysm shield 900 is positioned longitudinally and rotatably within the vessel 102 relative to the aneurysm 104. By viewing the aneurysm shield 900 in one or more different views, the aneurysm shield 900 is moved longitudinally and rotatably to position the first and second positioning markers 910, 912 relative to the aneurysm 104. As the aneurysm reticle pattern 914 is aligned with the aneurysm 104 the specialist can easily recognize the aneurysm shield 900 is correctly positioned and thereafter release the aneurysm shield 900 from the shield delivery catheter 1000. The aneurysm shield expands into the anchoring configuration shown in Figures 11A, B with the first and second draped wings 906, 908 and the corresponding first and second wing peripheral edges, 907, 909 engaged with the vessel to retain the aneurysm shield 900 in the desired orientation obtained during imaging with the positioning markers 910, 912.

Figures 12A-C show one example of a method for making an aneurysm shield 1200. The other aneurysm shields described herein are optionally constructed in a manner consistent with that used for the aneurysm shield 1200. Referring first to Figure 12A, an aneurysm shield blank 1201 is formed. In one example, the blank 1201 is formed by punching or die-cutting the blank from a larger piece of material (metal, plastic and the like) used as the base for the aneurysm shield 1200. Optionally, multiple blanks 1201 are punched or die-cut from a single piece of material. In another example, the blank 1201 is formed with another process including, but not limited to, etching, molding and the like.

As shown in Figure 12A, the aneurysm shield blank 1201 defines the perimeter of the aneurysm shield 1200 and includes first and second draped wings 1204, 1206 in a substantially undeformed and flat configuration. The shell 1202 of the aneurysm shield 1200 is continuous and substantially free of any perforations. The shield frame 1208 circumscribes the shell 1202 and is integral with the shell. As described above, in some examples, the shield frame 1208 and the shell 1202 are separate components coupled together during construction to form the aneurysm shield 1200.

Referring now to Figure 12B, the aneurysm shield blank 1201 is shown in a substantially flat or planar configuration with perforations 1210 formed in the shell 1202. As previously described, the perforations 1210 are formed with one or more methods including, but not limited to, etching, die-cutting, machining, laser cutting and the like. The perforations 1210 are formed in the shell 1202 to provide a specified porosity through the aneurysm shield 1200. In one example, the perforations 1210 open 25 percent or more of the corresponding area of the shell 1202 and permit throttled blood flow through the shell. Blood flow, at a substantially reduced velocity and pressure, reaches the tissues of the aneurysm covered by the shield thereby allowing the aneurysm to receive oxygen and heal over time without the stress of regular blood flow pressure and velocity. In other examples, the perforations 1210 allow blood flow through the shell 1202 and into branch vessels covered by the aneurysm shield 1200. For instance, where a branch vessel is close to an aneurysm, the aneurysm shield 1200 is placed over the aneurysm and the branch vessel orifice. Because the branch vessel is not otherwise blocked, blood flow through the perforations 1210 continues into the branch vessel.

In still other examples, the perforations are non-existent or form an open area less than 25 percent of the total area of the shell. Blood flow is substantially prevented through the aneurysm shield 1200 with such perforations. Optionally, the aneurysm shield 1200 does not include perforations (as in Figure 12A), and includes a continuous unbroken surface that substantially prevents any blood flow through the aneurysm shield 1200.

In other construction methods, the aneurysm shield 1200 is formed by overmolding, coupling or suturing the shell 204 of the aneurysm shield onto a shield frame, such as shield frame 202 (See Figure 2D). The aneurysm shield 1200 is optionally constructed with different materials in the shield frame 202 and the shell 204. For example, rigid materials, shape memory materials and the like are used in the shield frame 202, and the shell 204 includes pliable materials configured to easily conform to the shape of the vessel the shield 1200 is positioned within. The shell 204 includes materials selected for flexibility and desired porosity (or lack of porosity) including, but not limited to, plastics, metals, woven fibers and the like.

Figure 12C shows one example of the aneurysm shield 1200 after forming of the shield into the desired anchoring configuration (e.g., the configuration used to retain the shield within a desired location with the vasculature). The first and second draped wings 1204, 1206 drape from the shield spine 1212 of the shield 1200. The first and second draped wings 1204, 1206 are formed into the anchoring configuration by deflection of the wings 1204, 1206 along a mandrel in one example. In another example, the wings 1204, 1206 are formed into the anchoring configuration by heating of the aneurysm shield 1200 to near a solid to liquid transition temperature and shaping of the wings into the desired shape. The aneurysm shield 1200 is thereafter cooled while in the anchoring configuration. It still another example, where the aneurysm shield 1200 is formed with a shape memory material, the material is heated to a temperature sufficient to impart the desired shape (the anchoring configuration) and the shield is formed into the shape. Optionally, the shield frame 1208, if constructed separately, is formed into the desired shape and the shell 1202 is coupled with the frame before or after forming of the frame.

After formation of the aneurysm shield 1200 into the anchoring configuration, the aneurysm shield 1200 is stored for use. In one example, the aneurysm shield 1200 is stored in the anchoring configuration. In another example, the aneurysm shield 1200 is stored in the closed configuration (see Figure 4A) and ready for immediate implantation within a patient.

Figure 13 shows one example of a method 1300 for using an aneurysm shield. Reference is made in the description of method 1300 to aneurysm shields 400, 600 and the corresponding elements shown in Figures 4A, B and 6. Reference to the aneurysm shield 400 and its corresponding components is not intended to be limiting and includes corresponding reference to other aneurysm shields described herein as well as their equivalents. At 1302, the aneurysm shield 400 is positioned at an aneurysm location within a vessel. One example of an aneurysm location is shown in Figure 6 including the aneurysm 602 within the vessel 603. The aneurysm shield 400 is in the first closed configuration (see Figure 4A) with a first draped wing 402 adjacent to a second draped wing 404. The wing peripheral edges 405 are adjacent to each other and separated corresponding to the separation of the wings 402, 404.

At 1304, the aneurysm shield 400 is released at the aneurysm location. As previously described in one example, the aneurysm shield 400 is positioned within a shield delivery catheter and positioned in the vasculature at the aneurysm 602 and thereafter released. In still other examples, the aneurysm shield 400 is positioned relative to the aneurysm 602 with radiopaque markings on the aneurysm shield 400, such as the first and second positioning markers 910, 912 forming the aneurysm reticle pattern 914 (see Figures 9A, B). The first and second positioning markers 910, 912 assist in the positioning and corresponding releasing of the aneurysm shield 400 at the desired location and in the desired orientation relative to the aneurysm 602.

At 1306, the aneurysm shield 400 is anchored within the vessel 603 at the aneurysm 602. One example of an anchoring configuration is shown in Figure 4B with the first and second draped wings 402, 404 in an expanded configuration relative to the closed configuration shown in Figure 4A. As shown in Figure 6 the peripheral edges 601 of the wings are spread apart across an arcuate portion 618 of the vessel circumference, such as the vessel 603. The aneurysm shield 600 shown in Figure 6 is expanded and thereby positioned across the aneurysm 602. A bare portion of the vessel 620 – the inverse counter part to the arcuate portion of the vessel 618 – is left open and free of the aneurysm shield 400, 600 (see Figures 4A, B and 6). Endothelial cell growth along the aneurysm shield is thereby prevented along at least the bare portion of the vessel 620 shown in Figure 6. Constriction of the vessels 603 through endothelial cell growth along the aneurysm shields described herein is thereby substantially minimized.

At 1308, the aneurysm 602 is obstructed with the shell (a continuous or perforated shell) extending between the first and second draped wings 402, 404. In one example, obstructing the aneurysm with the perforated shell 412 of the aneurysm shield 400 includes throttling blood flow (aneurysm flow 608 shown in Figure 6) through the perforated shell 412. Throttling the blood flow into the aneurysm 602 provides blood to the tissue of the aneurysm 602 thereby facilitating healing and reabsorption of the aneurysm over time. The velocity of the throttled blood flow is substantially minimized and correspondingly decreases the stresses on the aneurysm 602 from the blood flow velocity. The risk of hemorrhaging at the aneurysm or continued growth of the aneurysm is thereby substantially minimized.

In another example, at 1312 obstructing the aneurysm 602 includes promoting blood flow, such as covered branch flow 610 (see Figure 6), through the perforated shell 412 of the aneurysm shield 400. Because the branch vessel 604 shown in Figure 6 is not a dead end, in contrast to the aneurysm 602, flow of blood through the branch vessel 604 is carried away from the vessel 603. The velocity of the covered branch flow 610 permits continued blood flow through the aneurysm shield 600 where the aneurysm shield 600 is covering the covered branch vessel 604. Stated another way endothelial cell growth is substantially retarded at the portion of the aneurysm shield 600 covering the covered branched vessel 604 because of the velocity of the covered branch flow 610 through the shield. In contrast, over time slower blood flow through the aneurysm shield 600 into the aneurysm 602 facilitates endothelial cell growth across the portion of the aneurysm shield covering the aneurysm 602. Endothelial cell growth may eventually seal off the aneurysm 602 from continued blood flow from the vessel 603.

In one example, where aneurysm flow 608 continues into the aneurysm 602 over time, the aneurysm 602 begins to heal and reabsorb into the wall of the vessel 603. As the aneurysm 602 continues to heal into the vessel 603 aneurysm flow 608 into the aneurysm gradually decreases. As the velocity of the aneurysm flow 608 decreases endothelial cell growth across the aneurysm shield 600 covering the aneurysm 602 precedes thereby slowly sealing off the aneurysm 602 and allowing for full reabsorption of the aneurysm into the vessel 603.

In one option, the method 1300 further includes exposing a bare portion of the vessel 620 as previously described. An uncovered branch vessel 606 (see Figure 6) is correspondingly exposed and unobstructed uncovered branch flow 612 is permitted though the uncovered branch vessel 606. Stated another way, the velocity of blood flow into the uncovered branch vessel 606 remains substantially unchanged after implantation and deployment of the aneurysm shields described herein within the vessel 603.

Several options for the method 1300 follow. In one example, positioning the aneurysm shield 400 at the aneurysm location within the vessel 603 includes positioning the aneurysm shield 400 along less than a vessel circumference of the vessel, such as the arcuate portion of the vessel 618 shown in Figure 6. A bare portion of the vessel 620 is left uncovered by the aneurysm shield 400, 600. In still another example, positioning the aneurysm shield 400, 600 includes viewing an aneurysm reticle pattern 914 on one or more of the aneurysm shield 600 or a positioning catheter such as the shield delivery catheter 700 shown in Figure 7. Optionally, positioning the aneurysm shield 400, 600 includes viewing the aneurysm reticle pattern 914 from two or more orientations relative to an aneurysm (see Figures 10A, B). Method 1300 further includes one or more of rotating or moving the aneurysm shield 400, 600 into alignment with the aneurysm based on the view of the aneurysm radical pattern 914 from the two or more orientations.

In another example, releasing the aneurysm shield 400, 600 includes removing a restraint coupled over at least one of the first and second draped wings 402, 404. In one example, a restraint is shown in Figure 8A and includes the shield sheath 802. In still another example, releasing the aneurysm shield 400, 600 includes at least one of the first and second draped wings 402, 404 spreading apart from the other of the second and first draped wings 402, 404. For instance, where the aneurysm shield 400, 600 is constructed with a shape memory material, as the aneurysm shield 400, 600 is exposed within the vessel the temperature of the surrounding bodily fluids triggers expansion of the aneurysm shield 400, 600 into the anchoring configuration shown in Figure 4B. In another option, where the aneurysm shield is constructed with a deflectable material and retained along the shield delivery catheter 700 in the closed configuration, removal of the shield sheath 802 allows the aneurysm shield to deflect into the original anchoring configuration. Expansion of the aneurysm shield 400, 600 engages the shield with the walls of the vessel 603 and positions the aneurysm shield 400, 600 at the desired location within the vessel.

In one option, anchoring the aneurysm shield 400, 600 within the vessel 603 includes spreading the first and second draped wings 402, 404 along less than 180 degrees of the vessel circumference, for instance, an arcuate portion of the vessel 618, as shown in Figure 6. In another example, anchoring the aneurysm shield 400, 600 includes spreading a shield frame 614 at the perimeter of the aneurysm shield 600. Spreading the shield frame 614 correspondingly spreads the shell 616 (e.g., a perforated shell or continuous shell) coupled with the shield frame 614. Optionally, spreading the shell 616 (including a perforated shell) includes the shield frame 614 biasing the shell into the anchoring configuration shown in Figures 4B and 6.

The method 1300 further includes in other examples articulating one or more of the first and second draped wings 506, 508 and the corresponding shell 504 along one or more undulated surfaces of a vessel (a non-linear portion of a vessel). The aneurysm shield 500 (see Figure 5) articulates into a configuration corresponding to the undulated vessel surface at articulation openings 516 in one or more of the first and second draped wings 506, 508 in the shell 504. The aneurysm shield 500 is thereby able to flushly mate with the vessel tissue surrounding the neck of the aneurysm and reliably prevent or throttle flow into the aneurysm according to the configuration of the shield.

## Conclusion

The aneurysm shields described herein provide a system and device for obstruction of an aneurysm when positioned within a vessel. The aneurysm shields cover only an arcuate portion of a vessel thereby leaving the remainder of the vessel free of the device. The arcuate configuration of the aneurysm shields allows for flow into vessels opposed to the aneurysm that would otherwise be concealed by devices extending around the circumference of the vessel or around a substantial portion of the vessel (e.g., greater than 270 degrees). Undesirable phenomenon, such as intimal hyperplatic response (i.e., endothelial cell growth) on the aneurysm shield is thereby substantially constrained to the arcuate portion of the vessel covered by the aneurysm shield as opposed to the entirety of the vessel circumference. Constriction of the vessel is thereby minimized over time while the aneurysm is covered at the same time by the aneurysm shield extending only over the arcuate portion of the vessel. Constriction of the circumference of the vessel and corresponding significant drops in pressure and flow rate as with other stent-like devices are thereby substantially avoided.

Further, the aneurysm shields and methods described herein are used with minimally invasive implantation techniques that traverse through the vasculature to position the shields at defects. Gross surgical techniques, including opening of the skull, manipulating overlying brain tissue, and clipping of an aneurysm from outside of the base vessel are thereby substantially avoided. Further still, reassembling of tissue and closing of the skull are also avoided with the minimally invasive implantation of the aneurysm shields. Moreover, the aneurysm shields are used with wide neck aneurysms that present difficulties with other devices, such as vaso-occlusive coils that are difficult to retain in these aneurysms. Because the aneurysm shield is coupled across the neck of the aneurysm and engaged with the surrounding wall of the vessel, positioning of a coil or other filler within the aneurysm is avoided.

Where the aneurysm shield includes perforations the perforations allow throttled blood flow into the aneurysm and the tissue surrounding the aneurysm. Throttled blood flow into the aneurysm and those tissues allows for healing and gradual reabsorbing of the aneurysm into the vessel wall. In a similar manner, where throttled blood flow is permitted through the aneurysm shield, dissolvable medicines and the like coated over the aneurysm shield are dispensed into the aneurysm over time by the throttled blood flow through the shield. In contrast, devices with continuous unbroken surfaces or surfaces with fine porosity that prevent all blood flow fail to deliver substantially any blood to the aneurysm tissues for healing and reabsorption of the aneurysm into the vessel wall.

Additionally, where the aneurysm shield includes perforations, blood flow is permitted through the shield for branch vessels covered by the shield. By including the perforations the aneurysm shield has greatly enhanced flexibility coupling with vessels having aneurysms near branch vessels. For instance, a specialist can comfortably position the shield over an aneurysm as desired while still permitting blood flow into adjacent branch vessels without concern for blocking blood flow into those adjacent branched vessels.

Further, the aneurysm shield is deliverable in a closed configuration and then deployed into an anchoring configuration where the first and second draped wings engage against the vessel wall and retain the aneurysm shield at the desired location within the vasculature. Supplemental anchors extending along the vessel wall (thereby creating locations for endothelial cell growth and corresponding vessel constriction) are avoided. Similarly, additional anchors deployed into the aneurysm itself are not needed because the first and second draped wings affirmatively anchor the aneurysm shield to the vessel walls and hold the aneurysm shield in place over the aneurysm.

Moreover, where the aneurysm shield includes positioning markers, the shield is easily deliverable through the vasculature and into a desired orientation within the vessel. The specialist aligns the markers on the aneurysm shield or shield delivery catheter with the aneurysm and affirmatively knows the shield is correctly positioned over the aneurysm by the alignment of the markers viewed through imaging. Trial and error type procedures for positioning aneurysm blocking devices is thereby substantially avoided through the use of the positioning markers.

Although the present disclosure has been described in reference to preferred embodiments, persons skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the disclosure. It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reading and understanding the above description. It should be noted that embodiments discussed in different portions of the description or referred to in different drawings can be combined to form additional embodiments of the present application. The scope of the disclosure should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

## IN THE CLAIMS

What is claimed is:

1. An aneurysm shield comprising:

a shield frame including:

a proximal frame end,

a distal frame end,

first and second draped wings extending between the proximal and distal frame ends, the first draped wing opposes the second draped wing,

a first peripheral edge extends along the first draped wing between the proximal and distal frame ends, and a second peripheral edge extends along the second draped wing between the proximal and distal frame ends, and the first and second draped wings are separated at the first and second peripheral edges;

a shell extending across the shield frame, the shell extends between the proximal and distal frame ends, and the shell extends between the first and second draped wings; and

the first and second draped wings are movable between a closed configuration and an anchoring configuration,

in the closed configuration the first draped wing is adjacent to the second draped wing, and

in the anchoring configuration one or more of the first and second draped wings is spread away from the other of the second and first draped wings, and the first and second peripheral edges are configured to engage with an arcuate portion of a vessel wall and anchor the shell at the arcuate portion.

2. The aneurysm shield of claim 1, wherein the shell includes a perforated shell.

3. The aneurysm shield of claim 2, wherein the perforated shell includes a perforated area configured to throttle flow into an aneurysm through the

perforated shell and promote flow into a branch vessel through the perforated shell.

4. The aneurysm shield of claim 3, wherein between 25 to 30 percent of the perforated area is perforated.

5. The aneurysm shield of claim 1, wherein the shell includes a continuous shell surface, and the continuous shell surface blocks all fluid flow through the continuous shell.

6. The aneurysm shield of claim 1, wherein the first and second draped wings extend the length of the shield frame from the proximal frame end to the distal frame end.

7. The aneurysm shield of claim 1, wherein the first and second peripheral edges are serrated.

8. The aneurysm shield of claim 1, wherein in the closed configuration one of the first and second draped wings is wrapped around the other of the second and first draped wings.

9. The aneurysm shield of claim 1, wherein one or more of the shell or shield frame includes an aneurysm reticle pattern configured for radiopaque viewing.

10. The aneurysm shield of claim 1, wherein the shell includes the shield frame.

11. The aneurysm shield of claim 1, wherein one or more of the shield frame and the shell includes one or articulation openings.

12. An aneurysm shield comprising:

a spine extending from a proximal end to a distal end;

a perforated shell extending from the spine, the perforated shell includes:

a first draped wing extending arcuately from the spine, the first draped wing includes a first wing surface extending between the proximal and distal ends of the spine,

a second draped wing extending arcuately from the spine, the second draped wing includes a second wing surface extending between the proximal and distal ends of the spine, and the first and second draped wings are separated along wing peripheral edges,

the perforated shell is configured for placement within a vessel with the first and second draped wings configured to retain the shell along an arcuate portion of a vessel wall, and

the perforated shell includes a perforated area configured to throttle blood flow into an aneurysm through the perforated area and promote blood flow into a branch vessel through the perforated area.

13. The aneurysm shield of claim 12, wherein between 25 to 30 percent of the perforated area is perforated.

14. The aneurysm shield of claim 12, wherein the first and second draped wings extend the length of the spine from the proximal end to the distal end of the spine.

15. The aneurysm shield of claim 12, wherein the first and second draped wings extending arcuately from the spine include the first and second draped wings bent at one or more angles relative to the spine.

16. The aneurysm shield of claim 12, wherein the spine and the perforated shell are integral.

17. The aneurysm shield of claim 12 further comprising a shield frame extending around a perforated shell perimeter.

18. The aneurysm shield of claim 17, wherein the shield frame includes a biasing material, and the biasing material is configured to urge at least one of the

first and second draped wings from the other of the second and first draped wings.

19. The aneurysm shield of claim 12, wherein the first and second draped wings are movable between a closed configuration and an anchoring configuration,

in the closed configuration a first wing peripheral edge of the first draped wing is adjacent to a second wing peripheral edge of the second draped wing, and

in the anchoring configuration the first and second draped wings are rotated around the spine with the first wing peripheral edge remote from the second wing peripheral edge, and the first and second wing peripheral edges are configured to engage with an arcuate portion of a vessel wall and anchor the perforated shell at the arcuate portion.

20. The aneurysm shield of claim 19, wherein the first and second draped wings are constructed with a memory material configured to move the first and second draped wings between the closed and anchoring configurations.

21. The aneurysm shield of claim 12, wherein a plurality of articulation openings are positioned near the wing peripheral edges.

22. A method of using an aneurysm shield comprising:

positioning an aneurysm shield at an aneurysm location within a vessel, the aneurysm shield is in a first closed configuration with a first draped wing adjacent to a second draped wing, and peripheral edges of the first and second draped wings are separated;

releasing the aneurysm shield at the aneurysm location;

anchoring the aneurysm shield within the vessel including the first and second draped wings spreading apart across an arcuate portion of a vessel circumference including the aneurysm; and

obstructing the aneurysm with a perforated shell extending between the first and second draped wings including:

throttling blood flow into the aneurysm through the perforated shell, and

promoting blood flow through the perforated shell to a branch vessel.

23. The method of claim 22, wherein positioning the aneurysm shield at the aneurysm location within the vessel includes positioning the aneurysm shield along less than a vessel circumference of the vessel.

24. The method of claim 22, wherein positioning the aneurysm shield includes viewing an aneurysm reticle pattern on one or more of the aneurysm shield or a positioning catheter.

25. The method of claim 24, wherein positioning the aneurysm shield includes:

viewing the aneurysm reticle pattern from two or more orientations relative to an aneurysm, and

one or more of rotating or moving the aneurysm shield into alignment with the aneurysm based on the view of the aneurysm reticle pattern from the two or more orientations.

26. The method of claim 22, wherein releasing the aneurysm shield includes removing a restraint coupled over at least one of the first and second draped wings.

27. The method of claim 22, wherein releasing the aneurysm shield includes at least one of the first and second draped wings spreading apart from the other of the second and first draped wings.

28. The method of claim 22, wherein anchoring the aneurysm shield within the vessel includes spreading the first and second draped wings along less than 180 degrees of the vessel circumference.

29. The method of claim 22, wherein anchoring the aneurysm shield includes spreading a shield frame at an aneurysm shield perimeter, and spreading the shield frame correspondingly spreads the perforated shell.

30. The method of claim 29, wherein spreading the perforated shell includes the shield frame biasing the perforated shell into an anchoring configuration.

31. The method of claim 22 further comprising articulating one or more of the first and second draped wings and the perforated shell along an undulated surface of a vessel, and the aneurysm shield articulates into a configuration corresponding to the undulated surface at articulation openings in one or more of the first and second draped wings and the perforated shell.

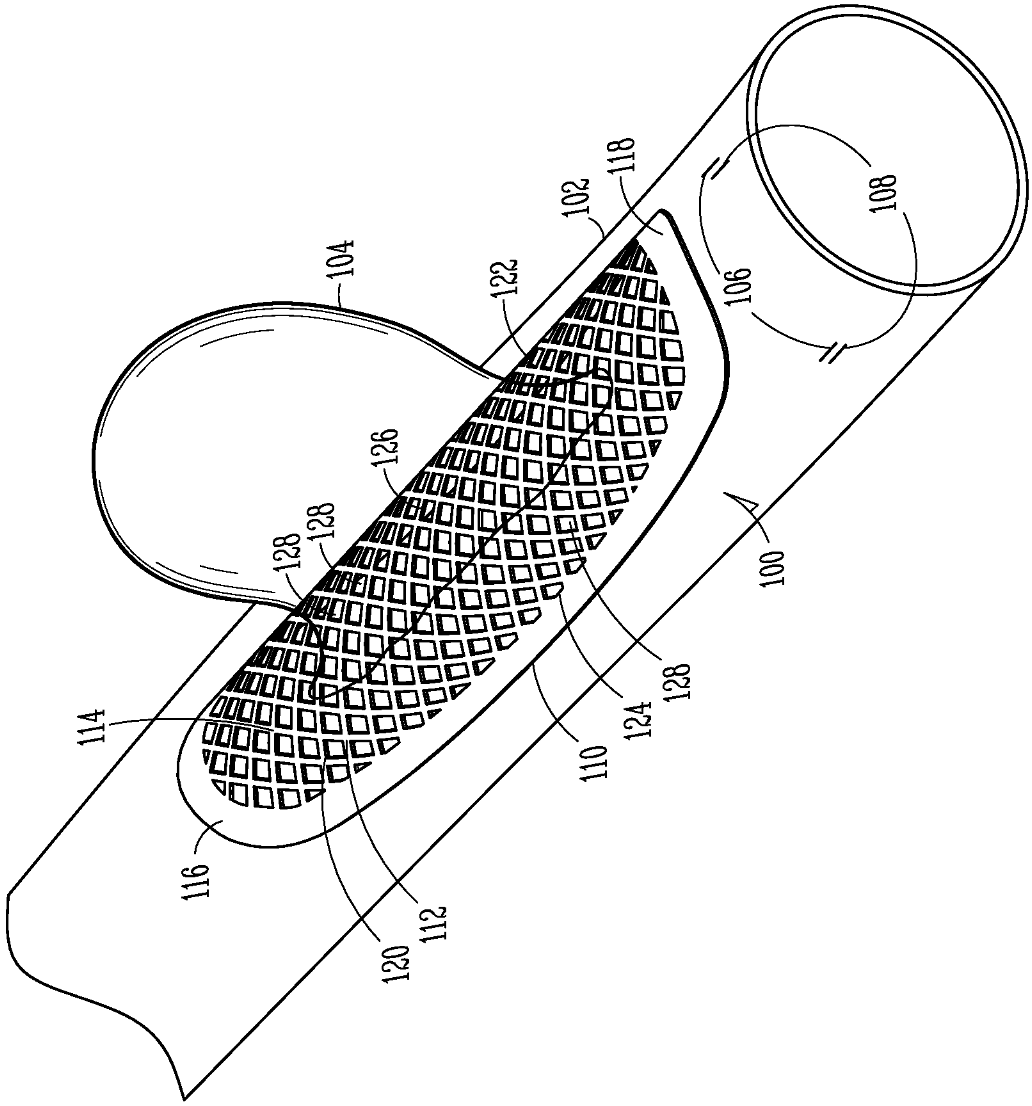

100
102
104
106
108
110
112
114
116
118
120
122
124
126
128
128
128
128

FIG. 1

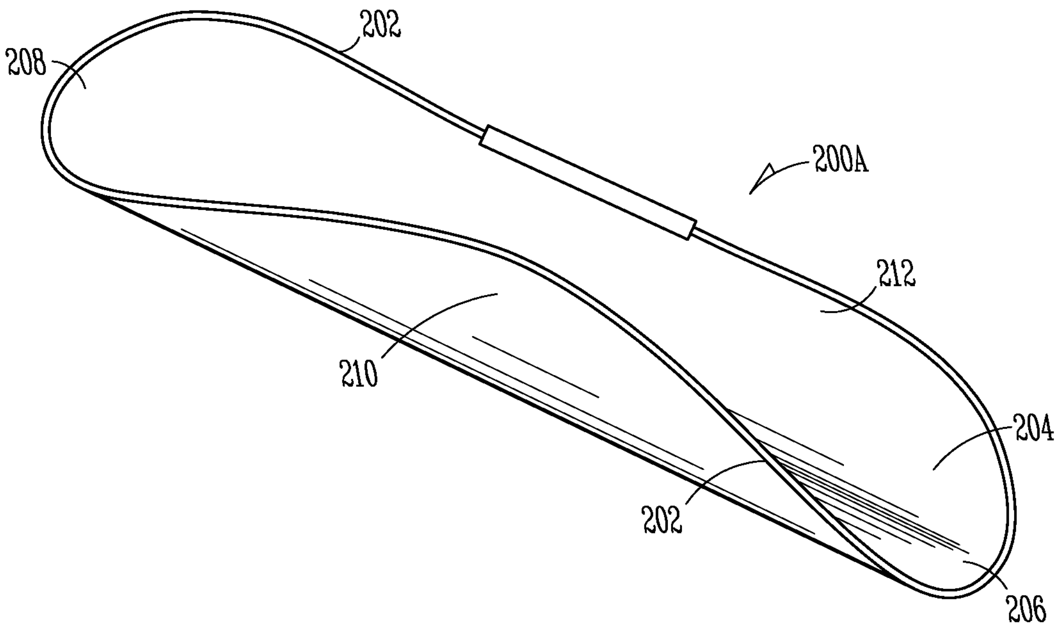

202
208
200A
212
210
204
202
206

FIG. 2A

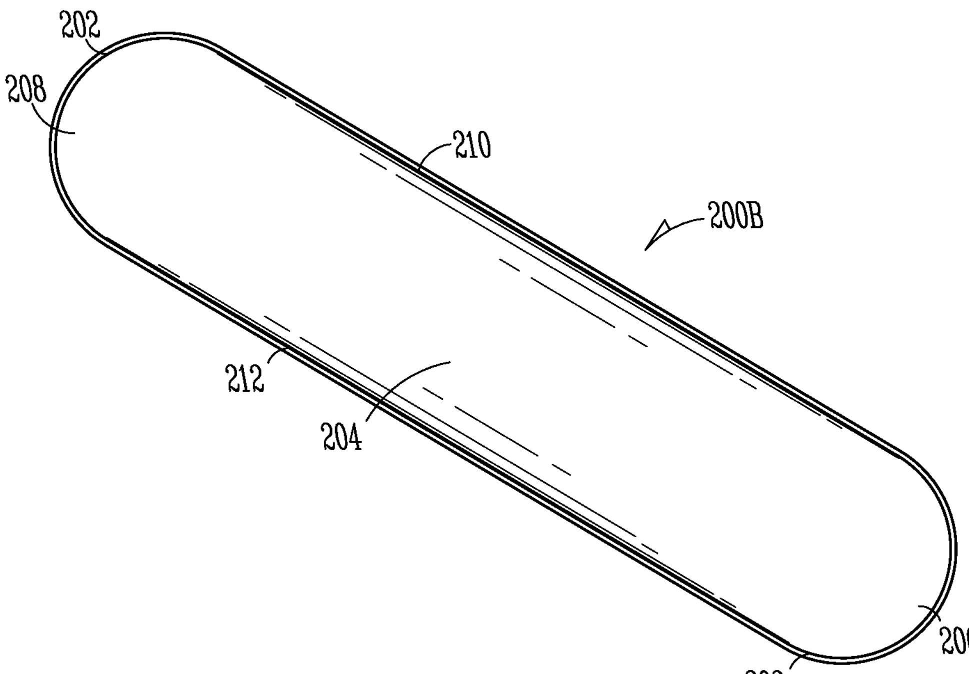

202
208
210
200B
212
204
206
202

FIG. 2B

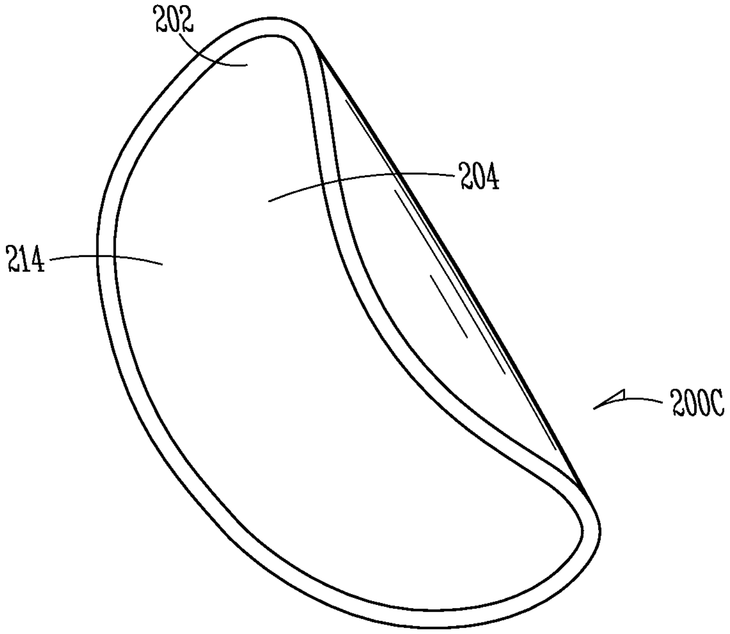



FIG. 2C

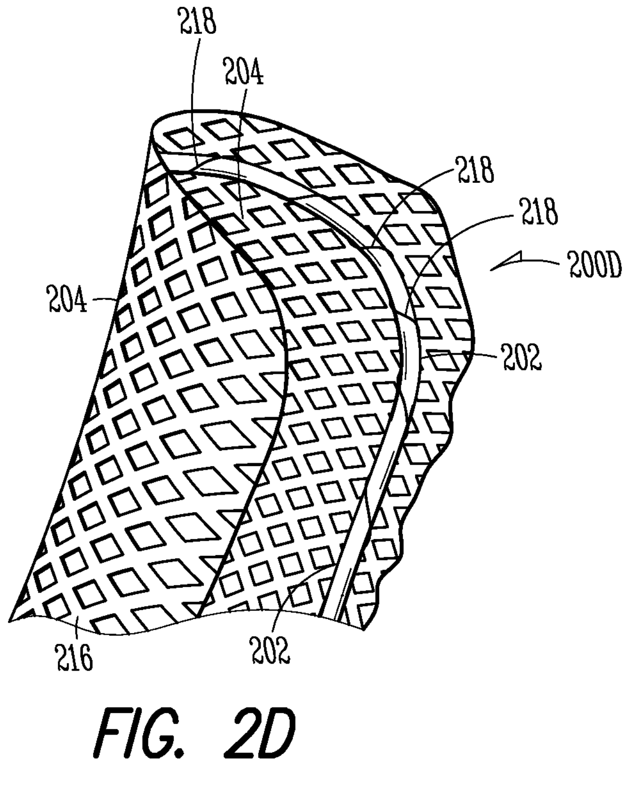



FIG. 2D

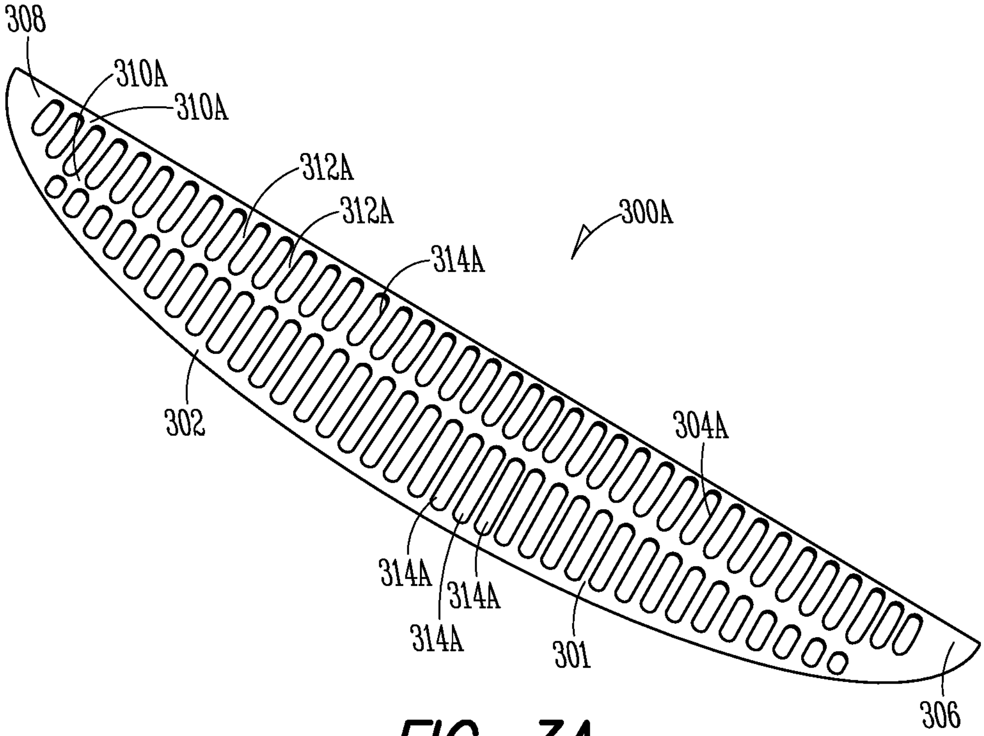

308
310A
310A
312A
312A
300A
314A
302
304A
314A
314A
314A
301
306

FIG. 3A

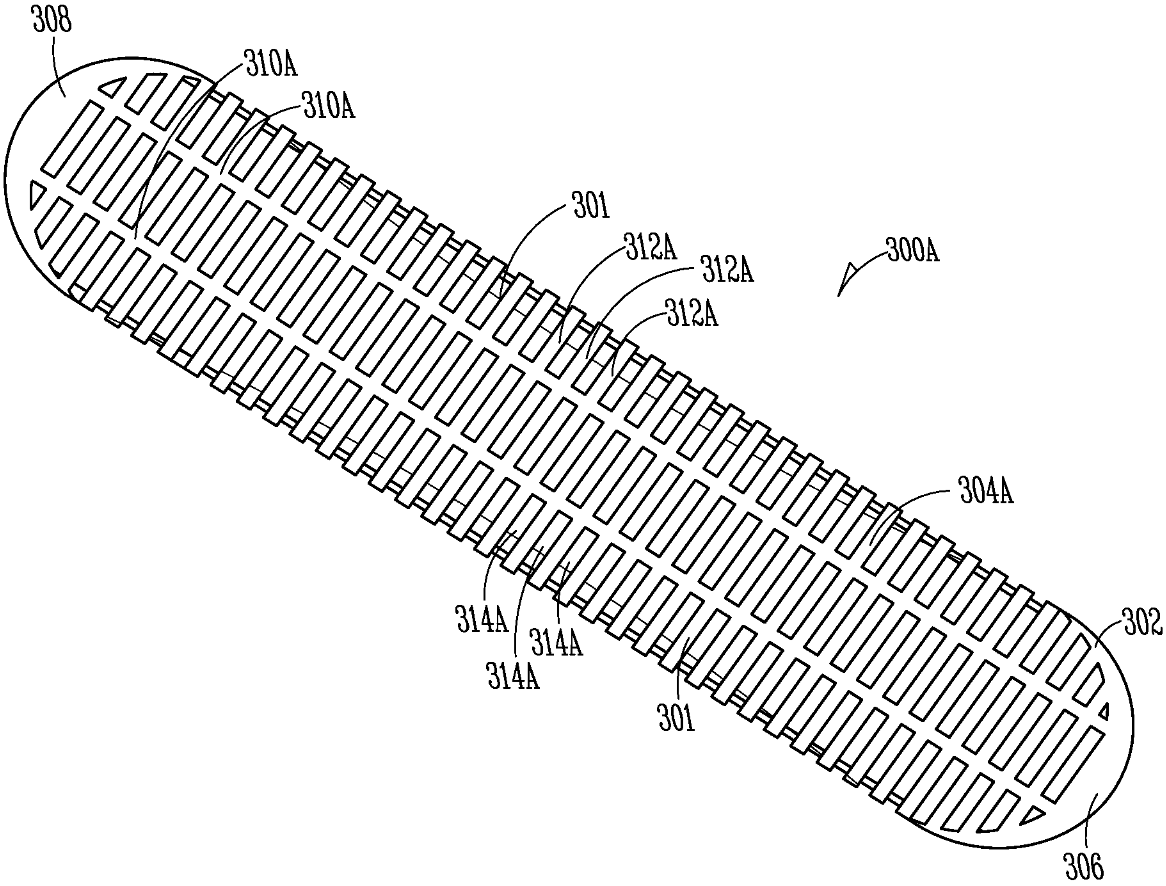

308
310A
310A
301
312A
312A
300A
312A
304A
314A
314A
314A
302
301
306

FIG. 3B

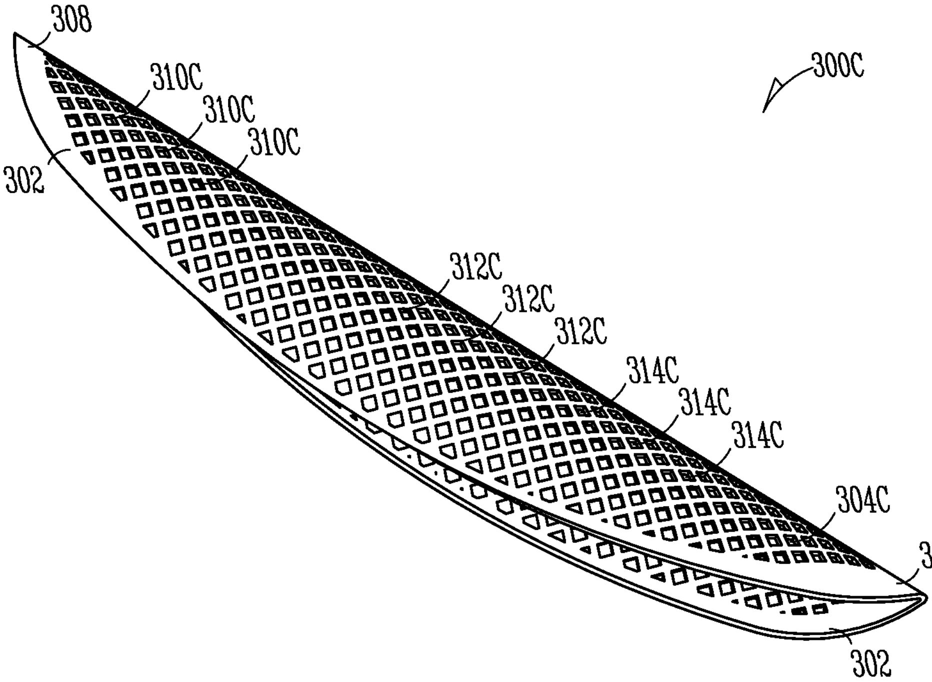

308
310C
310C
310C
300C
302
312C
312C
312C
314C
314C
314C
304C
306
302

FIG. 3C

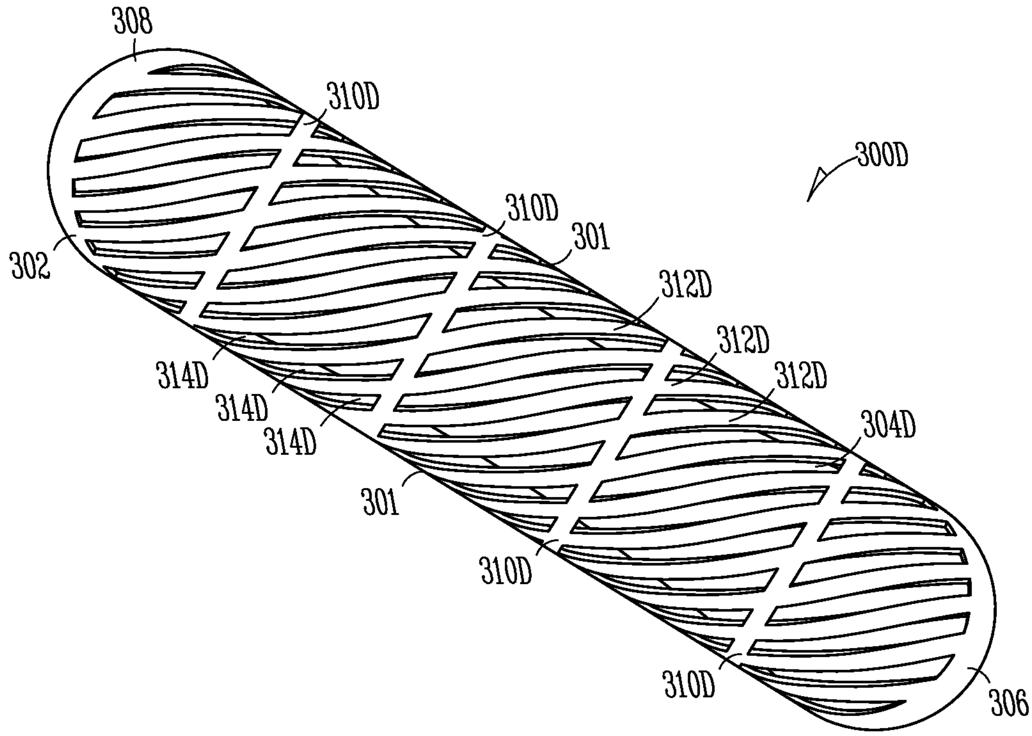
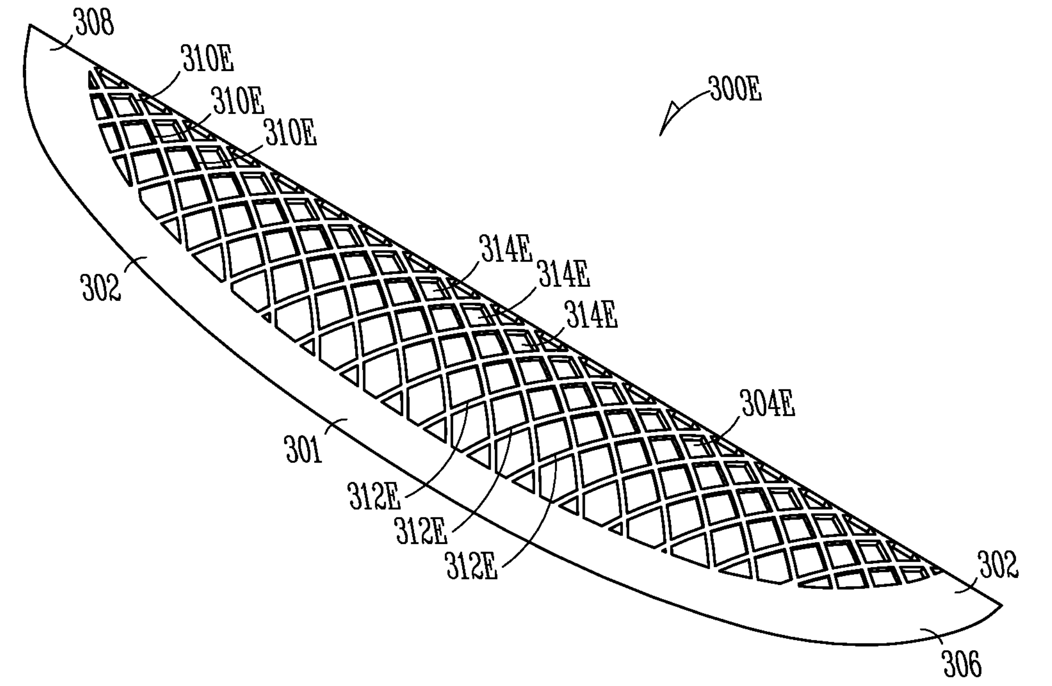
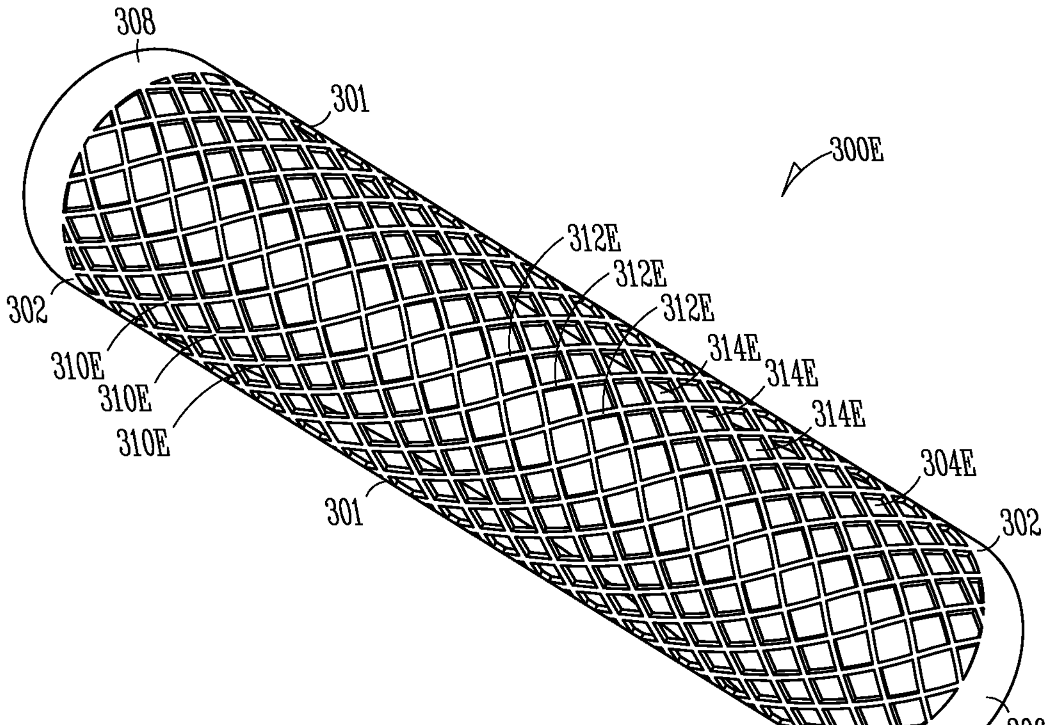

308
310D
300D
310D
301
302
312D
312D
312D
314D
314D
314D
304D
301
310D
310D
306

FIG. 3D



308
310E
310E
310E
300E
314E
314E
314E
302
304E
301
312E
312E
312E
302
306


FIG. 3E



308
301
300E
312E
312E
312E
302
314E
314E
314E
310E
310E
310E
304E
301
302
306


FIG. 3F

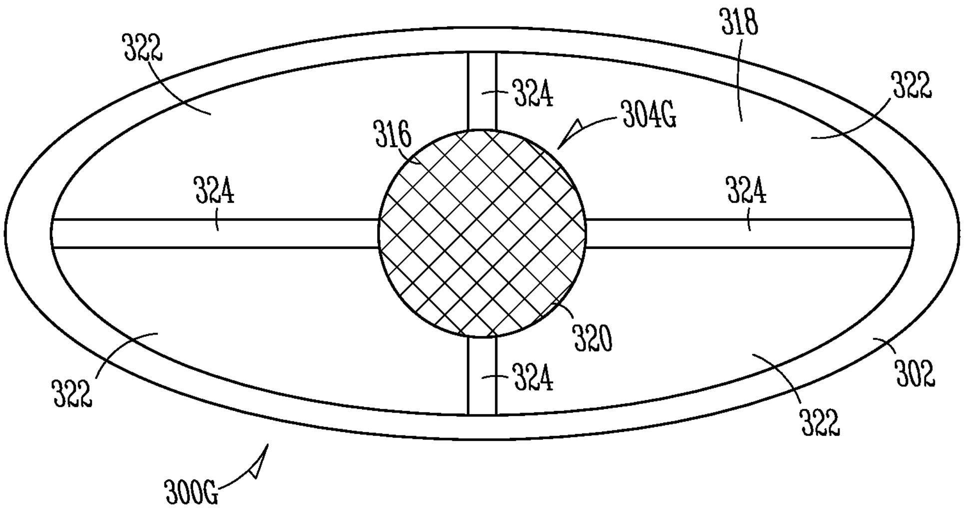

322
318
324
304G
322
316
324
324
320
302
322
324
322
300G

FIG. 3G

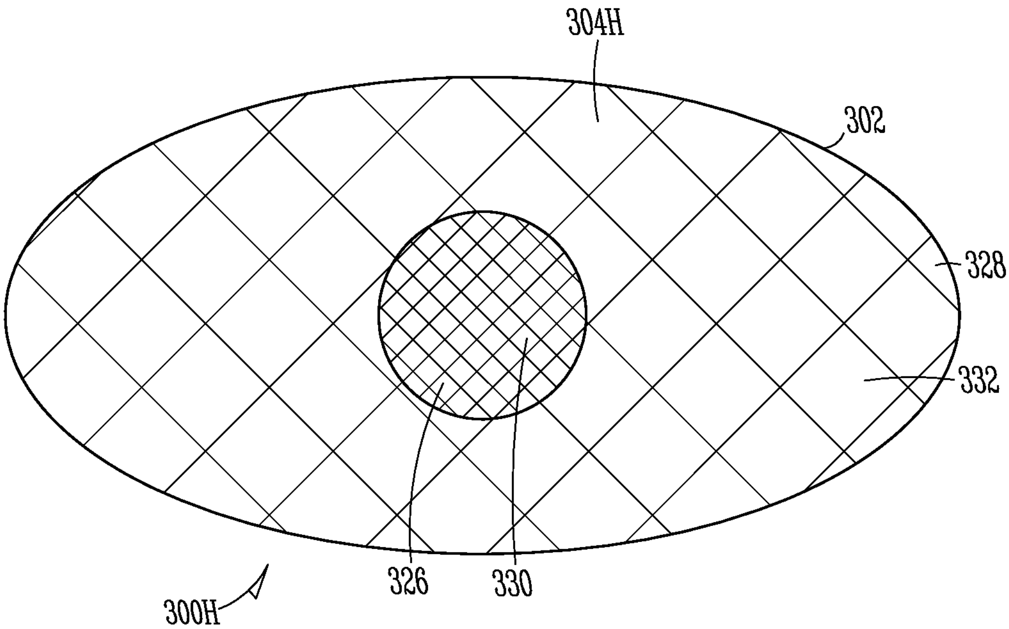

304H
302
328
332
326
330
300H

FIG. 3H

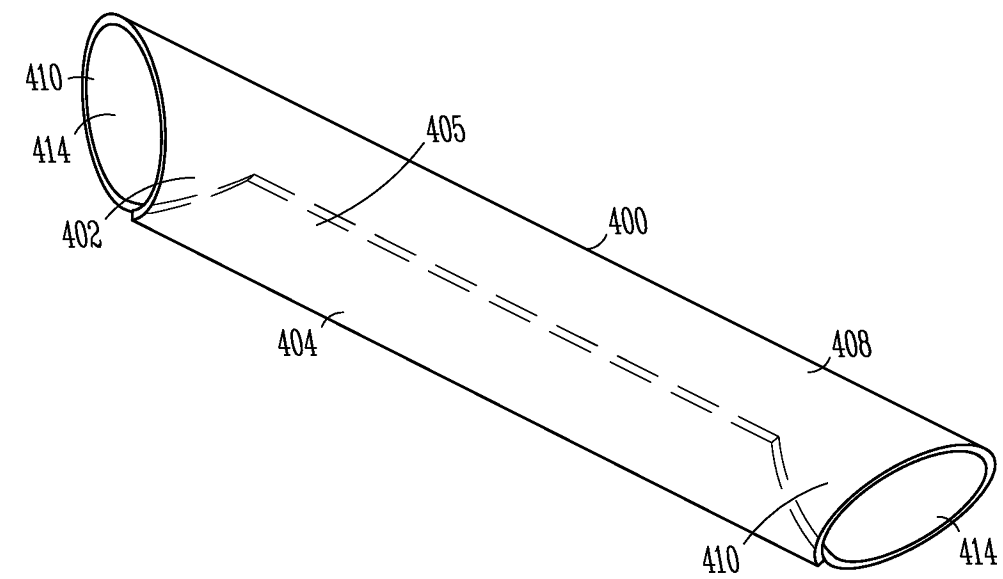

410
414
405
402
400
404
408
410
414

FIG. 4A

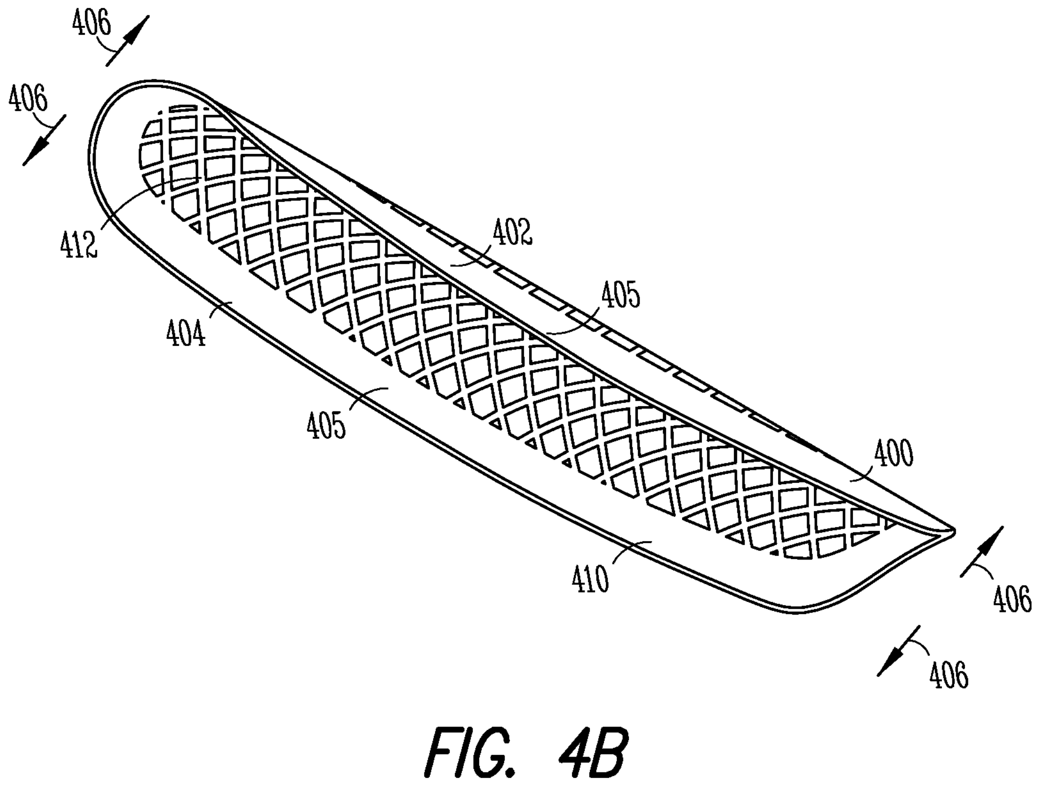

406
406
412
402
405
404
405
400
410
406
406

FIG. 4B

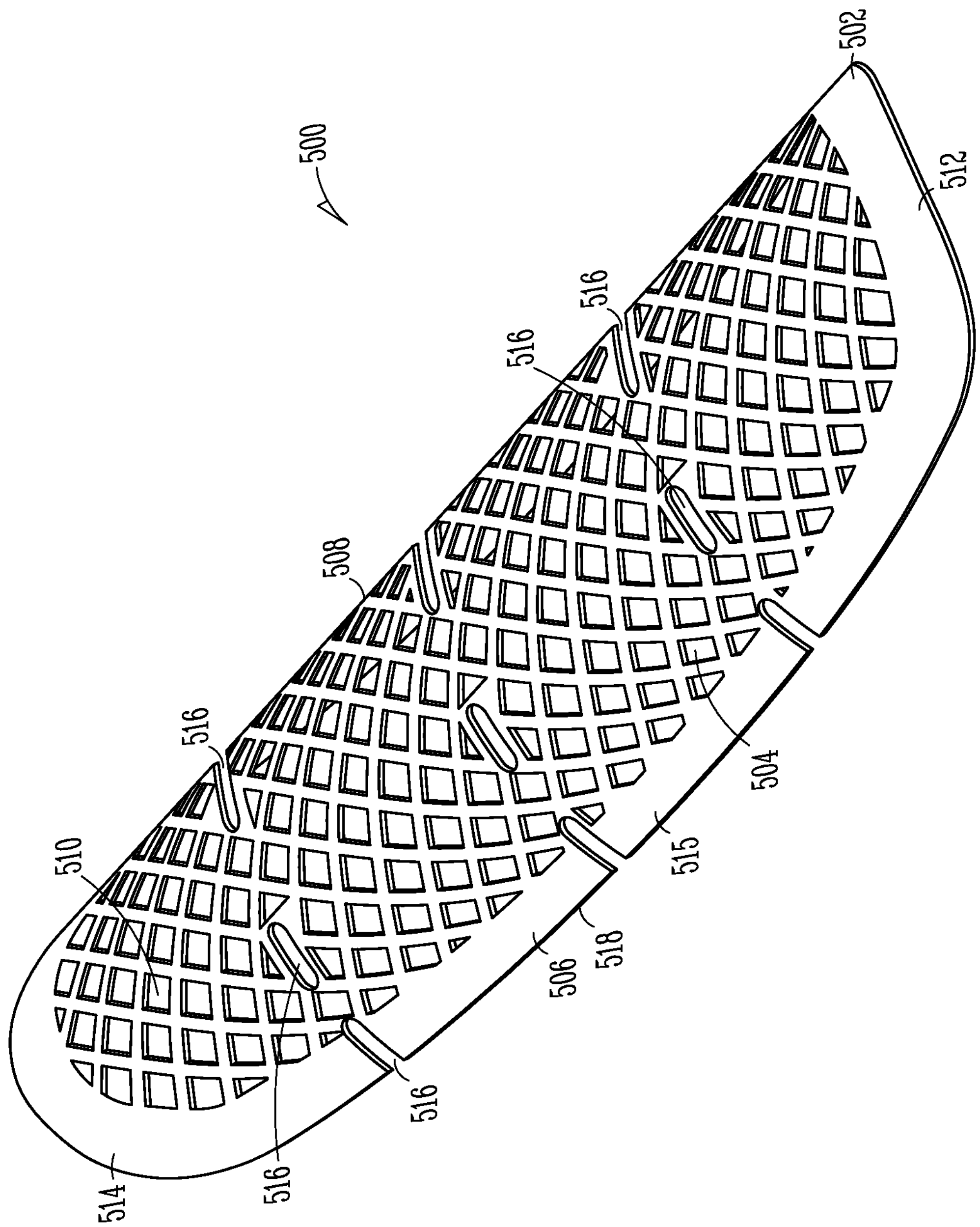



FIG. 5

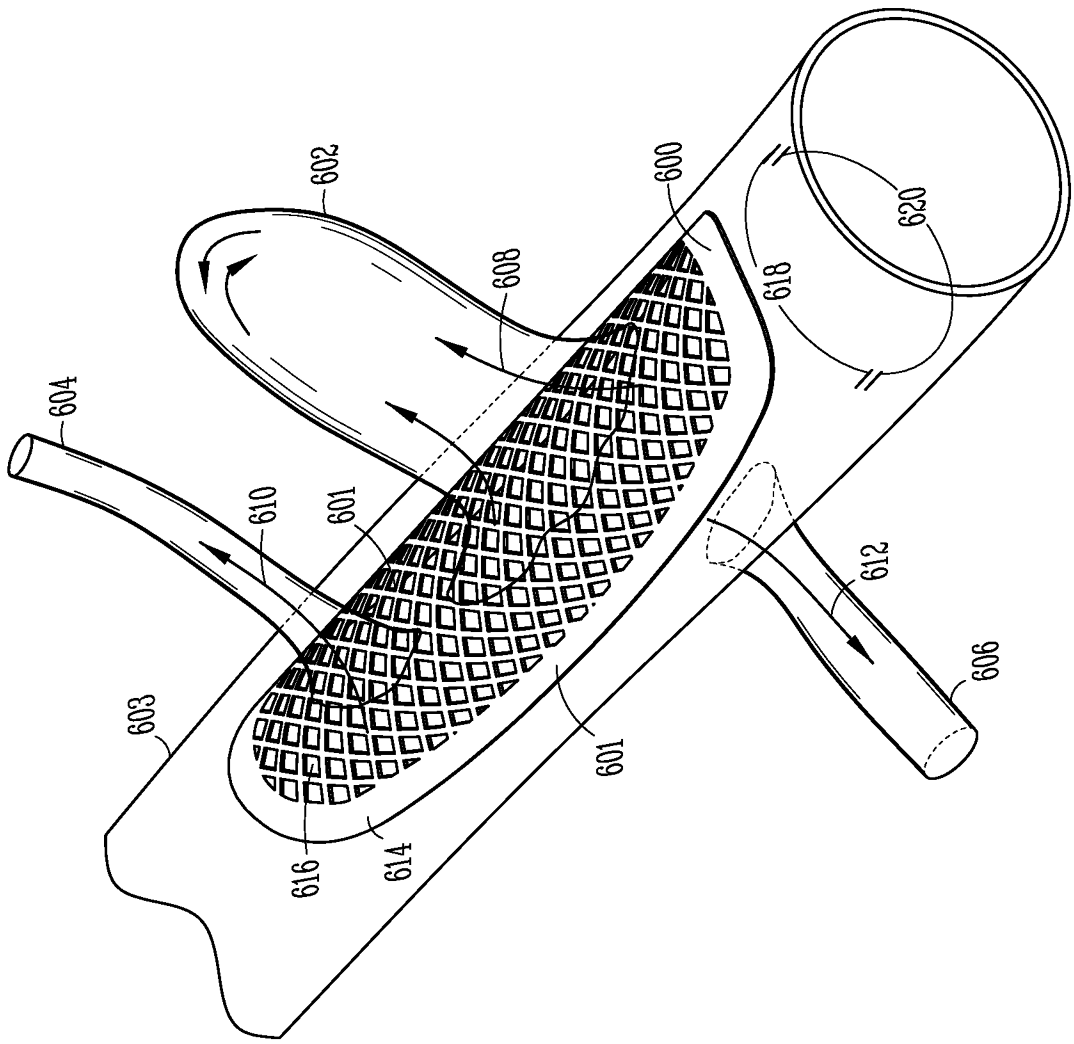



FIG. 6

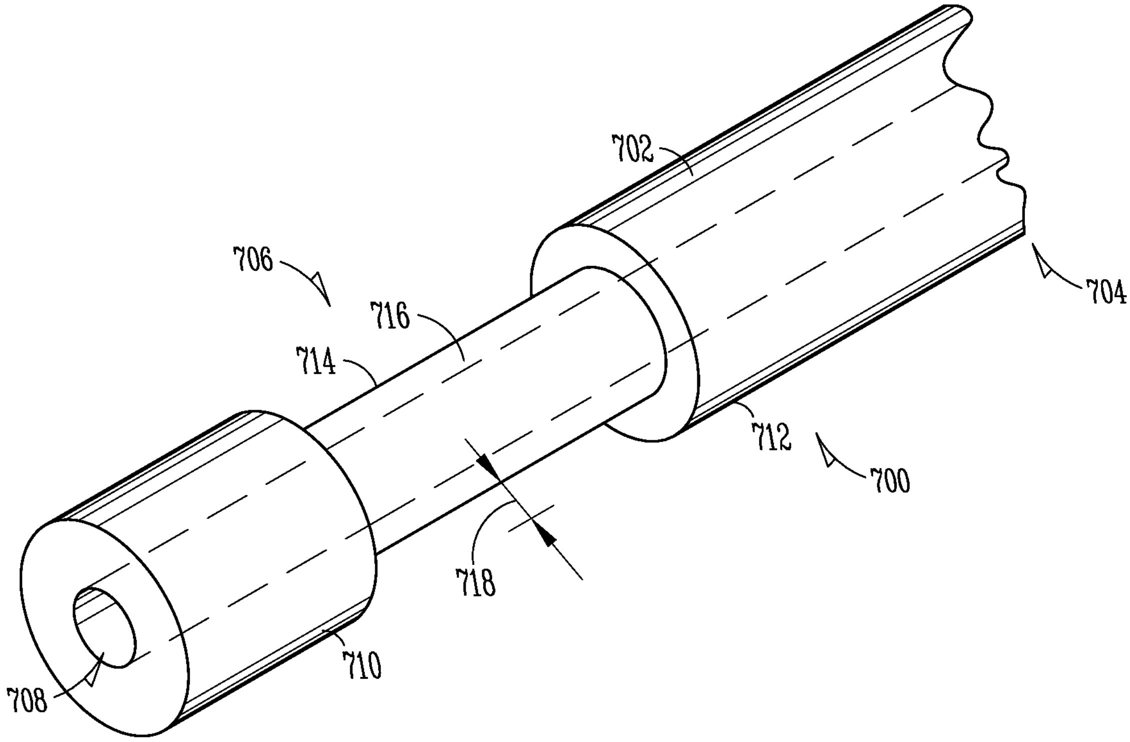



FIG. 7

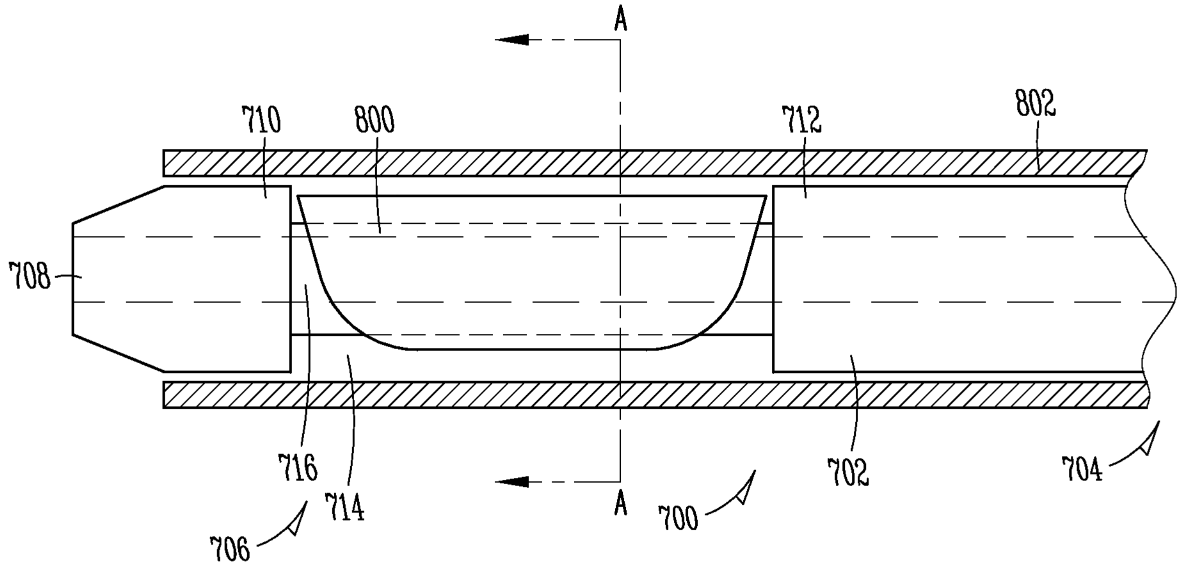
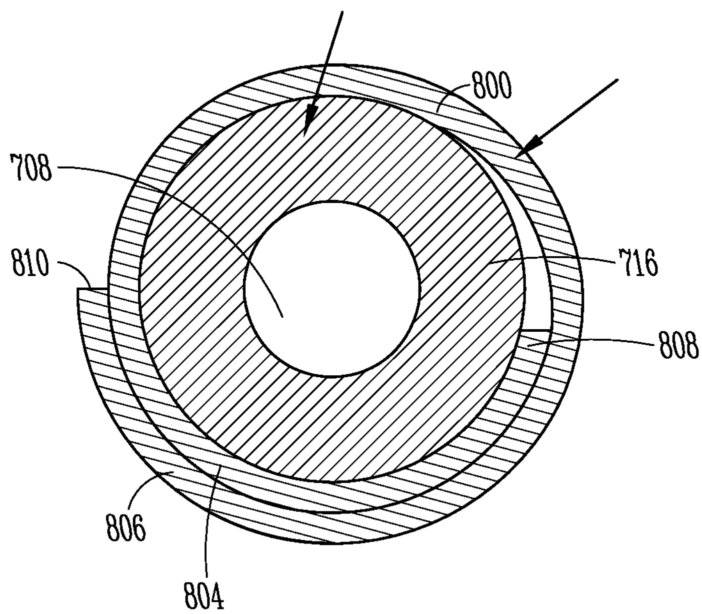



FIG. 8A




SECTION A-A

FIG. 8B

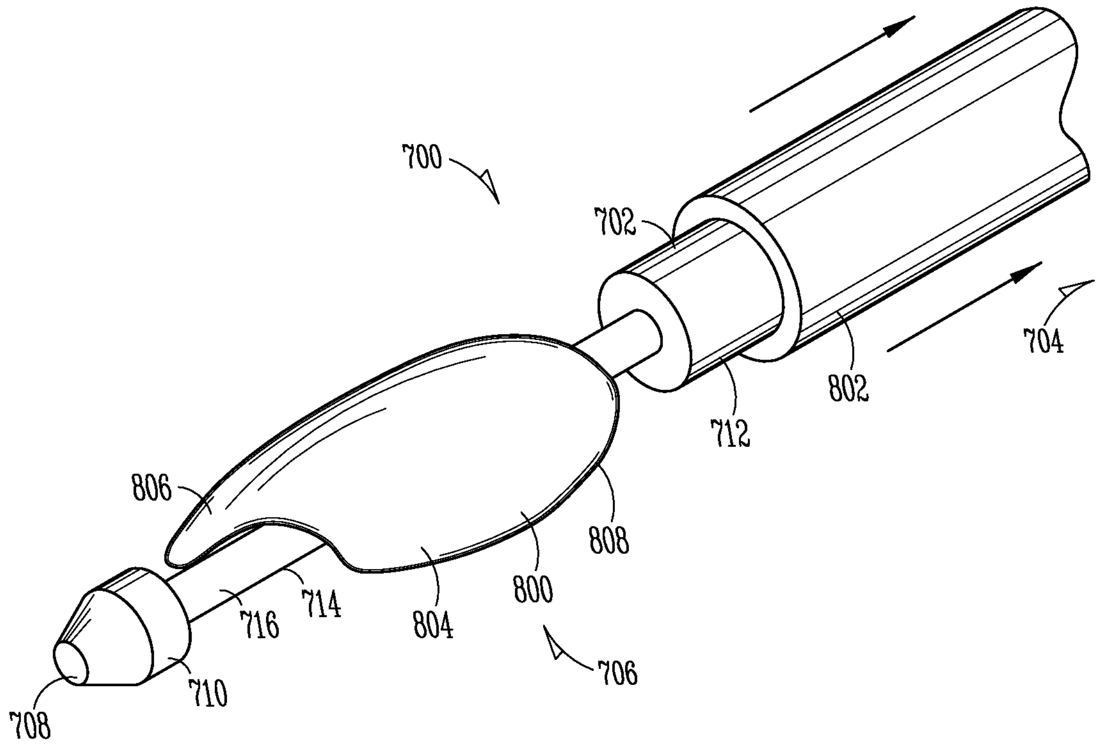



FIG. 8C

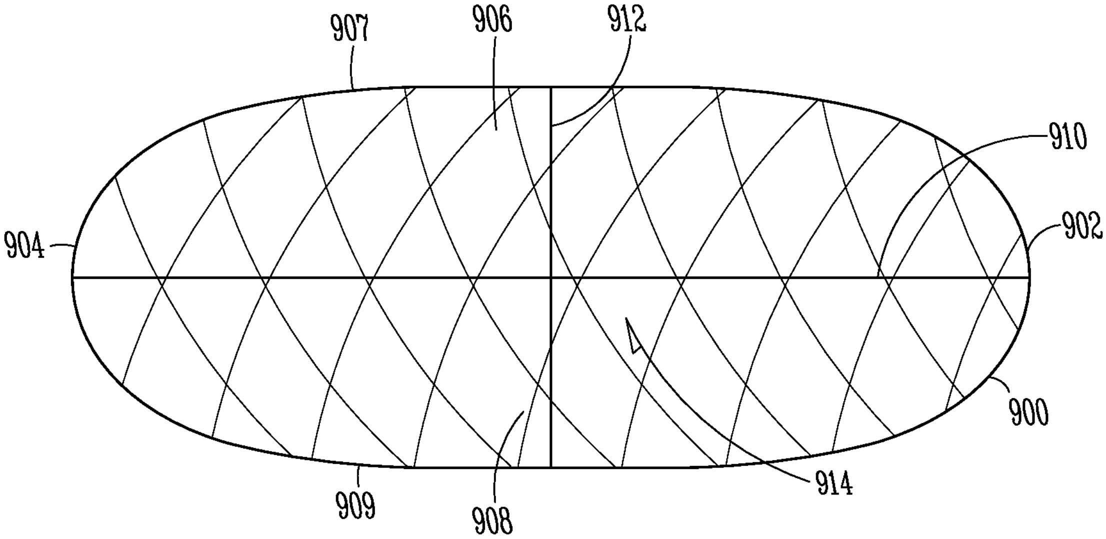

907
906
912
910
904
902
900
909
908
914

FIG. 9A

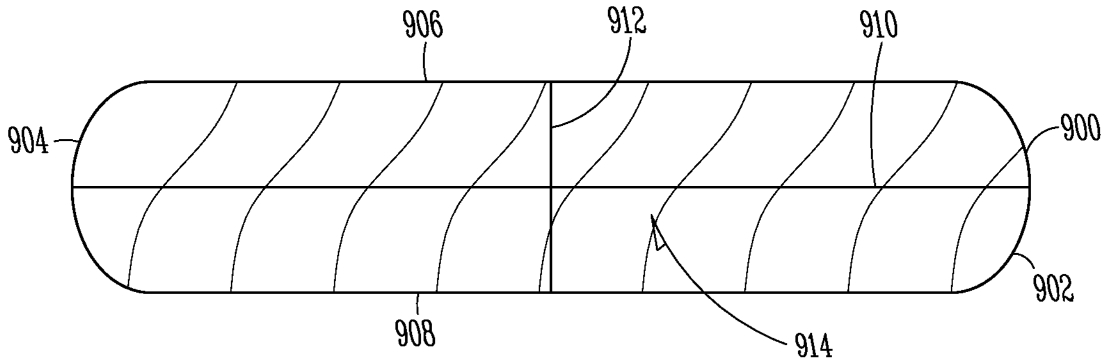

906
912
910
904
900
902
908
914

FIG. 9B

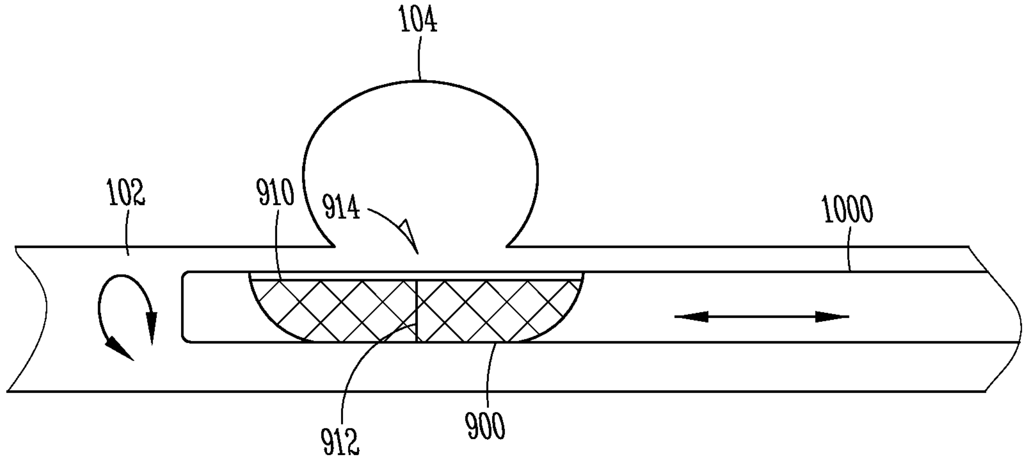



FIG. 10A

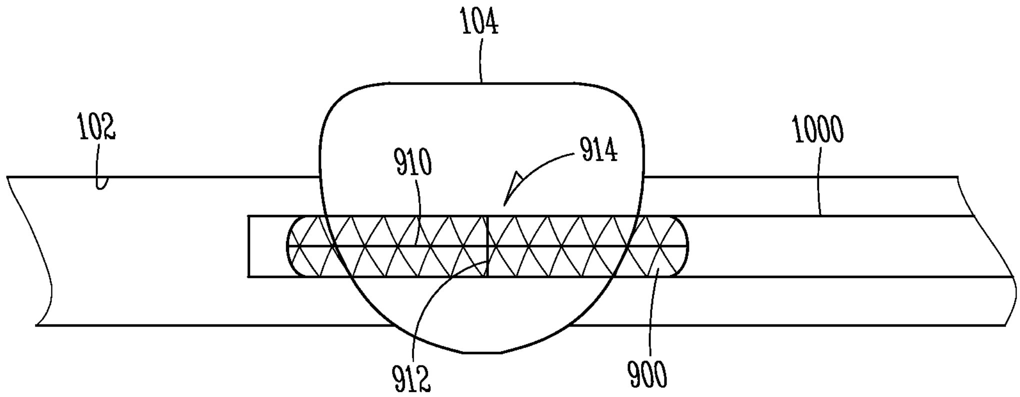



FIG. 10B

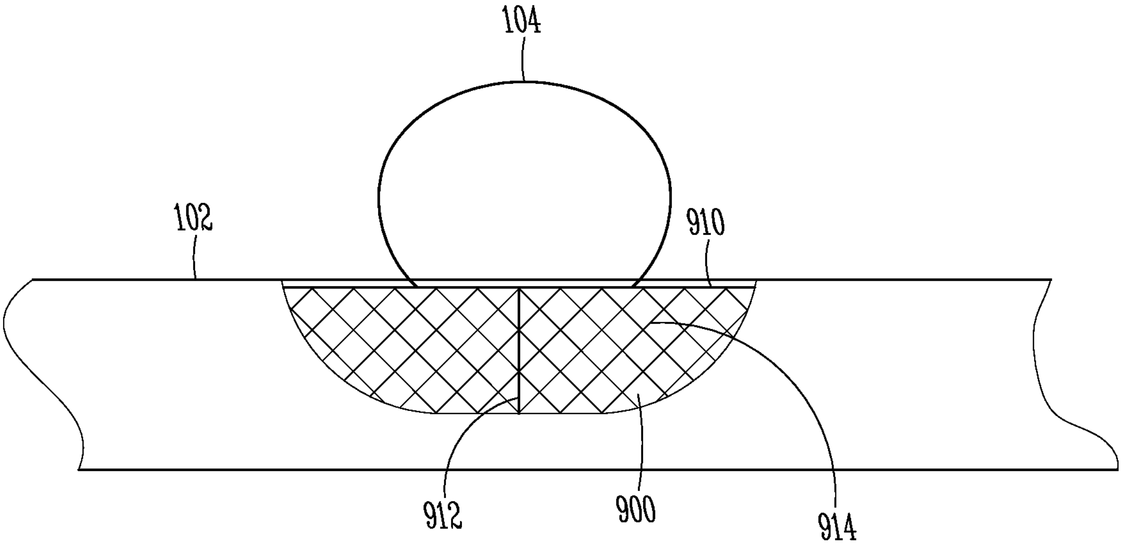



FIG. 11A

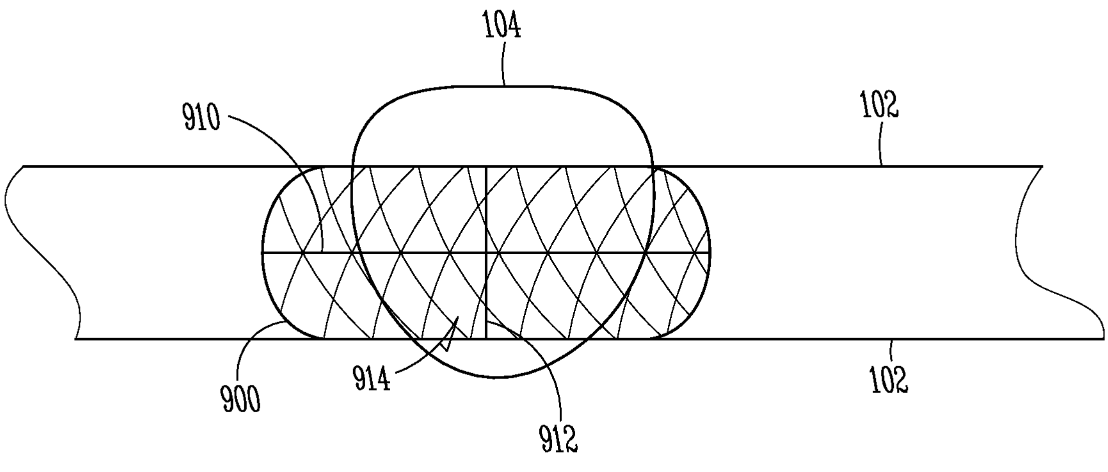



FIG. 11B

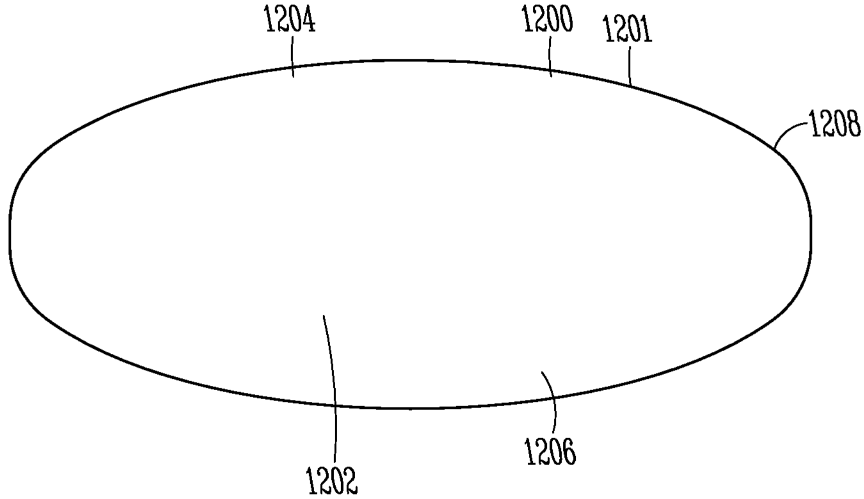



FIG. 12A

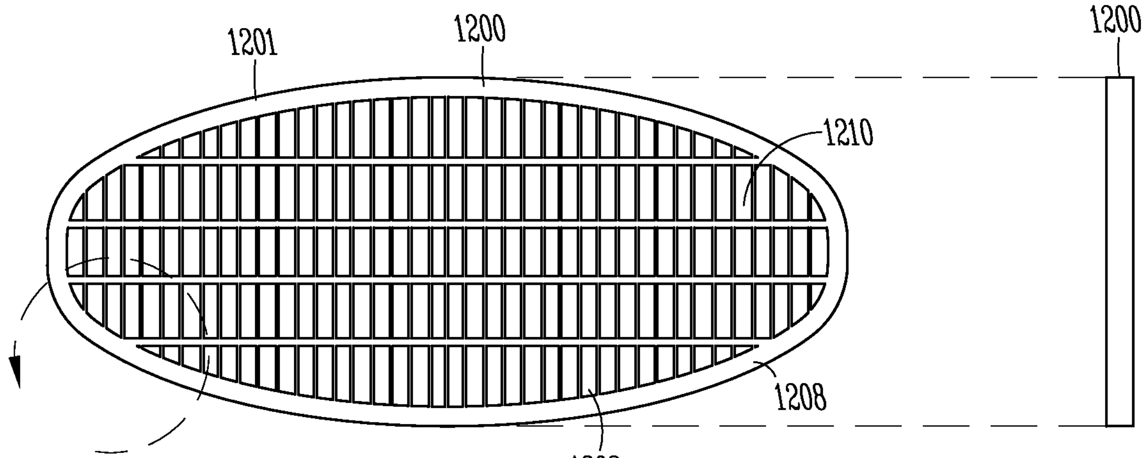



FIG. 12B

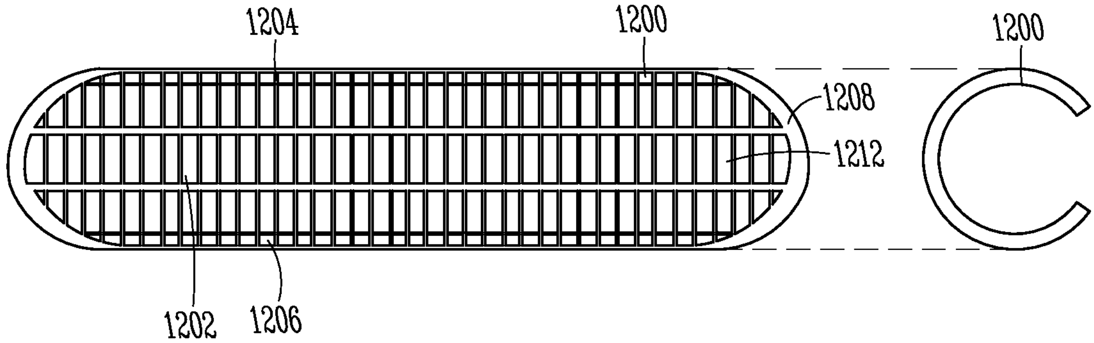



FIG. 12C

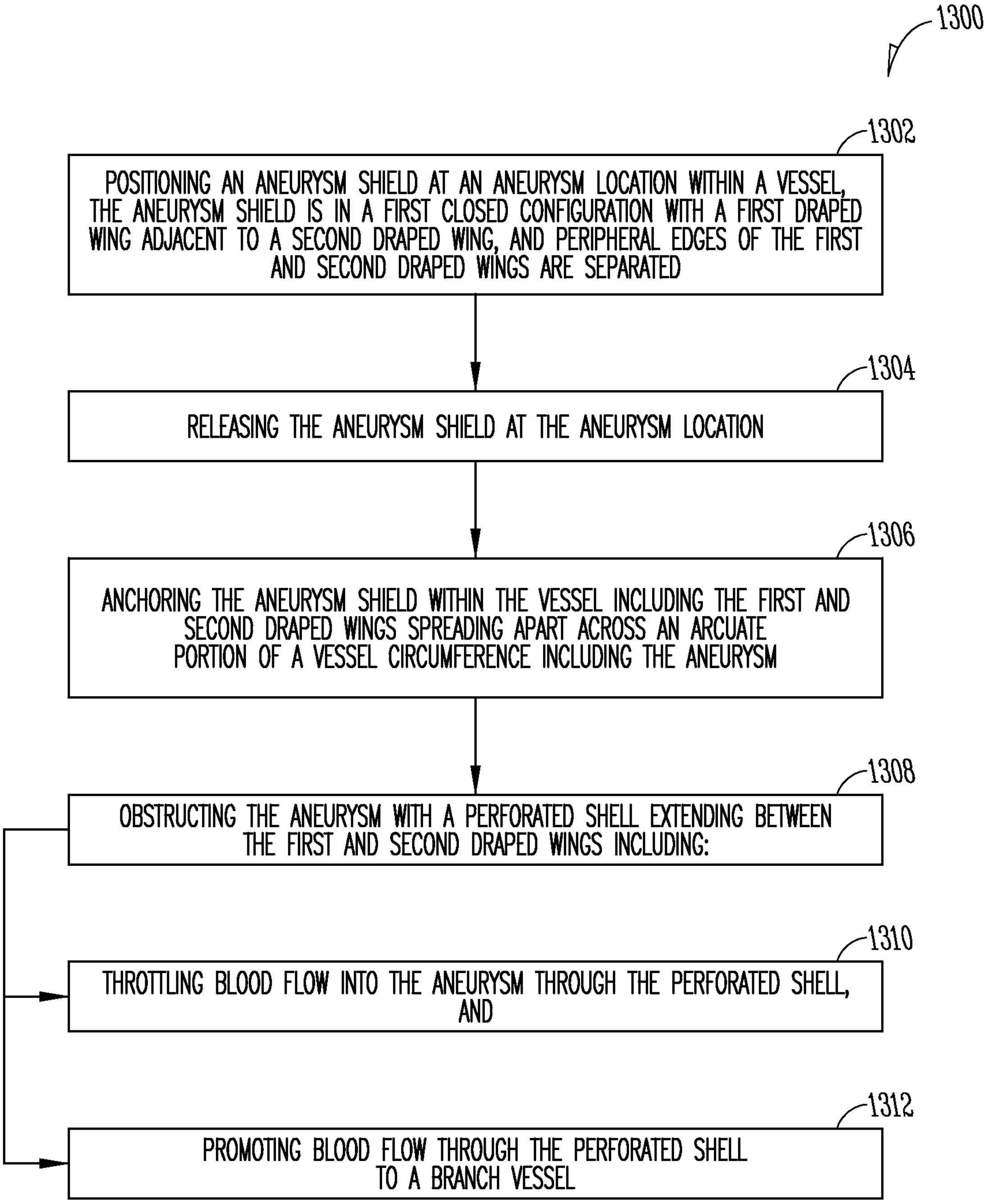

1300
1302
POSITIONING AN ANEURYSM SHIELD AT AN ANEURYSM LOCATION WITHIN A VESSEL, THE ANEURYSM SHIELD IS IN A FIRST CLOSED CONFIGURATION WITH A FIRST DRAPED WING ADJACENT TO A SECOND DRAPED WING, AND PERIPHERAL EDGES OF THE FIRST AND SECOND DRAPED WINGS ARE SEPARATED
1304
RELEASING THE ANEURYSM SHIELD AT THE ANEURYSM LOCATION
1306
ANCHORING THE ANEURYSM SHIELD WITHIN THE VESSEL INCLUDING THE FIRST AND SECOND DRAPED WINGS SPREADING APART ACROSS AN ARCUATE PORTION OF A VESSEL CIRCUMFERENCE INCLUDING THE ANEURYSM
1308
OBSTRUCTING THE ANEURYSM WITH A PERFORATED SHELL EXTENDING BETWEEN THE FIRST AND SECOND DRAPED WINGS INCLUDING:
1310
THROTTLING BLOOD FLOW INTO THE ANEURYSM THROUGH THE PERFORATED SHELL, AND
1312
PROMOTING BLOOD FLOW THROUGH THE PERFORATED SHELL TO A BRANCH VESSEL

*FIG. 13*

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/059530

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC(8) - A61B 17/08 (2011.01)
USPC - 606/158
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/08; A61M 29/00 (2011.01)
USPC - 606/158, 200, 213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US 2009/0228029 A1 (LEE) 10 September 2009 (10.09.2009) entire document | 12-18<br>---------------<br>1-11, 19-31 |
| Y | US 2004/0087998 A1 (LEE et al) 06 May 2004 (06.05.2004) entire document | 1-11, 19-20, 22-31 |
| Y | US 2003/0139802 A1 (WULFMAN et al) 24 July 2003 (24.07.2003) entire document | 7 |
| Y | US 2007/0191924 A1 (RUDAKOV) 16 August 2007 (16.08.2007) entire document | 9, 24-25 |
| Y | WO 99/40874 A1 (ROSS) 19 August 1999 (19.08.1999) entire document | 11, 21, 31 |
| A | US 6,309,367 B1 (BOOCK) 30 October 2001 (30.10.2001) entire document | 1-31 |
| A | US 2006/0195178 A1 (WEST) 31 August 2006 (31.08.2006) entire document | 1-31 |
| A | US 2007/0088387 A1 (ESKRIDGE et al) 19 April 2007 (19.04.2007) entire document | 1-31 |

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 January 2011 | 22 FEB 2011 |

| Name and mailing address of the ISA/US | Authorized officer: |
|---|---|
| Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |