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(54) SYSTEM AND METHOD FOR RETAINING VASO-OCCLUSIVE DEVICES WITHIN AN ANEURYSM

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(63) Continuation of application No. 10/121,980, filed on Apr. 12, 2002.

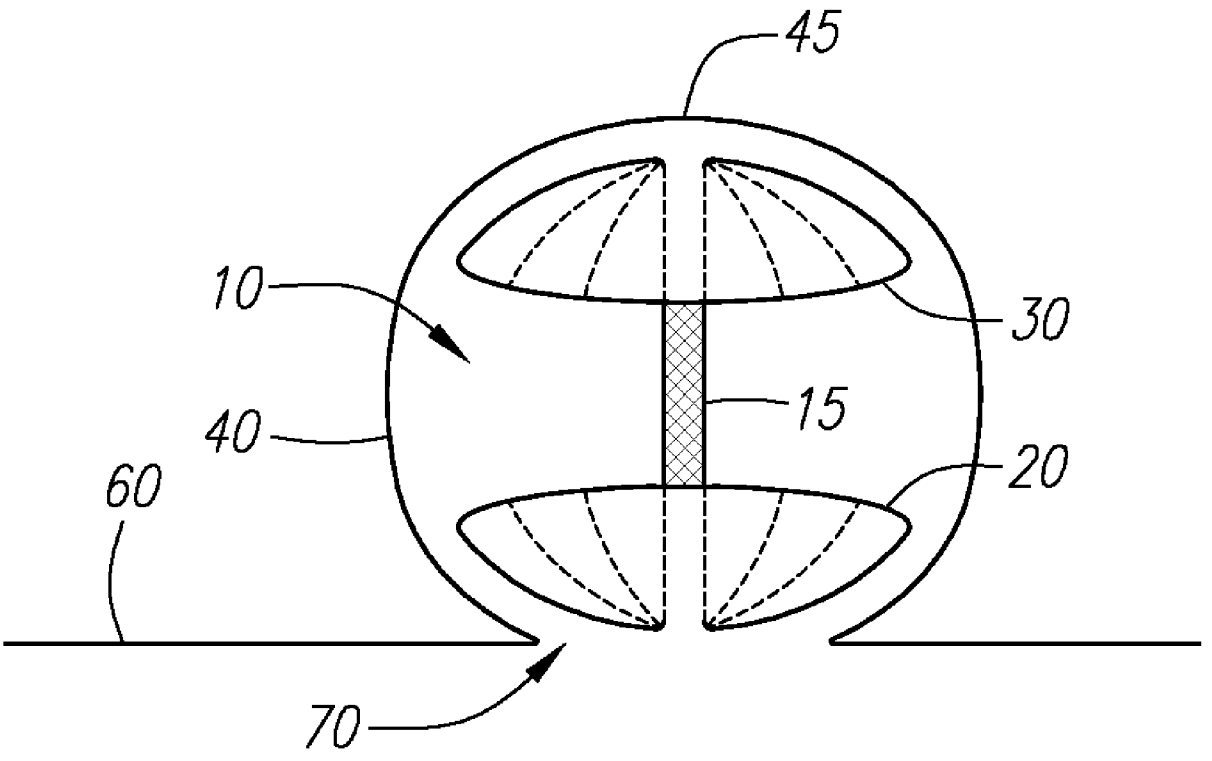
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(57) **ABSTRACT**

The present invention is directed to systems for occluding an aneurysm having an aneurysmal neck and an aneurysmal inner wall. Generally, a device in accordance with the present invention includes a mesh-like structure that is integrally composed of a shape-memory alloy such as NiTi. The device is deployed within the aneurysm through the aneurysmal neck. The device is configured to be in a deployed state and an undeployed state, and is configured to transition from the undeployed state to the deployed state by exposure to a higher temperature and/or by being unconstrained. The device may function to retain finer vaso-occlusive devices such as vaso-occlusive coils and/or embolic liquids. Furthermore, the device itself may function as a vaso-occlusive device.



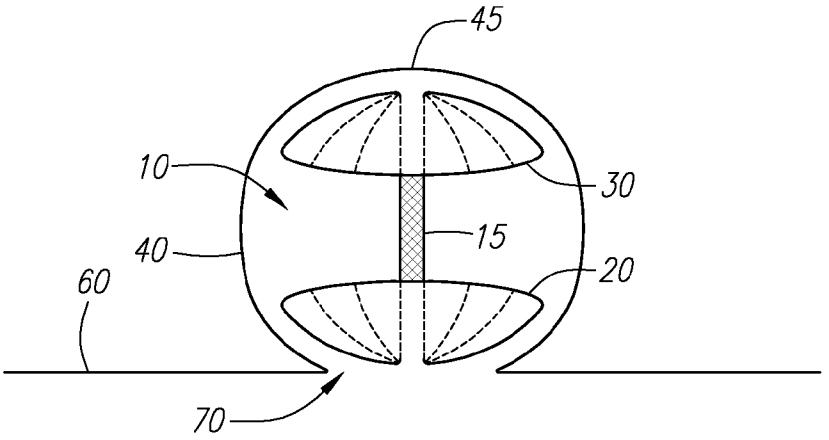


FIG. 1

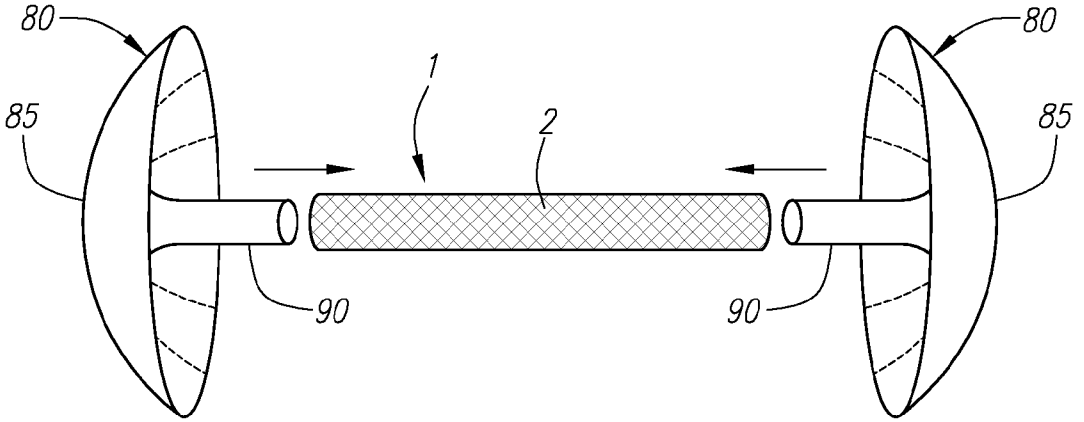


FIG. 2A

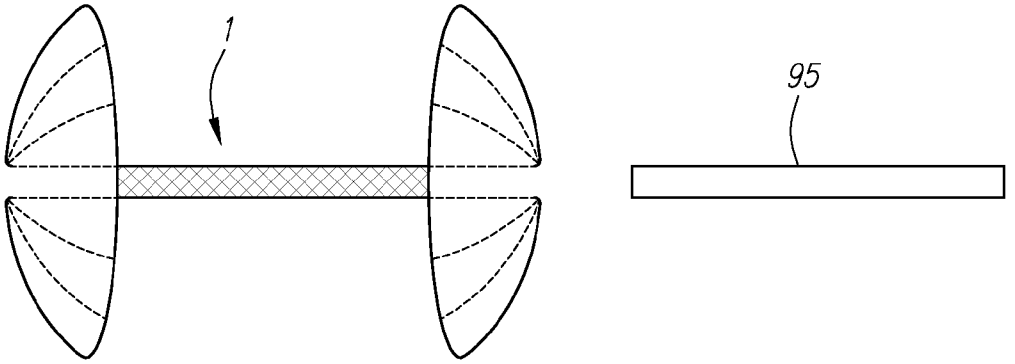


FIG. 2B

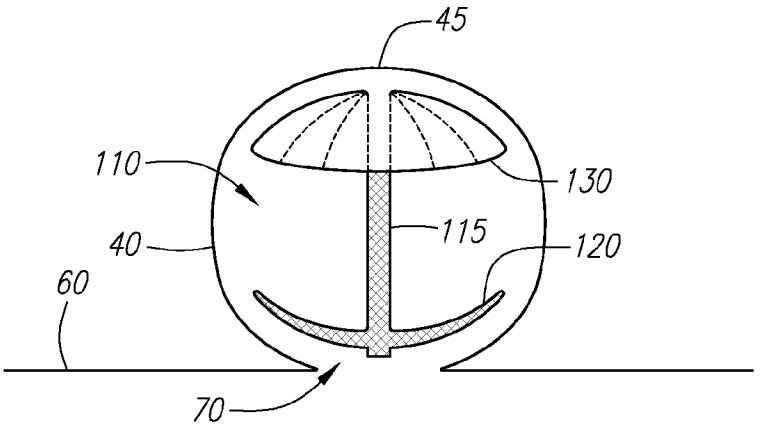


FIG. 3

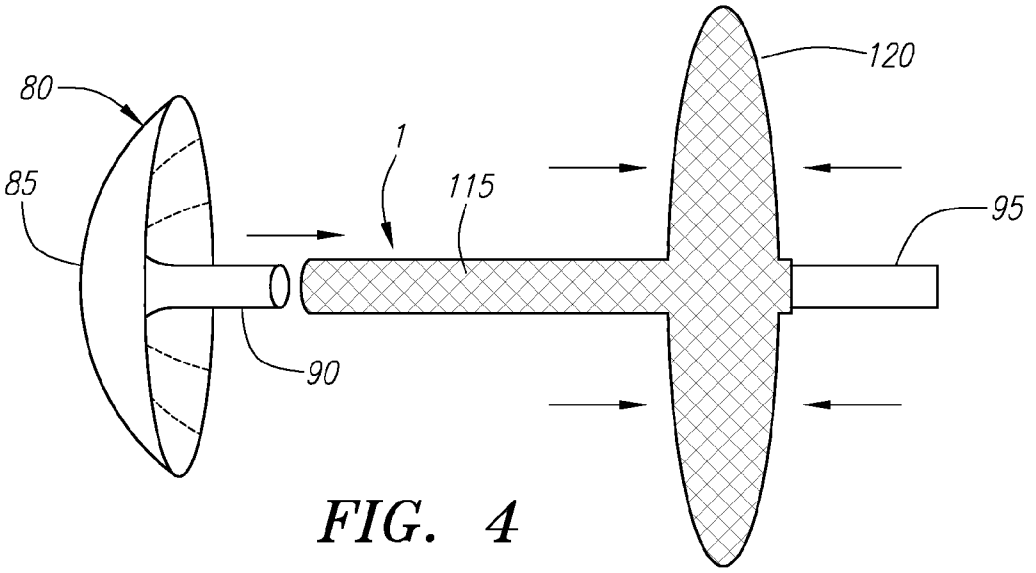


FIG. 4

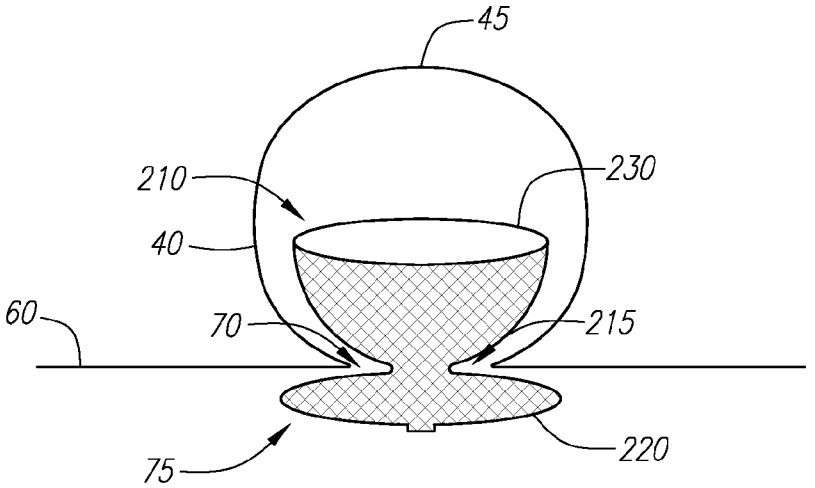


FIG. 5

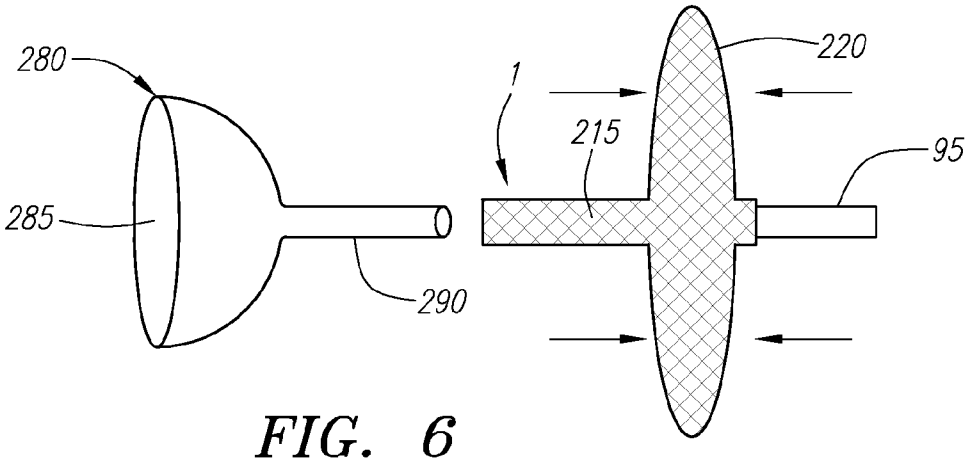


FIG. 6

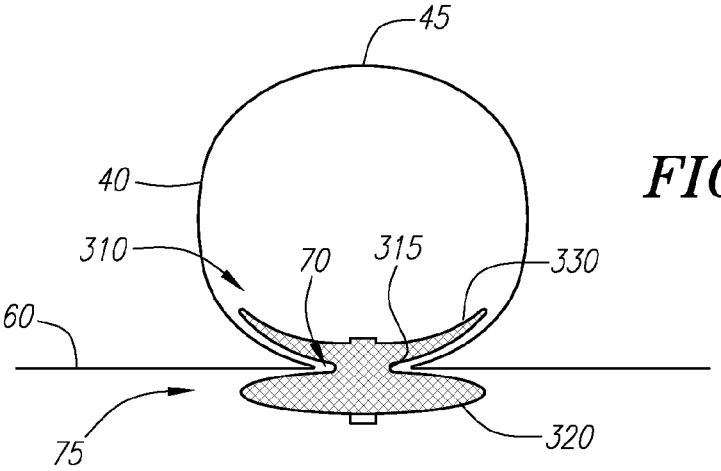


FIG. 7

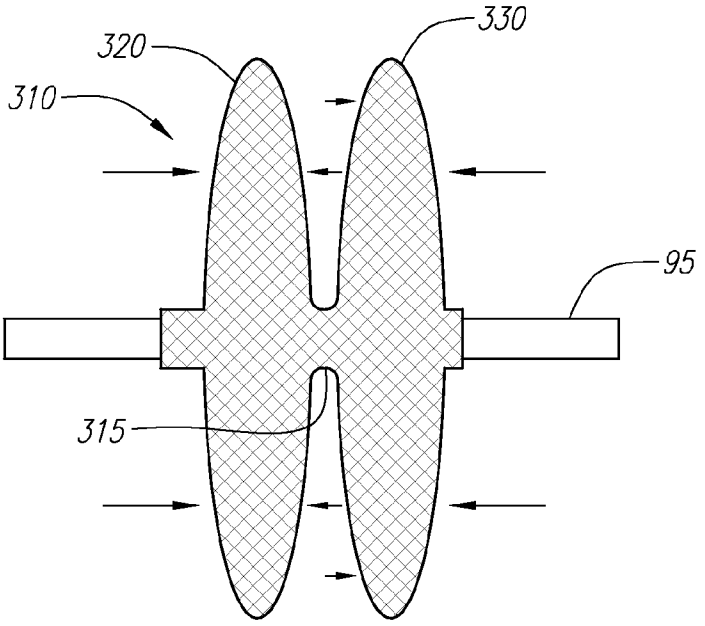


FIG. 8

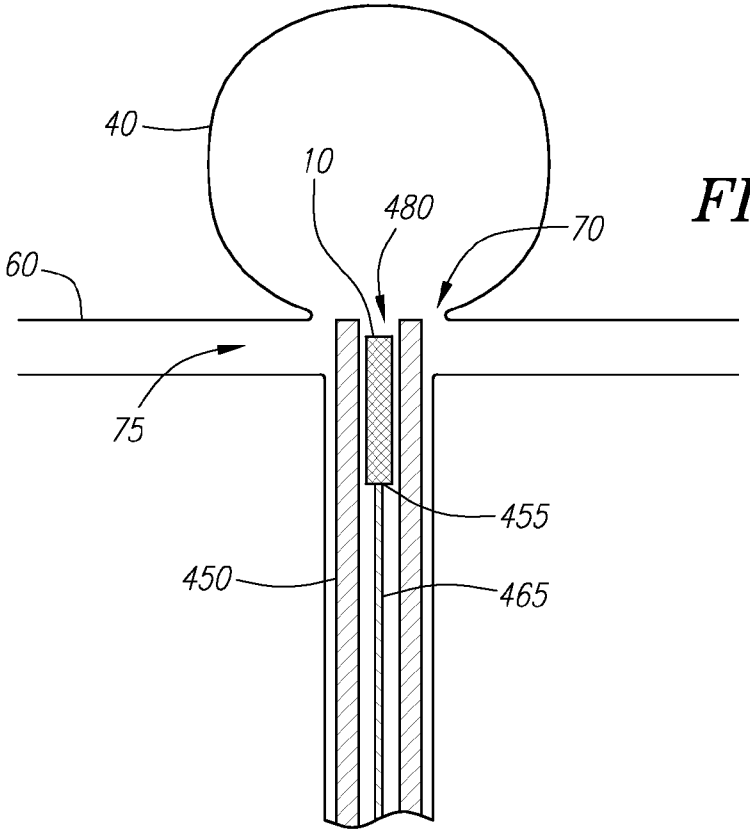


FIG. 9A

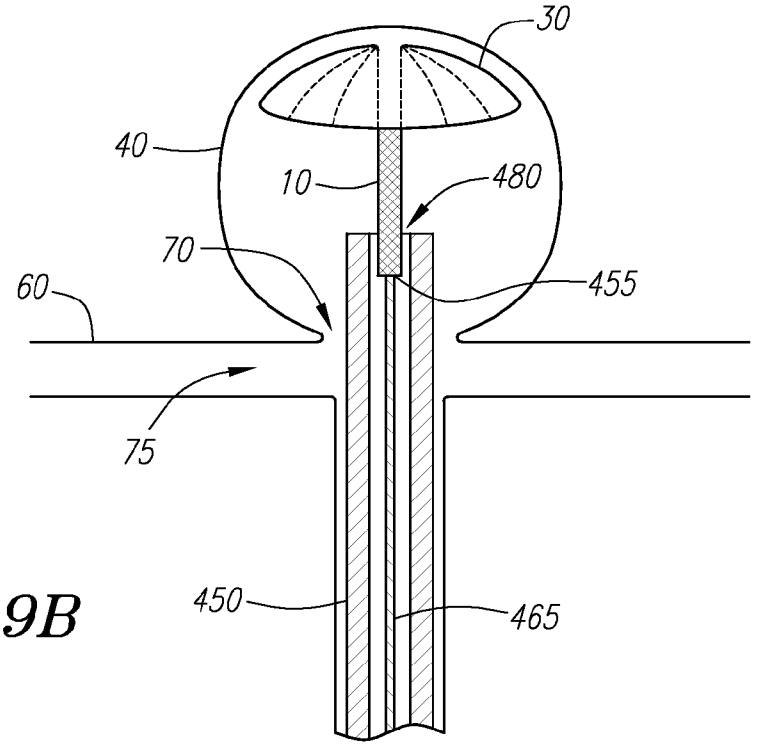


FIG. 9B

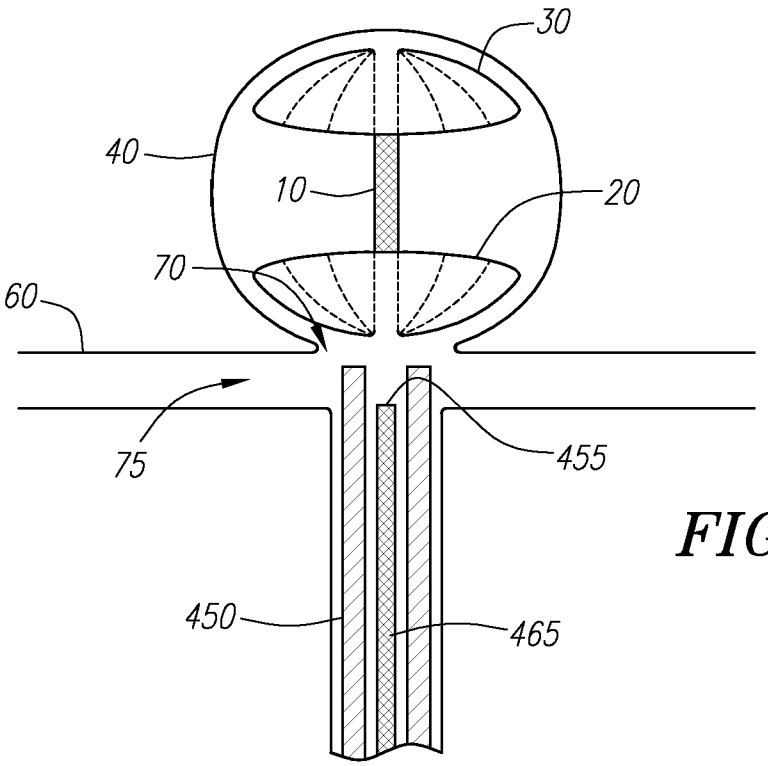


FIG. 9C

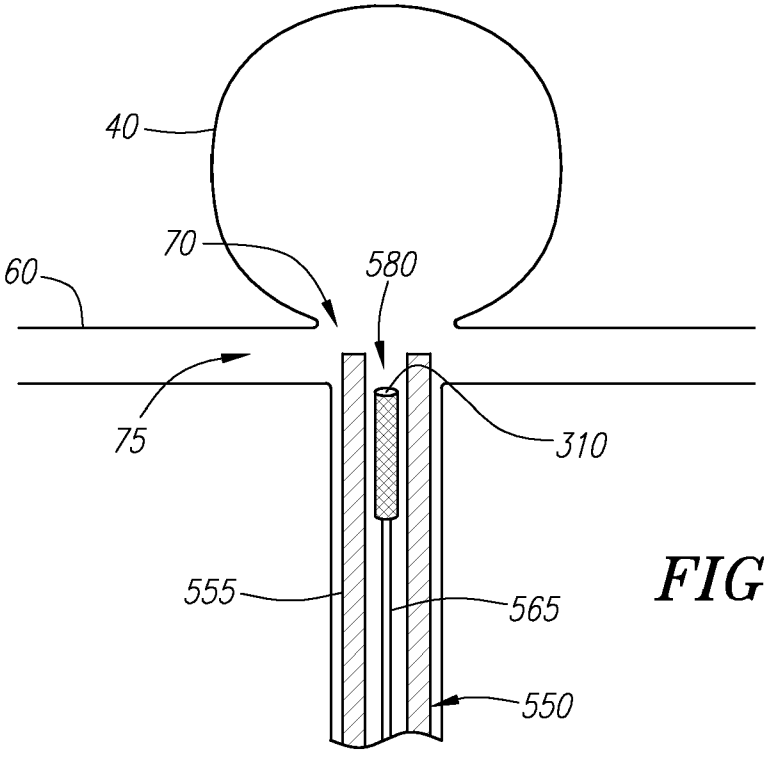


FIG. 10A

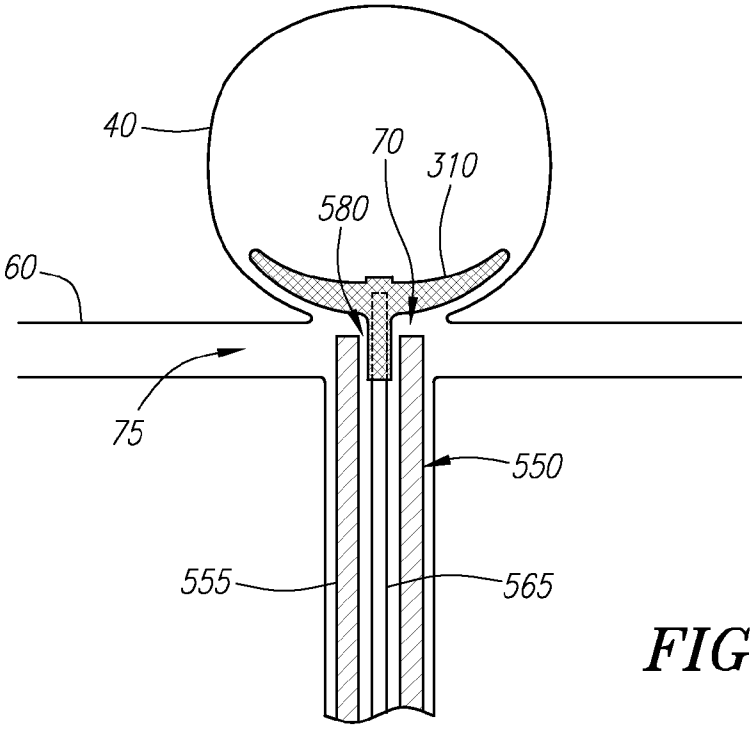


FIG. 10B

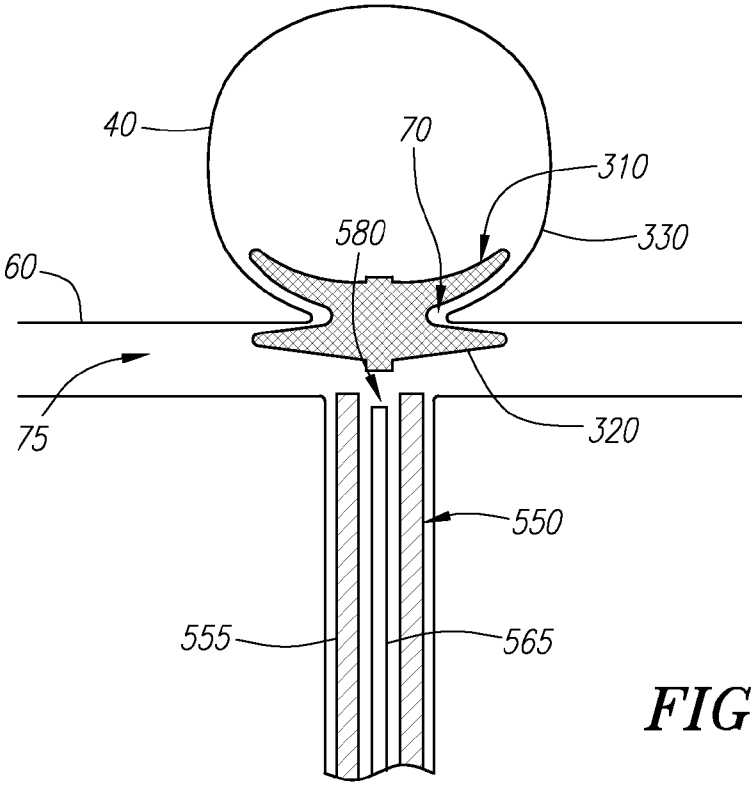


FIG. 10C

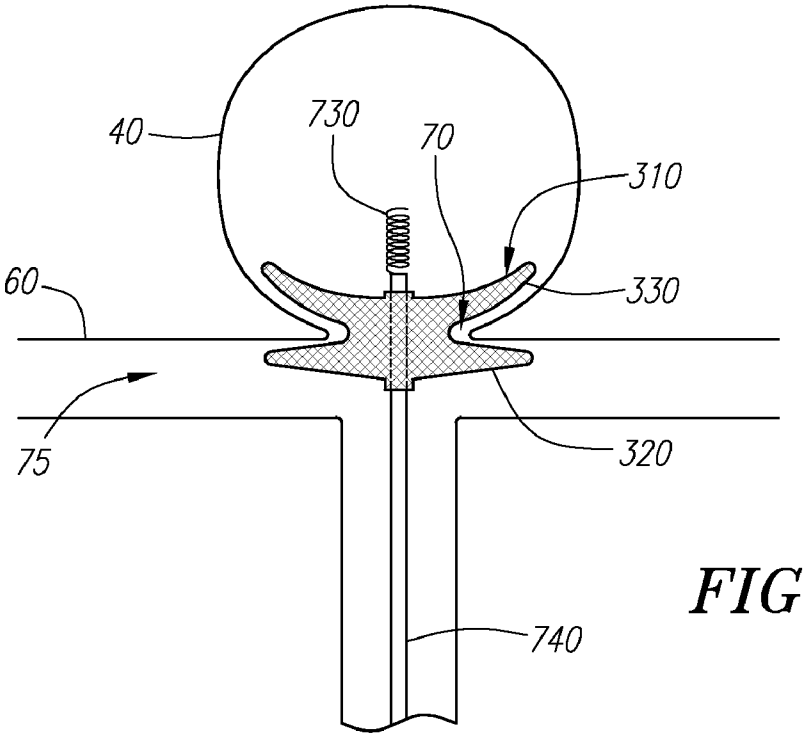


FIG. 10D

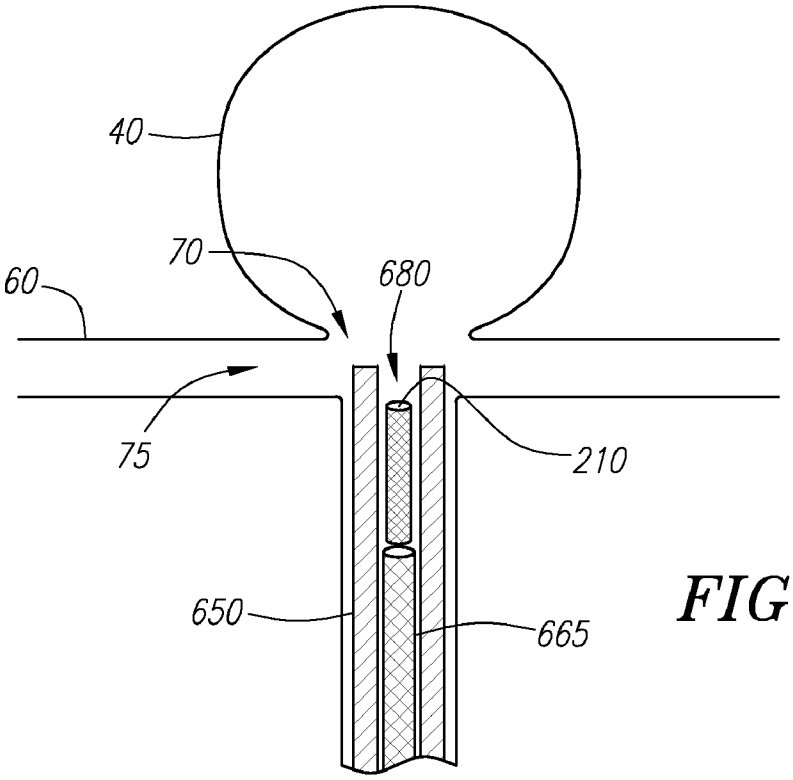


FIG. 11A

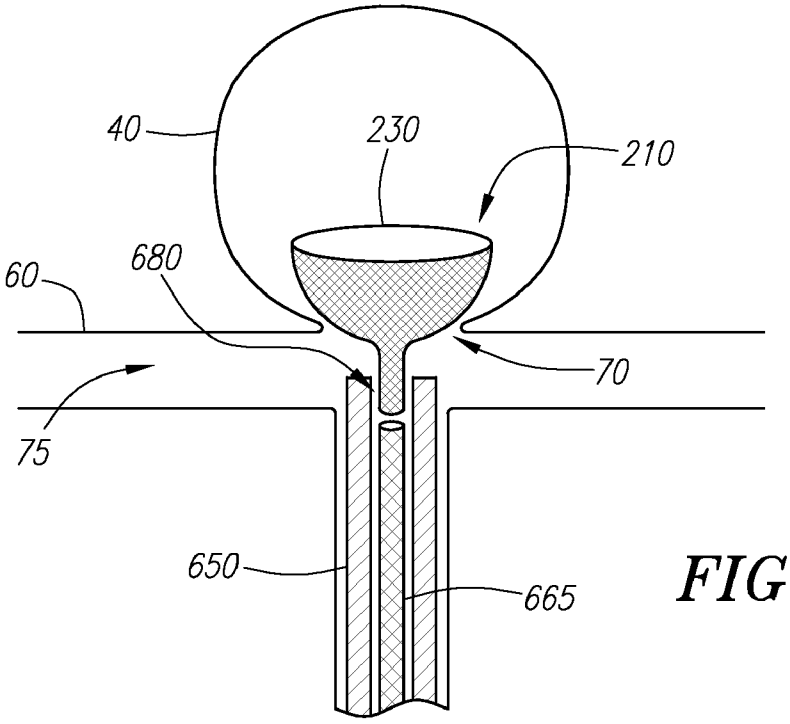


FIG. 11B

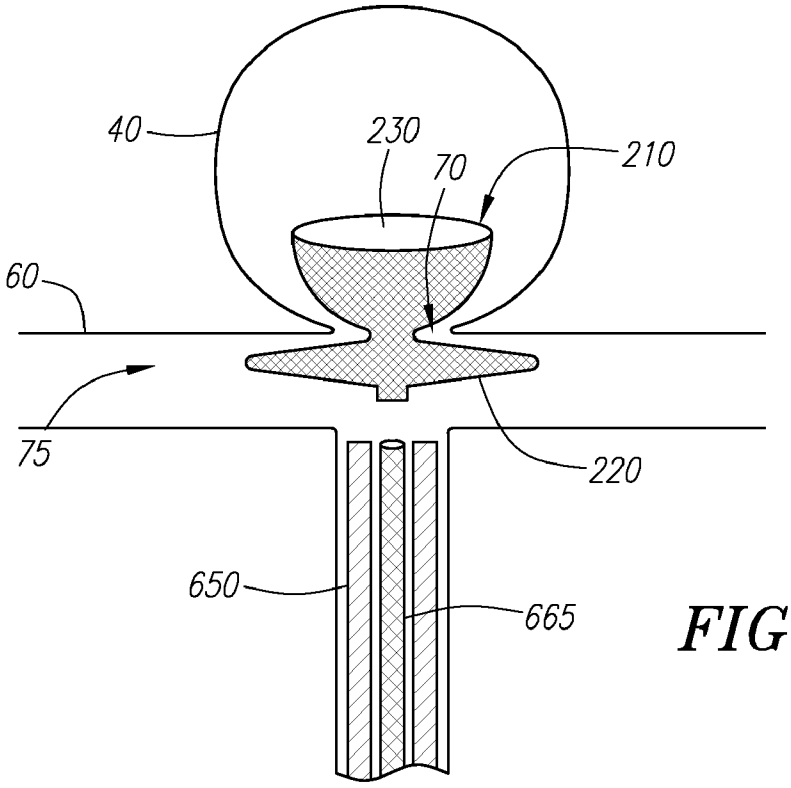


FIG. 11C

SYSTEM AND METHOD FOR RETAINING VASO-OCCLUSIVE DEVICES WITHIN AN ANEURYSM

RELATED APPLICATION DATA

[0001] The present application is a continuation of co-pending U.S. patent application Ser. No. 10/121,980 filed Apr. 12, 2002, which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to vaso-occlusion, and more particularly to systems and methods for retaining vaso-occlusive devices within an aneurysm.

BACKGROUND OF THE INVENTION

[0003] Different implantable medical devices have been developed for treating a number of ailments associated with body lumens. In particular, occlusive devices are useful in filling vascular or other body spaces. Some body spaces, such as vascular aneurysms, are formed due to a weakening in the wall of an artery. Often these aneurysms are the site of internal bleeding and stroke. A variety of different embolic agents are known to be, at least arguably, suitable for treatment of these anomalies. These treatments are commonly known as "artificial vaso-occlusion."

[0004] Over the past few years, advancements in the artificial occlusion of vessels and aneurysms have included the delivery and implantation of metal coils as vaso-occlusive devices. Implantable metal coils that are useful as artificial occlusion devices in vasculature lumens or aneurysms are herein referred to as "vaso-occlusive coils." Vaso-occlusive coils are generally constructed of a wire, usually made of a metal or metal alloy that is wound to a helix. The vaso-occlusive coil assumes an irregular shape upon discharge of the device from the distal end of the catheter. A variety of vaso-occlusive coils are known. For instance, U.S. Pat. No. 4,994,069, issued to Ritchart et al., shows a flexible, preferably coiled, wire for use in small vessel vaso-occlusion. Unlike vaso-occlusive coils used prior to that time, Ritchart et al. teach a coil that is fairly soft and is delivered to the site using a pusher within a catheter lumen. Upon discharge from the delivery catheter, the coil may undertake any number of random or regular configurations used to fill the site.

[0005] The coils may be used for small vessel sites, e.g., 0.5-6 mm in diameter. The coils themselves are described as being between 0.010 and 0.030 inches in diameter. The length of the coil wire is typically 15 to 20 times the diameter of the vessel to be occluded. The wire used to make up the coils may be, for instance, 0.002 to 0.006 inches in diameter. Tungsten, platinum, and gold threads or wires are said to be preferred. These coils have a variety of benefits including the fact that they are relatively permanent, they may be easily imaged radiographically, they may be located at a well defined vessel site, and they can be retrieved.

[0006] In addition to the various types of space filling mechanisms and geometries of vaso-occlusive coils, other particularized features of coil designs, such as mechanisms for delivering vaso-occlusive coils through delivery catheters and implanting them in a desired occlusion site, have also been described. The examples of categories of vaso-occlusive coils based upon their delivery mechanisms include pushable coils, mechanically detachable coils, and electrolytically detachable coils.

[0007] One example of the type of vaso-occlusive coil referred to above as the "pushable coil" is disclosed in Ritchart et al., discussed above. Pushable coils are commonly provided in a cartridge and are pushed or "plunged" from the cartridge into a delivery catheter lumen. A pusher advances the pushable coil through and out of the delivery catheter lumen and into the site for occlusion.

[0008] Mechanically detachable vaso-occlusive coils are typically integrated with a pusher rod and are mechanically detached from the distal end of that pusher after exiting a delivery catheter. Examples of such mechanically detachable vaso-occlusive coils are found in U.S. Pat. No. 5,261,916 to Engelson or U.S. Pat. No. 5,250,071 to Palermo.

[0009] Finally, examples of electrolytically detachable vaso-occlusive coils may be found in U.S. Pat. Nos. 5,122,136 and 5,354,295, each issued to Guglielmi et al. In these devices, the vaso-occlusive portion of the assembly is attached to a pusher via a small, electrolytically severable joint. The electrolytically severable joint is severed by the placement of an appropriate voltage on the core wire. The joint erodes in preference either to the vaso-occlusive coil itself or to the pusher core wire.

[0010] As noted above, aneurysms present a particularly acute medical risk due to the dangers of potential rupture of the thin wall inherent in such aneurysms. Occlusion of aneurysms by use of vaso-occlusive coils without occluding the adjacent artery is a special challenge and is a desirable method of reducing such risk of rupture. These vaso-occlusive devices are typically placed in an aneurysm in a manner described in U.S. Pat. No. 4,739,768 issued to Engelson. In particular, a microcatheter is initially steered into or adjacent to the entrance of an aneurysm, typically aided by the use of a steerable guidewire. The wire is then withdrawn from the microcatheter lumen and replaced by the vaso-occlusive coil. The vaso-occlusive coil is advanced through and out of the microcatheter, desirably being completely delivered into the aneurysm.

[0011] However, after, or perhaps during, delivery of the coil into the aneurysm, there is a specific risk that a portion of the coil might migrate out of the aneurysm entrance zone and into the feeding vessel. The presence of the coil in that feeding vessel may cause a highly undesirable occlusion there. Also, there is a quantifiable risk that the blood flow in the vessel and aneurysm may induce movement of the coil farther out of the aneurysm, resulting in a more developed embolus in the feeding vessel.

[0012] One type of aneurysm, commonly known as a "wide neck aneurysm," is known to present particular difficulty in the placement and retention of vaso-occlusive coils, because vaso-occlusive coils lacking substantial secondary shape strength may be difficult to maintain in position within an aneurysm no matter how skillfully they are placed. Wide neck aneurysms are herein referred to as aneurysms of vessel walls having a neck or "entrance zone" from the adjacent vessel, wherein the entrance zone has a diameter that either: (1) is at least 80% of the largest diameter of the aneurysm; or (2) is clinically observed to be too wide effectively to retain vaso-occlusive coils that are deployed using the techniques discussed above.

[0013] One approach to occlude such an aneurysm is described in U.S. Pat. No. 6,168,622, which describes a vaso-occlusive device with a secondary shape having a bulbous body portion and an anchor. The bulbous body portion is deployed within the aneurysm while the anchor is set just outside of the aneurysm, covering the aneurysm's neck or entrance zone. The device is integrally formed from a tube—clamped at both ends—of braided Nickel-Titanium (NiTi) wires. The bulbous body functions to occlude the aneurysm, while the anchor covers the entrance zone. In some cases, it may still be desirable to deploy vaso-occlusive coils with such a device, but the bulbous body of the vaso-occlusive device does not provide much space within the aneurysm to allow for insertion and deployment of the coils.

[0014] Accordingly, an improved system and method for occluding an aneurysm neck would be desirable.

SUMMARY OF INVENTION

[0015] The present invention is directed to systems and methods for occluding an aneurysm having an aneurysmal neck and an aneurysmal inner wall. Generally, a device in accordance with the present invention includes a mesh-like structure that may be integrally composed of a shape-memory alloy such as NiTi. The device may be deployed within the aneurysm through the aneurysmal neck. The device may be configured to be in a deployed state and an undeployed state, and may be configured to transition from the undeployed state to the deployed state by exposure to a higher temperature and/or by being released from a compressive force. The device may function to retain finer vaso-occlusive devices such as vaso-occlusive coils and/or embolic liquids. Furthermore, the device itself may function as a vaso-occlusive device. The device may be delivered to the aneurysm by, e.g., a catheter.

[0016] In accordance with a first aspect of the present invention, at least one of the proximal and distal ends of the mesh-like structure is configured to be inserted through the aneurysmal neck when in an undeployed state, and configured to flare open and expand against at least a portion of the aneurysmal inner wall when in a deployed state. Having a flared open end may advantageously allow the device to conform to the shape of the aneurysm.

[0017] In accordance with another aspect of the present invention, the distal end of the mesh-like structure may be configured to be inserted through the aneurysmal neck when in an undeployed state and configured to expand into a retainer against at least a portion of the aneurysmal inner wall when in a deployed state. The proximal end may be configured to expand into an anchor just outside of the aneurysm to secure the mesh-like structure in position.

[0018] Other objects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] In order to better appreciate how the above-recited and other advantages and objects of the present inventions are obtained, a more particular description of the present inventions briefly described above will be rendered by reference to specific embodiments thereof, which are illustrated in the accompanying drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0020] FIG. **1** is an illustration of a vaso-occlusive device constructed in accordance with a preferred embodiment of the present inventions, wherein the vaso-occlusive device is shown fully deployed within an aneurysm;

[0021] FIGS. **2**(*a*) and **2**(*b*) illustrate one preferred method of manufacturing the vaso-occlusive device of FIG. **1** in accordance with the present inventions;

[0022] FIG. **3** is an illustration of another vaso-occlusive device constructed in accordance with a preferred embodiment of the present inventions, wherein the vaso-occlusive device is shown fully deployed within an aneurysm;

[0023] FIG. **4** illustrates one preferred method of manufacturing the vaso-occlusive device of FIG. **3** in accordance with the present inventions;

[0024] FIG. **5** is an illustration of still another vaso-occlusive device constructed in accordance with a preferred embodiment of the present inventions, wherein the vaso-occlusive device is shown fully deployed within an aneurysm;

[0025] FIG. **6** illustrates one preferred method of manufacturing the vaso-occlusive device of FIG. **5** in accordance with the present inventions;

[0026] FIG. **7** is an illustration of still another vaso-occlusive device constructed in accordance with a preferred embodiment of the present inventions, wherein the vaso-occlusive device is shown fully deployed within an aneurysm;

[0027] FIG. **8** illustrates one preferred method of manufacturing the vaso-occlusive device of FIG. **7** in accordance with the present inventions;

[0028] FIGS. **9**(*a*)-(*c*) illustrate a preferred method of delivering and deploying the vaso-occlusive device of FIG. **1** into the aneurysm;

[0029] FIGS. **10**(*a*)-(*d*) illustrate a preferred method of delivering and deploying the vaso-occlusive device of FIG. **7** into the aneurysm; and

[0030] FIGS. **11**(*a*)-(*c*) illustrate a preferred method of delivering and deploying the vaso-occlusive device of FIG. **5** into the aneurysm.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0031] Turning to FIG. **1**, a vaso-occlusive element **10** constructed in accordance with a preferred embodiment of the present invention is shown completely deployed within an aneurysm **40** of a blood vessel **60**. The aneurysm **40** is shown with an oppositely disposed neck **70** and dome **45**. When deployed in its secondary shape, i.e., its deployed shape, the vaso-occlusive element **10** generally includes a central tubular element **15** and proximal **20** and distal **30** ends that are flared open into "umbrella" shapes. As illus-

trated, the flared opened ends **20**/**30** advantageously conform to the shape of the aneurysm **40**. The diameter of the proximal end **20** of the vaso-occlusive element **10** is larger than the neck **70**, and thus the proximal end **20** may completely cover the neck **70**.

[**0032**] As will be described in further detail below, the vaso-occlusive element **10** is manufactured from a relatively dense braid. In this manner, the proximal end **20** may densely cover the neck **70** and function as a retainer. Thus, finer vaso-occlusive devices, such as vaso-occlusive coils or embolic liquids, may effectively be retained within the aneurysm **40**, or at the least, the likelihood of these devices migrating out from the aneurysm **40** is minimized. Further, as can be appreciated by one of ordinary skill in the art, the relatively dense coverage of the proximal end **20** allows the vaso-occlusive element **10** itself to function as a vaso-occlusive device. The flared open distal end **30** is placed adjacent the dome **45** of the aneurysm **40** and allows the element **10** to safely conform to the shape of the dome **45**. This allows for the distal end **30** to function as an anchor and secure itself within the aneurysm **40** without the need to conform to the entire shape of the aneurysm **40**. Thus, the element **10** may conform to a large variety of shapes and sizes of aneurysms **40** since the element **10** need only be secured within the aneurysm **40** by conforming the flared open distal end **30** to the dome **45**.

[**0033**] Turning to FIGS. **2**(*a*)-(*b*), one preferred method of manufacturing the vaso-occlusive device **10** will now be described. First, a braided tubular element **1** is constructed by braiding multiple fine wires **2** together. The tubular element **1** may also be formed of wires with varying diameters braided together. It may be desirable to use a larger number of wires **2** when forming the tubular element **1**, resulting in a relatively dense braid, which provides denser coverage within the aneurysm **40**. Optionally, the tubular element **1** may be radiopaque. One method involves braiding a radiopaque fiber, such as platinum, Pt, or gold, Au, into the tubular element **1**. Another method involves plating or coating the tubular element **1** with radiopaque material. Additionally, one or more radiopaque markers may be added to the tubular element **1**.

[**0034**] Preferably, the wires **2** are made from a shape memory alloy, which can be of any type, but preferably is a "one way" trainable shape memory alloy. A preferable shape memory alloy for forming the braided tubular element **1** is Nickel-Titanium (NiTi)—e.g., 144 strands of 0.001" NiTi wires. Shape memory alloys comprise a unique class of metal alloys that, once trained, are configured to "remember" a preselected shape, i.e., deployed shape, and can return to the preselected shape even if subsequently reshaped. To be trained to "remember" a first preselected shape, the shape memory alloy is molded and heated at or above a training, or austenite, temperature to place the shape memory alloy in an austenite phase. In the austenite phase, the shape memory alloy is formed in the first preselected shape and then, once formed, is permitted to cool to a martensite finish temperature, whereupon the shape memory alloy enters a martensite phase. The martensite finish temperature can be any temperature that is less than the training temperature. Upon entering the martensite phase, the shape memory alloy has been trained to "remember" the first preselected shape. While in the martensite phase, the alloy is in a soft state and is formed into a second preselected shape, e.g., an undeployed shape. The shape memory alloy in the martensite phase is configured to maintain the second preselected shape and, if subsequently reheated to an activation temperature, automatically returns to the first preselected shape. The activation temperature can comprise any temperature that is greater than the martensite finish temperature and generally approximately equals the training temperature. Once the first preselected shape has been recovered, the shape memory alloy is configured to maintain the first preselected shape irrespective of temperature. Generally, as can be appreciated by one of ordinary skill in the art, the training, martensite finishing, and activation temperatures for a shape memory alloy are adjustable, depending on the composition. For example, a slight extra amount of Nickel added to a NiTi alloy composition can change the training temperature from 0.degree. C. to 100.degree. C.

[**0035**] Generally, the vaso-occlusive device **10** described above is delivered to the aneurysm **40** via a delivery catheter. The catheter delivers the device **10** to the aneurysm **40** and during the delivery, the device **10** maintains an undeployed shape, e.g., the original tubular shape—methods of delivery will be described in more detail below. When the device **10** is deployed, the device **10** expands into its deployed shape, e.g., having flared open proximal and distal ends **20**/**30**, as shown in FIG. **1**. Using a shape memory alloy to form the device **10** provides for alternative methods of expanding the device **10** into its deployed shape within the aneurysm **40**.

[**0036**] One method involves configuring the device **10** to self-expand within the aneurysm **40** when deployed and exposed to the temperature of the aneurysm **40**. To configure the device **10** to self-expand within the aneurysm **40** when deployed and exposed to the temperature of the aneurysm **40**, the training and activation temperatures are adjusted to be at, or just below, the temperature of the aneurysm, which is approximately 37.degree. Celsius—the human body temperature. The martensite temperature is adjusted to be at a lower temperature. With these temperatures set, the device **10** is heated to, or above the training temperature—austenite phase—and shaped into its desired deployed shape, as described above. Then, the temperature is lowered to, or below, the martensite finish temperature—martensite phase—and shaped into its desired undeployed shape. Subsequently, the device **10** is then placed inside the catheter as will be described below. The catheter can be constructed of a material that insulates the device **10** from the outside environment and maintains the temperature of the device **10** below the activation temperature. Thus, when the catheter is inserted into the lumen **75** of the blood vessel **60**, the device **10** does not expand into its deployed shape within the catheter. When the device **10** is deployed into the aneurysm **40** and exposed to the aneurysm temperature, the temperature of the device will rise at or above the activation temperature, and the device **10** will expand into its deployed shape. Because the alloy is preferably "one way" trained, the device **10** will then be configured to maintain the deployed shape irrespective of the temperature, as described above.

[**0037**] An alternative method for expanding the device **10** into its deployed shape within the aneurysm utilizes the super-elastic characteristic of shape memory alloys. After the device **10** is configured to maintain its deployed shape irrespective of the temperature, as described above, the device **10** is then maintained in its austenite phase. When the device **10** is in its austenite phase, the device **10** is super-

elastic, i.e., the device **10** may be deformed to a certain degree and still be able to return to its deployed shape. The device **10** is then placed within the catheter as will be described below, with the inner wall of the catheter compressing the device **10** into its undeployed shape. When the device **10** is released out of the catheter into the aneurysm **40**, the uncompressed device **10** automatically expands into its deployed shape because of its super-elasticity.

[**0038**] Further details on the structure and manufacturing process of braided tubular elements **1** are disclosed in U.S. Pat. No. 6,168,622 issued to Mazzochhi, column 4, line 33 to column 6, line 24, and FIGS. **1**A and **1**B, of which are hereby incorporated by reference.

[**0039**] Forming the deployed shape shown in FIG. **1** is achieved by using two mandrels **85**, each having a cylindrical portion **90** and an umbrella dome-shaped mold **85**, as illustrated in FIG. **2**(*a*). To flare open the ends of the element **1**, each end is placed over the cylindrical portion **90** of a mandrel **85** and compressed against the dome **85**, causing the ends to conform to the shape of the dome **85** and flare open. The assembly of the two mandrels **80** and the element **1** is then heated at or above the training temperature to place the element **1** in the austenite phase. The assembly is maintained at that temperature until the deployed shape has been formed.

[**0040**] Then, the assembly is cooled to, or below, the martensite finishing temperature to place the element **1** in the martensite phase. In the martensite phase, the mandrels **80** are removed from the element **1**, and the element **1** is formed into an undeployed shape, e.g., the original tubular shape. This may be achieved by placing the element **1** over a cylindrical mandrel **95** and compressing the flared ends to conform to the shape of the cylindrical mandrel **95**, as shown in FIG. **2***b*. Subsequently, the element **1** may be reheated to the activation temperature, causing the element **1** to return to the deployed shape. Once the deployed shape has been recovered, the element **1** is configured to maintain the deployed shape irrespective of temperature.

[**0041**] Turning to FIG. **3**, another vaso-occlusive element **110** constructed in accordance with a preferred embodiment of the present invention is shown completely deployed within the aneurysm **40**. As with the embodiment in FIG. **1**, the vaso-occlusive element **110**, when deployed, generally includes a central tubular element **115** and a flared distal end **130**. The vaso-occlusive element **110** further includes a proximal end **120** shaped as a flattened disk, which functions as a retainer. The proximal end **130** has a diameter larger than the diameter of the neck **70**, and thus completely covers the entrance zone **150**. The flattened disk **130** has a layer of braided wires on both sides, and thus may advantageously provide two layers of braided wires to cover the entrance zone **150** instead of one layer with the flared open proximal end **20** shown in FIG. **1**. As with the flared open distal end **30** of the vaso-occlusive element **10**, shown in FIG. **1**, the flared open distal end **130** is placed adjacent the dome **45** of the aneurysm **40** and allows the element **110** to safely conform to the shape of the dome **45**.

[**0042**] Turning to FIG. **4**, one preferred method of manufacturing the vaso-occlusive device **110** shown in FIG. **3** will now be described. As described above, a braided tubular element **1** is first constructed. Forming the deployed shape is achieved by using one of the mandrels **85** shown in FIG. **2**(*a*) and the cylindrical mandrel shown in FIG. **2**(*b*), as illustrated in FIG. **4**. As described above, to flare open the distal end of the element **1**, the distal end is placed over the cylindrical portion **90** of the mandrel **85** with the dome **80** and compressed against the dome **80**, causing the distal end to flare open. To form the flattened disk **120**, the proximal end is placed on the cylindrical mandrel **95**. The proximal tip and a portion of the central tubular portion **115** are then compressed together along the axis of the cylindrical mandrel **95**. This causes the proximal end to expand into a flattened disk **120**.

[**0043**] The assembly of the two mandrels **80**/**95** and the element **1** is then heated at or above the training temperature to place the element **1** in the austenite phase. The assembly is maintained at that temperature until the deployed shape **110** has been formed. Then, the assembly is cooled to, or below, the martensite finishing temperature to place the element **110** in the martensite phase. In the martensite phase, the mandrels **80**/**95** are removed from the element **110**, and the element **110** is formed into an undeployed shape, e.g., the original tubular shape **1**. This is achieved by placing the element **110** over the cylindrical mandrel **95** and compressing the flared open end and flattened disk to conform to the shape of the cylindrical mandrel **95**, as shown in FIG. **2**(*b*). If the element **1** is configured to expand into its deployed shape upon exposure to a higher temperature, then the element **1** may be placed within a delivery catheter in preparation for deployment, as described above. Alternatively, if the element **110** is configured to expand upon being released by a compressive force, then the element **1** is reheated to, or above, the activation temperature, causing the element **1** to return to the deployed shape **110** and to be configured to maintain the deployed shape **110** irrespective of temperature.

[**0044**] Turning to FIG. **5**, another vaso-occlusive element **210** constructed in accordance with a preferred embodiment of the present invention is shown deployed within the aneurysm **40**. When in a deployed shape, the element **210** generally includes a central portion **215** and a distal end flared open into a "cup" shape **230**. Alternatively, the distal end may be flared open into a "cone" shape. The vaso-occlusive element **210** further includes a proximal end **220** shaped as a flattened disk. The proximal end **220** has a diameter larger than the diameter of the neck **70**. Only the flared open cup shape **230** is deployed within the aneurysm **40**, whereas the flattened disk **220** is deployed in the lumen **75** of the blood vessel **60** just outside of the aneurysm **40**, functioning as an anchor for the element **210**. The cup shaped distal end **230** may retain fine vaso-occlusive devices such as vaso-occlusive coils and embolic liquids.

[**0045**] Turning to FIG. **6**, one preferred method of manufacturing the vaso-occlusive device **310** shown in FIG. **5** will now be described. As described above, a braided tubular element **1** is first constructed. Forming the deployed shape is achieved by using a mandrel **280** having a cup shaped dome **285** facing outward coupled to a cylindrical portion **290** and a cylindrical mandrel **95**. To form the cup shape, the distal end of the element **1** is placed over the cylindrical portion **290** of the mandrel **280** having the dome **285** and compressed against the dome **285**, causing the distal end to flare open into a cup shape. To form the flattened disk, the proximal end is placed over the cylindrical mandrel **95**. The proximal tip and a portion of the central tubular portion **215**

are then compressed together along the axis of the cylindrical mandrel **95**. This causes the proximal end to expand into a flattened disk **220**.

[**0046**] The assembly of the two mandrels **280**/**95** and the element **1** is then heated at or above the training temperature to place the element **1** in the austenite phase. The assembly is maintained at that temperature until the deployed shape **210** has been formed. Then, the assembly is cooled to, or below, the martensite finishing temperature to place the element **210** in the martensite phase. In the martensite phase, the mandrels **280**/**95** are removed from the element **210**, and the element **210** is formed into an undeployed shape, e.g., the original tubular shape **1**. This may be achieved by placing the element **210** over the cylindrical mandrel **95** and compressing the flared open end and flattened disk to conform to the shape of the cylindrical mandrel **95**. If the element **1** is configured to expand into its deployed shape upon exposure to a higher temperature, then the element **1** may be placed within a delivery catheter in preparation for deployment, as described above. Alternatively, if the element **110** is configured to expand upon being released by a compressive force, then the element **1** is reheated to, or above, the activation temperature, causing the element **1** to return to the deployed shape **110** and to be configured to maintain the deployed shape **110** irrespective of temperature.

[**0047**] Turning to FIG. **7**, another vaso-occlusive element **310** constructed in accordance with a preferred embodiment of the present invention is shown deployed within the aneurysm **40**. When in a deployed shape, the element **310** generally includes a central portion **315** and first and second flattened disks **330**/**320** formed at the distal and proximal ends respectively. Only the first flattened disk **330** at the distal end is deployed within the aneurysm **40** whereas the second flattened disk **320** is deployed within the lumen **75** of the blood vessel **60** just outside of the aneurysm **40**, functioning as an anchor to secure the element **310** in its position. The first flattened disk **330** provides a wider coverage than the cup shape **230** shown in FIG. **5**. As with the other devices described above, this device **310** may also retain fine vaso-occlusive devices such as vaso-occlusive coils and embolic liquids. The central portion **315** may be conventionally sealed to prevent the fine vaso-occlusive devices from migrating out.

[**0048**] Turning to FIG. **8**, one preferred method of manufacturing the vaso-occlusive device **310** shown in FIG. **7** will now be described. As described above, a braided tubular element **1** is first constructed. Forming the deployed shape is achieved by using a cylindrical mandrel **95**, as illustrated in FIG. **8**. To form the first flattened disk **330**, the distal end is placed on the cylindrical mandrel **95**. The distal tip and a portion of the central tubular portion **315** are then compressed together along the axis of the cylindrical mandrel **95**. This causes the distal end to expand into a flattened disk **330**. To form the second flattened disk **320**, the proximal end is placed on the cylindrical mandrel **95**. The proximal tip and a portion of the central tubular portion **315** are then compressed together along the axis of the cylindrical mandrel **95**. This causes the proximal end to expand into a flattened disk **320**.

[**0049**] The assembly of the mandrel **95** and the element **1** is then heated at or above the training temperature to place the element **1** in the austenite phase. The assembly is maintained at that temperature until the deployed shape **310** has been formed. Then, the assembly is cooled to, or below, the martensite finishing temperature to place the element **310** in the martensite phase. In the martensite phase, the mandrel **95** is removed from the element **310**, and the element **310** is formed into an undeployed shape, e.g., the original tubular shape **1**. This may be achieved by placing the element **310** over the cylindrical mandrel **95** and compressing the flattened disks **320**/**330** to conform to the shape of the cylindrical mandrel **95**, as shown in FIG. **2**(*b*). If the element **1** is configured to expand into its deployed shape upon exposure to a higher temperature, then the element **1** may be placed within a delivery catheter in preparation for deployment, as described above. Alternatively, if the element **110** is configured to expand upon being released by a compressive force, then the element **1** is reheated to, or above, the activation temperature, causing the element **1** to return to the deployed shape **110** and to be configured to maintain the deployed shape **110** irrespective of temperature.

[**0050**] Generally, as mentioned above, the vaso-occlusive devices described above are delivered to an aneurysm within a blood vessel via a delivery catheter. Referring to FIGS. **9**(*a*)-(*c*), a method of deploying a vaso-occlusive device, and in this case the vaso-occlusive device **10**, to the aneurysm **40** via a delivery catheter **450** is illustrated. Turning first to FIG. **9**(*a*), the catheter **450** is steered to just within the neck **70** of the aneurysm **40**. At this point, the vaso-occlusive device **10** is in its undeployed shape, and is coupled to an inner guidewire **465** via an electrolytically severable joint **455**. The assembly of the vaso-occlusive device **10** and the guidewire **465** extends through the lumen of the delivery catheter **450** such that the device **10** is positioned at the distal end of the catheter **450**.

[**0051**] Turning to FIG. **9**(*b*), the guidewire **465** is then pushed toward the distal end of the catheter **450** causing the vaso-occlusive device **10** to extend out of the distal end of the catheter **450**, through the neck **70**, and into the aneurysm **40**. As the vaso-occlusive device **10** is pushed out of the catheter **450**, the portion of the device **10** that is free from the constraints of the catheter **450** expands into its deployed shape, e.g., the distal end **30** flares open.

[**0052**] As described above, the device **10** may be configured to be in its martensite phase when delivered to the aneurysm **40** and expand upon exposure to the temperature of the aneurysm **40**. Thus, when outside of the catheter **450**, the temperature of the device **10** rises and the device **10** enters the austenite phase and expands into its deployed shape. Alternatively, the device **10** may be configured to be super-elastic and automatically expand upon being—unconstrained by the catheter **450**.

[**0053**] Turning now to FIG. **9**(*c*), the guidewire **465** continues to push the device **10** out of the catheter until the proximal end **20** of the device **10** is deployed within the aneurysm **40**, expanding into its deployed shape, e.g., the proximal end **20** flares open, as described above with the distal end **30**. To release the device **10** from the catheter **450** a current is applied to the guidewire **465**, which causes the joint **455** to sever from the proximal end **20** of the catheter **10**. Further discussion of the construction of, placement of, and other physical details of such electrolytically severable

joints may be found in U.S. Pat. No. 5,122,136 to Guglielmi et al.; U.S. Pat. No. 5,354,295 to Guglielmi et al.; and U.S. Pat. No. 5,624,449 to Pham et al; and others. It should be noted that other types of vaso-occlusive devices, such as vaso-occlusive device **110**, can be delivered within the aneurysm **40** in the manner described immediately above.

[**0054**] Alternatively, referring to FIGS. **10**(*a*)-(*c*), a retractable sheath method of delivering a vaso-occlusive device, and in this case vaso-occlusive device **310**, to the aneurysm **40** is illustrated. Turning to FIG. **10**(*a*), the catheter **550** is steered to just within the neck **70** of the aneurysm **40**. At this point, the vaso-occlusive device **10** is in its undeployed shape, and is placed over an inner guidewire **565** that extends through the lumen **580** of the delivery catheter **565**. The outer wall **555** of the catheter **565** that defines the lumen **580** functions as a sheath. The assembly of the vaso-occlusive device **310** and the guidewire **565** extends through the lumen **580** of the delivery catheter **450** such that the device **10** is positioned at the distal end of the catheter **550**.

[**0055**] Turning to FIG. **10**(*b*), the guidewire **565** is then pushed so that the distal end of vaso-occlusive device **310** extends out of the catheter **550**, through the neck **70**, and into the aneurysm **40**. Once unconstrained from the catheter **550**, the distal end **330** of the device **310** is allowed to expand into a first flattened disk adjacent the inner wall near the neck **70** within the aneurysm **40**.

[**0056**] As described above, the device **310** may be configured to be in its martensite phase when delivered to the aneurysm **40** and expand upon exposure to the temperature of the aneurysm **40**. Thus, when outside of the catheter **550**, the temperature of the device **310** rises and the device **310** enters the austenite phase and expands into its deployed shape. Alternatively, the device **310** may be configured to be super-elastic and expand upon being unconstrained by the catheter **550**.

[**0057**] Turning now to FIG. **10**(*c*), the guidewire **565** continues to push the device **310** out of the catheter until the proximal end **320** of the device **310** is deployed just outside of the aneurysm **40**, expanding into its deployed shape, e.g., a second flattened disk, as described above with the distal end **330**. To release the device **310** from the catheter **450**, the guidewire **565** is pulled out of the device **310** and the catheter **550** is pulled out of the aneurysm **40** and blood vessel **60**. The expanded **310** device is secured in position within the aneurysm **40** and will not be pulled out with the catheter **550**. It should be noted that other types of vaso-occlusive devices, such as vaso-occlusive device **310**, can be delivered within the aneurysm **40** in the manner described immediately above.

[**0058**] As mentioned above, a vaso-occlusive device, such as vaso-occlusive device **310**, may function as a vaso-occlusive device and/or function as a vaso-occlusive device retainer. In this regard, after deployment, finer vaso-occlusive devices **730** may be delivered into the aneurysm **40** to be retained by the device **310**, as illustrated in FIG. **10**(*d*). This is achieved by maintaining an axial lumen within a vaso-occlusive device to allow a catheter **740** to fit through and insert materials such as vaso-occlusive coils **730** or embolic liquids to further improve thrombogenecity within the aneurysm **700**.

[**0059**] In another alternative, turning to FIGS. **11**(*a*)-(*c*), a push method of delivering a vaso-occlusive device, and in this case vaso-occlusive device **210**, to the aneurysm **40** is illustrated. Turning to FIG. **11**(*a*), the catheter **650** is steered to just within the neck **70** of the aneurysm **40**. At this point, the vaso-occlusive device **210** is in its undeployed shape, and is placed within the lumen **680** of a delivery catheter **650** near the distal tip of the catheter **650**, which is steered to aneurysm **40**, just outside of the neck **70**. A guidewire **665**, extending through the lumen **655** is positioned such that it is capable of pushing the device **210** out of the catheter **650** and into the aneurysm **40**, where the device **230** may expand into its deployed shape, as described above.

[**0060**] Turning to FIG. **11**(*b*), the guidewire **665** is then pushed so that the distal end of vaso-occlusive device **210** extends out of the catheter **650**, through the neck **70**, and into the aneurysm **40**. Once unconstrained from the catheter **550**, the distal end **230** of the device **210** is allowed to expand into a flared open cup shape adjacent the inner wall near the neck **70** within the aneurysm **40**.

[**0061**] As described above, the device **210** may be configured to be in its martensite phase when delivered to the aneurysm **40** and expand upon exposure to the temperature of the aneurysm **40**. Thus, when outside of the catheter **650**, the temperature of the device **210** rises and the device **210** enters the austenite phase and expands into its deployed shape. Alternatively, the device **210** may be configured to be super-elastic and expand upon being unconstrained by the catheter **650**.

[**0062**] Turning now to FIG. **11**(*c*), the guidewire **665** continues to push the device **210** out of the catheter until the proximal end **220** of the device **210** is deployed just outside of the aneurysm **40**, expanding into its deployed shape, e.g., a flattened disk, as described above with the distal end **230**. The catheter **650** is then pulled out of the aneurysm **40** and blood vessel **60** to separate itself from the device **210**. The expanded **210** device is secured in position within the aneurysm **40** and will not be pulled out with the catheter **650**. It should be noted that other types of vaso-occlusive devices, such as vaso-occlusive device **210**, can be delivered within the aneurysm **40** in the manner described immediately above.

[**0063**] While embodiments of the present invention have been shown and described, various modifications may be made without departing from the spirit and scope of the present invention, and all such modifications and equivalents are intended to be covered.

1. A vaso-occlusive device for use in occluding an aneurysm having an aneurysmal neck and an aneurysmal inner wall, comprising:

a mesh-like structure comprising a proximal end and a distal end, the distal end configured to be inserted through the aneurysmal neck when in an undeployed state, and configured to flare open and expand against at least a portion of the aneurysmal inner wall when in a deployed state, the proximal end configured to flare open and expand against one of

a portion of the aneurysmal inner wall, and

a portion of a vessel wall adjacent to the aneurysmal neck,

when in a deployed state,

wherein the mesh-like structure further comprises a tubular element extending between the proximal and distal ends.

2. The vaso-occlusive device of claim 1, wherein the proximal end is configured to be inserted through the aneurysmal neck when in an undeployed state, and to flare open and expand against at least a portion of the aneurysmal inner wall when in a deployed state, and wherein the tubular element is sized to fit within the aneurysm when in a deployed state.

3. The vaso-occlusive device of claim 1, wherein the proximal end is configured to flare open and expand against at least a portion of the vessel wall adjacent to the aneurysmal neck when in a deployed state, and wherein the tubular element is sized to fit through the aneurismal neck when in a deployed state.

4. The vaso-occlusive device of claim 1, wherein at least one of the proximal end and distal end is configured to expand by heat activation into the deployed state.

5. The vaso-occlusive device of claim 1, wherein at least one of the proximal end and distal end is configured to expand into the deployed state upon release of a compressive force.

6. The vaso-occlusive device of claim 1, wherein the mesh-like structure is formed from a plurality of braided fine wires.

7. The vaso-occlusive device of claim 1, wherein the mesh-like structure is composed of a NiTi alloy.

8. The vaso-occlusive device of claim 6, wherein the fine wires have varying diameters.

9. The vaso-occlusive device of claim 6, wherein one or more of the fine wires are radiopaque.

10. The vaso-occlusive device of claim 1, wherein the mesh-like structure is coated with radiopaque material.

11. The vaso-occlusive device of claim 1, further comprising radiopaque markers coupled to the mesh-like structure.

12. A catheter assembly for occluding an aneurysm having an aneurysmal neck and an aneurysmal inner wall, comprising:

a delivery catheter having a distal end; and

a mesh-like structure detachably coupled to the distal end of the catheter, the mesh-like structure comprising a proximal end and a distal end, the distal end configured to be inserted through the aneurysmal neck when in an undeployed state, and configured to flare open and expand against at least a portion of the aneurysmal inner wall when in a deployed state, the proximal end configured to flare open and expand against one of

a portion of the aneurysmal inner wall, and

a portion of a vessel wall adjacent to the aneurysmal neck,

when in a deployed state,

wherein the mesh-like structure further comprises a tubular element extending between the proximal and distal ends.

13. The catheter assembly of claim 12, wherein the proximal end is configured to be inserted through the aneurysmal neck when in an undeployed state, and to flare open and expand against at least a portion of the aneurysmal inner wall when in a deployed state, and wherein the tubular element is sized to fit within the aneurysm when in a deployed state.

14. The catheter assembly of claim 12, wherein the proximal end is configured to flare open and expand against at least a portion of the vessel wall adjacent to the aneurysmal neck when in a deployed state, and wherein the tubular element is sized to fit through the aneurismal neck when in a deployed state

15. The catheter assembly of claim 12, wherein the at least one of the proximal end and distal end is configured to expand by heat activation into the deployed state.

16. The catheter assembly of claim 12, wherein the at least one of the proximal end and distal end is configured to expand into the deployed state upon releasing a compressive force.

17. The catheter assembly of claim 12, wherein the mesh-like structure is formed from a plurality of braided fine wires.

18. The catheter assembly of claim 12, wherein the mesh-like structure is composed of a NiTi alloy.

19. The catheter assembly of claim 17, wherein the fine wires have varying diameters.

20. The catheter assembly of claim 17, wherein the fine wires are radiopaque.

21. The catheter assembly of claim 12, wherein the mesh-like structure is coated with radiopaque material.

22. The catheter assembly of claim 12, further comprising radiopaque markers coupled to the mesh-like structure.

23. The catheter assembly in claim 12, wherein the mesh-like structure is capable of being delivered to the aneurysm using a method selected from a group consisting of an electrolytically severable method, a retractable sheath method, and a push method.

24. A vaso-occlusive device for use in occluding an aneurysm having an aneurysmal neck and an aneurysmal inner wall, the aneurysm residing in a vessel having a vessel inner wall, the device comprising:

a mesh-like structure comprising a retainer and an anchor, the retainer configured to be inserted through the aneurysmal neck when in an undeployed state, and configured to expand against a portion of the aneurysmal inner wall surrounding the aneurysmal neck when in a deployed state, wherein a portion of the aneurysmal inner wall is not covered by the mesh-like structure, the anchor configured to expand against a portion of the vessel inner wall adjacent the aneurysmal neck when in a deployed state

wherein the anchor is shaped as a flattened disk.

25. The vaso-occlusive device of claim 24, wherein the mesh-like structure further comprises a central tubular element, and the retainer and anchor are formed at opposing ends of the central tubular element.

26. The vaso-occlusive device in claim 24, wherein the retainer is shaped as a flattened disk.

27. The vaso-occlusive device in claim 24, wherein the retainer is shaped as a flared open cup.

28. The vaso-occlusive device of claim 24, wherein the retainer and anchor are configured to expand by heat activation into the deployed state.

29. The vaso-occlusive device of claim 24, wherein the retainer and anchor are configured to expand into the deployed state when unconstrained.

30. The vaso-occlusive device of claim 24, wherein the mesh-like structure is formed from a plurality of braided fine wires.

31. The vaso-occlusive device of claim 24, wherein the mesh-like structure is composed of a NiTi alloy.

32. The vaso-occlusive device of claim 30, wherein the plurality of fine wires have varying diameters.

33. The vaso-occlusive device of claim 30, wherein the fine wires are radiopaque.

34. The vaso-occlusive device of claim 24, wherein the mesh-like structure is coated with radiopaque material.

35. The vaso-occlusive device of claim 24, further comprising radiopaque markers coupled to the mesh-like structure.

36. A catheter assembly for occluding an aneurysm having an aneurysmal neck and an aneurysmal inner wall, comprising:

a delivery catheter having a distal end; and

a mesh-like structure detachably coupled to the distal end of the catheter, the mesh-like structure comprising a retainer and an anchor, the retainer configured to be inserted through the aneurysmal neck when in an undeployed state, and configured to expand against a portion of the aneurysmal inner wall surrounding the aneurysmal neck when in a deployed state, wherein a portion of the aneurysmal inner wall is not covered by the mesh-like structure, the anchor configured to expand against a portion of the vessel inner wall adjacent the aneurysmal neck when in a deployed state

wherein the anchor is shaped as a flattened disk.

37. The vaso-occlusive device of claim 36, wherein the mesh-like structure further comprises a central tubular element, and the retainer and anchor are formed at opposing ends of the central tubular element.

38. The vaso-occlusive device in claim 36, wherein the retainer is shaped as a flattened disk.

39. The vaso-occlusive device in claim 36, wherein the retainer is shaped as a flared open cup.

40. The vaso-occlusive device of claim 36, wherein the retainer and anchor are configured to expand by heat activation into the deployed state.

41. The vaso-occlusive device of claim 36, wherein the retainer and anchor are configured to expand into the deployed state when unconstrained.

42. The vaso-occlusive device of claim 36, wherein the mesh-like structure is formed from a plurality of braided fine wires.

43. The vaso-occlusive device of claim 36, wherein the mesh-like structure is composed of a NiTi alloy.

44. The vaso-occlusive device of claim 42, wherein the plurality of fine wires have varying diameters.

45. The vaso-occlusive device of claim 42, wherein the fine wires are radiopaque.

46. The vaso-occlusive device of claim 36, wherein the mesh-like structure is coated with radiopaque material.

47. The vaso-occlusive device of claim 36, further comprising radiopaque markers coupled to the mesh-like structure.

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