US 20250262041A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2025/0262041 A1**

(43) **Pub. Date: Aug. 21, 2025**

Navia et al.

(54) **STROKE PREVENTION DEVICES, SYSTEMS, AND METHODS**

(71) Applicant: **3DT Holdings, LLC**, San Diego, CA (US)

(72) Inventors: **Jose A. Navia**, Buenos Aires (AR); **Ghassan S. Kassab**, La Jolla, CA (US); **Ane Beatriz Eguzkitza Bazar**, Barcelona (ES)

(73) Assignee: **3DT Holdings, LLC**, San Diego, CA (US)

(21) Appl. No.: **19/192,243**

(22) Filed: **Apr. 28, 2025**

Related U.S. Application Data

(63) Continuation-in-part of application No. PCT/US23/36060, filed on Oct. 26, 2023.

(60) Provisional application No. 63/419,653, filed on Oct. 26, 2022.

Publication Classification

(51) **Int. Cl.**

A61F 2/01 (2006.01)

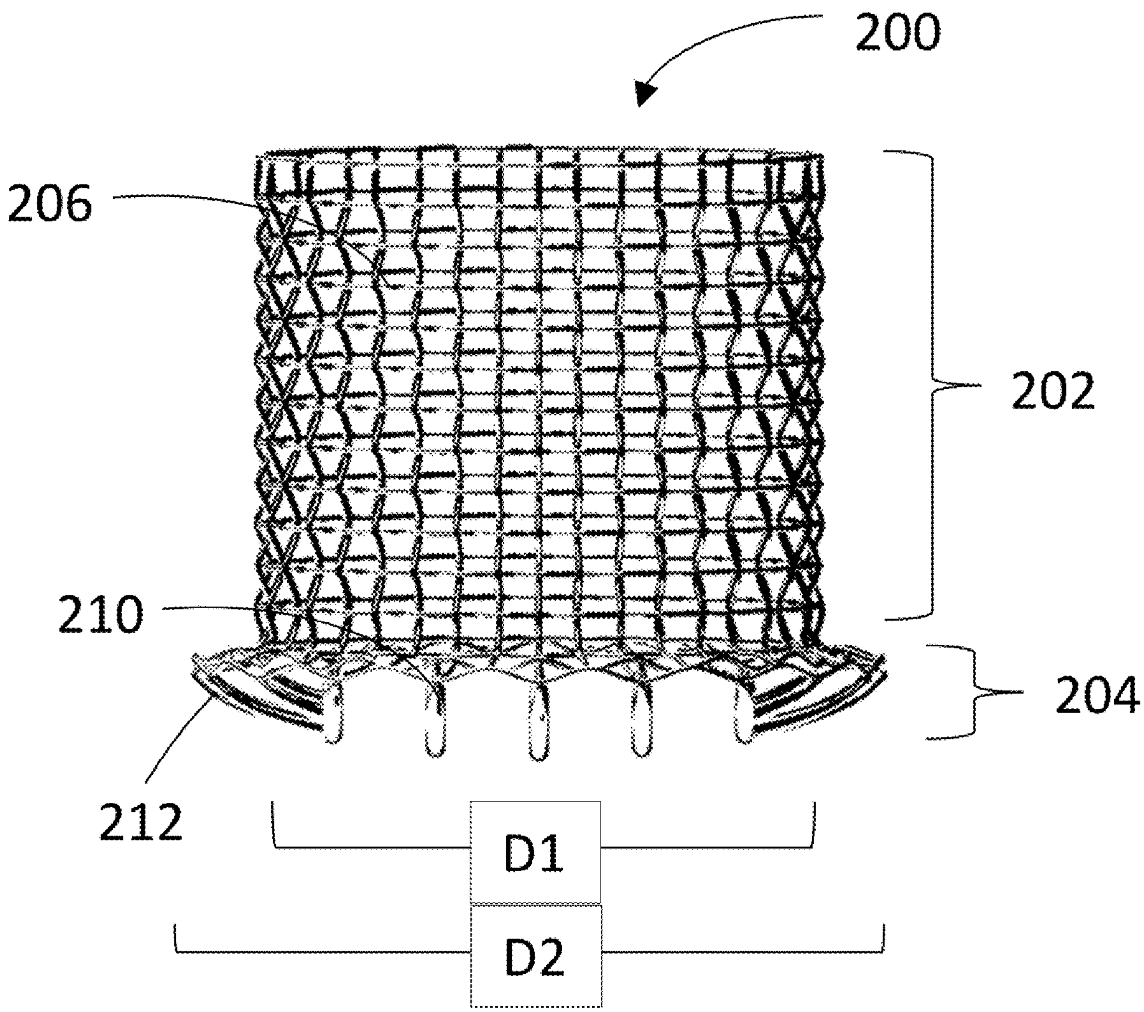
A61F 2/90 (2013.01)

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

CPC ***A61F 2/0103*** (2020.05); ***A61F 2/0105*** (2020.05); ***A61F 2/011*** (2020.05); ***A61F 2/90*** (2013.01); *A61F 2002/016* (2013.01); *A61F 2210/0076* (2013.01); *A61F 2250/0039* (2013.01); *A61F 2250/006* (2013.01); *A61F 2250/0098* (2013.01)

(57) **ABSTRACT**

Deflection devices, systems, and methods for the prevention of stroke configured and negatively charged to filter emboli in the bloodstream and prevent advancement into the artery extending from the aortic arch. Devices may be formed as a single structure or a composite device. Additionally, a retrieval system is provided, including a sleeve catheter and a retrieval device slidably disposed therein, the retrieval device including one or more attachment portions configured to engage at least a portion of a device positioned within an artery extending from the aortic arch.



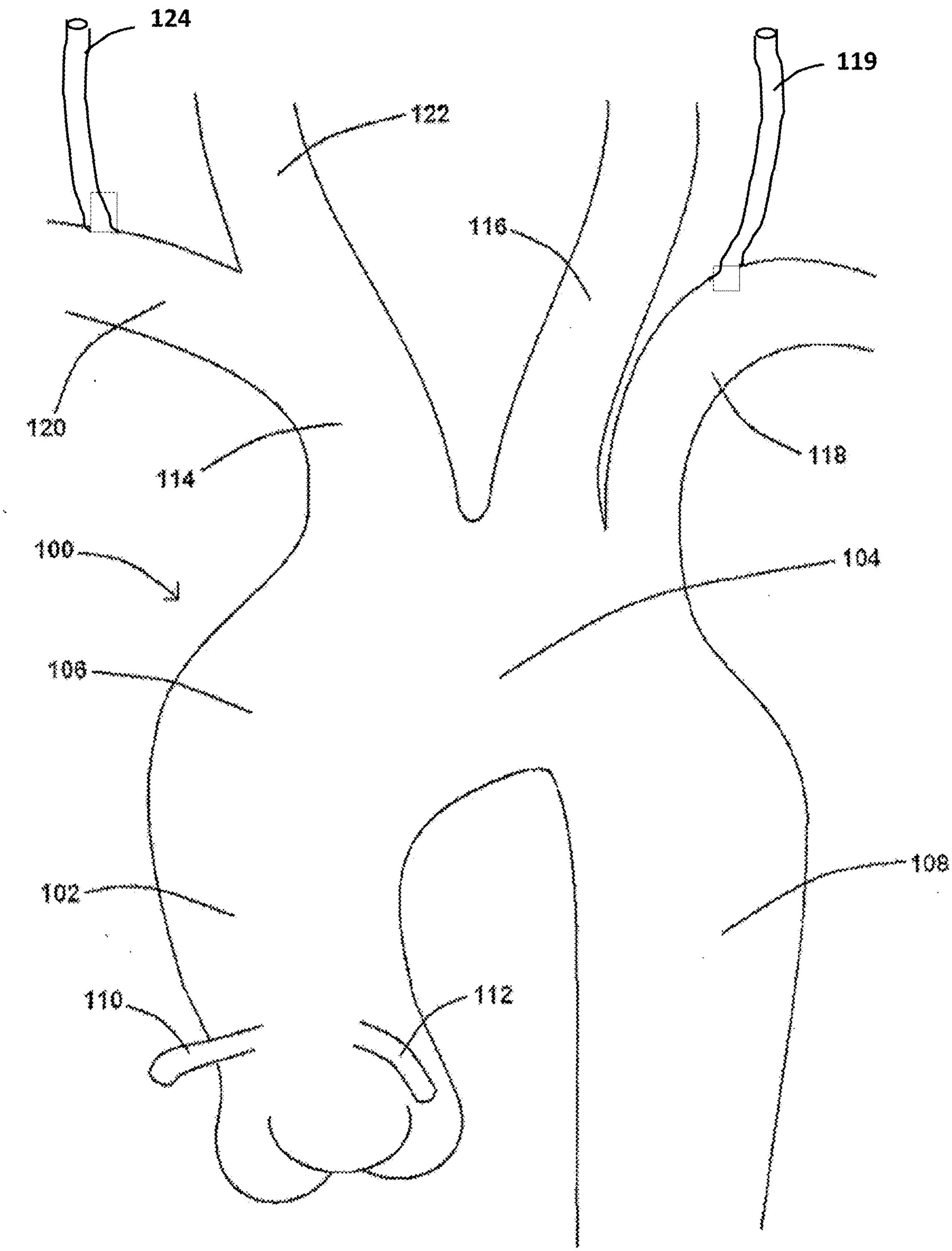


FIG. 1

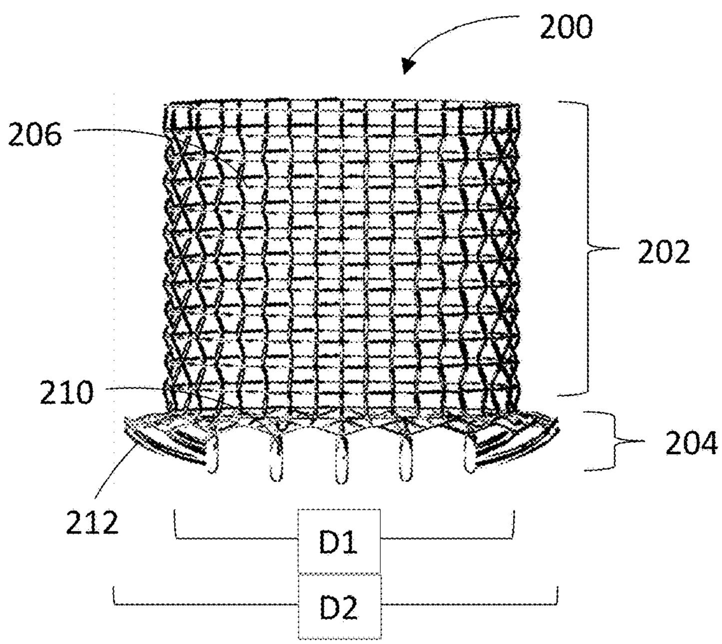


FIG. 2A

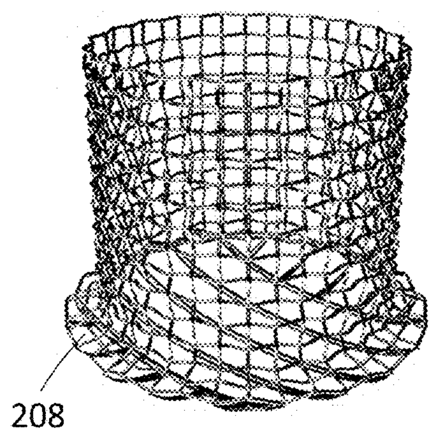


FIG. 2B

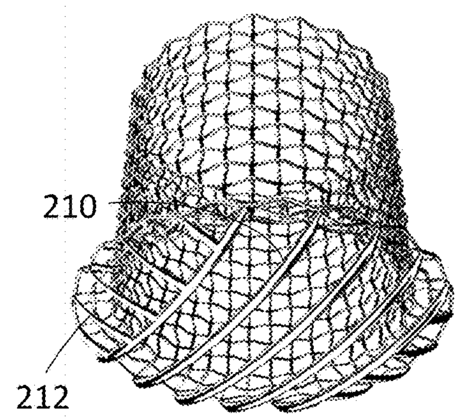


FIG. 2C

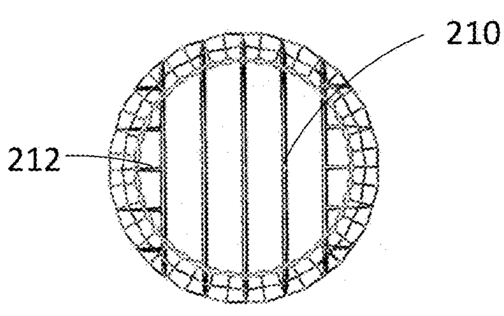


FIG. 2D

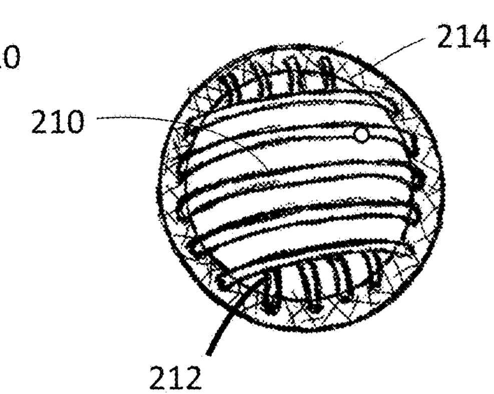


FIG. 2E

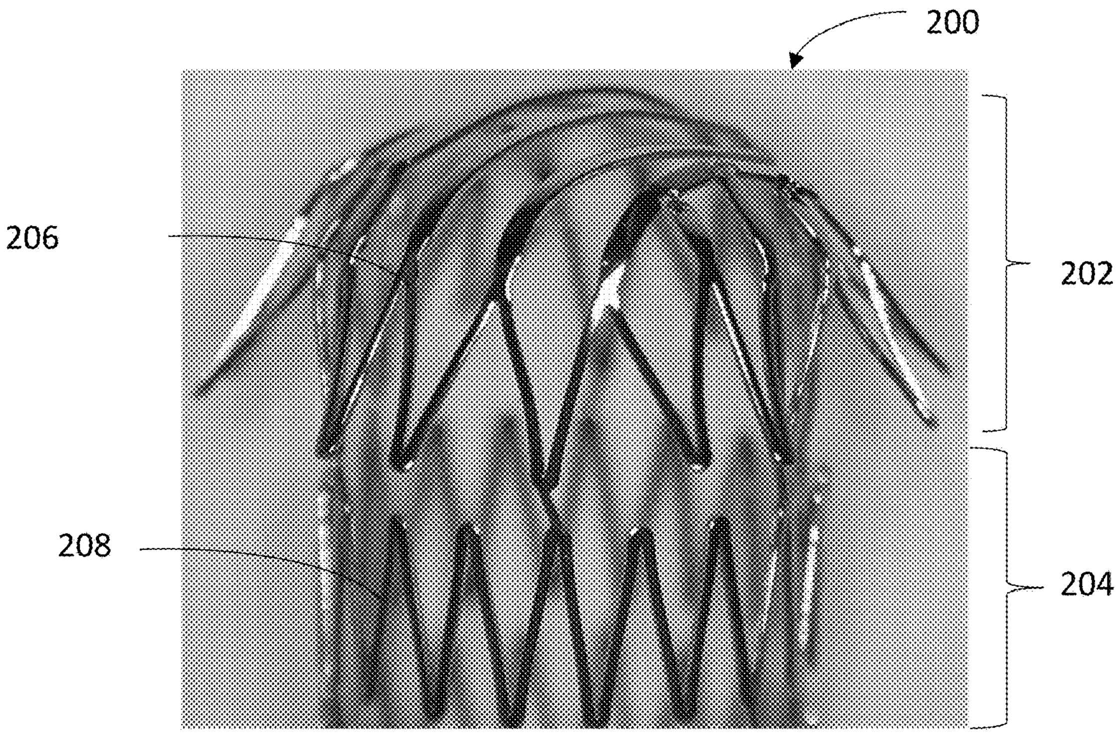


FIG. 2F

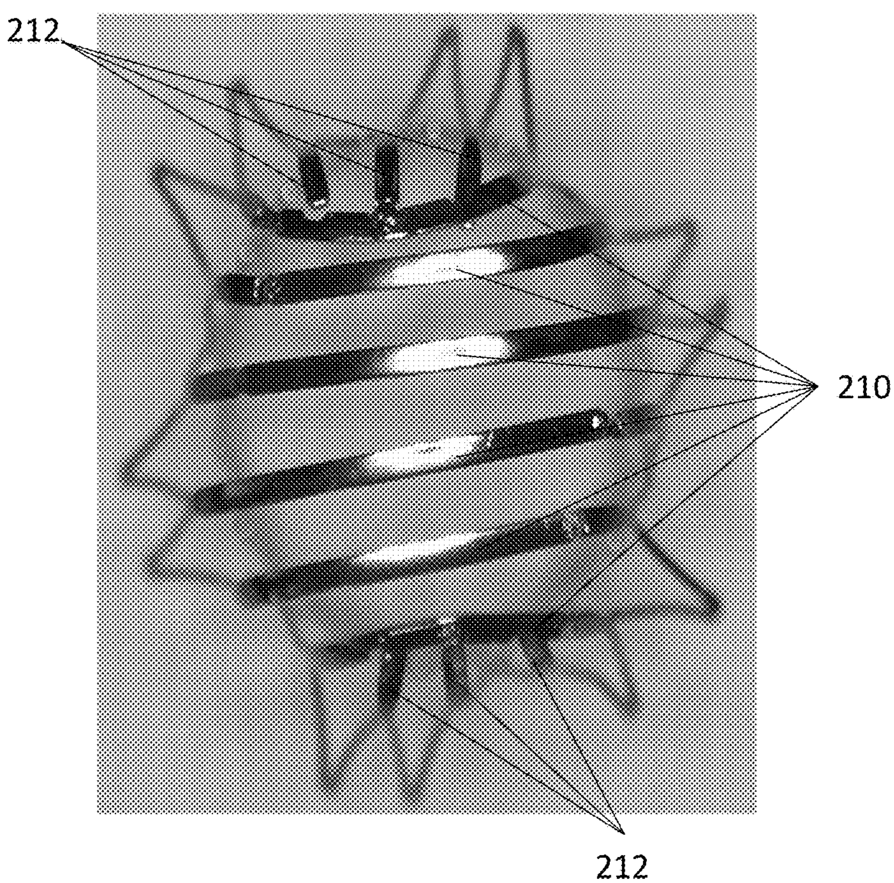


FIG. 2G

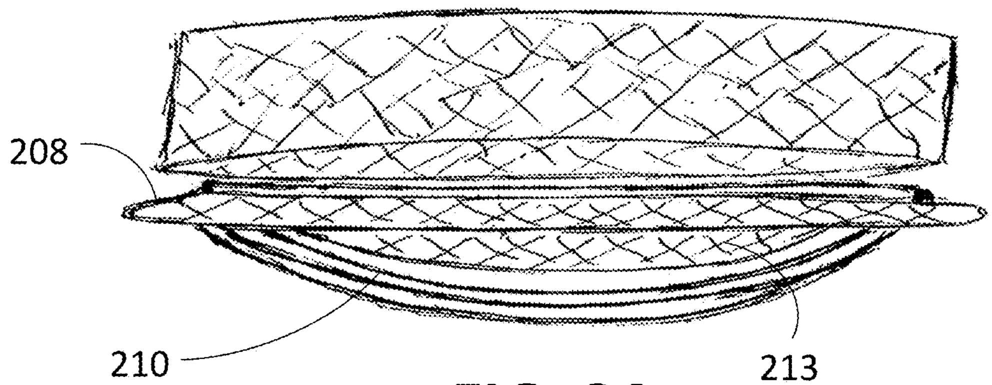


FIG. 3A

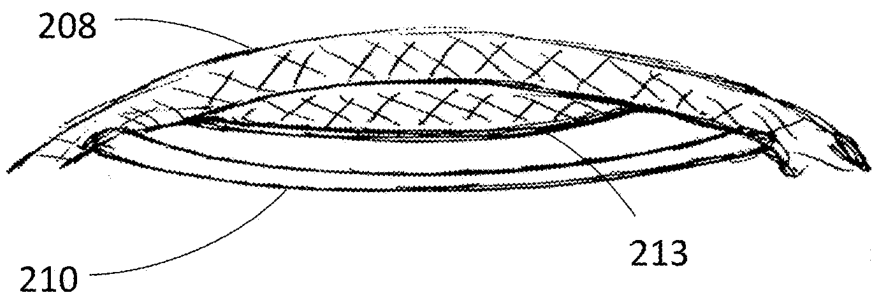


FIG. 3B

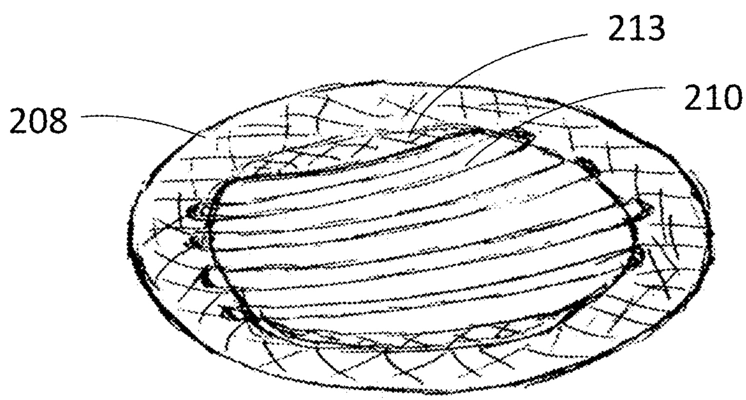


FIG. 3C

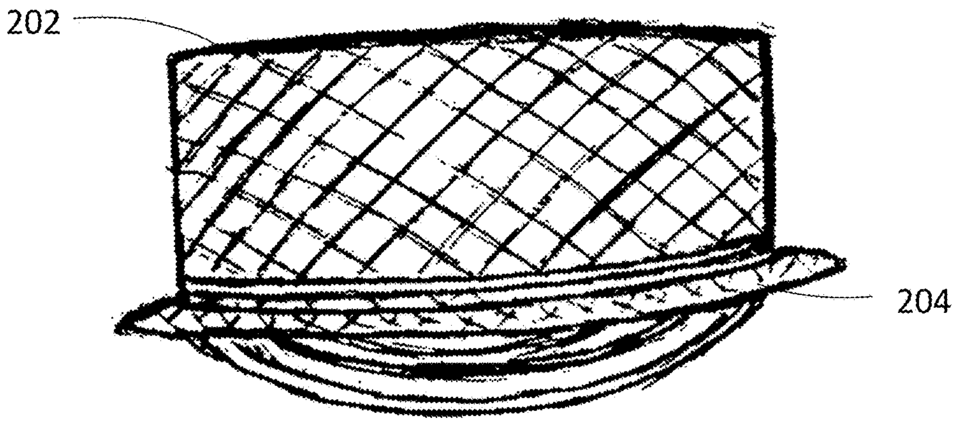


FIG. 4A

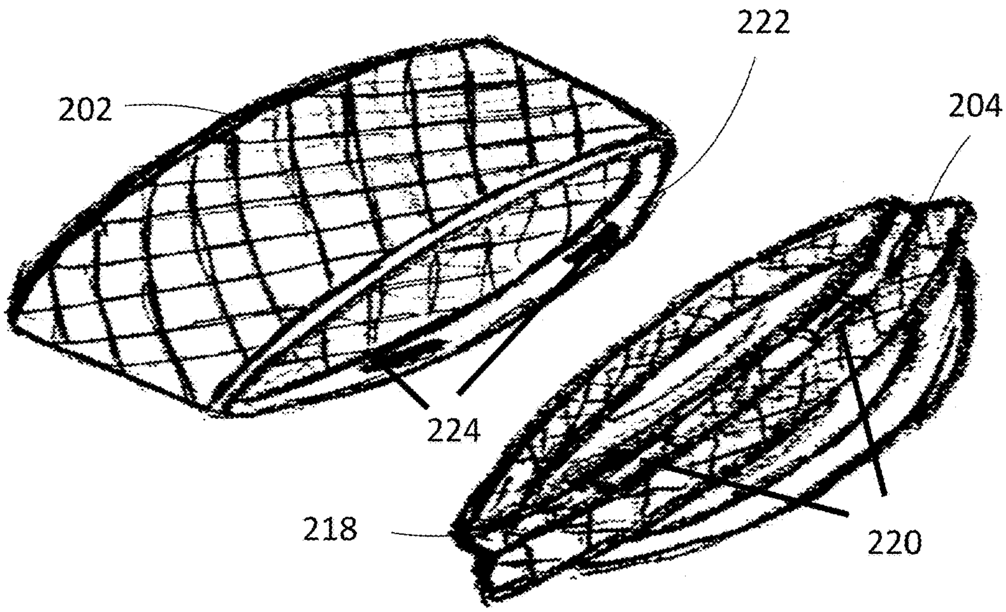


FIG. 4B

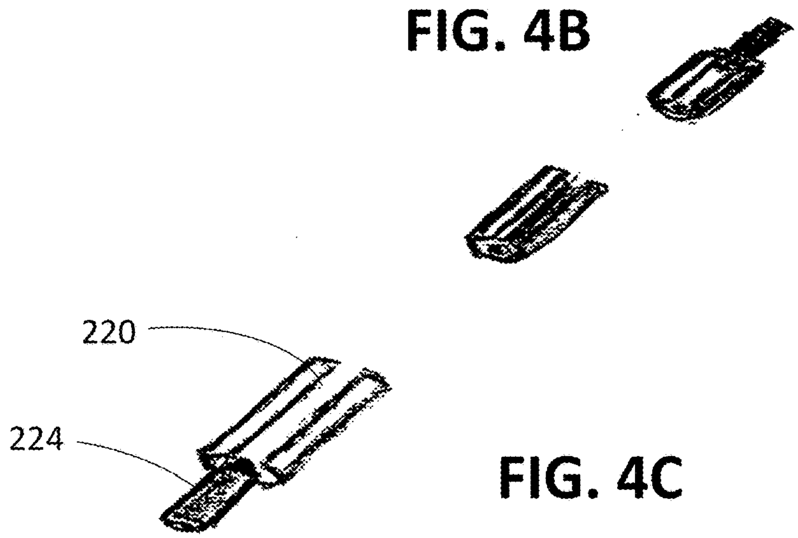


FIG. 4C

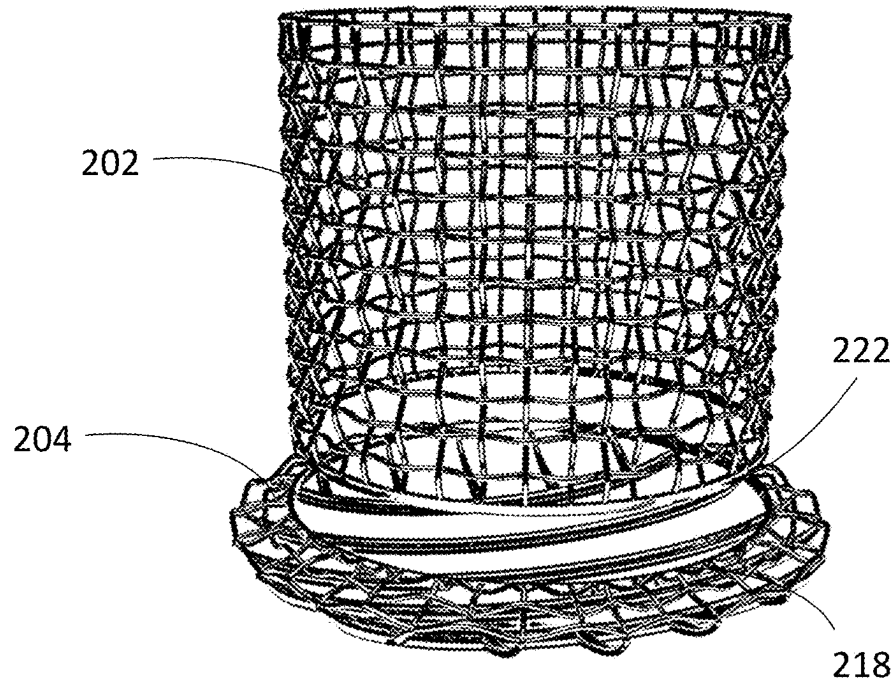


FIG. 5A

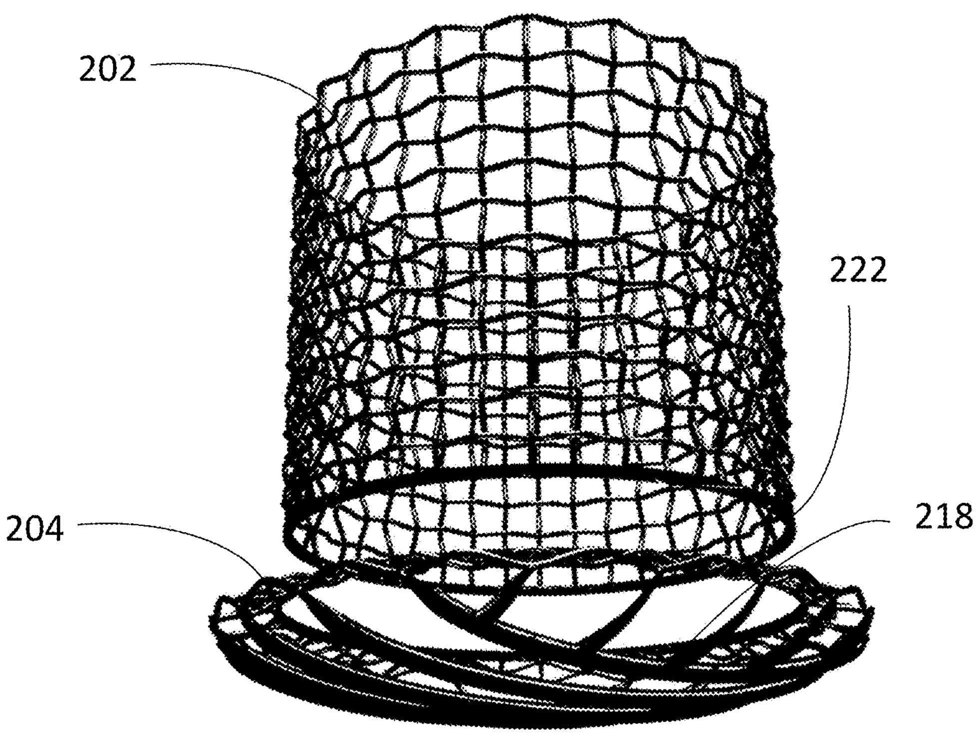


FIG. 5B

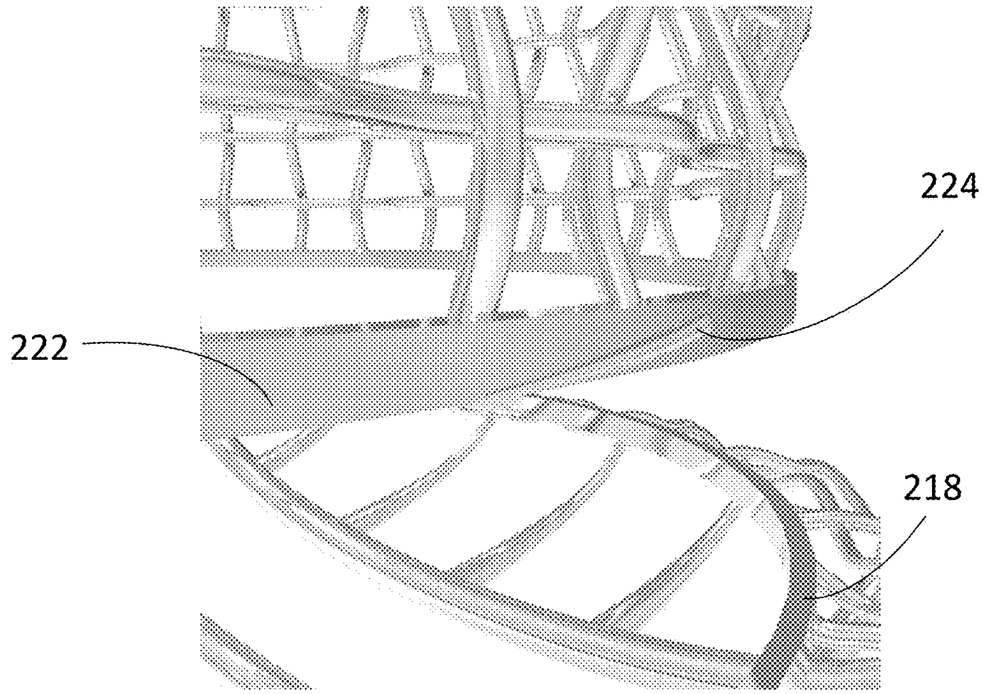


FIG. 5C

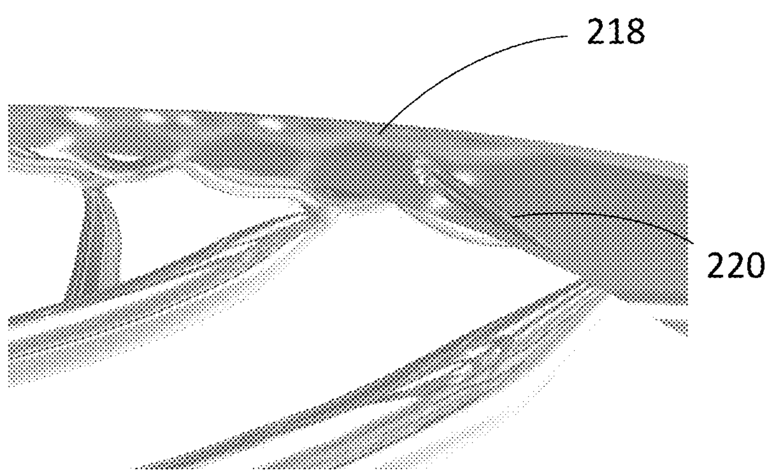


FIG. 5D

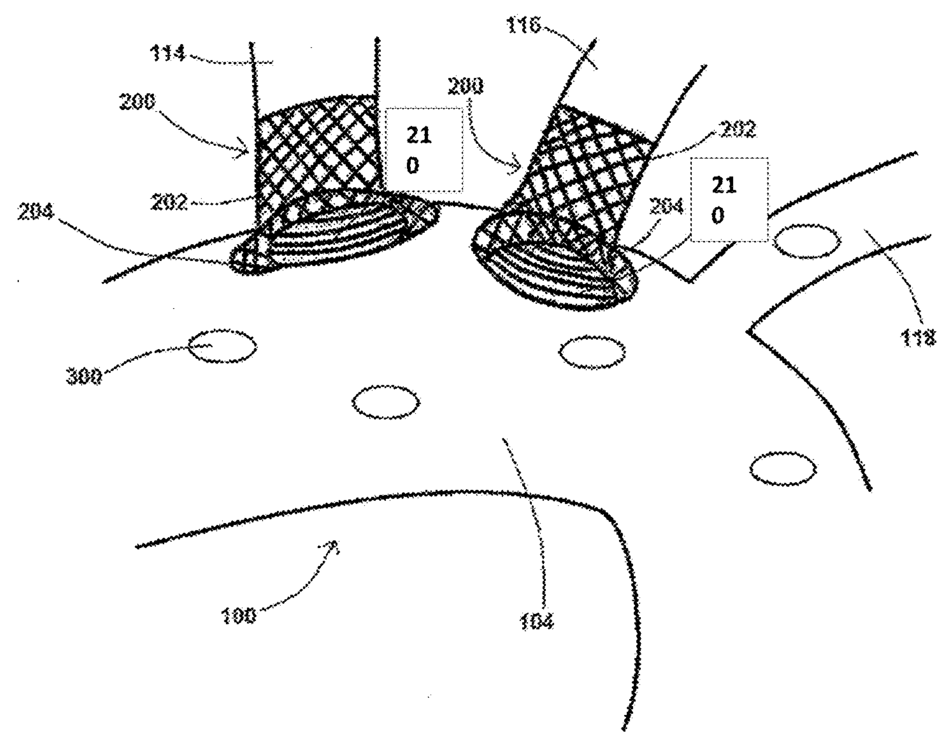

114
116
200
200
21
0
202
202
204
204
21
0
300
118
100
104

FIG. 6A

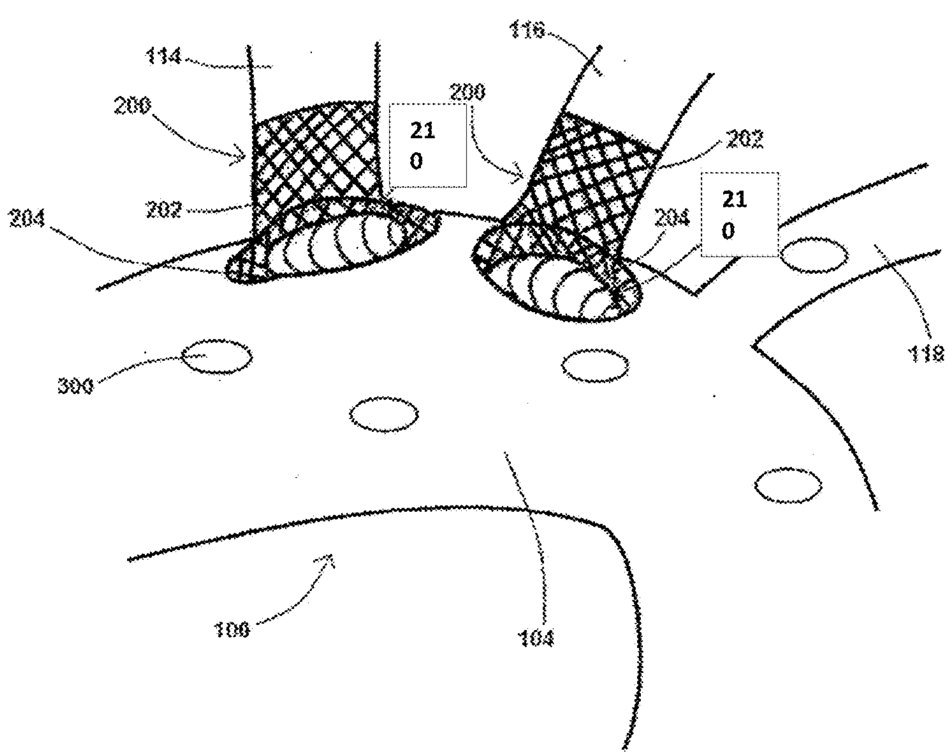

114
116
200
200
21
0
202
202
204
204
21
0
300
118
100
104

FIG. 6B

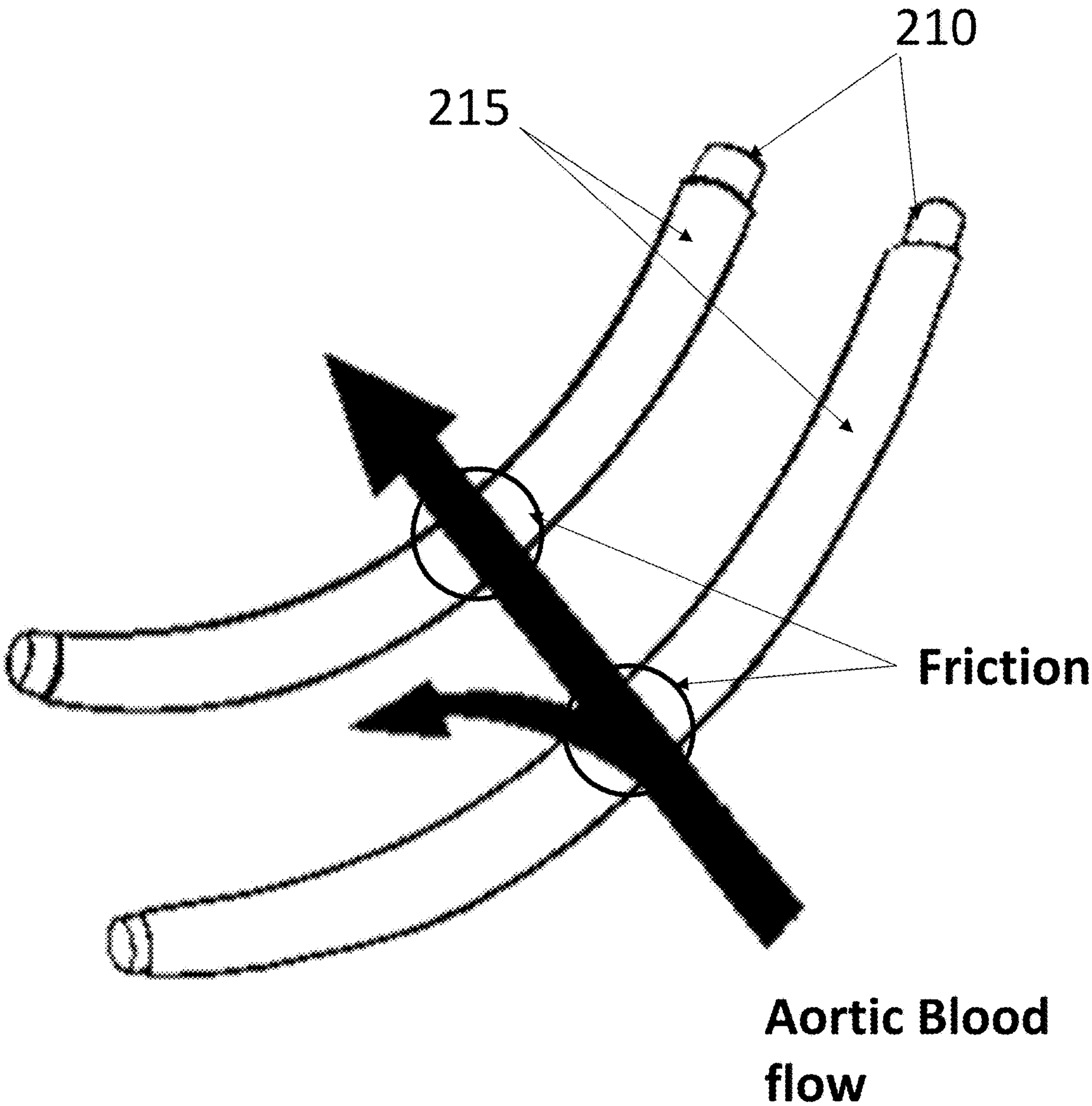


FIG. 6C

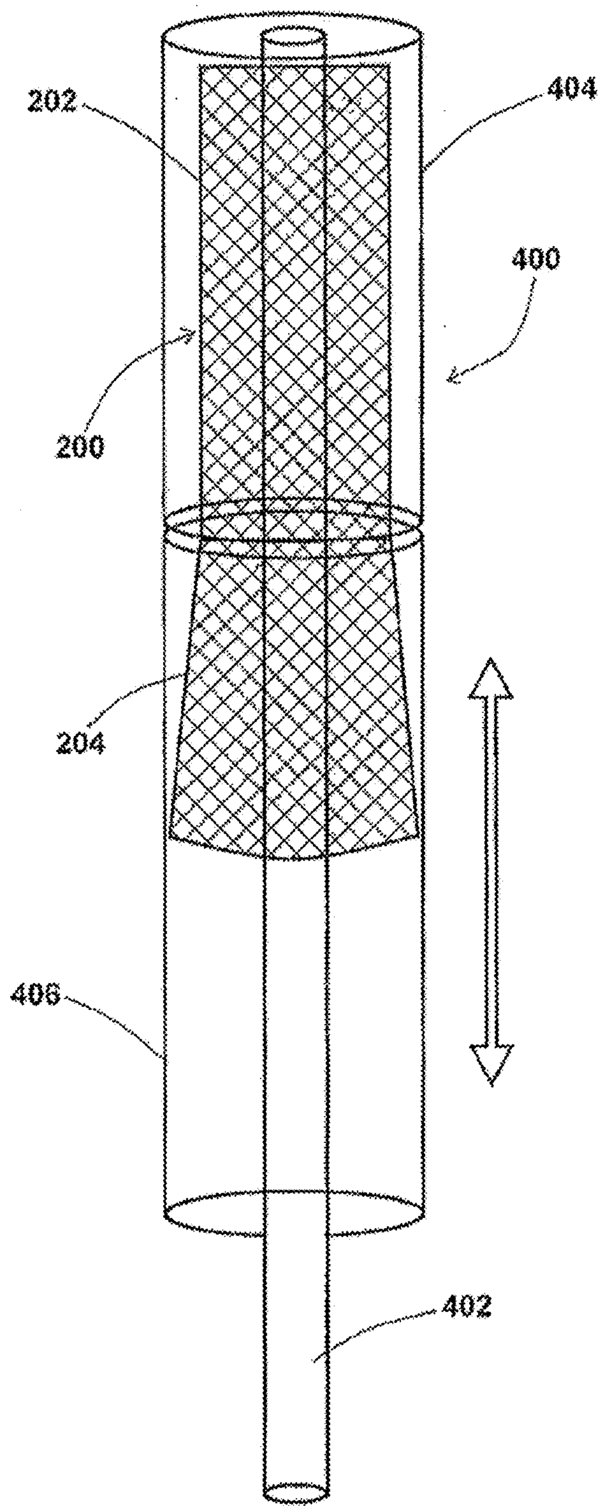


FIG. 7

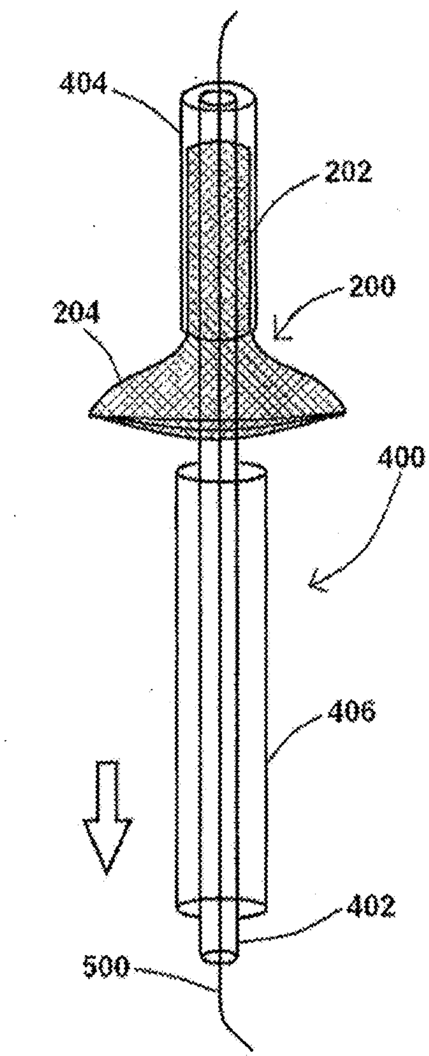


FIG. 8A

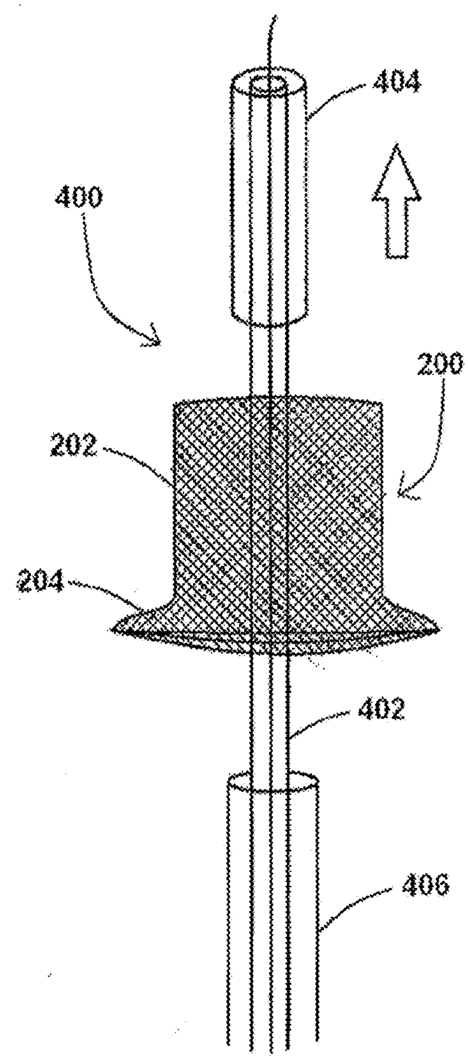


FIG. 8B

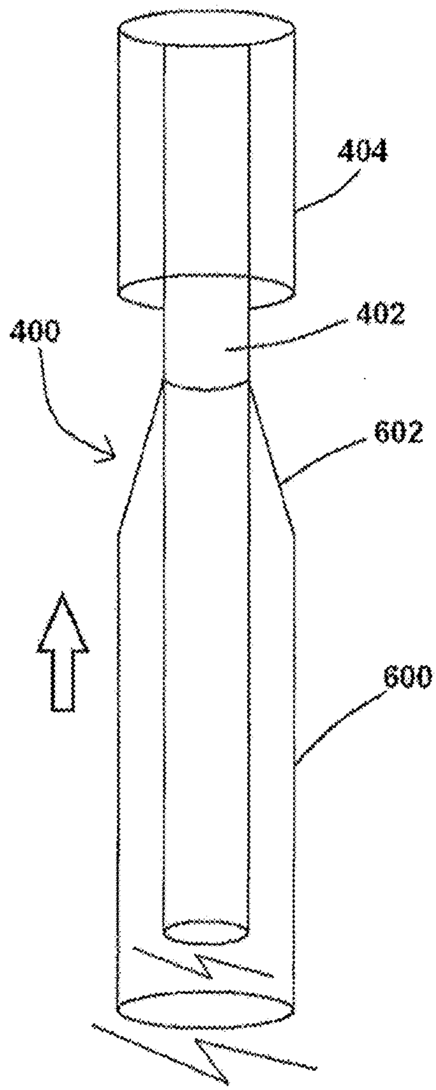


FIG. 9A

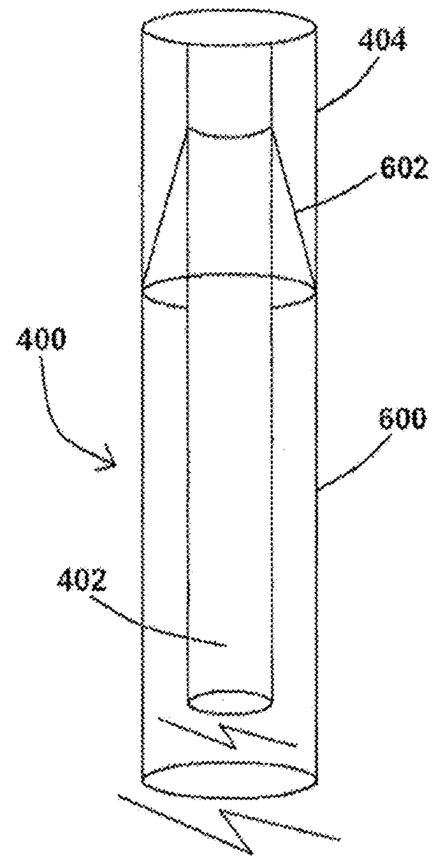


FIG. 9B

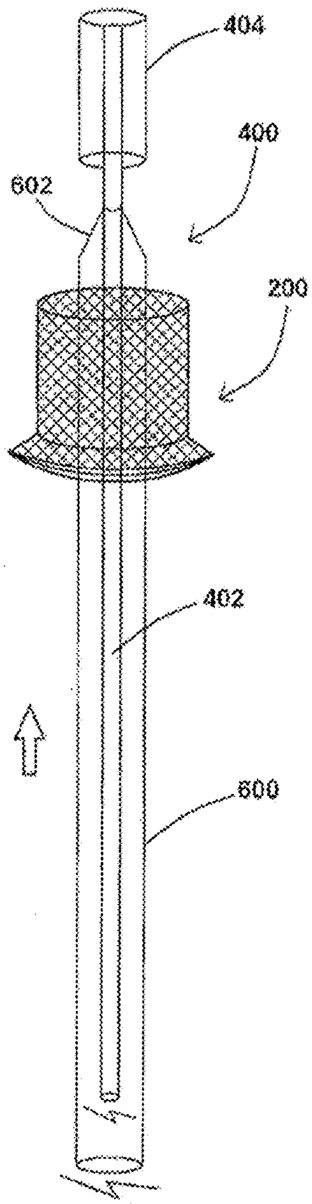


FIG. 9C

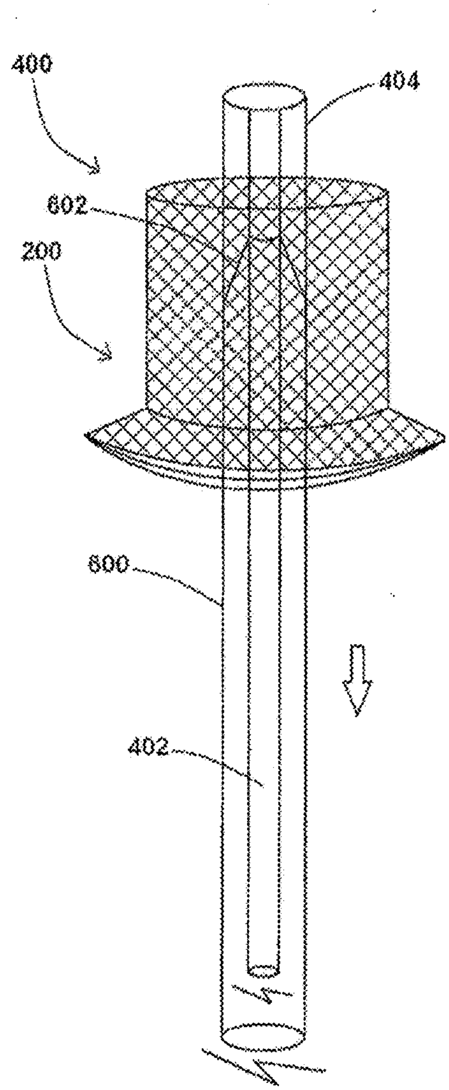


FIG. 9D

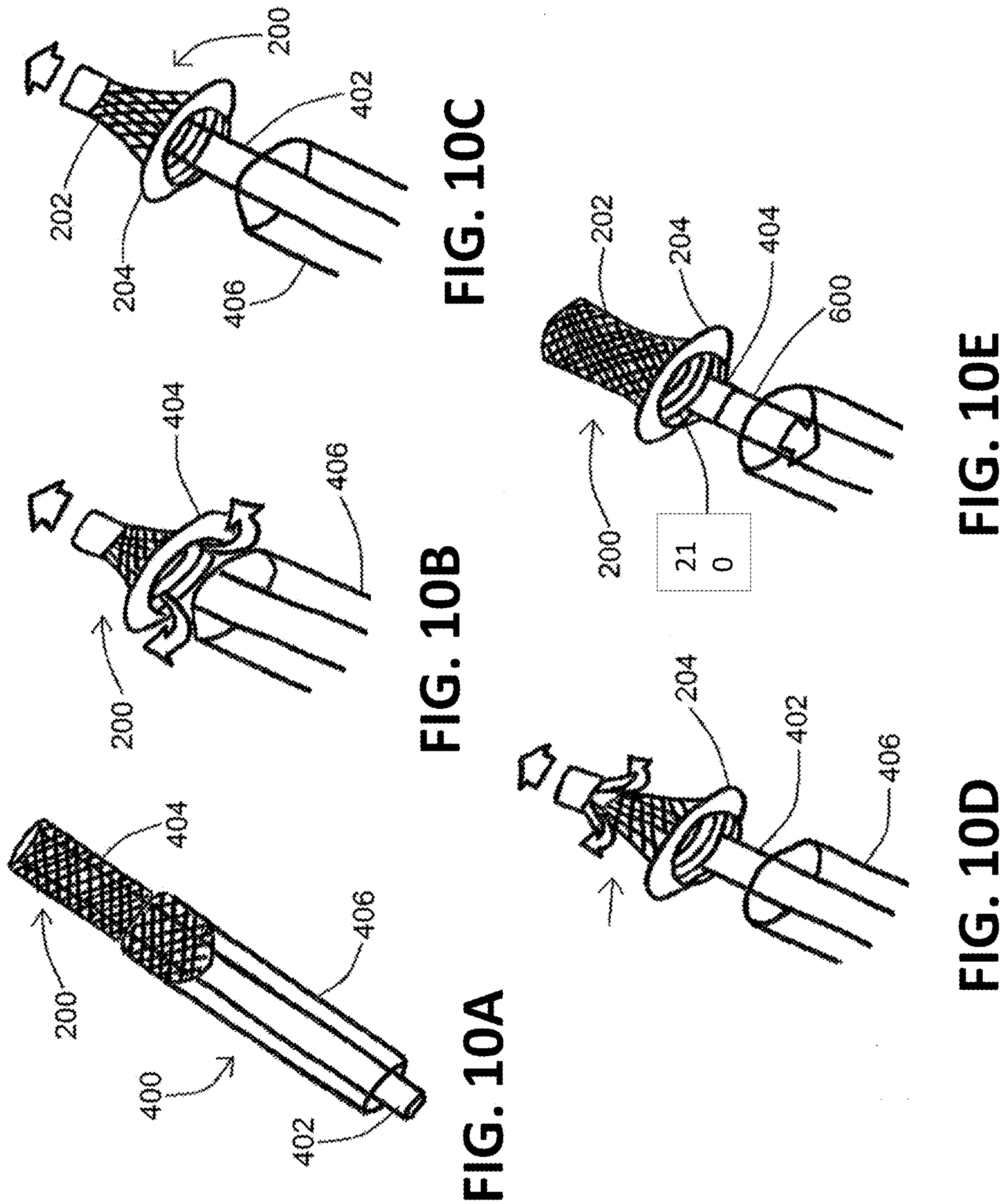


FIG. 10A

FIG. 10B

FIG. 10C

FIG. 10D

FIG. 10E

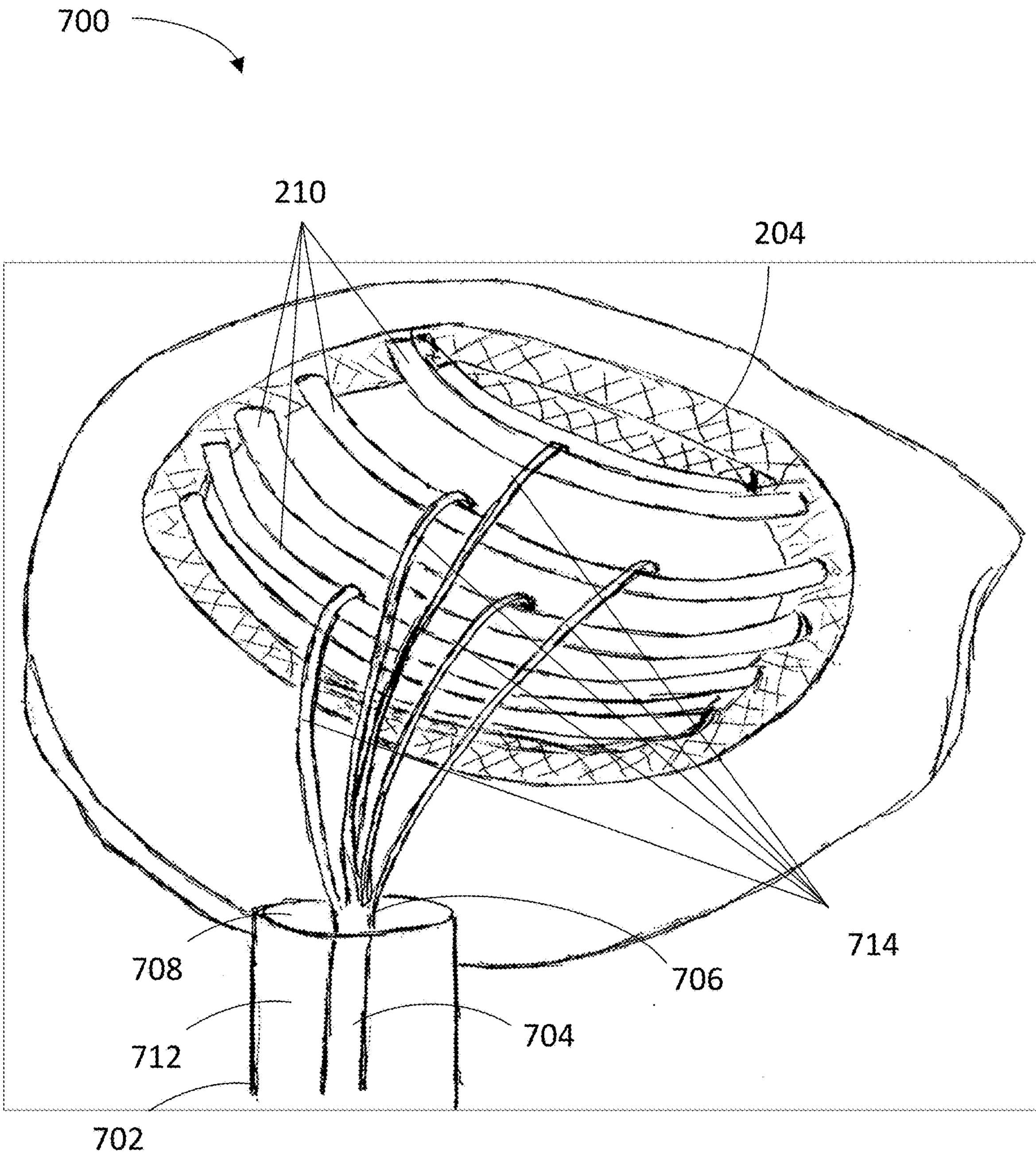


FIG. 11

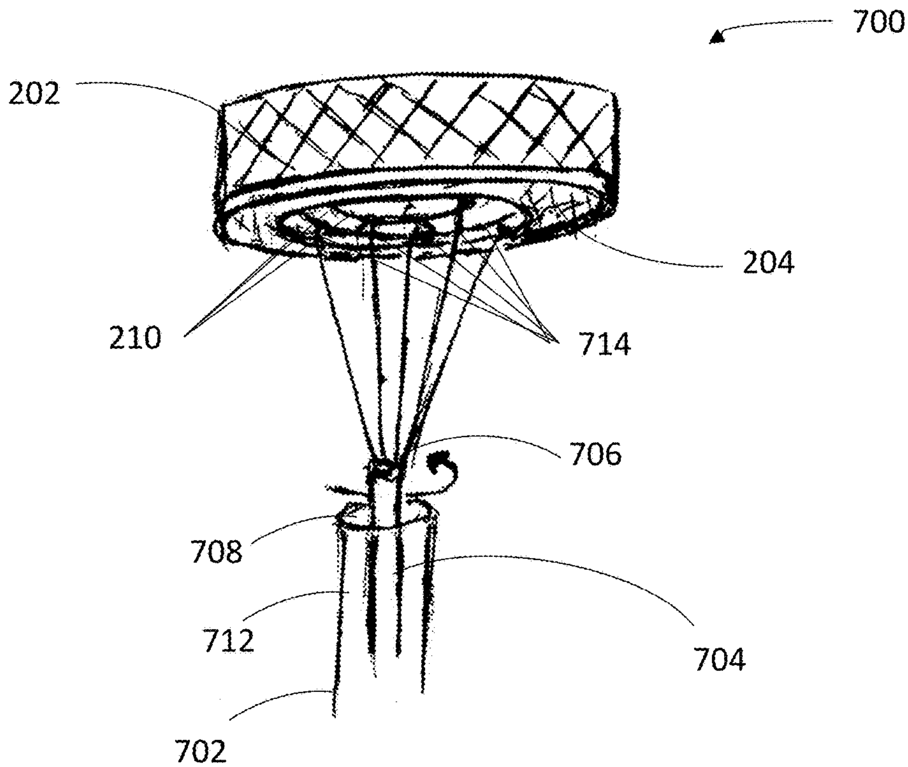


FIG. 12A

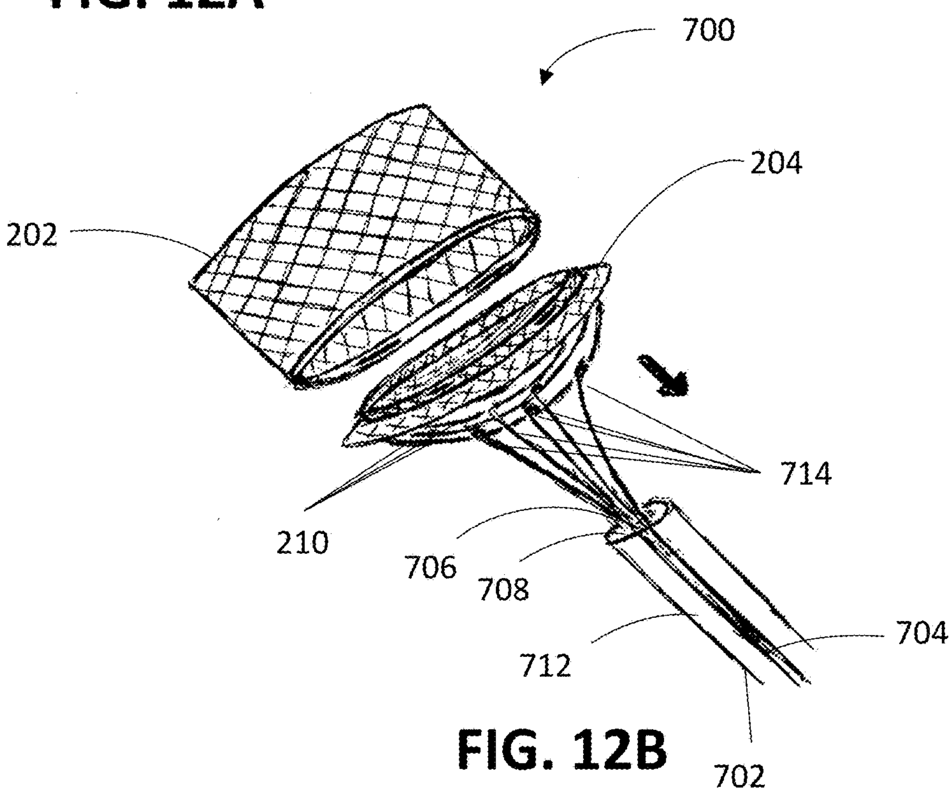


FIG. 12B

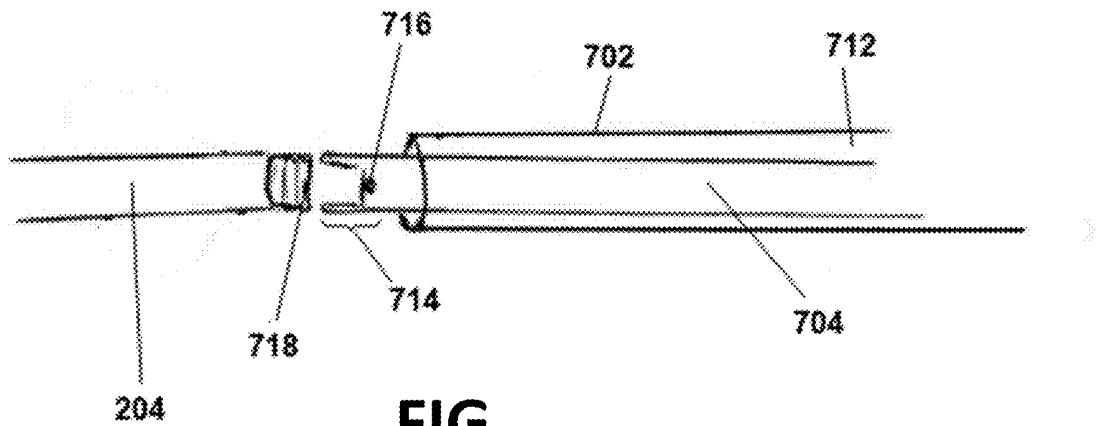


FIG. 13A

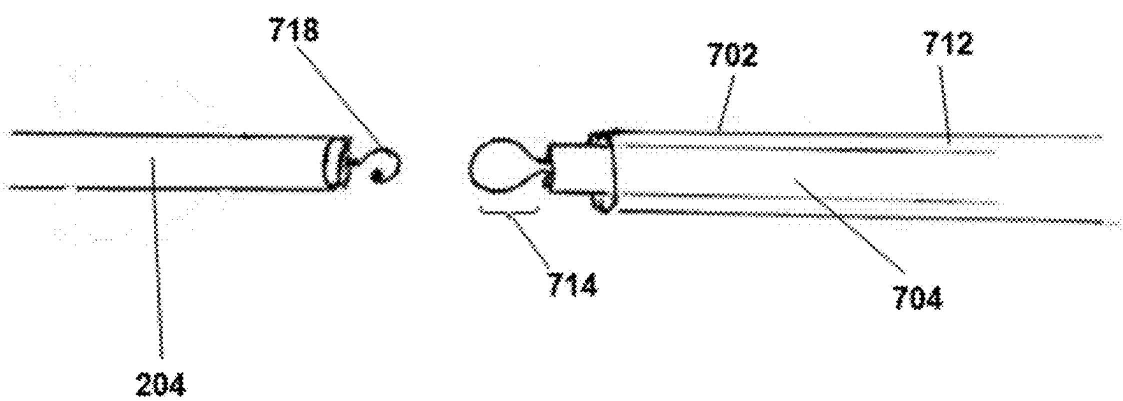


FIG. 13B

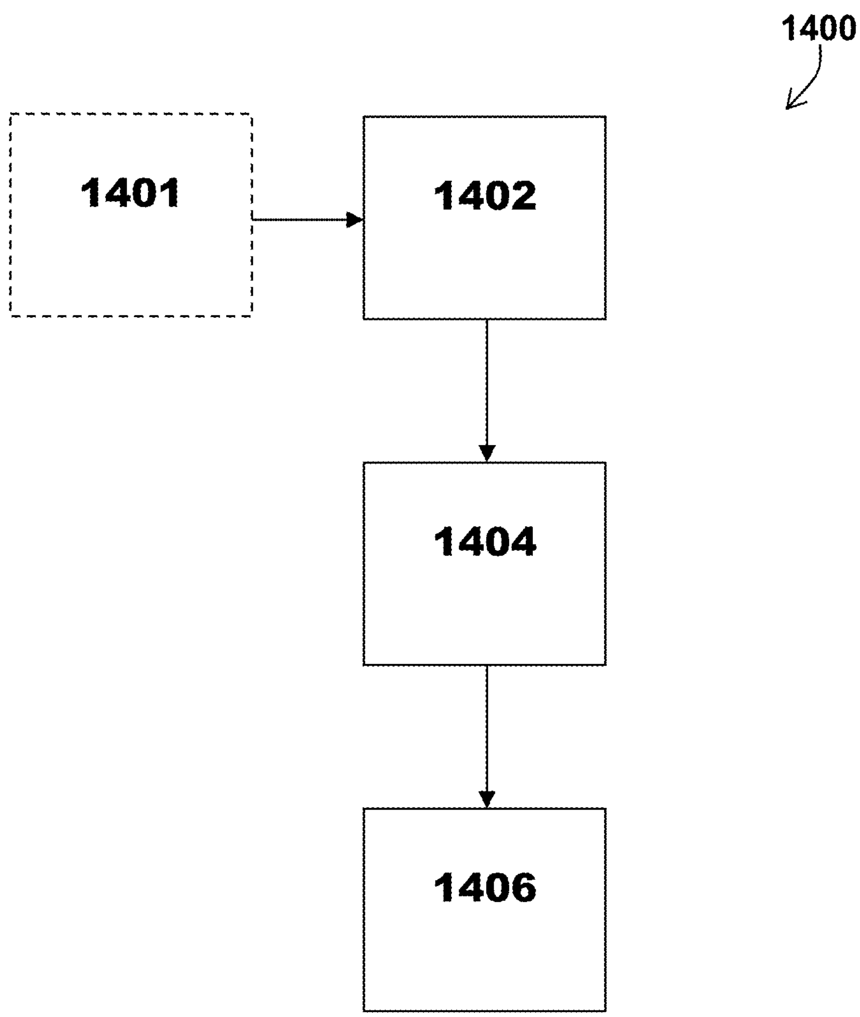


FIG. 14

STROKE PREVENTION DEVICES, SYSTEMS, AND METHODS

PRIORITY

[0001] The present patent application is related to, and claims the priority benefit of, International Application No. PCT/US23/36060, filed on Oct. 26, 2023, which is related to, and claims the priority benefit of, U.S. Provisional Patent Application Ser. No. 63/419,653, filed on Oct. 26, 2022, the contents of which are hereby incorporated by reference in their entirety into this disclosure.

BACKGROUND

[0002] A stroke is defined as a rapidly developing loss of brain function due to a disturbance in the blood supply to the brain. This can be due to ischemia (lack of blood supply) caused by thrombosis or embolism or due to a hemorrhage. As a result, the affected area of the brain is unable to function, leading to the inability to move one or more limbs on one side of the body, the inability to understand or formulate speech, or the inability to see one side of the visual field amongst others.

[0003] Stroke is ranked as the second leading cause of death worldwide, with an annual mortality rate of about 5.5 million people. For those who survive, it causes chronical disability in up to 50% of them. Stroke affects the elderly the most, resulting in a growing problem given the progressive ageing of the global population, with the proportion of individuals aged ≥85 years being expected to increase threefold worldwide by the year 2035.

[0004] Atrial Fibrillation (AF), a heart condition that causes an irregular and often abnormally fast heart rate with a significant reduction in the cardiac output, is known to cause an increase in embolus propensity, and is associated with a six-fold increase in risk of stroke. It represents the most common arrhythmia diagnosed in clinical practice and its prevalence rises steadily from 0.4-1% among the general population to 8% by 80 years of age. Moreover, stroke risk from AF increases exponentially with age, with an estimated 1.45-fold increase for each subsequent decade, reaching an annual risk as high as 23.5% in patients with AF aged 80 to 90 years. Compared with non-AF-related strokes, AF-related strokes are almost twice as likely to be fatal and to cause severe disability in survivors, increasing the length of hospital stay and reducing the likelihood of patients returning to their home, with associated significantly higher mean direct costs per patient.

[0005] Ischemic strokes account for 80% of stroke cases while hemorrhagic strokes account for the remaining 20%. Among ischemic strokes, 20% to 30% are cardioembolic. Cardioembolisms may result from three mechanisms: thrombus formation in the left cardiac chamber, release of material from an abnormal valvular surface, or abnormal passage from the venous to the arterial circulation (ie: paradoxical embolism). Echocardiographic and pathologic studies suggest that approximately 90% of strokes with an identified source, can be attributed to thrombus formation in the left atrial appendage.

[0006] The mechanism of formation in turn determines the nature and size of cardioembolisms, which are found in a heterogeneous range of types and sizes. The most frequent type of debris in the former corresponds to fibrin and thrombotic material, representing 74%, with tissue-derived material and calcium deposits in lower proportion. Embolisms may have a range of sizes, but those of arising from the cardiac chambers are often large and hence especially likely to cause severe stroke, disability and death. The more common high risk cardioembolic conditions are atrial fibrillation, recent myocardial infarction, mechanical prosthetic valve, dilated myocardiopathy, mitral rheumatic stenosis, and more recently, Transcatheter Aortic Valve Replacement (TAVR).

[0007] TAVR has emerged as an alternative, rapidly evolving non-invasive procedure for patients with severe aortic stenosis and medium-to-high surgical risk. By 2025, there will be an estimated 280,000 TAVR procedures performed worldwide. Although this highly promising treatment modality results in less morbidity, shorter time to recovery and similar mortality rates, it is still associated with one of the most devastating and feared complications: cerebral embolism, which in turn may cause stroke. Stroke is associated with a 6-fold increase in mortality in TAVR cohorts, a moderate to severe permanent disability in up to 40% of survivors, a 4.7-fold increased risk of permanent work disability, social isolation and significant financial strain in 80% of stroke survivors, and an increased risk of readmission in patients with stroke after cardiac catheterization.

[0008] The time in between the TAVR procedure and the cardioembolic event is an important factor when choosing stroke prevention treatments. Most of them occur in the acute phase following TAVR where cerebral embolic events are frequent. Nonetheless, a significant number of strokes occur between days 2 and 30 post-TAVR, and evidence is mounting on ischemic brain lesions being produced after day 30, with long-term neurological symptoms. Early stroke is mainly due to debris embolization during the procedure, whereas later events are associated with patient specific factors. In a 5-year retrospective cohort study involving 101,430 patients receiving TAVRs in the US, the median time to stroke events was 2.0 days (IQR, 1.0-5.0) days post-TAVR. Of all patients with 30-day stroke events, 1119 patients (48.9%) had a stroke within 1 day and 1567 (68.4%) within 3 days. Of all those with strokes, 2096 patients (91.5%) had ischemic strokes and 128 (5.6%) had hemorrhagic strokes. In the ADVANCE trial, within the first months after TAVR using the CoreValve™, half of the reported strokes occurred on the day of the procedure or the first post-procedural day, and the other half between day 2 and day 30.

[0009] Regarding the size of debris, a wide range was identified during TAVR in 86% of patients. The median size of debris was 1 mm (IQR: 0.6 to 1.5 mm) and varied between 0.1 and 9 mm. Fibrin and thrombotic material (size varied between 0.2 and 6.2 mm) was found in 74% of patients. More recently, it has been suggested that microembolisms released after the TAVR periprocedural period may be causing Silent Brain Infarcts (SBIs), finding new ischemic brain lesions in TAVR patients in 74% to 100% of patients on diffusion-weighted magnetic resonance imaging (DW-MRI).

[0010] SBI is increasingly recognized in patients with cardiac conditions, particularly AF in elderly patients and those undergoing Transcatheter Aortic Valve Implantation (TAVI). While these infarcts often go unnoticed due to a lack of acute symptoms, they are associated with a threefold increase in stroke risk and are considered a precursor to ischemic stroke. Moreover, accumulating evidence suggests that SBI may contribute to the development of dementia, depression, and cognitive decline, particularly in the elderly population. The burden of SBI is substantial, with studies showing that up to 11 million Americans may experience a silent stroke annually. In AF patients, SBIs are common and can lead to progressive brain damage, even in those receiving anticoagulation therapy. Even though microembolisms may not produce a large proportion of symptomatic strokes, the situation is especially worrying given that TAVRs are being implanted in increasingly younger and lower risk patients, hence potentially increasing the prevalence of dementia.

[0011] Emerging data from clinical trials and real-world registries demonstrate the benefits of anticoagulation compared to no therapy, with a clinical advantage of Non-vitamin K Antagonist OACs (NOAC) compared to conventional Anticoagulation with Vitamin K Antagonists (VKAs). Even though these benefits are also observed in elderly patients, non-adherence to Oral Anticoagulant (OAC) treatment, associated comorbidities and additional risk factors can significantly increase the incidence and severity of cerebrovascular accidents. In this age group, a delicate balance may exist between multiple conditions, being thrombotic disease, Chronic Kidney Disease (CKD), cancer, Coronary Artery Disease (CAD) and Heart Failure (HF) some of the most challenging scenarios encountered in clinical practice.

[0012] Considering the difficulties with anticoagulant treatments, it is only reasonable to devise Cerebral Embolic Protection Devices (CEPDs) capable of matching or surpassing current OAC efficacy. For strokes triggered by AF or other conditions extended in time, there are no currently-approved CEPDs in the market. Therefore, any long-term device capable of blocking embolisms would be a radical improvement for a large population at risk.

[0013] For TAVR-associated strokes, current CEPDs provide protection only during the procedure and up to 2 days after the procedure. Nonetheless, as explained above, risk of stroke may not be limited to the procedure itself or the perioperative period. However, the clogging of current long-term CEPDs impedes them from being used to prevent ischemic strokes >2 days post-TAVR. Therefore, a CEPD able to filter small debris in the long term post-TAVR is needed.

[0014] Despite advancements in TAVI technology, cerebrovascular events, including silent brain lesions, continue to pose significant challenges, underscoring the need for improved preventive strategies and therapeutic approaches.

BRIEF SUMMARY

[0015] Aspects of the current subject matter relate to stroke prevention devices, systems and methods directed toward solving some of the above-identified problems, such as based on filtering the highest number of cardioembolism microparticles (10-600 microns) that cause asymptomatic multiple small brain infarcts (SBI).

[0016] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, the device comprising a stent portion and a filter portion. The stent portion has a first end and a second end and is sized and shaped to fit within an artery extending from an aortic arch. The filter portion is positioned at the second end of the stent portion and is sized and shaped to prevent the device from advancing into the artery extending from the aortic arch in which the stent portion may be positioned. The filter portion comprises at least two sets of two or more parallel, convex struts. The at least two sets of two or more parallel convex struts of the device are positioned across an opening defined within the second end of the stent portion and configured to divert an embolus from entering the artery when the first end of the stent portion is positioned within the artery. In at least one exemplary embodiment, when the device is positioned within the artery extending from an aortic arch, the two or more parallel convex struts of a first of the at least two sets of parallel convex struts are positioned either approximately perpendicular to, in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch, and the two or more parallel convex struts of a second of the at least two sets of parallel convex struts are positioned perpendicular to the first set of parallel convex struts. In accordance with some embodiments, the filter portion is autoexpandable from a collapsed configuration to an expanded configuration.

[0017] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, the device comprising a filter portion, the filter portion comprising two or more parallel, convex struts positioned either approximately perpendicular to, in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch, and at least one flange extending from the filter portion configured to be bendable such that it can be folded up or down from the filter portion.

[0018] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, the device comprising a stent portion, the stent portion comprising a substantially cylindrical shape. In accordance with some embodiments, the stent portion comprises an extension mesh comprising multiple wires. In accordance with some embodiments, the stent portion has a length between about 0.8 cm to about 2.5 cm. In accordance with some embodiments, the stent portion has a diameter between about 6 mm to about 8 mm when the stent portion is in an expanded configuration. In accordance with some embodiments, the stent portion has a diameter between about 1.8 mm to about 2.0 mm when the stent portion is in a compressed configuration.

[0019] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, wherein the device is comprised of a material selected from the group consisting of stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, tantalum, nitinol, nickel-titanium, polymer materials, and a shape-memory polymer.

[0020] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, the device comprising a filter portion having one or more radiopaque markers positioned thereupon. In accordance with some embodiments, the one or more radiopaque markers are positioned relative to the two or more parallel convex struts. In accordance with some embodiments, when the first end of the stent portion is positioned within the artery extending from an aortic arch, the one or more radiopaque markers facilitate alignment of the device so that the two or more parallel convex struts are positioned either approximately perpendicular to, or in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch. In at least one exemplary embodiment of a device for the prevention of stroke of the present disclosure, the diameter of each of the two or more parallel convex struts is between about 0.25 mm and about 1.0 mm, inclusive. In another embodiment, the two or more parallel convex struts are positioned between about 0.75 mm to about 1.0 mm, inclusive, from one another. In yet another embodiment, the two or more parallel convex struts are flexible.

[0021] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, the device comprising a filter portion, the filter portion comprising a first set of two or more parallel, convex struts positioned either approximately perpendicular to, in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch. The two or more parallel, convex struts are negatively charged, for example by coating them with different minerals, nanoparticles, and biological components (e.g., negative nanoparticles of graphene OX), and in some embodiments, in order to repel the clots that are also negatively charged, as well as reduce the maximum possible hemolysis.

[0022] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, wherein the device is coated with graphene oxide, plus bovine serum albumin and/or gold magnetic nanoparticles and/or silver magnetic nanoparticles, with a negative charge within physiological limits.

[0023] In accordance with some embodiments described herein, there is provided a device for the prevention of stroke, the device comprising a stent portion and a filter portion. The stent portion has a first end and a second end and is sized and shaped to fit within an artery extending from an aortic arch. The filter portion is removably attached to the second end of the stent portion and is sized and shaped to prevent the device from advancing into the artery extending from the aortic arch in which the stent portion may be positioned. The filter portion comprises two or more parallel, convex struts and is configured such that when the filter portion is attached to the second end of the stent portion, the two or more parallel convex struts of the device are positioned across an opening defined within the second end of the stent portion and configured to divert an embolus from entering the artery when the first end of the stent portion is positioned within the artery. In at least one exemplary embodiment, when the device is positioned within the artery extending from an aortic arch, the two or more parallel convex struts are positioned either approximately perpendicular to, in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch. Once the device has been positioned within the artery extending from an aortic arch, the filter portion can be removed from the stent portion and from the patient leaving only the stent portion remaining in the artery.

[0024] In accordance with some embodiments described herein, there is provided a retrieval system for the prevention of stroke of the present disclosure, the system comprising at least one device for the prevention of stroke, a sleeve catheter and a retrieval device. The at least one device comprises a stent portion having a first end and a second end (the stent portion sized and shaped to fit within an artery extending from an aortic arch), a filter portion positioned at the second end of the stent portion (the filter portion sized and shaped to prevent the device from advancing into the artery extending from the aortic arch in which the first end of the stent portion may be positioned), and two or more parallel convex struts positioned across an opening defined within the second end of the stent portion, the two or more parallel convex struts configured to divert an embolus from entering the artery when the first end of the stent portion is positioned within the artery. The sleeve catheter is configured for intravascular insertion and advancement, the sleeve catheter comprising a proximal end, an open distal end, and a lumen extending therebetween, and the retrieval device slidably disposed within the lumen of the sleeve catheter, the retrieval device comprising a proximal end for manipulation by a user and a distal end comprising one or more second attachment portions, wherein each of the one or more second attachment portions of the retrieval device are configured to engage the first attachment portion of the filter portion of the device. In accordance with some embodiments, the system comprises a conical dilator sized and shaped to slidingly engage the hypotube. In accordance with some embodiments, the conical dilator comprises a tapered distal and a proximal end. In accordance with some embodiments, the folder has an inner diameter, and wherein the tapered distal end of the conical dilator is sized and shaped to fit within the inner diameter of the folder. In accordance with some embodiments, when the device is positioned within the artery extending from an aortic arch, the two or more parallel convex struts either approximately perpendicular to, in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch. In accordance with some embodiments, the retrieval device of the system comprises one or more wires. In accordance with some embodiments, the system comprises two devices for prevention of a stroke. In accordance with some embodiments, the first attachment portion of the filter portion comprises a screw tip and a first magnet and the second attachment portion of the retrieval device comprises a screw hole and a second magnet, and the screw tip and the first magnet of the first attachment portion are configured to securely engage with the screw hole and the second magnet of the second attachment portion, respectively. In accordance with some embodiments, the second attachment portion of the retrieval device comprises a lace component and the first attachment portion of the filter portion comprises a hook tip configured to engage the lace component of the retrieval device.

[0025] In accordance with some embodiments described herein, there is provided a method for preventing stroke of the present disclosure, the method comprising the steps of introducing a device for preventing stroke into a body, navigating the device within the body until the device reaches an aortic arch, and positioning the device within a first vessel branching from the aortic arch so that the two or more convex struts are positioned either approximately perpendicular to, or in a direction of (i.e. approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch. In another embodiment, in the step of introducing a device for preventing stroke into a body, the device comprises an stent portion having a first end and a second end, a filter portion coupled with the second end of the stent portion and sized and shaped to prevent the device from advancing into the artery extending from the aortic arch in which the first end of the stent portion may be positioned, and two or more convex struts positioned across an opening defined within the second end of the stent portion. Here, the stent portion may be sized and shaped to fit within an artery extending from the aortic arch and/or the two or more convex struts of the device may be configured to divert an embolus from entering the artery when the first end of the stent portion is positioned within the artery. In accordance with some embodiments, the step of positioning the device is performed by aligning the device within the vessel by detecting one or more radiopaque markers positioned upon the device. Furthermore, placement of the device within the first vessel does not significantly affect upstream blood flow patterns. In an additional embodiment, the step of positioning the device comprises positioning the device within an innominate artery.

[0026] In accordance with some embodiments described herein, there is provided a method for preventing stroke of the present disclosure, the method comprising the steps of introducing a second device for preventing stroke into the body; navigating the second device within the body until the second device reaches the aortic arch; and positioning the second device within a second vessel branching from the aortic arch. In this manner, two or more convex struts of the second stent are positioned either approximately perpendicular to, in a direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch. In another embodiment, the step of positioning the second device comprises positioning the second device within a left common carotid artery. In accordance with some embodiments, the step of positioning the first device comprises positioning the first device within an innominate artery (or right brachiocephalic trunk), wherein the first device is capable of diverting an embolus from entering the innominate artery and thus the right common carotid artery and the right subclavian artery, and the second device is capable of diverting the embolus from entering the left common carotid artery. Additionally, a third device may be positioned within a left subclavian artery, which gives rise to the left vertebral artery (LVA). In general, the LVA is more dominant than the right vertebral artery (RVA) and therefore has a larger posterior brain vascular territory.

[0027] In accordance with some embodiments described herein, there is provided a method for preventing stroke of the present disclosure, the method comprising the step of anchoring the device within the first vessel by deploying the stent portion and the filter portion of the device. Additionally, the step of anchoring the device within the first vessel may further comprise moving the stent portion from a collapsed position to an expanded position and moving the filter portion from a collapsed position to an expanded position. In accordance with some embodiments, the method further comprises the steps of retrieving the filter portion from the first vessel and removing the filter portion from the body. In accordance with some embodiments, the steps of retrieving the filter portion from within the first vessel and removing the filter portion from the body further comprise the steps of: introducing a retrieval system into the body, navigating the sleeve catheter within the body until the open distal end of the sleeve catheter reaches an aortic arch, advancing the distal end of the retrieval catheter through the open distal end of the sleeve catheter so that the one or more attachment portions engage the filter portion of the device, rotating the filter portion to disengage it from the stent portion, and withdrawing the filter portion from the first vessel, and withdrawing the filter portion and the retrieval system from the body. In accordance with some embodiments, the step of introducing a retrieval system into the body further comprises the retrieval system comprising a sleeve catheter configured for intravascular insertion and advancement, the sleeve catheter comprising a proximal end, an open distal end, and a lumen extending therebetween, and a retrieval device slidably disposed within the lumen of the sleeve catheter, the retrieval device comprising a proximal end for manipulation by a user and a distal end comprising one or more attachment portions, each of which are configured to engage the filter portion of the device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] FIG. **1** shows a diagram of at least a portion of an aorta, according to the present disclosure;

[0029] FIGS. **2**A-**2**E show an exemplary embodiment of a device for the prevention of stroke, according to the present disclosure;

[0030] FIGS. **2**F-**2**G show an exemplary embodiment of a device for the prevention of stroke, according to the present disclosure;

[0031] FIGS. **3**A-**3**C show an exemplary embodiment of a device comprising at least one foldable flange, according to the present disclosure;

[0032] FIGS. **4**A-**4**B show an exemplary embodiment of a composite device for the prevention of stroke, according to the present disclosure;

[0033] FIG. **4**C shows an exemplary embodiment of the attachment mechanisms of the device of FIGS. **4**A and **4**B;

[0034] FIGS. **5**A-**5**B show an exemplary embodiment of a device for the prevention of stroke, according to the present disclosure;

[0035] FIGS. **5**C-**5**D show an exemplary embodiment of the attachment mechanisms of the device of FIGS. **5**A and **5**B;

[0036] FIG. **6**A shows exemplary devices for the prevention of stroke positioned within arteries extending from a portion of an aorta with the convex struts in alignment with blood flow, according to the present disclosure;

[0037] FIG. **6**B shows exemplary devices for the prevention of stroke positioned within arteries extending from a portion of an aorta with the convex struts in alignment approximately perpendicular to blood flow, according to the present disclosure;

[0038] FIG. **6**C shows a blown up, semi-cut-away view of a portion of an exemplary device for the prevention of stroke positioned within arteries;

[0039] FIG. **7** shows an exemplary embodiment of a device for the prevention of stroke, according to the present disclosure;

[0040] FIGS. **8**A and **8**B show an exemplary system of the present disclosure with portions thereof being moved to allow for device deployment, according to the present disclosure;

[0041] FIGS. **9**A and **9**B show at least a portion of an exemplary system for preventing stroke, said system comprising a conical dilator useful to facilitate removal of at least a portion of the exemplary system from the body, according to the present disclosure;

[0042] FIGS. **9**C and **9**D show additional embodiments of an exemplary system for preventing stroke, according to the present disclosure;

[0043] FIGS. **10**A-**10**E show various steps of a method for positioning a device within a body, according to the present disclosure;

[0044] FIG. **11** shows at least a portion of an exemplary system for retrieving a portion of a device previously positioned within a body, according to the present disclosure;

[0045] FIGS. **12**A and **12**B show various steps of a method for retrieving a portion of a device previously positioned within a body, according to the present disclosure;

[0046] FIGS. **13**A and **13**B show embodiments of an attachment portion of an exemplary system for retrieving a device previously positioned within a body; and

[0047] FIG. **14** shows a flow chart of an exemplary method for preventing stroke according to the present disclosure.

[0048] An overview of the features, functions and/or configurations of the components depicted in the various figures will now be presented. It should be appreciated that not all of the features of the components of the figures are necessarily described. Some of these non-discussed features, such as various couplers, etc., as well as other discussed features, are inherent from the figures themselves. Other non-discussed features may be inherent in component geometry and/or configuration.

DETAILED DESCRIPTION

[0049] For purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of this disclosure is thereby intended. Furthermore, numerous specific details are set forth in order to provide a thorough understanding of the present disclosure. Particular examples may be implemented without some or all of these specific details. In other instances, well known devices or processes have not been described in detail so as to not unnecessarily obscure the present disclosure. It will thus be appreciated that aspects and features of apparatus and methods discussed herein which are not described in detail may be implemented in accordance with any conventional techniques for implementing such aspects and features.

[0050] Various systems, methods and techniques of the present disclosure will sometimes describe a connection between two components. Words such as attached, affixed, coupled, connected, and similar terms with their inflectional morphemes are used interchangeably, unless the difference is noted or made otherwise clear from the context. These words and expressions do not necessarily signify direct connections but include connections through mediate components and devices. It should be noted that a connection between two components does not necessarily mean a direct, unimpeded connection, as a variety of other components may reside between the two components of note. Consequently, a connection does not necessarily mean a direct, unimpeded connection unless otherwise noted. Furthermore, wherever feasible and convenient, like reference numerals are used in the figures and the description to refer to the same or like parts or steps. Additionally, the drawings are in a simplified form and not to precise scale.

[0051] The disclosure of the present application provides various devices, systems, and methods for the prevention of stroke. The devices, systems, and methods disclosed herein facilitate stroke prevention, in part, by addressing specific areas of the heart and diverting the trajectories of blood clots away therefrom with minimal to no influence on resistance of blood flow through such areas and/or significantly affect upstream blood flow patterns.

[0052] A diagram of at least a portion of an exemplary aorta is shown in FIG. **1**. An aorta **100** is the main trunk of a vascular system which conveys oxygenated blood to the tissues of a body. It begins at the upper part of the left ventricle, where it may be approximately 3 cm in diameter in an adult human. As shown in FIG. **1**, and at the union of the ascending aorta **102** with the aortic arch **104** (or the "arch of aorta"), the caliber of the vessel is increased, owing to a bulging of its right wall. This dilatation is termed the aortic bulb **106** (or bulb of the aorta), and on transverse section shows a somewhat oval figure. The ascending aorta **102** is contained within the pericardium and is enclosed in a tube of the serous pericardium. It ascends for a short distance (the ascending aorta **102** is about 5 cm in length in an adult human), arches backward, and then descends within the thorax and abdomen (the descending aorta **108**) and ends into the right and left common iliac arteries (about 1.7 cm in diameter in an adult human). The right coronary **110** and the left coronary **112**, as shown in FIG. **1**, branch from the ascending aorta **102**.

[0053] There are three arteries that branch from the aortic arch **104**, namely the innominate artery (or right brachiocephalic trunk) **114**, the left common carotid artery **116**, and the left subclavian artery **118**. As shown in FIG. **1**, the left vertebral artery (LVA) **119** branches off from the left subclavian artery **118**. The LVA **119** irrigates the greater posterior part of the brain. Instead of arising from the highest part of the aortic arch **104**, these branches may spring from the commencement of the aortic arch **104** or the upper part of the ascending aorta **102**. The distance between the aortic arch **104** or the upper part of the ascending aorta **102** at their origins may be increased or diminished, the most frequent variation being the approximation of the left common carotid artery **116** toward the innominate artery **114**. In addition, and as shown in FIG. **1**, the innominate artery **114** branches into the right subclavian artery **120** and the right common carotid artery **122**, and the right vertebral artery (RVA) **124** branches off from the right subclavian artery **120**.

[0054] Ischemic strokes, the most common type of stroke, occur when blood clots or other debris are swept through the bloodstream and lodge in one or more of the aortic branches **114**, **116**, **118**. As the innominate and left common carotid arteries **114**, **116**, **118**, ultimately supply blood to the brain, the partial or complete blockage thereof reduces or inhibits blood flow to the brain, thus increasing the risk of ischemic stroke. Ejection dynamics of blood clots from the left ventricle is diverse and random, with clots having different release velocities at different stages of the cardiac cycle. Furthermore, blood clots can vary in size—typically in the range of about 2 mm to about 6 mm—which can also have a significant effect on clot velocity and their flow patterns as they leave the heart. In addition, the hemodynamics in the aortic arch **104** are typically characterized as complex flow patterns due to the arch curvature and branches **114**, **116**, **118**. Accordingly, clot trajectory is a complex function of aortic flow conditions, discrete phase behavior of clots, and their dynamic interactions. To prevent ischemic stroke, not only must clots be prevented from lodging within the aortic branches **114**, **116**, **118**, but the solution must be mindful of the complexity of the aortic flow field and not generate a substantial resistance to flow therethrough.

[0055] The devices, systems, and methods of the present application are configured to maintain a balance between efficacy in deflecting blood clots from an artery extending from the aortic arch **104** and affecting minimal influence on resistance to blood flow therethrough. In this manner, such deflection devices, systems and methods can ensure diversion of blood clots away from the aortic branches **114**, **116**, **118**, rather than blocking clots on the device and thereby obstructing the underlying arteries.

[0056] FIGS. **2**A-**2**E show an exemplary embodiment of a device of the present application for the prevention of stroke. In application, such device (and any embodiments thereof) may be used with one or more of the aortic branches **114**, **116**, **118** to deflect the trajectory of blood clots destined for the structures of the aorta **100** with negligible change in blood flow resistance. As shown in FIG. **2**A, an exemplary device **200** may comprise a stent comprising a stent portion **202** and a filter portion **204**. Stent portion **202**, as shown in FIG. **2**A, may comprise a cylindrical stent sized and shaped to fit securely within an aortic branch. An exemplary stent portion **202** may comprise, for example, extension mesh **206** comprising multiple wires as shown in FIG. **2**A. Filter portion **204** may comprise an inner diameter (shown as D**1** in FIG. **2**A) and an outer diameter (shown as D**2**), whereby D**2** is larger than D**1**. In at least one embodiment, device **200** is collapsible, similar to a traditional stent. Alternatively, or additionally, the device **200** (or independent components thereof) may be autoexpandable to facilitate secure anchoring within an artery and/or the long-term stability of the device **200** after placement.

[0057] In at least one embodiment of device **200** of the disclosure of the present application, device **200** comprises an autoexpandable metallic stent comprising a proximal flange (filter portion **204**) and a distal cylindrical tube (stent portion **202**). In an exemplary embodiment, stent portion **202** is approximately 0.8 cm to 2.5 cm in length. In at least one embodiment of device **200**, the diameter of the stent is approximately 6 to 8 mm. Suitable material for a device **200** includes but is not limited to, stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, tantalum, nitinol, nickel-titanium, polymer materials, and various shape-memory polymers known in the art, including polyurethane, polytetrafluoroethylene or polytetrafluoroethene (PTFE), or another synthetic material.

[0058] Filter portion **204**, as shown in the exemplary embodiments shown in FIGS. **2**A-**2**C, comprises filter mesh **208** comprising multiple wires. The filter portion **204** may comprise any length and/or diameter that is effective to impede the progression of the device **200** within an artery when positioned within a body. In at least one embodiment, the filter portion **204** is between about 2 mm and about 5 mm in length. Furthermore, the filter portion **204** may be configured to move between a collapsed position having a smaller diameter for delivery and/or retrieval of the device **200** (see FIG. **7**) and an expanded position having a larger diameter (see FIG. **2**A). For example, in at least one embodiment, the filter portion **204** is comprised of an autoexpandable material such that when the filter portion **204** is released from a delivery mechanism, it automatically moves into the expanded position to assist in anchoring the device **200** within an artery of interest.

[0059] Alternatively, as shown in FIGS. **2**F-**2**G, device **200** may be configured such that the extension mesh **206** of stent portion **202** and filter mesh **208** of the filter portion **204** are configured in a zig-zag pattern.

[0060] In an exemplary embodiment of device **200** of the disclosure of the present application, the device **200** may be formed as a single structure as shown in FIGS. **2**A-**2**E (or **2**F-**2**G). Alternatively, in another exemplary embodiment of device **200** of the disclosure of the present application, device **200** may be a composite device in which stent portion **202** and filter portion **204** are separate components releasably connected to one another, as shown in FIGS. **4**A-**4**C and **5**A-**5**D. Stent section **202** and filter section **204** may be releasably connected to one another by any appropriate means. For example, as depicted in FIGS. **4**A-**5**D, filter section **204** may include a rim **218** having a groove or channel **220** provided on an inner surface of rim **218** rim, and stent section **202** may include a rim **222** having at least one protrusion **224** provided on an outer surface of rim **222**, wherein the channel **220** and the protrusion **224** are configured to operably engage one another upon placement of the rim **218** of filter section **204** within the rim **222** of stent section **202** and rotation of the filter section, thereby latching the filter section **204** and stent section **202** together. The filter section **204** can then be rotated in an opposite direction to disconnect it from the stent section **202** such that the filter section **204** can be removed from the stent section **202**. Furthermore, rim **218** and rim **222** may be configured to move between a collapsed position having a smaller diameter for delivery and/or retrieval of the device **200** and an expanded position having a larger diameter similar to filter section **204** and stent section **202**. The channel **220** and at least one protrusion **224** are depicted on the filter section **204** and stent section **202** respectively, but it is contemplated that the arrangement can reversed such that the channel **220** is on the stent portion **202** and the at least one protrusion is on the filter section **204**. Alternatively, other fixing methods may be used to connect filter section **204** and stent section **202**, such as magnetic coupling, or other similar methods.

[0061] As shown in FIGS. **2**A-**2**F, the device **200** also comprises two or more convex struts **210** operable to divert, for example, an embolus, from entering the inner portion of device **200** (the inner portion defined by stent portion **202**) while still allowing blood to flow therethrough without significantly affecting flow resistance. Convex struts **210** are one example of such an embolus diversion portion of device **200**, noting that other embodiments of an embolus diversion not comprising convex struts **210** may be useful with device **200**. For example, and instead of convex struts **210**, an exemplary embolus diversion portion may comprise a mesh (similar to, for example, extension mesh **206** and/or flange mesh **208**), whereby such a mesh is operable to divert an embolus from entering the inner portion of device **200**.

[0062] Convex struts **210**, in an exemplary embodiment, are positioned along device **200** to cover the proximal orifice of the cylindrical stent (device **200**). In at least one embodiment of a device **200** of the disclosure of the present application, the diameter of each convex strut **210** is approximately 0.25 mm to 1.0 mm, and the distance between each convex strut **210** is approximately 0.75 mm to 1.0 mm. In at least one exemplary embodiment, the diameter of each convex strut **210** is approximately 0.75 mm and the distance between each convex strut **210** is approximately 0.75 mm, which has been found to provide beneficial deflection efficacy with respect to emboli while affecting only negligible change in flow resistance through the underlying artery.

[0063] The device **200** also comprises two sets of at least two or more lateral struts **212**, the first set of two or more lateral struts **212** extending from one of the outermost convex struts **210** in a direction away from the rest of the convex struts **210** to filter mesh **208**, and the second set of two or more lateral struts **212** extending from the other of the outermost convex strut **210** in a direction away from the rest of the convex struts **210** to filter mesh **208** as shown in FIGS. **2**A-**2**E. The lateral struts **212** are operable to divert, for example, an embolus, from entering the inner portion of device **200** (the inner portion defined by stent portion **202**) while still allowing blood to flow therethrough without significantly affecting flow resistance.

[0064] Lateral struts **212** are positioned to cover the gap between the outermost convex struts **210** and filter mesh **208**. In at least one embodiment of a device **200** of the disclosure of the present application, the diameter of each lateral strut **212** is approximately 0.25 mm to 1.0 mm, and the distance between each lateral strut **212** is approximately 0.75 mm to 1.0 mm. In at least one exemplary embodiment, the diameter of each lateral strut **212** is approximately 0.75 mm and the distance between each lateral strut **212** is approximately 0.75 mm, which has been found to provide beneficial deflection efficacy with respect to emboli while affecting only negligible change in flow resistance through the underlying artery.

[0065] It will be appreciated that the number of convex struts **210** and lateral struts **212** present on the device **200** may be customized according to a user's preferences and/or patient specifications. Furthermore, each convex strut **210** and/or lateral strut **212** of the device **200** need not be configured identically; indeed, device **200** may be configured to employ various combinations of convex strut **210** and/or lateral strut **212** diameters, intervals, and heights. Moreover, the convex struts **210** and/or lateral struts **212** may also comprise varying cross-sectional areas and/or a non-spherical profile of the convex envelope. Convex struts **210** and lateral struts **212** may comprise material the same and/or similar to the material used to prepare other portions of device **200**, and may also be a combination of a metal plus polyurethane, polytetrafluoroethylene or polytetrafluoroethene (PTFE), or another synthetic material.

[0066] In at least one embodiment, convex struts **210** and lateral struts **212** may be semi-rigid or flexible in order to allow the removal of a hypotube **402** (see FIGS. **7**-**8**B) and/or allow the passage of a catheter stent device, including device **200**, for stenting the carotid artery, for example, if it develops an atherosclerotic plaque. In an exemplary embodiment, the shape of the convex struts **210** and/or lateral struts **212** can be convex or semi-convex in order to be easily and constantly "washed" by the aortic blood flow and therefore avoid local thrombosis. If an embolus lands on a strut, the strut shape will also allow it to wash off to the periphery not only preventing the embolus from entering the brain vascular system, but also deflecting the embolus away from the ostium of the artery to ensure the blood flow therethrough does not become restricted or blocked (i.e., the embolus does not stick to the convex struts **210** or lateral struts **212**, but rather deflects off).

[0067] Lateral struts **210** are one example of an embolus diversion portion of device **200** to cover the gap between the outermost convex struts **210** and filter mesh **208**, noting that other embodiments of an embolus diversion not comprising lateral struts **212** may be useful with device **200**. For example, and instead of lateral struts **212**, an exemplary embolus diversion portion may comprise two or more lateral mesh flanges **213** (similar to, for example, extension mesh **206** and/or flange mesh **208**), as shown in FIGS. **3**A-**3**C, whereby such lateral mesh flanges **213** extend from the filter mesh **208** positioned proximal the outermost convex struts **210**, and are configured to be foldable such that when folded the lateral mesh flanges **213** cover the gap between the outermost convex struts **210** and filter mesh **208**, and thus operable to divert, for example, an embolus, from entering the inner portion of device **200** (the inner portion defined by stent portion **202**) while still allowing blood to flow therethrough without significantly affecting flow resistance.

[0068] In at least one embodiment, some portion or all of the device **200**, but at least convex struts **210**, lateral struts **212** and/or lateral mesh flanges **213**, are negatively charged, for example by coating them with a coating **215** that may comprise different minerals, nanoparticles, and biological components (e.g., negative nanoparticles of graphene OX), in order to repel the clots that are also negatively charged, as well as reduce the maximum possible hemolysis. For example, highly stable and biocompatible supramolecular-aptamer functionalized graphene oxide (GO) nanosheets may be used to coat convex struts **210**, lateral struts **212** and/or lateral mesh flanges **213**. Supra-$TBA_{15/29}$-GO has good biocompatibility and low cytotoxicity toward mammalian cells. Other coating materials could include Chitosan, Bovine serum protein, etc., all of which decrease hemolysis thrombosis and cytotoxicity, and are negatively charged. In at least one exemplary embodiment, some portions or all portions of the device **200**, but at least convex struts **210**, lateral struts **212** and/or lateral mesh flanges **213**, are covered with a negatively charged coating **215** comprising graphene oxide plus Bovine Serum Albumin (BSA). The combination of GO and BSA creates a surface that inherently maintains a negative charge. GO's functional groups can ionize to provide negative charges, while BSA stabilizes these charges through its protein structure. As blood flows through the aorta, the mechanical interaction between the blood and the device **200**, or the struts **210** and/or **212** of the device **200** induces a triboelectric effect. The GO-BSA coating ensures that the triboelectric effect continuously generates and maintains the negative charge necessary to repel negatively charged clots, and microparticles. Some alternative microparticles that can be integrated with the negatively charged coating for enhanced electronegative surface charges and biocompatibility may include gold microparticles, silver microparticles, alumina (Al_2O_3) microparticles, and/or titanium dioxide (TiO_2) microparticles.

[0069] In addition, and in the exemplary embodiment shown in FIG. **2**E, device **200** may further comprise one or more radiopaque markers **214** located proximally and/or distally on device **200** to aid the placement of device **200** within a body. For example, in at least one embodiment, one or more radiopaque markers **214** are positioned on the filter portion **204** in a location(s) relative to the convex struts **210** of the device **200**. Accordingly, when the device **200** is positioned within an artery, the one or more markers **214** on the device **200** can be visualized to identify the orientation of the convex struts **210** relative to the direction of the blood flow.

[0070] Exemplary devices for the prevention of stroke positioned within a portion of an aorta are shown in FIGS.

6A and 6B. While the devices **200** illustrated in FIGS. **6**A and **6**B both comprise a filter portion **204** and a stent portion **202** having extension mesh **206**, it will be understood that any embodiments of the device **200** of the present disclosure can be positioned pursuant to and are capable of the same functionality described in connection with FIGS. **6**A and **6**B.

[0071] As shown in FIGS. **6**A and **6**B, two devices **200** are positioned within arteries branching from aorta **100**, with one device **200** positioned partially within innominate artery **114** and another device **200** positioned partially within left common carotid artery **116**. While two devices **200** are illustrated in FIGS. **6**A and **6**B positioned partially within innominate artery **114** and left common carotid artery **116**, it will be understood that the devices **200** can be positioned in any of innominate artery **114**, left common carotid artery **116** and/or left subclavian artery **118**. It will also be understood that a third device **200** of the present disclosure can be included and positioned in the left subclavian artery pursuant to and is capable of the same functionality described in connection with FIGS. **6**A and **6**B. Device **200** within innominate artery **114** is positioned such that stent portion **202** is positioned within a portion of innominate artery **114** extending from aortic arch **104** and filter portion **204** prevents device **200** from advancing further into innominate artery **114**. Similarly, a device **200** is shown in FIGS. **6**A and **6**B positioned within left common carotid artery **116** such that stent portion **202** is located within a portion of left common carotid artery **116** extending from aortic arch **104** and filter portion **204** prevents device **200** from advancing further into left common carotid artery **116**. In at least one embodiment, filter portion **204** completely covers and exceeds the size of the entrance of the artery in which device **200** is positioned. In an exemplary embodiment of device **200** positioned within an artery as referenced herein, the distal cylindrical portion of the stent (stent portion **202** of device **200**) additionally or alternatively anchors device **200** by applying radial force to the arterial walls of the artery in which device **200** is placed. In this manner, both the stent portion **202** and the filter portion **204** may act to anchor the device **200** in place when positioned within an artery.

[0072] As shown in the exemplary embodiments of device **200** shown in FIG. **6**A, convex struts **210** are aligned in a direction similar to the flow of blood within aorta **100**. In such an alignment, and as blood flows through aorta **100**, an embolus **300** present within aorta **100** (specifically within the aortic arch **104**) would be guided by the blood flow along convex struts **210** and across the proximal opening of the aortic branch. As shown in FIG. **6**B, the convex struts **210** of both devices **200** are aligned in a direction approximately perpendicular to the flow of blood within aorta **100**. In such an alignment, an embolus **300** present within aorta **100** would contact convex struts **210** and be deflected therefrom with little or no risk of embolus **300** being trapped therein. As referenced herein, convex struts **210** may also be positioned in the direction of (i.e., approximately parallel with), or in an oblique manner relative to, blood flow within the aortic arch **104** as shown in FIG. **6**A. In application, the device **200** may be positioned within an artery to achieve any orientation of the convex struts **210** relative to the flow field that may be desired in accordance with patient specifications and/or user preference.

[0073] Positioning the devices **200** as shown in FIGS. **6**A and **6**B prevents an embolus **300** from entering the innominate artery **114** and the left common carotid artery **116** but allows the embolus **300** to enter the left subclavian artery **118**. Because the innominate and left common carotid arties **114**, **116** supply blood flow to the brain, in this example, the devices **200** thus prohibit the embolus **300** from advancing to the brain vascular system, thereby significantly reducing a patient's risk of ischemic stroke. Instead, the embolus **300** is allowed to flow into other arteries—such as the femoral or iliac arteries, for example—where such embolus **300** can be filtered from or sucked out of the blood stream using an appropriate medical procedure. In other words, such an arrangement of devices **200** may effectively prevent a patient from having a stroke by deflecting any embolus **300** present in the blood stream away from the vessels that feed the brain and instead routing such emboli **300** to a location where they may be easily and safely removed.

[0074] In summary, and as described above with respect to FIGS. **6**A and **6**B, for example, the present disclosure provides a device **200**, which may be referred to as a percutaneous carotid emboli rerouting device, configured for individual delivery to an artery given off by the aortic arch **104** (namely the innominate artery **114**, the left common carotid artery **116**, and the left subclavian artery **118**) to avoid the passage of embolic or thromboembolic material (an embolus **300**, which may be, for example, a clot, calcium, etc.) to the brain vascular system. Furthermore, the present disclosure provides for the provision of more than one of these devices **200** to the arteries off the aortic arch **104** such that an arrangement of devices **200** prevents thromboembolic stroke in patients with different cardiovascular diseases from cardiac origin.

[0075] At least one goal of the devices, systems, and methods of the present disclosure is to reroute an embolus distally to the arterial system (iliac or femoral arteries) to avoid disabling stroke, decrease mortality and avoid physical impairment with a poor quality of life. As previously mentioned, unlike stroke, medical or surgical treatment of the peripheral arterial embolus (fibrinolitic drugs, surgical embolectomy, or endovascular embolus suction) can be provided with little residual effect. This may be particularly useful to patients who have undergone medical procedures associated with a high risk of stroke and/or blood clots being released following the procedures (e.g., transcatheter aortic valve implantation ("TAVI"), mitral valve replacement, calcific mitral valve insufficiency, balloon dilation, etc.). For example, the general risk of stroke after TAVI is about three percent (3%), which increases to about six to ten percent (6-10%) thirty days following the procedure, and again to about seventeen to twenty-four percent (17-24%) one year following the procedure. As such, while TAVI (or similar procedures) is often used to repair a patient's heart and/or circulatory system, the procedure often results in brain damage due to its side-effect of increasing the occurrence of blood clots.

[0076] The devices, systems and methods of the present disclosure can be used in connection with such patients to divert the resulting clots. Moreover, the devices, systems and methods described herein are also particularly applicable to patients who cannot receive anticoagulants, are prone to clots forming in the left atrial appendage and entering the bloodstream, or simply present an elevated risk for brain damage due to stroke. The risk of brain damage can also generally be reduced with the elderly by employing the devices, systems and methods disclosed herein.

[0077] An exemplary embodiment of a system for preventing stroke of the present disclosure is shown in FIG. **7**. As shown in FIG. **7**, system **400** comprises a hypotube **402** having a distal end and a proximal end, and in at least one exemplary embodiment, hypotube **402** comprises a folder **404** coupled to the distal end of hypotube **402**. In the embodiment shown in FIG. **7**, system **400** further comprises a device **200**, whereby a stent portion **202** of device **200** is shown positioned within at least part of folder **404** and a filter portion **204** of device **200** is positioned within at least part of a sleeve **406** and around hypotube **402** proximally of folder **404**. Sleeve **406**, as shown in this exemplary embodiment, slidingly engages hypotube **402** and may be moved in a forward or backward direction as indicated by the arrow in the figure.

[0078] In at least one embodiment, device **200** is an autoexpandable metallic stent mounted over a hypotube **402** as shown in FIG. **7**. Device **200** may be compressed by sleeve **406** and folder **404** such that both the stent portion **202** and the filter portion **204** are in their collapsed positions. In at least one embodiment, at least part of system **400** has a diameter of 7 Fr to 8 Fr (2.3 to 2.7 mm), with an exemplary device **200** having a compressed diameter of about 1.8 to 2.0 mm.

[0079] FIGS. **8**A and **8**B show exemplary embodiments of at least portions of systems for preventing stroke of the present disclosure. As shown in FIG. **8**A, an exemplary system **400** comprises hypotube **402** to which folder **404** is coupled thereto. System **400**, as shown in FIGS. **8**A and **8**B, further comprises sleeve **406** slidingly engaged around hypotube **402**. Device **200** may be positioned at least partially within folder **404** and sleeve **406** prior to deployment, whereby the stent portion **202** of device **200** may be positioned within at least part of folder **404** in a collapsed position, and whereby the proximal portion (i.e., the filter portion **204**) of device **200** may be positioned within at least part of a sleeve **406** in a collapsed position (as shown in FIG. **7**).

[0080] As shown in FIG. **8**A, device **200** may be partially deployed as follows. First, and in an exemplary method of positioning a stent within a body, a wire **500** (a guide wire, for example) may be advanced within a body at or near a desired location of device **200** deployment. When wire **500** has been advanced, hypotube **402**, along with any portions of system **400** coupled to hypotube **402**, may be advanced along wire **500** within the body. As shown in FIGS. **8**A and **8**B, initial advancement of at least a portion of system **400** may comprise advancement of hypotube **402**, folder **404**, sleeve **406**, and device **200** positioned within folder **404** and sleeve **406**.

[0081] When device **200** has been positioned within a body at or near a desired position, sleeve **406** may be withdrawn toward the proximal end of hypotube **402** (in the direction of the arrow shown in the figure). This step may be performed prior to, during, or after the step of positioning the distal end of hypotube **402** within a vessel (for example, a vessel branching off the aortic arch **104**). As sleeve **406** is slid toward the proximal end of hypotube **402**, the filter portion **204** of device **200** is allowed to expand as shown in FIG. **8**A. While at this step the filter portion **204** is deployed, the stent portion **202** remains within the folder **404**. Accordingly, the stent portion **202** remains undeployed and does not yet engage or anchor to an arterial wall.

[0082] Further deployment of device **200** within a body is shown in FIG. **8**B. As shown in FIG. **8**B, and upon movement of folder **404** away from device **200** (in a direction shown by the arrow in the figure, for example), stent portion **202** of device **200** may deploy as shown in FIG. **8**B. As folder **404** is moved away from device **200** (by, for example, advancement of hypotube **402** within a body), stent portion **202** of device **200** is no longer positioned within folder **404**, thereby permitting expansion/deployment of stent portion **202**.

[0083] FIGS. **9**A and **9**B show exemplary embodiments of at least a portion of a system for preventing stroke. In at least one embodiment, system **400** comprises a conical dilator **600** slidingly engaged around a hypotube **402** coupled to a folder **404**. As shown in FIG. **9**A, an exemplary conical dilator **600** may comprise a tapered distal end **602**, wherein the tapered distal end **602** is sized and shaped to engage the inside of folder **404**. To engage folder **404**, conical dilator **600** may slide along hypotube **402** in a direction indicated by the arrow in FIG. **9**A. An exemplary embodiment of the engagement of conical dilator **600** and folder **404** is shown in FIG. **9**B.

[0084] Engagement of conical dilator **600** with folder **404**, as shown in FIGS. **9**A and **9**B, may facilitate the removal of at least a portion of system **400** from a body after positioning device **200**. For example, and as shown in FIGS. **8**A and **8**B, after deployment of device **200** within a body, the portion of system **400** comprising folder **404** is positioned, for example, further within a vessel than device **200**. Removal of the portion of the system **400** comprising hypotube **402** and folder **404** would require, for example, pulling that portion of system **400** back through device **200**. As shown in the exemplary embodiments of FIGS. **8**A-**9**B, folder **404** may, for example, become caught on device **200** and/or a portion of a body, preventing effective removal of that portion of system **400**.

[0085] In at least one embodiment, and by engaging folder **404** with conical dilator **600**, folder **404**, along with the portion of system **400** coupled to folder **404**, may be removed from a body after placement of a device **200** as shown in FIGS. **9**C and **9**D. As shown in FIG. **9**C, and after a device **200** has been deployed, a user of system **400** may slide a conical dilator **600** along hypotube **402** in a direction indicated by the arrow. Conical dilator **600**, in the example shown in FIGS. **9**C and **9**D, is sized and shaped to fit within the spaces between convex struts **210** of device **200**. After conical dilator **600** has engaged folder **404**, as shown in FIG. **9**D, when hypotube **402** is withdrawn from the body in a direction indicated by the arrow, folder **404** is also removed from the body without becoming caught on device **200**.

[0086] In at least one embodiment of a system for preventing stroke of the present disclosure, system **400** comprises a device **200**, a hypotube **402**, and a folder **404** coupled to hypotube **402** at or near the distal end of hypotube **402**. Device **200**, in at least one embodiment, may be autoexpandable, i.e. device **200** has a "memory" allowing it to expand to a native configuration after being retracted/compressed to fit within, for example, folder **404** and sleeve **406**. System **400**, in at least one embodiment, may further comprise, or be used in connection with, a femoral catheterization kit known and used in the marketplace.

[0087] Now referring to FIG. **14**, at least one method of preventing stroke will now be described using the components of the previously described systems for reference and explanatory purposes. Primarily, at step **1402**, the device **200** is positioned within a body. In at least one exemplary embodiment of the present disclosure, the percutaneous placement of the percutaneous carotid emboli rerouting device (device **200**) may be performed in an angiography procedure room. Prior to positioning device **200** at step **1402**, a user may optionally perform a contrast aortogram, for example, to map out the aortic arch **104** and where the cerebral vessels merge with aortic arch **104** (optional step **1401**). For safety, patient preparation and sterile precautions are recommended as for any angioplasty procedure.

[0088] In at least one embodiment of the method **1400** for preventing stroke, the optional step **1401** of the method **1400** additionally or alternatively comprises performing a percutaneous angiogram using technique(s) known in the art under local anesthesia. As referenced above, the percutaneous angiogram maps the aortic arch **104** so that a user of a device **200** and/or system **400** of the present disclosure can, for example, select an appropriately-sized device **200** and/or system **400** (or portion(s) thereof) when performing the procedure.

[0089] At step **1402**, to facilitate positioning the device **200** within a body, a user may introduce a wire **500** (such as guide wire as shown in FIG. **8**A) to reach the innominate artery **114**, the left common carotid artery **116** and/or the left subclavian artery **118**. After wire **500** has been positioned, portions of system **400** may be mounted over the guide wire **500** and progressed to the level of the entrance of the innominate artery **114**, the left common carotid artery **116** and/or the left subclavian artery **118**. Said portions of system **400** may include hypotube **402** and a folder **404** distally mounted thereto, and may further comprise a sleeve **406**, wherein an exemplary device **200** may be positioned at least partially within folder **404** and sleeve **406**, as shown in FIG. **10**A. After the device(s) **200** are properly positioned at step **1402**, the method **1400** advances to step **1404** where the device(s) **200** are deployed.

[0090] Deployment of device **200** at step **1404**, in an exemplary embodiment of a method of the present application for performing the same, is as a follows. Under fluoroscopy, sleeve **406** may be pulled back to allow the delivery of the proximal portion of the stent (the filter portion **204** of device **200**) as shown in FIG. **10**B. The diameter of filter portion **204** that exceeds the diameter of the innominate artery **114**, the left common carotid artery **116** and/or the left subclavian artery **118** impedes the progression of device **200** within said arteries, thus giving the user/operator time to deliver and anchor the second portion of the stent (the stent portion **202** of device **200**) by, for example, forward progression of hypotube **402** as shown in FIGS. **8**B and **10**C. In addition to preventing the device **200** from progressing within the artery, when the filter portion **204** is expanded upon delivery to the artery of interest, such structures also provide support over the aortic wall of the aortic arch **104** at the level of proximal aortic ostium in which the device **200** is deployed.

[0091] In at least one embodiment, deployment of the device **200** at step **1404** may be facilitated through the use of radiopaque markers **214**. Where the device **200** comprises radiopaque markers **214**, prior to anchoring the stent portion **202** of the device **200**, such markers **214** can be used to assist with ensuring proper alignment. Specifically, the user/operator can visualize the radiopaque markers **214** through fluoroscopy or other technology and rotate the device **200** accordingly so that the convex struts **210** are positioned as desired relative to the direction of blood flow within the aortic arch **104**. In this manner, the radiopaque markers **214** can facilitate placement and orientation of the device **200**. In various embodiments, device **200** can be positioned approximately perpendicular to, or in a direction of (i.e. approximately parallel with), or in an oblique manner relative to, blood flow in the aortic arch **104**, and can even be positioned/deployed in an oblique manner (not parallel or perpendicular), should such a deployment be desired.

[0092] When device **200** has been positioned at step **1402** and deployed at step **1404**, the method **1400** may advance to step **1406** where the hypotube **402** and folder **404** are removed from the body, for example, by introducing conical dilator **600** as described herein. In at least one example, the tapered distal end **602** of conical dilator **600** is advanced until it engages folder **404** of hypotube **402**, as shown in FIGS. **9**A-**9**D, **10**D and **10**E, effectively forming a single unit (conical dilator **600**+hypotube **402**+optionally wire **500** (not shown)). This "unit" may then be removed through the convex struts **210** as shown in FIG. **10**E, and distally to the femoral artery for which at least part of system **400** was initially introduced.

[0093] Now referring to FIGS. **11**-**13**B, an exemplary system **700** for preventing stroke of the present disclosure is shown. At times, temporary placement of the filter portion **204** of the devices **200** disclosed herein may be desired (as opposed to chronic or permanent placement). In such cases, it is necessary to retrieve the filter portion **204** of the device **200**, from the patient after a prescribed period of time has elapsed or other indications are observed. System **700** comprises a retrieval system for use in retrieving the filter portions **204** of device **200** previously positioned within an artery extending from the aortic arch **104**.

[0094] System **700** comprises a sleeve catheter **702**, a retrieval device **704**, and at least one device **200**. The sleeve catheter **702** is configured for intravascular insertion and advancement, and comprises an open distal end **708**, a proximal end (not shown), and a lumen **712** extending therebetween. The retrieval device **704** is slidably disposed within the lumen **712** of the sleeve catheter **702** and comprises a proximal end (not shown) for manipulation by a user/operator and a distal end **706** configured for advancement through the open distal end **708** of the sleeve catheter **702**. The distal end **706** of the retrieval device **704** further comprises one or more attachment portions **714** positioned thereon, each of which are configured to engage the filter portion **204** of device **200**.

[0095] The retrieval device **704** may comprise any configuration suitable for slidably advancing through the lumen **712** and through the open distal end **708** of the sleeve catheter **702**. For example, in the embodiments shown in FIGS. **11**-**12**B, the retrieval device **704** comprises one or more wires. Alternatively, in the embodiment of FIGS. **13**A and **13**B, the retrieval device **704** comprises an elongated catheter having one or more attachment portions **714** configured to engage the filter portion **204** of the device **200**. Furthermore, the proximal portion (the filter portion **204**) of the device **200** may be additionally configured to engage or receive the attachment portion(s) **714** of the retrieval device **704**.

[0096] Now referring back to FIGS. **11**-**12**B, an embodiment of a system **700** for retrieving the filter portion **204** of device **200** is shown. This embodiment of the system **700**

has a retrieval device **704** comprising one or more wires slidably disposed within the lumen **712** of the sleeve catheter **702**. Each of the wires of the retrieval device **704** of this embodiment comprises an attachment portion **714** configured to securely grab the convex struts **210** of filter portion **204**. For example, an attachment portion **714** may be curved or comprise a hook capable of grabbing one of the convex struts **210** of the filter portion **204**. Alternatively, the attachment portion **714** may comprise any other configuration capable of securely grabbing at least one of the convex struts **210** of the filter portion **204** such that a sufficient amount of force can be exerted on the filter portion **204**.

[0097] While FIGS. **11**A-**12** illustrate embodiments of the system **700** comprising a retrieval device **704** having wires, the retrieval device **704** of the system **700** may comprise any configuration suitable for slidably advancing through the lumen **712** and the open, distal end **708** of the sleeve catheter **702**. FIGS. **13**A and **13**B show two non-limiting examples of such alternative embodiments of a retrieval device **704**. In these embodiments, the retrieval device **704** comprises an elongated catheter having an attachment portion **714** on or near its distal-most end. Likewise, the proximal portion (filter portion **204**) of the device **200** may be configured to correspond with the attachment portion **714** of the retrieval device **704**. For example, in the embodiment shown in FIG. **13**A, the attachment portion **714** of the retrieval device **704** defines a cavity having female threads disposed therein and a magnet **716**, while the filter portion **204** of the device **200** comprises a corresponding portion **718** having male screw threads and a magnet. Similarly, FIG. **13**B shows an embodiment where the attachment portion **714** of the retrieval device **704** comprises a lace and the corresponding portion **718** of the filter portion **204** comprises a corresponding hook tip. Accordingly, in each of the aforementioned embodiments, the device **200** may be easily engaged by the attachment portion **714** of the retrieval device **704**.

[0098] After the attachment portion **714** of the retrieval device **704** is securely coupled with the filter portion **204** of device **200** (via the corresponding portion **718** or otherwise), a user/operator can manipulate the proximal end (not shown) of the retrieval device **704** and thus manipulate the filter portion **204**. In this manner, a user/operation may rotate the filter portion **204** relative to the stent portion **202** and thus disengage the filter portion **204** from the stent portion **202** as described above with regard to the device **200** in FIGS. **4**A-**5**D. After the filter portion **204** is disengaged, it is caused to shift from the expanded position to the collapsed position by pulling the retrieval device **704** in a retrograde manner into the sleeve catheter **702** thereby forcing the filter portion **204** into its collapsed position as it is pulled with the retrieval device **704** into the sleeve catheter **702**, and retrieval device **704** (and thus the collapsed filter portion **204**) is then slidably removed from the sleeve catheter **702** and the patient's body.

[0099] The various devices, systems, and methods for preventing stroke of the present disclosure have various benefits to patients with various diseases and/or disorders of the heart and/or circulatory system. For example, patients with chronic atrial fibrillation (non-valvular atrial fibrillation), recurrence transient ischemic attack, atrial fibrillation and anticoagulation contraindications, and/or left atrial appendage thrombosis may have their risk of stroke either reduced or eliminated by way of an exemplary devices, systems, and/or method of the present disclosure. In addition, patients with acute myocardial infarct with left ventricular thrombus, atrial flutter or fibrillation (ablation and pulmonary vein isolation), cardiomyopathy with left ventricular enlargement, non-obstructive thrombus of a mechanical heart valve, patent foramen ovale (cryptogenic ischemic stroke) and/or an acute infection endocarditis with valve vegetation without valve insufficiency under medical treatment (vegetation >1 cm which currently oblige to surgical remotion) may also benefit from the present disclosure.

[0100] Furthermore, it is noted that the various devices, systems, and methods for preventing stroke of the present disclosure have advantages as compared to anticoagulant and antiplatelet therapies, as not all patients are suitable for such therapies (given the high risk of bleeding, for example), and the relative cost of such therapies, which would be substantially higher as compared to the devices and systems as referenced herein. The various devices and systems would be useful for various aortic arch configurations, noting that there is diversity among arches.

[0101] While various embodiments of devices, systems, and methods for the prevention of stroke have been described in considerable detail herein, the embodiments are merely offered by way of non-limiting examples of the disclosure described herein. It will therefore be understood that various changes and modifications may be made, and equivalents may be substituted for elements thereof, without departing from the scope of the disclosure. Indeed, this disclosure is not intended to be exhaustive or to limit the scope of the disclosure.

[0102] Further, in describing representative embodiments, the disclosure may have presented a method and/or process as a particular sequence of steps. However, to the extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. Other sequences of steps may be possible. Therefore, the particular order of the steps disclosed herein should not be construed as limitations of the present disclosure. In addition, disclosure directed to a method and/or process should not be limited to the performance of their steps in the order written. Such sequences may be varied and still remain within the scope of the present disclosure.

1. A device for the prevention of stroke, the device comprising:

a stent portion having a first end and a second end and sized and shaped to fit within an artery extending from an aortic arch; and

a filter portion positioned at the second end of the stent portion and sized and shaped to prevent the device from advancing into the artery extending from the aortic arch in which the stent portion may be positioned, the filter portion comprising at least two sets of two or more parallel, convex struts positioned across an opening defined within the second end of the stent portion, the at least two sets of two or more parallel, convex struts configured to divert an embolus from entering the artery when the first end of the stent portion is positioned within the artery.

2. The device of claim **1**, wherein the at least two sets of two or more parallel convex struts comprises a first set of parallel convex struts and a second set of parallel convex struts.

3. The device of claim **2**, wherein when the device is positioned within the artery extending from an aortic arch, the first set of two or more parallel convex struts are positioned approximately perpendicular to a direction of blood flow within the aortic arch and the second set of two or more parallel convex struts are positioned perpendicular to the first set of parallel convex struts.

4. The device of claim **2**, wherein when the device is positioned within the artery extending from an aortic arch, the first set of two or more parallel convex struts are positioned in a direction of blood flow within the aortic arch and the second set of two or more parallel convex struts are positioned perpendicular to the first set of parallel convex struts.

5. The device of claim **1**, wherein the filter portion is removably attached to the second end of the stent portion.

6. The device of claim **1**, wherein the stent portion has a length between about 0.8 cm to about 2.5 cm.

7. The device of claim **1**, wherein the stent portion has a diameter between about 6 mm to about 8 mm when the extension portion is in an expanded configuration.

8. The device of claim **1**, wherein the stent portion has a diameter between about 1.8 mm to about 2.0 mm when the extension portion is in a compressed configuration.

9. The device of claim **1**, wherein the device is comprised of a material selected from the group consisting of stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, tantalum, nitinol, nickel-titanium, polymer materials, and a shape-memory polymer.

10. The device of claim **1**, wherein the filter portion comprises a planar flange.

11. The device of claim **1**, further comprising:

one or more radiopaque markers positioned upon the filter portion.

12. The device of claim **11**, wherein the one or more radiopaque markers are positioned relative to the first set of two or more parallel convex struts.

13. The device of claim **11**, wherein when the device is positioned within the artery extending from an aortic arch, the one or more radiopaque markers facilitate alignment of the device so that the first set of two or more parallel convex struts are positioned approximately perpendicular to a direction of blood flow within the aortic arch.

14. The device of claim **11**, wherein when the device positioned within the artery extending from an aortic arch, the one or more radiopaque markers facilitate alignment of the device so that the first set of two or more parallel convex struts are positioned in a direction of blood flow within the aortic arch.

15. The device of claim **1**, wherein the diameter of each strut of the at least two sets of two or more parallel convex struts is between about 0.25 mm and 0.5 mm.

16. The device of claim **2**, wherein each strut of the first set of two or more parallel convex struts are positioned between about 0.5 mm to 1.5 mm from one another, and each strut of the second set of two or more parallel convex struts are positioned between about 0.5 mm to 1.5 mm from one another.

17. The device of claim **1**, wherein the at least two sets of two or more parallel, convex struts are negatively charged.

18. The device of claim **1**, wherein the at least two sets of two or more parallel, convex struts are coated with a coating comprising graphene oxide.

19. The device of claim **18**, wherein the coating further comprises bovine serum albumin.

20. The device of claim **18**, wherein the coating further comprises at least one microparticle from the group consisting of gold microparticles, silver microparticles, alumina microparticles, and titanium dioxide microparticles.

21. A system for preventing stroke, the system comprising:

- a device for the prevention of stroke, the device comprising:
  - a stent portion having a first end and a second end and sized and shaped to fit within an artery extending from an aortic arch; and
  - a filter portion positioned at the second end of the stent portion and sized and shaped to prevent the device from advancing into the artery extending from the aortic arch in which the stent portion may be positioned, the filter portion comprising at least two sets of two or more parallel, convex struts positioned across an opening defined within the second end of the stent portion, the at least two sets of two or more parallel, convex struts configured to divert an embolus from entering the artery when the first end of the stent portion is positioned within the artery;
- a hypotube having a distal end and a proximal end;
- a folder coupled to the distal end of the hypotube, the folder sized and shaped to receive at least a portion of the device for the prevention of stroke; and
- a sleeve positioned circumferentially around the hypotube proximal to the folder, the sleeve sized and shaped to receive at least a portion of the device for the prevention of stroke.

22. The system of claim **21**, wherein the at least two sets of two or more parallel convex struts of the device comprises a first set of parallel convex struts and a second set of parallel convex struts perpendicular to the first set of parallel convex struts.

23. The system of claim **21**, wherein the filter portion of the device is removably attached to the second end of the stent portion of the device.

24. The system of claim **21**, wherein the stent portion and the filter portion are autoexpandable.

25. The system of claim **21**, wherein the device is comprised of a material selected from the group consisting of stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, tantalum, nitinol, nickel-titanium, polymer materials, and a shape-memory polymer.

26. The system of claim **21**, wherein the filter portion of the device comprises a planar flange.

27. The system of claim **21**, wherein the at least two sets of two or more parallel, convex struts are negatively charged.

28. The system of claim **21**, wherein the at least two sets of two or more parallel, convex struts are coated with a coating comprising graphene oxide.

29. The system of claim **28**, wherein the coating further comprises bovine serum albumin.

30. The device of claim **28**, wherein the coating further comprises at least one microparticle from the group consisting of gold microparticles, silver microparticles, alumina microparticles, and titanium dioxide microparticles.

* * * * *