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(54) **EMBOLIC PROTECTION DEVICE**

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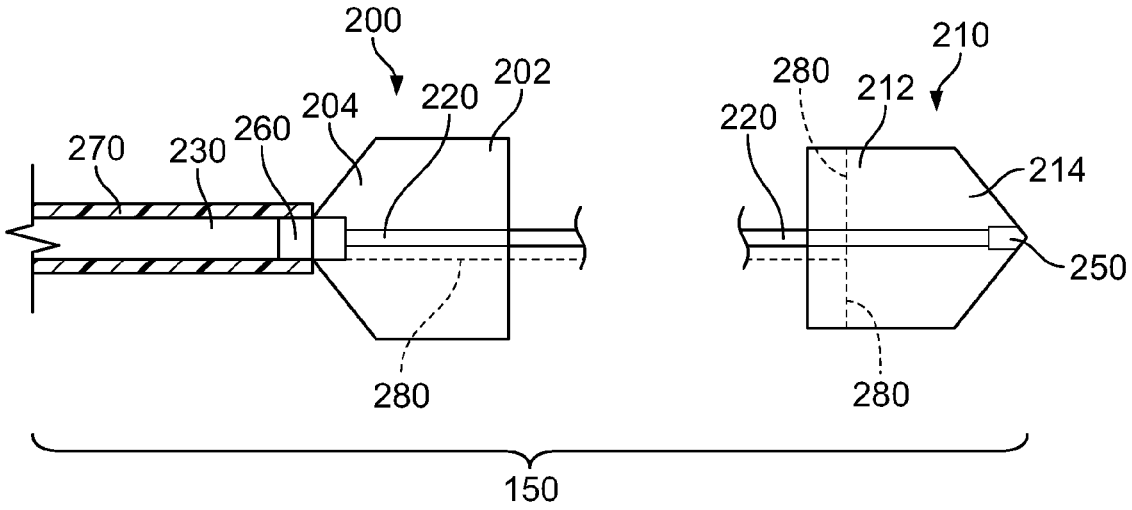
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(57) **ABSTRACT**

Embolic protection devices useful for filtering emboli during interventional cardiac, vascular, or other procedures are described. The device can include first and second expandable mesh filters having open and closed ends. The first filter is attached to a catheter at its closed end. The second filter is attached to a steerable guide wire at its closed end. The second filter includes a cinching wire circumferentially attached to the filter. The filters are deployed in separate vessels, such as the brachiocephalic artery and the left common carotid artery. A procedure is performed, and the filters trap any emboli travelling through the path of the filters. At the end of the procedure, the second filter is closed using the cinching wire, and retracted into the first filter. Both the first and second filters are collapsed into a sheath and removed from the body with along with any emboli trapped in the filters.



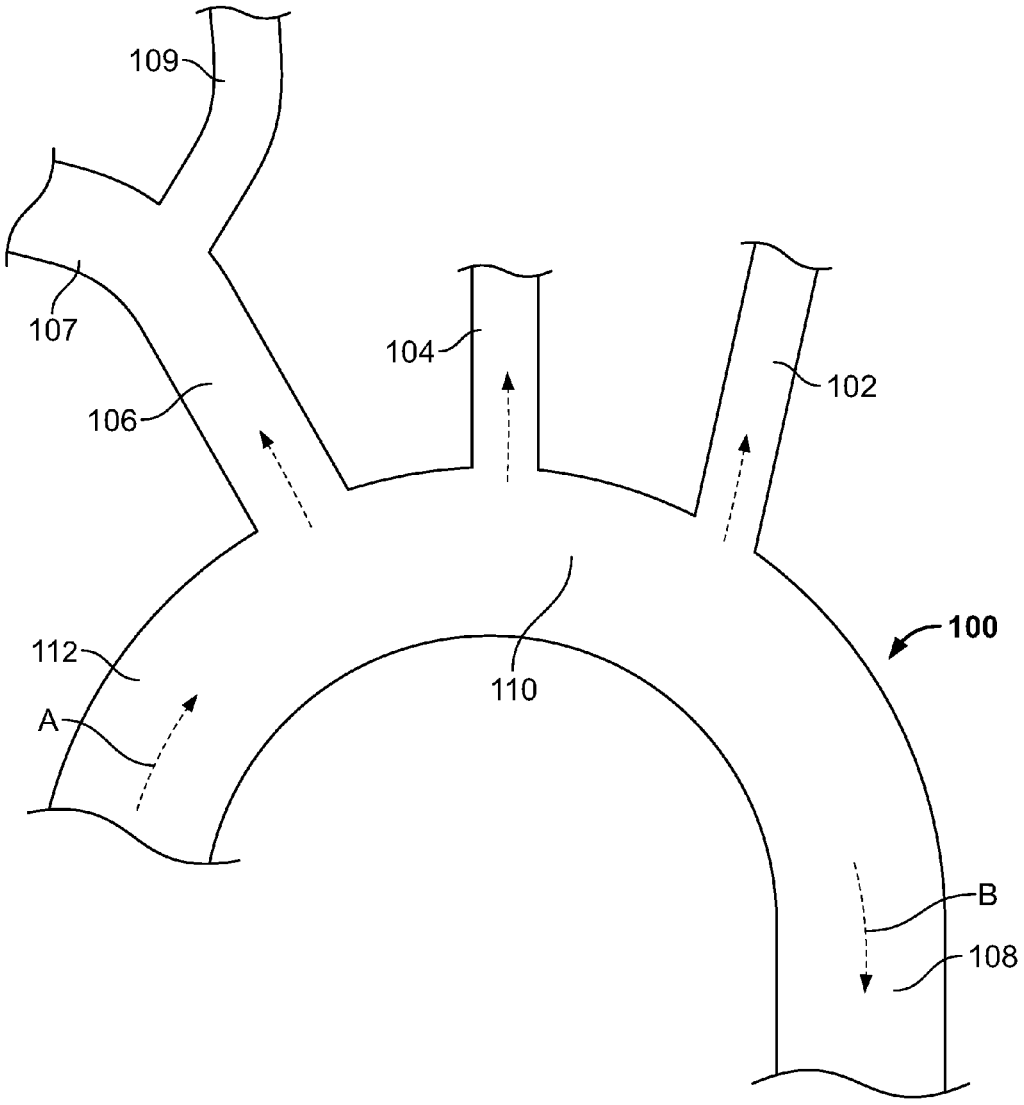



FIG. 1

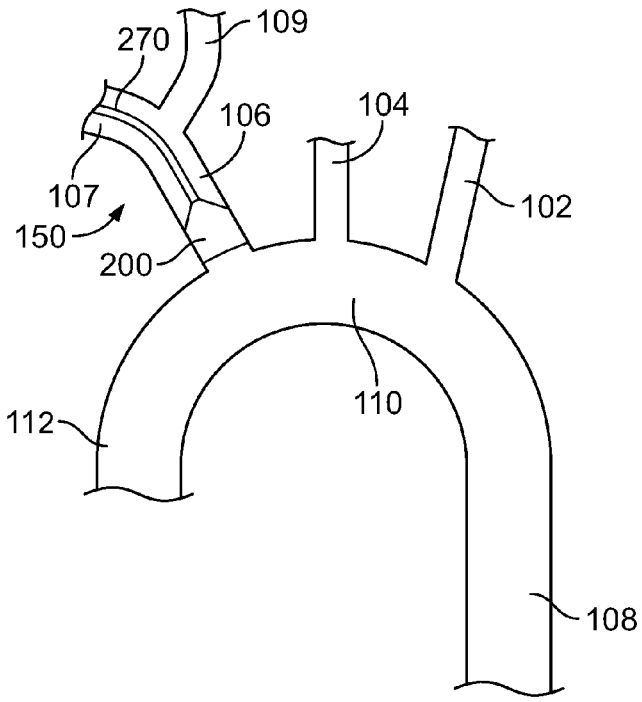

270
109
106
104
107
150
200
102
110
112
108

FIG. 2

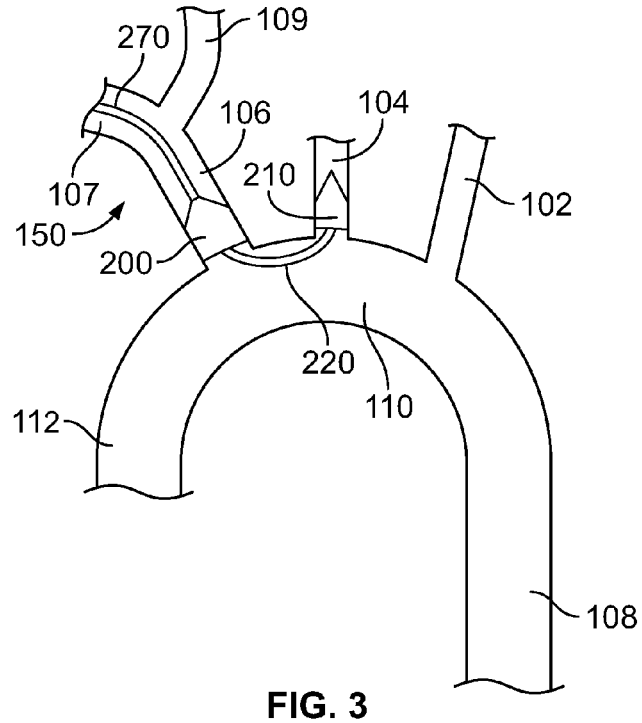

270
109
106
104
210
107
150
200
102
220
110
112
108

FIG. 3

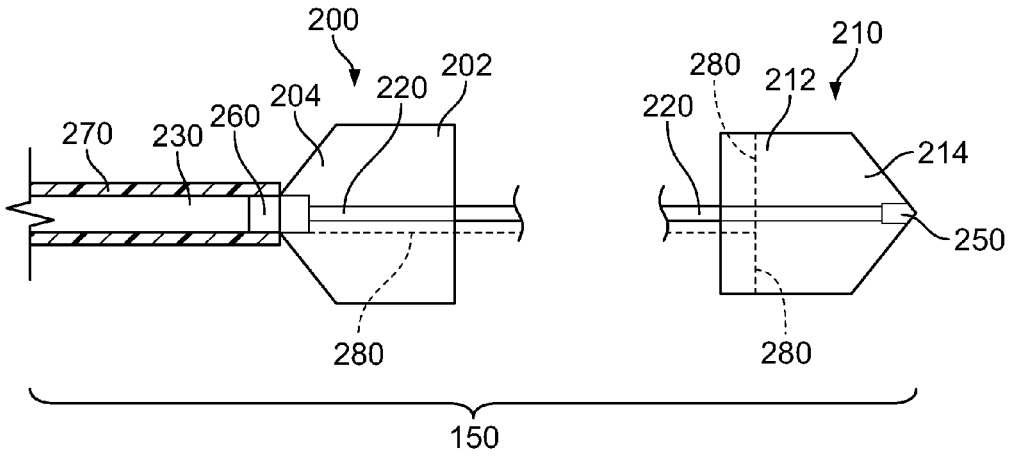

200
202
204
220
260
270
230
280
210
280
212
220
214
250
280
150

FIG. 4

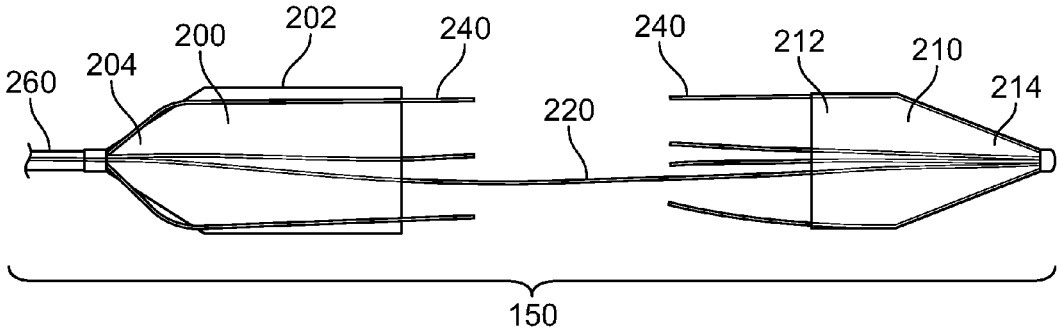

260
204
200
202
240
220
240
212
210
214
150

FIG. 5

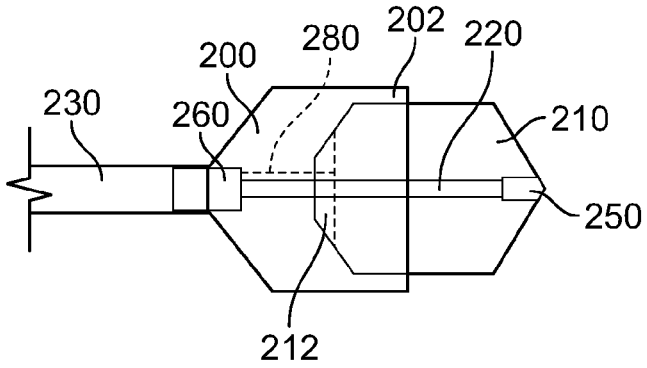



FIG. 6

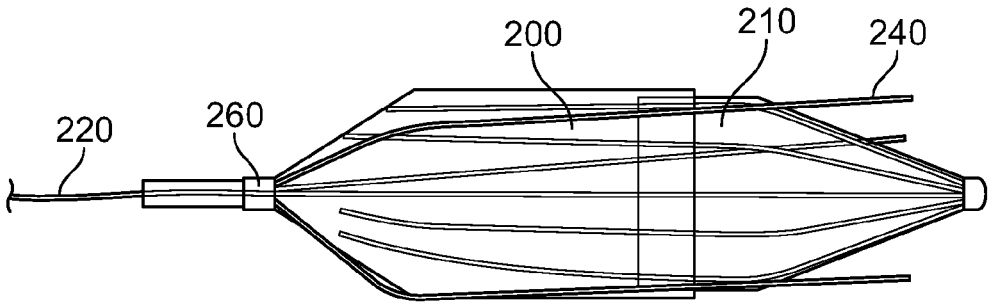



FIG. 7

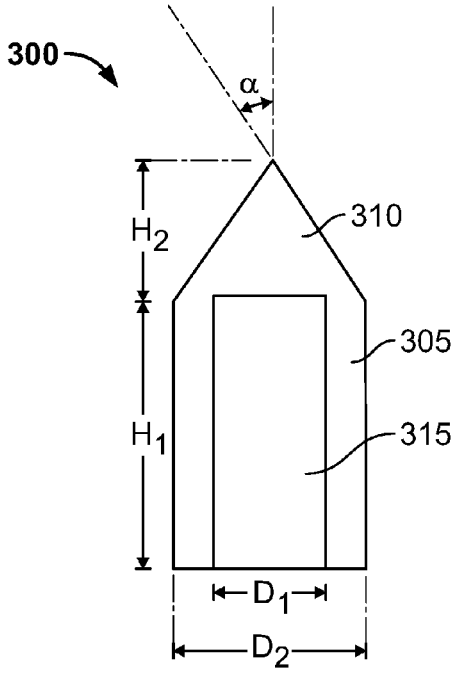



FIG. 8

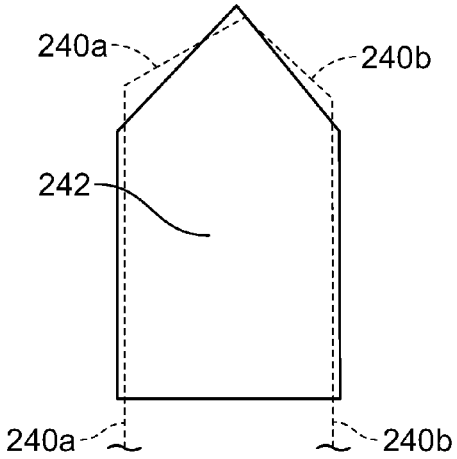



FIG. 9

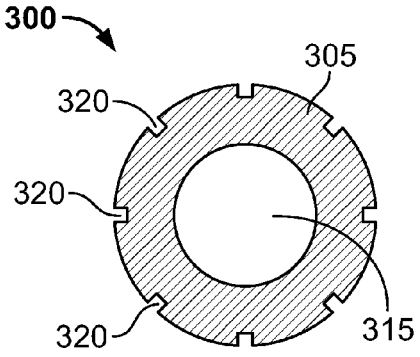



FIG. 10

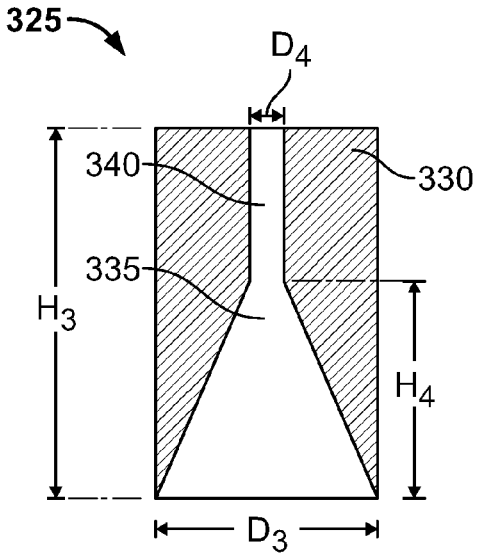



FIG. 11

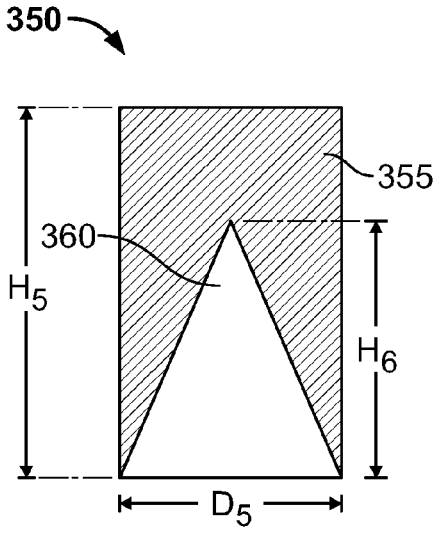



FIG. 12

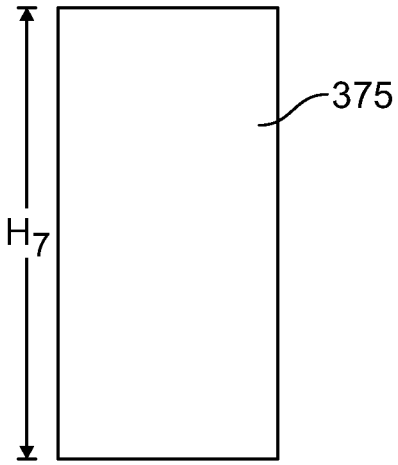



FIG. 13

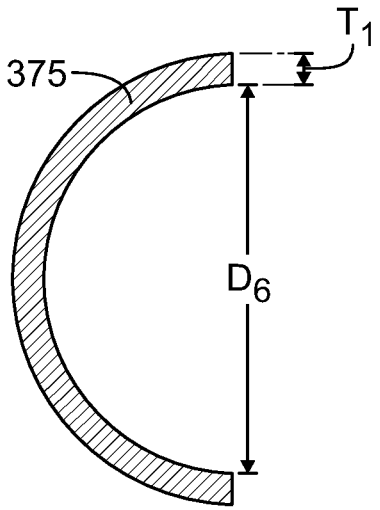



FIG. 14

# EMBOLIC PROTECTION DEVICE

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application is a divisional of U.S. patent application Ser. No. 13/782,657, filed Mar. 1, 2013, the disclosure of which is hereby incorporated by reference herein.

## BACKGROUND OF THE DISCLOSURE

**[0002]** The present disclosure is related to protecting against embolism, and more particularly to devices, systems, and methods for the filtration and removal of debris within blood vessels.

**[0003]** Arterial embolism is a sudden interruption of blood flow to an organ or body part due to an embolus, e.g., debris or a clot. During a surgical intervention, such as a cardiac intervention, a vascular intervention, or a coronary intervention, tissue, plaque, and/or other masses may be dislodged due to the intervention, resulting in an embolus. These emboli are capable of traveling far from their origins, migrating to other sites of the vasculature and resulting in potentially life threatening complications. For example, an embolus may travel through the carotid artery and inhibit the flow of blood to the brain, which may result in the death of brain cells, i.e., cause a stroke. A blockage of the carotid arteries is the most common cause of a stroke.

## BRIEF SUMMARY OF THE DISCLOSURE

**[0004]** In one embodiment according to the present disclosure, an embolic protection device includes a first filter having an open end and a closed end, the closed end being connected to a tube having a conduit. The device also includes a second filter having an open end and a closed end. The second filter is connected to a first wire, and the first wire extends into the conduit of the tube. A second wire has a first portion and a second portion. The first portion of the second wire is circumferentially attached to the open end of the second filter, and the second portion of the second wire extends into the conduit of the tube.

**[0005]** In another embodiment according to the present disclosure, a method of providing embolic protection to a patient includes the steps of delivering a sheath into a first blood vessel of the patient, the sheath housing a first filter and a second filter, deploying the first filter in the first blood vessel with a first guide structure, and deploying the second filter in a second blood vessel with a second guide structure. An additional step includes cinching an open end of the second filter with a cinching wire attached to the open end of the second filter.

**[0006]** In another embodiment according to the present disclosure, an embolic protection device includes a first filter having a closed proximal end and an open distal end, the closed proximal end having a conical shape and the open distal end having a cylindrical shape. The device also includes a second filter having an open proximal end and a closed distal end, the open proximal end having a cylindrical shape and the closed distal end having a conical shape. The device additionally includes a catheter having a proximal end, a distal end, and a lumen extending therebetween, the distal end of the catheter being fixed to the closed proximal end of the first filter. The device includes a steerable guide wire having a proximal end and a distal end, the distal end of the steerable guide wire being fixed to the closed distal end of the second filter. The device further includes a cinching wire having a first portion and a second portion, the first portion of the cinching wire being circumferentially attached to the open proximal end of the second filter. The steerable guide wire and the second portion of the cinching wire extend through the open distal end of the first filter and further through the lumen of the catheter.

**[0007]** In still a further embodiment according to the present disclosure, an embolic protection device includes a first filter and a second filter, each filter having an open end and a closed end defining an interior region therebetween. The device includes a catheter coupled to the closed end of the first filter. A first wire extends through a portion of the catheter and the interior regions of the first and second filters, and has an end attached to the closed end of the second filter. The second filter is configured to be at least partially received within the interior region of the first filter by manipulation of the first wire.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0008]** FIG. **1** illustrates a schematic view of the aorta.

**[0009]** FIG. **2** illustrates a schematic view of a proximal basket of an embolic protection device being introduced into the aorta.

**[0010]** FIG. **3** illustrates a schematic view of a distal basket of the embolic protection device of FIG. **2** being deployed into the left common carotid artery.

**[0011]** FIG. **4** illustrates a sectional side view of the embolic protection device of FIGS. **2-3** including the distal basket and the proximal basket according to an embodiment of the present disclosure.

**[0012]** FIG. **5** illustrates a side view of the embolic protection device of FIG. **4**.

**[0013]** FIG. **6** illustrates a sectional side view of the embolic protection device of FIG. **4** with the distal basket cinched and being retracted into the proximal basket.

**[0014]** FIG. **7** illustrates a side view of the embolic protection device of FIG. **4** with the distal basket retracted into the proximal basket.

**[0015]** FIG. **8** illustrates a vertical sectional view of an inner mold used to produce a filter for an embolic protection device according to an embodiment of the present disclosure.

**[0016]** FIG. **9** illustrates a schematic view of the positioning of struts in a filter of an embolic protection device according to an embodiment of the present disclosure.

**[0017]** FIG. **10** illustrates a horizontal sectional view of an alternate embodiment of an inner mold used to produce a filter for an embolic protection device according to an embodiment of the present disclosure.

**[0018]** FIG. **11** illustrates a vertical sectional view of an outer mold used to produce a filter for an embolic protection device according to an embodiment of the present disclosure.

**[0019]** FIG. **12** illustrates a vertical sectional view of an alternate embodiment of an outer mold used to produce a filter for an embolic protection device according to an embodiment of the present disclosure.

**[0020]** FIG. **13** illustrates a side view of a clam shell used to produce a filter for an embolic protection device according to an embodiment of the present disclosure.

**[0021]** FIG. **14** illustrates a top view of the clam shell of FIG. **13**.

## DETAILED DESCRIPTION

**[0022]** A continuing need exists for devices and systems that inhibit emboli from traveling to parts of a patient's vasculature where they may block blood flow to critical organs and threaten the life of the patient.

**[0023]** Particular embodiments of the present disclosure are described with reference to the accompanying drawings. In the figures and in the description that follow, like reference numerals identify similar or identical elements. As shown in the drawings and as described throughout the following description, the term "proximal" refers to the end of the device that is closer to the user and the term "distal" refers to the end of the device that is farther from the user.

**[0024]** FIG. **1** illustrates aorta **100**, the largest artery in the body, originating from the left ventricle (not shown) and extending down to the abdomen. Blood flows as indicated by arrow "A" from the left ventricle, through the aortic valve (not shown), through ascending aorta **112** to aortic arch **110**. Three major arteries branch from aortic arch **110**. Brachiocephalic artery **106** branches into right subclavian artery **107**, supplying blood to the right arm, and right common carotid artery **109**, supplying blood to the head and neck. Left common carotid artery **104** supplies blood to the head and neck. Left subclavian artery **102** supplies blood to the left arm. Blood from ascending aorta **112** not passing through one of these three arteries continues down descending aorta **108** as shown by arrow "B". Variations of the anatomy illustrated in FIG. **1** are possible and sometimes are relatively common. For example, about 10% of the population has a common brachiocephalic trunk, in which both common carotid arteries **104**, **109** and right subclavian artery **107** arise from a single trunk off aortic arch **110**. During interventional surgical, cardiac, and/or vascular procedures, there is a risk that emboli may break free and travel up ascending artery **112** and cause a blockage of brachiocephalic artery **106**, right common carotid artery **109**, and/or left common carotid artery **104**, causing reduced blood flow to the brain and possibly a stroke. Devices and methods described herein may be used during interventional procedures to capture and remove emboli from the body.

**[0025]** Referring to FIG. **2**, in one embodiment, embolic protection device **150** includes a first filter in the nature of proximal basket **200**. Proximal basket **200** is a collapsible/expandable mesh basket with pores that are large enough to allow for the passage of blood, but small enough to trap emboli passing into proximal basket **200**.

**[0026]** Embolic protection device **150**, attached to the distal end of catheter **230** (shown in FIG. **4**), is introduced into or near the ostium of a blood vessel, such as brachiocephalic artery **106** of aortic arch **110**, via introducer sheath **270**. Introducer sheath **270** may be initially introduced into the femoral artery, subclavian artery, or other vessel as is known in the art. During introduction, proximal basket **200** is in a collapsed state within introducer sheath **270**. Once introducer sheath **270** is placed near the ostium of brachiocephalic artery **106**, catheter **230** is pushed distally until proximal basket **200** exits the confines of introducer sheath **270**. For embodiments in which proximal basket **200** is a collapsible/expandable mesh basket, proximal basket **200** will automatically open to its expanded configuration as seen in FIG. **2**. The expansion is such that substantially all the blood flowing through brachiocephalic artery **106** passes through proximal basket **200**.

**[0027]** Now referring to FIG. **3**, once proximal basket **200** is expanded in brachiocephalic artery **106**, a second filter, in the nature of distal basket **210**, is then deployed. Distal basket **210** is connected to steerable guidewire **220** which extends through proximal basket **200** and into catheter **230** (shown in FIG. **4**). Distal basket **210** may also take the form of a collapsible/expandable mesh basket with pores that are large enough to allow for the passage of blood, but small enough to trap emboli passing into distal basket **210**. Prior to deployment, for example during introduction into the body, distal basket **210** may be collapsed within proximal basket **200**, which itself is in a collapsed configuration. During deployment, distal basket **210** may automatically open to its expanded configuration once pushed distally out of proximal basket **200** via steerable guidewire **220**. In its expanded configuration, distal basket **210** can be directed to or near the ostium of a nearby vessel, such as left common carotid artery **104**, using steerable guidewire **220**.

**[0028]** With both baskets **200**, **210** expanded in the desired blood vessel, a cardiac or vascular intervention or other procedure can be performed. Such a cardiac or vascular intervention or other procedure may dislodge or otherwise result in emboli moving through the blood. If an embolus travels into the path of the expanded proximal basket **200** or distal basket **210**, the embolus will become trapped in the mesh of the respective basket. Baskets **200**, **210** remain in the expanded configuration for the duration of the cardiac or vascular interventional procedure. Once the interventional procedure is complete, distal basket **210** can be cinched closed to trap any emboli therein. After cinching, distal basket **210** is pulled into proximal basket **200**, and both baskets **200**, **210** and catheter **230** are removed from the patient along with any emboli trapped during the procedure. As catheter **230** and baskets **200**, **210** pass back into introducer sheath **270**, baskets **200**, **210** are forced into a collapsed configuration inside introducer sheath **270**. The cinching and removal steps are described more fully below with reference to FIGS. **6-7**.

**[0029]** Referring now to FIG. **4**, embolic protection device **150** shown in FIGS. **2-3** is illustrated in further detail. Baskets **200**, **210** each have a cylindrically shaped open portion **202**, **212**, with a conically shaped closed end portion **204**, **214** respectively. Baskets **200**, **210** are each formed of a braided mesh structure supported by struts **240** (struts **240** illustrated in FIG. **5**).

**[0030]** For example, the mesh of baskets **200**, **210** can be a braided superelastic metal alloy such as nickel-titanium alloy of the type sold under the designation NITINOL. As one example, 32-strand NITINOL braid may be used. Alternately, or in addition, 72-strand or 144-strand NITINOL braid may be used. A braid of approximately 0.0010-0.0015 inch (0.025-038 mm) diameter can be used for the mesh of baskets **200**, **210**.

**[0031]** Still referring to FIG. **4**, distal basket **210** is coupled to steerable guidewire **220**, which extends through proximal basket **200** and further through catheter **230**. As illustrated in FIG. **4**, closed end portion **204** of proximal basket **200** faces the proximal end of embolic protection device **150**. Cylindrically shaped open portion **202** of proximal basket **200** faces the distal end of embolic protection device **150**. Distal basket **210** is generally in line with proximal basket **200** by virtue of steerable guidewire **220**, but in the opposite orientation. As such, cylindrically shaped open portion **212** of distal basket **210** faces the proximal end

of embolic protection device **150**, and closed end portion **214** faces the distal end of embolic protection device **150**.

**[0032]** The shape of proximal basket **200** and distal basket **210** is maintained by virtue of the shape-maintaining material forming the baskets **200**, **210**. For example, NITINOL can be heat set to a particular shape, such as the generally cylindrical and/or conical shapes described above with reference to baskets **200**, **210**. The process of heat setting is described in greater detail below with reference to FIGS. **8-14**. Baskets **200**, **210** are also elastic such that they each may be radially collapsed into a collapsed configuration. The collapsed configuration may be particularly useful for creating a low profile of baskets **200**, **210**, such that they may be delivered into the body in an introducer sheath **270** in the low profile collapsed condition. The shape memory of baskets **200**, **210** helps ensure that, upon a reduction of compressive forces, baskets **200**, **210** automatically radially expand from the low profile, collapsed condition into the expanded configuration. The shape taken in the expanded configuration is dictated by the shape in which the material was heat set.

**[0033]** The distal end of steerable guidewire **220** is connected to end screw **250** of distal basket **210**. End screw **250** is internally threaded to threadingly engage with external threads on the distal end of steerable guidewire **220**. Other mating configurations are also possible, for example external threading on end screw **250** and internal threading on steerable guidewire **220**. Steerable guidewire **220** extends distally from end screw **250** through an approximate midline of proximal basket **200**. Steerable guidewire **220**, having an outer diameter smaller than the inner diameter of catheter **230**, extends further distally through an approximate midline of catheter **230**. The proximal end of the steerable guidewire **220** can extend to a proximal end of the system (not shown) where a user is able to steer guidewire **220**, and in turn, steer distal basket **210**. Steerable guidewire **220** may, for example, include a pullable guidewire having at least one relatively stiff portion and one relatively flexible portion for positioning distal basket **210**. Steerable guidewire **220** may include a pushable guidewire to which tension may be applied to steer distal basket **210** into the desired location. Mechanisms for steerable guidewires are known in the art and not described further herein.

**[0034]** The proximal end of proximal basket **200** is coupled to hypotube **260**, which, in turn, is coupled to the distal end of catheter **230**. Hypotube **260** may be formed as an integral part of catheter **230** or may be separately attached, such as with adhesives or through welding. The outer diameter of catheter **230** is small enough to pass through the inner diameter of introducer sheath **270**. For example, the catheter **230** may be between about 3-15 French, 4-12 French, 5-8 French, or approximately 6-7 French.

**[0035]** Still referring to FIG. **4**, elongated cinch wire **280** (shown as a broken line), which may for example be a suture or other suitable cable-type material, extends generally around the circumference of cylindrical portion **212** of distal basket **210** and back through proximal basket **200** and catheter **230**. Cinch wire **280** may, for example, weave in and out of the mesh structure of distal basket **210** in a purse string configuration. Cinch wire **280** may additionally or alternately attach circumferentially to two or more struts **240** (described in more detail below with reference to FIG. **5**) in distal basket **210**. Cinch wire **280** extends through the catheter **230** to a proximal end (not shown) where the user is able to control cinch wire **280**, for example, with a pulling motion. Pulling cinch wire **280** proximally causes distal basket **210** to constrict at the point of attachment, much like pulling a purse string. This functions to further secure emboli trapped in distal basket **210**, described in more detail below with reference to FIGS. **6-7**.

**[0036]** Now referring to FIG. **5**, the mesh of baskets **200**, **210** can be structurally reinforced with struts **240**, such as solid, elongated pieces of superelastic metal alloy, such as NITINOL. In one example, each strut **240** is between about 0.005-0.015 inches (0.127-0.381 mm) or approximately 0.010 inches (0.254 mm) in diameter. Each strut **240** is about ten times as thick as the mesh braid and aids baskets **200**, **210** in maintaining the generally cylindrical shape of open portions **202**, **212**. By helping to maintain the generally cylindrical shape of open portions **202**, **212**, struts **240** also help ensure that baskets **200**, **210** maintain contact with the walls of vessels in which they are deployed. Referring back to FIG. **3**, for example, struts **240** help proximal basket **200** maintain contact with the walls of brachiocephalic artery **106**. Similarly, struts **240** help distal basket **210** maintain contact with the walls of left common carotid artery **104**. This contact of baskets **200**, **210** to the walls of the blood vessels increases the likelihood of trapping emboli that pass into the blood vessels.

**[0037]** Now referring back to FIG. **5**, each basket **200**, **210** can have one or more struts **240** and the exact number of struts in each basket **200**, **210** is largely a matter of design choice. Generally, more struts **240** in a basket results in an improved ability of the mesh to maintain its cylindrical shape when in the expanded condition. However, more struts **240** in a basket results in an increased profile of the basket when the basket is in the collapsed configuration. Therefore the specific number and design of struts **240** in proximal basket **200** and distal basket **210** depends on the materials used, the particular application of the device, and the desired performance of the device.

**[0038]** Generally, struts **240** in proximal basket **200** are spaced equally around cylindrically shaped portion **202**. For example, three struts would be placed 120° apart, four struts would be placed 90° apart, etc. Each strut **240** begins distal to the distal end of cylindrically shaped open portion **202** of proximal basket **200**. Struts **240** extend proximally, generally parallel to, and along the surface of, cylindrically shaped open portion **202**. Struts **240** follow the surface of proximal basket **200** and curve toward conical closed end portion **204**. All struts **240** in proximal basket **200** meet at conical closed end portion **204**. The structure of struts **240** in distal basket **210** is similar, with the directionality being reversed. In other words, struts **240** of distal basket **210** extend past the mesh of distal basket **210** in the proximal direction, and each meet at the proximal conical closed end portion **214**.

**[0039]** In the embodiment illustrated in FIG. **5**, proximal basket **200** includes three struts **240** while distal basket **210** includes four struts. As will become clear below, the ability of distal basket **210** to achieve a small profile is one design factor. As such, in an embodiment, distal basket **210** has fewer struts **240** than proximal basket **200**, such as three struts in distal basket **210** and four struts in proximal basket **200**. The process for manufacturing baskets **200**, **210**, including struts **240**, is described in more detail below with reference to FIGS. **8-10**.

**[0040]** Now referring to FIG. **6**, distal basket **210** is illustrated cinched closed and being retracted into proximal basket **200**. After insertion of embolic protection device **150** and completion of a surgical intervention, embolic protection device **150** is extracted from the patient. Prior to extraction, distal basket **210** is retracted proximally into proximal basket **200**. Prior to the retraction step, distal basket **210** is cinched closed to reduce the likelihood of emboli escaping distal basket **210** and re-entering the blood stream. As described above with reference to FIG. **4**, pulling cinch wire **280** causes distal basket **210** to constrict like pulling a purse string. In an embodiment, the pulling force required to cinch distal basket **210** closed is minimal and does not substantially cause movement of distal basket **210** proximally toward proximal basket **200**.

**[0041]** The constricting action allows distal basket **210**, with any trapped emboli therein, to be fully or nearly fully sealed before attempting to retract distal basket **210** into proximal basket **200**. Any agitation of baskets **200**, **210** may increase the likelihood of a trapped embolus escaping back into the blood stream. Such agitation may occur when retracting distal basket **210** into proximal basket **200**. By fully, or nearly fully, sealing open portion **212** of distal basket **210** with cinch wire **280** prior to retraction, the likelihood of an embolus trapped within distal basket **210** inadvertently re-entering the blood stream during retraction is significantly reduced.

**[0042]** In other words, prior to cinching, distal basket **210** is in the expanded configuration, with open end **212** having a pre-cinched diameter. The cinching action collapses open end **212** of distal basket **210** to a smaller, post-cinched diameter. This is possible due to the expandable/collapsible nature of distal basket **210**. Even when open portion **212** is collapsed due to the cinching action, the rest of distal basket **210** remains in a generally expanded configuration. The post-cinched diameter of open portion **212** is smaller than the diameter of open portion **202** of proximal basket **200** when proximal basket **200** is in the expanded configuration. These relative diameters help ensure that open portion **212** of distal basket **210** can be retracted into open portion **202** of proximal basket **200** after being cinched.

**[0043]** Now referring to FIG. **7**, distal basket **210** is illustrated retracted into proximal basket **200**. The user may accomplish this by pulling steerable guidewire **220** proximally until open end **212** of distal basket **210** is proximal of open end **202** of proximal basket **200**. In this configuration, distal basket **210** and proximal basket **200** form a fully or nearly fully sealed filter unit. Distal basket **210** and proximal basket **200** can be considered a sealed filter unit in this configuration because distal basket **210** partially or fully occupies open cylindrical portion **202** of proximal basket **200**. During extraction of embolic protection device **150**, both distal basket **210** and proximal basket **200** are radially collapsed and removed through introducer sheath **270**, as described above with reference to FIG. **4**. These movements may agitate emboli trapped within proximal basket **200** or distal basket **210**. However, because distal basket **210** is located partially within proximal basket **200** during the collapsing action as a sealed filter unit, agitated emboli are unlikely to escape back into the blood stream. As proximal basket **200** and distal basket **210** proximally pass through introducer sheath **270**, baskets **200**, **210** radially collapse into introducer sheath **270**. Once in the collapsed configuration, both baskets **200**, **210** can be extracted from the patient, with any emboli trapped during the interventional procedure securely remaining within the confines of the collapsed baskets **200**, **210** throughout extraction.

**[0044]** Turning now generally to FIGS. **8-14**, devices useful for the manufacturing of proximal and distal baskets **200**, **210** are shown. To produce proximal and/or distal baskets **200**, **210**, tubular braided mesh **242** (illustrated in FIG. **9**) is fitted over inner mold **300**, as seen in FIG. **8**. Inner mold **300** provides a structure upon which proximal basket **200** or distal basket **210** may be formed. Inner mold **300** can be formed from a range of materials that withstand heating, are commonly available, are durable and have good heat transfer properties. For example, brass or similar materials can be used for the inner mold **300**. In the illustrated embodiment, inner mold **300** resembles the shape of proximal and distal baskets **200**, **210**, having generally cylindrical portion **305** and conical portion **310**. The interior of cylindrical portion **305** can include hollow portion **315**. Hollow portion **315** may reduce the mass of inner mold **300** and reduce the time necessary for any heating or cooling of inner mold **300**.

**[0045]** The dimensions of inner mold **300** can be varied for baskets of different sizes. For example, the following dimensions of inner mold **300** may be useful for forming proximal basket **200**. Height $H_1$ of cylinder portion **305** is between about 1-2 inches (25.4-50.8 mm) or approximately 1.5 inches (38.1 mm). Height $H_2$ of conical portion **310** is between about 0.5-1.1 inches (12.7-27.94 mm) or approximately 0.8 inches (20.32 mm). Diameter $D_1$ of hollow portion **315** is between about 0.25-0.75 inches (6.35-19.05 mm) or approximately 0.5 inches (12.7 mm). Diameter $D_2$ of cylindrical portion **305** is between about 0.5-1 inches (12.7-25.4 mm) or approximately 0.748 inches (19 mm). Angle $\alpha$ of conical portion **310** is between about 15°-25°, or approximately 20°.

**[0046]** Inner mold **300** with a similar shape but different dimensions can be used for distal basket **210**. For example, the following dimensions of inner mold **300** may be useful for forming distal basket **210**. Height $H_1$ of cylinder portion **305** is between about 1-2 inches (25.4-50.8 mm) or approximately 1.5 inches (38.1 mm). Height $H_2$ of conical portion **310** is between about 0.25-0.75 inches (6.35-19.05 mm) or approximately 0.5 inches (12.7 mm). Diameter $D_1$ of hollow portion **315** is between about 0.25-0.75 inches (6.35-19.05 mm) or approximately 0.5 inches (12.7 mm). Diameter $D_2$ of cylindrical portion **305** is between about 0.5-1 inches (12.7-25.4 mm) or approximately 0.787 inches (20 mm). Angle $\alpha$ of conical portion **310** is between about 25°-35°, or approximately 30°.

**[0047]** The provided dimensions are merely illustrative and are in no way meant to limit the scope of the disclosure. These dimensions can be varied for different preferences or applications. For example, in one embodiment, inner mold **300** used to form proximal basket **200** has a larger diameter $D_2$ of cylindrical portion **305** than inner mold **300** used to form distal basket **210**. In this embodiment, the larger diameter $D_2$ of proximal basket **200** inner mold **300** results in a larger diameter of proximal basket **200**. This configuration may make it easier to retract distal basket **210** into proximal basket **200**, described above in relation to FIG. **7**.

**[0048]** Once tubular braided mesh **242** is on inner mold **300**, struts **240** are inserted between the mesh and inner mold **300** in the desired configuration. Struts **240** may be equally spaced. For example, in a basket with four struts

**240**, the struts may be placed every 90°, whereas in a basket with three struts, the struts may be placed every 120°. The number and exact spacing of struts **240**, however, is largely a matter of design choice as discussed in detail above.

**[0049]** Referring now to FIG. **9**, placement of two struts **240***a*, **240***b* within braided mesh **242** is illustrated. Inner mold **300** is omitted from FIG. **9** for clarity of illustration. Each strut **240***a*, **240***b* is initially placed between braided mesh **242** and cylindrical portion **305** of inner mold **300**. Struts **240***a*, **240***b* are advanced toward conical portion **310** of inner mold, and are passed through the mesh near the angled transition of inner mold **300** from cylindrical portion **305** to conical portion **310**. Struts **240***a*, **240***b* are then woven back inside the mesh and guided toward the tip of conical portion **310**.

**[0050]** To aid in the introduction and weaving of struts **240**, the outer surface of cylindrical portion **305** of inner mold **300** can include a plurality of notches or grooves **320** running the length of cylindrical portion **305**. As shown in FIG. **10**, grooves **320** aid in inserting struts **240** between braided mesh **242** and inner mold **300**, especially if braided mesh **242** is tightly fitted over inner mold **300**.

**[0051]** For proximal basket **200**, after guiding struts **240** toward the tip of the conical portion **310**, struts **240** are situated on or near the outer surface of a cylindrical structure, such as hypotube **260** (illustrated in FIGS. **5-6**). Hypotube **260** can be between about 0.125-0.375 inches long (3.175-9.525 mm), or approximately 0.25 inches long (6.35 mm). Hypotube **260** is between about 10-15 gauge, or approximately 13 gauge. Struts **240** are then cinched to hypotube **260** by a marker band (not illustrated). Marker bands are known in the art and can be formed of, for example, a radiopaque material such as platinum iridium that allows for visualization inside the body. Struts **240**, the marker band and hypotube **260** are joined together, such as by adhesives, soldering, brazing, or laser welding to remove any excess material.

**[0052]** For distal basket **210**, after guiding struts **240** toward the tip of conical portion **310** of inner mold **300**, struts **240** are joined with the braid atop of end screw **250** (shown in FIG. **4**) and cinched using a marker band. Struts **240**, the marker band and end screw **250** are joined together, such as by adhesives, soldering, brazing, or laser welding to remove any excess material.

**[0053]** Now referring to FIG. **11**, outer mold **325** is illustrated. After welding proximal basket **200**, outer mold **325** is placed over the conical portion **310** of the inner mold, sandwiching braided mesh **242** therebetween. Outer mold **325** includes cylindrical portion **330** and hollow conical portion **335** within cylindrical portion **330**. Hollow conical portion **335** is generally dimensioned to correspond to conical portion **310** of inner mold **300**. Outer mold **325** can also include hollow conduit **340** connecting the tip of hollow conical portion **335** to the outside of outer mold **325**. Hollow conduit **340** is dimensioned to accept hypotube **260** and other elements extending from the tip of conical portion **204** of proximal basket **200**.

**[0054]** Outer mold **325**, which can be used while forming proximal basket **200**, can be a variety of sizes depending on the desired size of proximal basket **200**. In one embodiment, height $H_3$ of outer mold **325** is between about 1-2 inches (25.4-50.8 mm) or approximately 1.5 inches (38.1 mm). Height $H_4$ of hollow conical portion **335** is between about 0.5-1.1 inches (12.7-27.94 mm) or approximately 0.8 inches (20.32 mm). Diameter $D_3$ of outer mold **325** is between about 0.5-1.0 inches (12.7-25.4 mm) or approximately 0.748 inches (19 mm). Diameter $D_4$ of hollow conduit **340** is between about 0.125 inches and 0.25 inches (3.175-6.35 mm) or approximately 0.1875 inches (4.76 mm). As with inner mold **300**, outer mold **325** may be formed from a range of materials that withstand heating, are commonly available, are durable and have good heat transfer properties. For example, brass or similar materials can be used for outer mold **325**.

**[0055]** Now referring to FIG. **12**, outer mold **350** is illustrated. After welding distal basket **210**, outer mold **350** is placed over conical portion **310** of inner mold **300**, sandwiching braided mesh **242** therebetween. Outer mold **350** includes cylindrical portion **355** and hollow conical portion **360** within cylindrical portion **355**. Hollow conical portion **360** is generally dimensioned to correspond to conical portion **310** of inner mold **300**.

**[0056]** Outer mold **350**, which can be used while forming distal basket **210**, can be a variety of sizes depending on the desired size of distal basket **210**. In one embodiment, height $H_5$ of outer mold **350** is between about 1-2 inches (25.4-50.8 mm) or approximately 1.5 inches (38.1 mm). Height $H_6$ of the hollow conical portion **360** is between about 0.25-0.75 inches (6.35-19.05 mm) or approximately 0.5 inches (12.7 mm). Diameter $D_5$ of outer mold **350** is between about 0.5-1 inches (12.7-25.4 mm) or approximately 0.787 inches (20 mm). As with inner mold **300**, outer mold **350** may be formed from a range of materials that withstand heating, are commonly available, are durable and have good heat transfer properties. For example, brass or similar materials can be used for outer mold **350**.

**[0057]** Referring to FIGS. **13-14**, clam shell **375** is illustrated in side and top views, respectively. A pair of clam shells **375** (only one clam shell illustrated in FIGS. **13-14**) may be used in conjunction with inner mold **300**, as well as either outer mold **325** or outer mold **350**, to sandwich braided mesh **242** into the desired configuration. Each clam shell **375** approximates a hollow half-cylinder, generally corresponding to the shape of cylindrical portion **305** of inner mold **300**. Two clam shells **375** are each fitted over opposing sides of cylindrical portion **305** of inner mold **300**. Since each clam shell **375** approximates a hollow half cylinder, two clam shells **375** form an outer hollow cylinder that completely surrounds and sandwiches cylindrical portion **305** of inner mold **300**.

**[0058]** An embodiment of clam shell **375** that can be used with inner mold **300** may have height $H_7$ of between about 1-2 inches (25.4-50.8 mm) or approximately 1.5 inches, (38.1 mm). Clam shell **375** may have thickness $T_1$ of between about 0.075-0.175 inches (1.9-4.45 mm) or approximately 0.125 inches (3.175 mm). If clam shell **375** is used to form proximal basket **200**, it may have diameter $D_6$ of between about 0.760-1.01 inches (19.3-25.65 mm). If clam shell **375** is used to form distal basket **210**, it may have diameter $D_6$ of between about 0.799-1.049 inches (20.29-26.64 mm). As with inner mold **300**, clam shells **375** may be formed from a range of materials that withstand heating, are commonly available, are durable and have good heat transfer properties. For example, brass or similar materials can be used for clam shells **375**.

**[0059]** The clam shells **375** may be fitted onto cylindrical portion **305** of inner mold **300** before, after, or at the same time that either outer mold **235** (if forming proximal basket

200) or outer mold 350 (if forming distal basket 210) is fitted onto conical portion 310 of inner mold 300. Outer mold 325 or outer mold 350 may simply rest on top portions of clam shells 375, and need not attach to clam shells 375. As described above with reference to FIGS. 8 and 11-14, braided mesh 242 is fitted over inner mold 300 and surrounded on top by outer mold 325 (or outer mold 350) and surrounded on the sides by two clam shells 375. Once braided mesh 242 is sandwiched on all sides, it takes the shape of the molds applied. In this embodiment, the shape is a cylinder which is open on one side and which is conical on the other side.

[0060] When braided mesh 242 is a material that has shape memory, such as NITINOL, the sandwiched braid may be heated to set the desired shape. The assembly including inner mold 300, outer mold 325 (or outer mold 350), clam shells 375 and sandwiched mesh with struts 240 is heated. A thermocouple lead may be used near the mesh to determine temperature of the mesh. The mesh is heated to between about 475°-575° C., or approximately 530° C., to set the shape of the mesh. For different mesh materials, and even for different compositions of NITINOL, different temperatures may be required for heat setting. Once set, the assembly is cooled, for example in an ambient water bath. Once cooled, clam shells 375 and outer mold 325 (or outer mold 350) may be removed. The mesh may be taken off inner mold 300, with the end product being proximal basket 200 (if outer mold 325 was used) or distal basket 210 (if outer mold 350 was used). Any excess mesh or struts 240 may be trimmed.

[0061] All provided dimensions, temperatures, angles, and materials are merely illustrative and are in no way meant to limit the scope of the disclosure. For example larger or smaller inner molds 300, outer molds 325, 350 and clam shells 375 may be used for larger or smaller baskets to be used in larger or smaller vessels in the body.

[0062] Although the disclosure herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present disclosure. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present disclosure.

1. A method of providing embolic protection to a patient comprising the steps of:

delivering a sheath into a first blood vessel of the patient, the sheath housing a first filter in a collapsed condition and a second filter in a collapsed condition;

deploying the first filter in the first blood vessel using a first guide member to transition the first filter to an expanded condition so that blood flows into an open end of the first filter;

deploying the second filter in a second blood vessel using a second guide member to transition the second filter to an uncinched expanded condition so that blood flows into an open end of the second filter;

cinching the open end of the second filter with a cinch wire attached to the open end of the second filter to transition the second filter into a cinched expanded condition in which the open end of the second filter has a reduced diameter compared to the uncinched expanded condition; and

retracting the second guide member to pull the second filter in the cinched expanded condition at least partially into the first filter in the expanded condition.

2. The method of claim 1, further comprising:

retracting the first filter into the sheath while the second filter is at least partially within the first filter.

3. The method of claim 2, further comprising:

removing the first filter from the patient, wherein the second filter remains at least partially within the first filter during the removal of the first filter from the patient.

4. The method of claim 1, wherein during delivery of the sheath, the second filter is at least partially within the first filter.

5. The method of claim 1, wherein the first filter and the second filter each include a mesh structure.

6. The method of claim 1, wherein the second filter includes a plurality of struts having free ends extending beyond the open end of the second filter.

7. The method of claim 6, wherein cinching the open end of the second filter causes the free ends of the plurality of struts of the second filter to draw closer to one another in the cinched expanded condition of the second filter.

8. The method of claim 7, wherein during the step of retracting the second guide member, the free ends of the plurality of struts of the second filter guide the second filter into the first filter.

9. The method of claim 6, wherein the plurality of struts of the second filter maintain the open end of the second filter in a cylindrical shape in the expanded condition of the second filter.

10. The method of claim 9, wherein the first filter includes a plurality of struts with free ends extending beyond the open end of the first filter.

11. The method of claim 10, wherein as the second filter is retracted into the first filter, the free ends of the plurality of struts of the first filter are positioned radially outward of the second filter.

12. The method of claim 1, wherein deploying the second filter includes translating the second guide member with respect to the first filter.

13. The method of claim 12, wherein the second guide member extends through the first filter.

14. The method of claim 1, wherein cinching the open end of the second filter includes pulling the cinch wire through the sheath.

15. The method of claim 14, wherein the cinch wire extends through the first filter.

16. The method of claim 14, wherein, upon pulling the cinch wire, the second filter remains in substantially the same translational position with respect to the first filter.

17. The method of claim 14, wherein the second filter has a conical portion adjacent the open end of the second filter.

18. The method of claim 17, wherein, as the cinch wire is pulled to transition the second filter from the uncinched expanded condition to the cinched expanded condition, the conical portion of the second filter retains substantially the same shape.

19. The method of claim 1, wherein the reduced diameter of the open end of the second filter inhibits emboli trapped within the second filter from exiting the second filter in the cinched expanded condition of the second filter.

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