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(71) Applicant: IMPERATIVE CARE, INC. [US/US]; 1359 Dell Avenue, Campbell, California 95008 (US).

(72) Inventors: JANSEN, Lex Philip; 1359 Dell Avenue, Campbell, CA 95008 (US). YOURGENLOW, Ashoor Shahbazi; 1359 Dell Avenue, Campbell, CA 95008 (US). YEE, Brandon; 1359 Dell Avenue, Campbell, CA 95008 (US). DOAN, Hao; 1359 Dell Avenue, Campbell, CA 95008 (US). BLUM, David; 1359 Dell Avenue, Campbell, CA 95008 (US). YANG, Yi; 1359 Dell Avenue, Campbell, CA 95008 (US).

(74) Agent: DELANEY, Karoline, A.; KNOBBE, MARTENS, OLSON & BEAR, LLP, 2040 Main Street, 14th Floor, Irvine, California 92614 (US).

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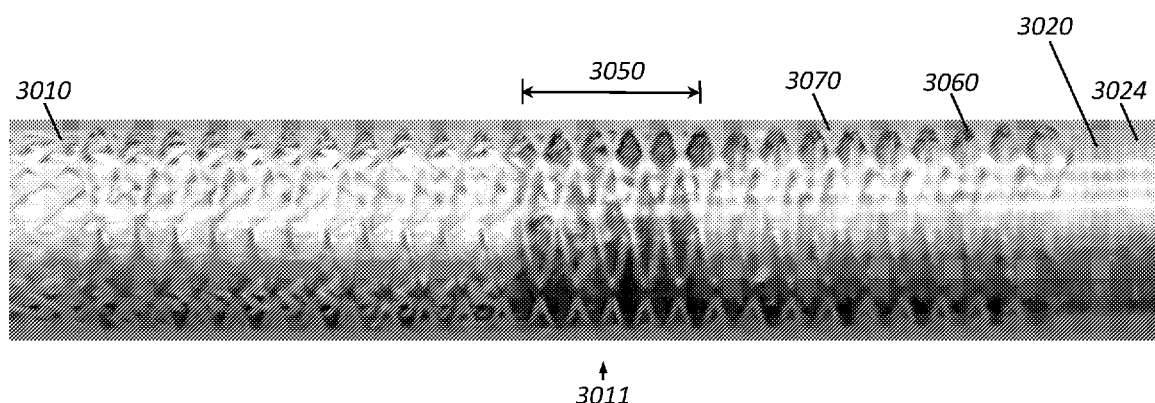


FIG. 12

(57) Abstract: An enhanced flexibility catheter is provided, such as for distal neurovascular access or aspiration. The catheter includes an elongate flexible body, having a proximal end, a distal end, and a side wall defining a central lumen. The side wall includes a distal zone including a helical coil and a transition between the distal zone and a proximal zone of the side wall. The transition serves to provide superior kink resistance between the distal zone and the proximal zone.



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ENHANCED FLEXIBILITY NEUROVASCULAR CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the priority benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 62/987,546, filed March 10, 2020. The entirety of which is hereby are incorporated by reference herein.

BACKGROUND

[0002] Stroke is the third most common cause of death in the United States and the most disabling neurologic disorder. Approximately 700,000 patients suffer from stroke annually. Stroke is a syndrome characterized by the acute onset of a neurological deficit that persists for at least 24 hours, reflecting focal involvement of the central nervous system, and is the result of a disturbance of the cerebral circulation. Its incidence increases with age. Risk factors for stroke include systolic or diastolic hypertension, hypercholesterolemia, cigarette smoking, heavy alcohol consumption, and oral contraceptive use.

[0003] Hemorrhagic stroke accounts for 20% of the annual stroke population. Hemorrhagic stroke often occurs due to rupture of an aneurysm or arteriovenous malformation bleeding into the brain tissue, resulting in cerebral infarction. The remaining 80% of the stroke population are ischemic strokes and are caused by occluded vessels that deprive the brain of oxygen-carrying blood. Ischemic strokes are often caused by emboli or pieces of thrombotic tissue that have dislodged from other body sites or from the cerebral vessels themselves to occlude in the narrow cerebral arteries more distally. When a patient presents with neurological symptoms and signs which resolve completely within 1 hour, the term transient ischemic attack (TIA) is used. Etiologically, TIA and stroke share the same pathophysiologic mechanisms and thus represent a continuum based on persistence of symptoms and extent of ischemic insult.

[0004] Emboli occasionally form around the valves of the heart or in the left atrial appendage during periods of irregular heart rhythm and then are dislodged and follow the blood flow into the distal regions of the body. Those emboli can pass to the brain and cause an embolic stroke. As will be discussed below, many such occlusions occur in the middle cerebral artery (MCA), although such is not the only site where emboli come to rest.

[0005] When a patient presents with neurological deficit, a diagnostic hypothesis for the cause of stroke can be generated based on the patient's history, a review of stroke risk factors, and a neurologic examination. If an ischemic event is suspected, a clinician can tentatively assess whether the patient has a cardiogenic source of emboli, large artery extracranial or intracranial disease, small artery intraparenchymal disease, or a hematologic or other systemic disorder. A head CT scan is often performed to determine whether the patient has suffered an ischemic or hemorrhagic insult. Blood would be present on the CT scan in subarachnoid hemorrhage, intraparenchymal hematoma, or intraventricular hemorrhage.

[0006] Traditionally, emergent management of acute ischemic stroke consisted mainly of general supportive care, e.g. hydration, monitoring neurological status, blood pressure control, and/or anti-platelet or anti-coagulation therapy. In 1996, the Food and Drug Administration approved the use of Genentech Inc.'s thrombolytic drug, tissue plasminogen activator (t-PA) or Activase®, for treating acute stroke. A randomized, double-blind trial, the National Institute of Neurological Disorders and t-PA Stroke Study, revealed a statistically significant improvement in stroke scale scores at 24 hours in the group of patients receiving intravenous t-PA within 3 hours of the onset of an ischemic stroke. Since the approval of t-PA, an emergency room physician could, for the first time, offer a stroke patient an effective treatment besides supportive care.

[0007] However, treatment with systemic t-PA is associated with increased risk of intracerebral hemorrhage and other hemorrhagic complications. Patients treated with t-PA were more likely to sustain a symptomatic intracerebral hemorrhage during the first 36 hours of treatment. The frequency of symptomatic hemorrhage increases when t-PA is administered beyond 3 hours from the onset of a stroke. Besides the time constraint in using t-PA in acute ischemic stroke, other contraindications include the following: if the patient has had a previous stroke or serious head trauma in the preceding 3 months, if the patient has a systolic blood pressure above 185 mm Hg or diastolic blood pressure above 110 mmHg, if the patient requires aggressive treatment to reduce the blood pressure to the specified limits, if the patient is taking anticoagulants or has a propensity to hemorrhage, and/or if the patient has had a recent invasive surgical procedure. Therefore, only a small percentage of selected stroke patients are qualified to receive t-PA.

[0008] Obstructive emboli have also been mechanically removed from various sites in the vasculature for years. Mechanical therapies have involved capturing and removing the clot, dissolving the clot, disrupting and suctioning the clot, and/or creating a flow channel through the clot. One of the first mechanical devices developed for stroke treatment is the MERCI Retriever System (Concentric Medical, Redwood City, Calif.). A balloon-tipped guide catheter is used to access the internal carotid artery (ICA) from the femoral artery. A microcatheter is placed through the guide catheter and used to deliver the coil-tipped retriever across the clot and is then pulled back to deploy the retriever around the clot. The microcatheter and retriever are then pulled back, with the goal of pulling the clot, into the balloon guide catheter while the balloon is inflated and a syringe is connected to the balloon guide catheter to aspirate the guide catheter during clot retrieval. This device has had initially positive results as compared to thrombolytic therapy alone.

[0009] Other thrombectomy devices utilize expandable cages, baskets, or snares to capture and retrieve clot. Temporary stents, sometimes referred to as stentriever or revascularization devices, are utilized to remove or retrieve clot as well as restore flow to the vessel. A series of devices using active laser or ultrasound energy to break up the clot have also been utilized. Other active energy devices have been used in conjunction with intra-arterial thrombolytic infusion to accelerate the dissolution of the thrombus. Many of these devices are used in conjunction with aspiration to aid in the removal of the clot and reduce the risk of emboli. Suctioning of the clot has also been used with single-lumen catheters and syringes or aspiration pumps, with or without adjunct disruption of the clot. Devices which apply powered fluid vortices in combination with suction have been utilized to improve the efficacy of this method of thrombectomy. Finally, balloons or stents have been used to create a patent lumen through the clot when clot removal or dissolution was not possible.

[0010] Notwithstanding the foregoing, there remains a need for new devices and methods for treating vasculature occlusions in the body, including acute ischemic stroke and occlusive cerebrovascular disease.

SUMMARY

[0011] In accordance with one aspect, there is provided an enhanced flexibility neurovascular catheter, comprising: an elongate flexible body, having a proximal end, a distal

end and a side wall defining a central lumen, a distal zone of the side wall comprising: a tubular inner liner; a soft tie layer separated from the lumen by the inner liner; a helical coil surrounding the tie layer, adjacent windings of the coil spaced progressively further apart in the distal direction; and an outer jacket surrounding the helical coil, the outer jacket formed from a plurality of tubular segments positioned coaxially about the coil; wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D. In one aspect of present disclosure, the tubular liner is formed by dip coating a removable mandrel. In another aspect of present disclosure, the tubular liner comprises PTFE.

[0012] In yet another aspect of present disclosure, the tie layer comprises polyurethane. The tie layer may have a wall thickness of no more than about 0.005 inches and may extend along at least the most distal 20 cm of the flexible body. In one aspect of present disclosure, the coil comprises a shape memory material. The coil may comprise Nitinol, and the Nitinol may comprise an Austenite state at body temperature.

[0013] In one aspect of present disclosure, the outer jacket is formed from at least five discrete tubular segments. The outer jacket may be formed from at least nine discrete tubular segments. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 20D. The difference in durometer between a proximal one of the tubular segments and a distal one of the tubular segments may be at least about 30D.

[0014] In another aspect of present disclosure, the enhanced flexibility neurovascular catheter, further comprises a tension support for increasing the tension resistance in the distal zone. The tension support may comprise a filament and may comprise an axially extending filament. The axially extending filament may be carried between the inner liner and the helical coil. The axially extending filament may increase the tensile strength to at least about 5 pounds.

[0015] In accordance with one aspect, there is provided an enhanced flexibility catheter, comprising: an elongate flexible body having a proximal end, a distal end and a side wall defining a central lumen, wherein the side wall comprises a distal zone comprising a helical coil, and a transition between the distal zone and a proximal zone of the side wall, wherein the transition comprises a distal surface that matches at least a portion of a proximal

surface of the helical coil of the distal zone. In some embodiments, the matching creates a uniform gap between the at least a portion of the proximal surface of the helical coil of the distal zone and the distal surface of the transition. In some embodiments, the distal surface of the transition comprises a step. In some embodiments, the distal surface of the transition comprises a step wherein a tangential surface of the step matches a termination of the helical coil of the distal zone. In some embodiments, the transition comprises a tubular body. In some embodiments, the transition comprises a tubular body comprising a planar proximal surface. In some embodiments, the transition comprises a durometer between a durometer of the proximal zone and a durometer of the distal zone. In some embodiments, the transition comprises platinum and a platinum alloy. In some embodiments, the platinum alloy comprises about 90% Platinum and about 10% Iridium. In some embodiments, the proximal zone of the side wall comprises a braid. In some embodiments, the side wall further comprises a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the helical coil of the distal zone surrounds the tie layer and the braid of the proximal zone surrounds the tie layer. In some embodiments, the elongate flexible body further comprises an outer jacket formed from a plurality of tubular segments and extending coaxially about the helical coil, wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D. In some embodiments, the elongate flexible body further comprises an axially extending filament within the side wall.

[0016] In accordance with one aspect, there is provided an enhanced flexibility catheter comprising: an elongate flexible body having a proximal end, a distal end and a side wall defining a central lumen, wherein the side wall comprises a distal zone comprising a helical coil, and a transition between the distal zone and a proximal zone of the side wall, wherein the transition comprises a distal surface comprising a step, and the distal surface matches at least a portion of a proximal surface of the helical coil of the distal zone. In some embodiments, the matching creates a uniform gap between the at least a portion of the proximal surface of the helical coil of the distal zone and the distal surface of the transition. In some embodiments, the step of the distal surface of the transition comprises a 5/1000 pitch cut from the distal surface. In some embodiments, a tangential surface of the step matches a termination of the helical coil of the distal zone. In some embodiments, the transition comprises a tubular

body. In some embodiments, the transition comprises a tubular body comprising a planar proximal surface. In some embodiments, the transition comprises a durometer between a durometer of the proximal zone and a durometer of the distal zone. In some embodiments, the transition comprises platinum and a platinum alloy. In some embodiments, the platinum alloy comprises about 90% Platinum and about 10% Iridium. In some embodiments, the proximal zone of the side wall comprises a braid. In some embodiments, the side wall further comprises a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the helical coil of the distal zone surrounds the tie layer and the braid of the proximal zone surrounds the tie layer. In some embodiments, the elongate flexible body further comprises an outer jacket formed from a plurality of tubular segments and extending coaxially about the helical coil, wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D. In some embodiments, the elongate flexible body further comprises an axially extending filament within the side wall.

[0017] Any of the foregoing catheters may be provided with a transition support over a junction between two dissimilar wall constructions, such as over the braid to coil junction, to improve bending characteristics of the catheter. Thus, there is provided an enhanced flexibility catheter, comprising: an elongate flexible body having a proximal end, a distal end, and a side wall defining a central lumen, wherein the side wall comprises: a proximal zone comprising a tubular braid and a first helical coil; a distal zone comprising a second helical coil, and a transition between the distal zone and the proximal zone, wherein the transition comprises a distal end of the tubular braid within 1 cm of a proximal end of the second helical coil, and the first helical coil extends distally beyond the transition.

[0018] The distal end of the tubular braid may be within 5 mm, within 2mm or in contact with the proximal end of the second helical coil. The first helical coil may be formed from a wire having a first diameter, and the second helical coil may be formed from a wire having a second, larger diameter. The first helical coil may comprise stainless steel, and the second helical coil may comprise Nitinol.

[0019] A distal section of the braid may be heat annealed for a length of at least about one or two cm and typically no more than 10 cm or 5 cm. The first and second helical

coils may be provided with an axial overlapping intertwined zone having a length of at least about 5mm or 2cm or 5cm but generally no more than about 20 cm

[0020] The side wall may further comprise a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the second helical coil of the distal zone is adjacent the tie layer and the braid of the proximal zone is adjacent the tie layer. The elongate flexible body may further comprise an outer jacket formed from a plurality of axially adjacent tubular segments wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D. The elongate flexible body may further comprise an axially extending filament within the side wall.

[0021] The catheter may further comprise a tubular support having a proximal end surrounding a distal portion of the braid and a distal end surrounding a proximal portion of the second coil. The tubular support may comprise a slotted metal tube.

[0022] There is also provided an enhanced flexibility catheter, comprising: an elongate flexible body having a proximal end, a distal end, and a side wall defining a central lumen, wherein the side wall comprises: a proximal tubular braid having a distal end adjacent a proximal end of a helical coil to form a junction, a tubular metal support spanning the junction; and an outer jacket surrounding the tubular support. The catheter may further comprise an axial filament extending distally from beneath the tubular support.

[0023] The side wall may further comprise a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the helical coil of the distal zone surrounds the tie layer and the braid of the proximal zone surrounds the tie layer. The elongate flexible body may further comprise an outer jacket formed from a plurality of axially adjacent tubular segments extending coaxially about the helical coil, wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

[0024] There is also provided a method of making an enhanced flexibility catheter. The method comprises forming a catheter comprising a braid in a proximal zone of the catheter; placing at least a portion of the braid of the catheter over a mandrel; annealing a distal section of the braid comprising induction heating the braid and mandrel in a coil; and visibly monitoring a parameter change of the braid. Induction heating the braid may comprise placing

the braid and mandrel within an ERDO induction heater. The parameter change comprises a color change of the braid. The distal annealed section may have an axial length of no more than about 2 cm.

[0025] Any feature, structure, or step disclosed herein can be replaced with or combined with any other feature, structure, or step disclosed herein, or omitted. Further, for purposes of summarizing the disclosure, certain aspects, advantages, and features of the embodiments have been described herein. It is to be understood that not necessarily any or all such advantages are achieved in accordance with any particular embodiment disclosed herein. No individual aspects of this disclosure are essential or indispensable. Further features and advantages of the embodiments will become apparent to those of skill in the art in view of the Detailed Description which follows when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] FIG. 1 is a side elevational schematic view of an intracranial aspiration catheter in accordance with the some embodiments, with a distal segment in a proximally retracted configuration.

[0027] FIG. 2 is a side elevational view as in FIG. 1, with the distal segment in a distally extended configuration.

[0028] FIGS. 3A–3F depict a sequence of steps in accordance with some embodiments involved in accessing a neurovascular occlusion for aspiration.

[0029] FIG. 4 illustrates a cross-sectional elevational view of a catheter wall according to some embodiments.

[0030] FIG. 5A illustrates a cross-sectional elevational view of a catheter wall according to some embodiments, showing one or more axially extending filaments.

[0031] FIG. 5B describes a side elevational view of the catheter of FIG. 5A

[0032] FIG. 5C illustrates a cross-sectional view taken along the line C-C of FIG. 5B, showing one or more axially extending filaments.

[0033] FIG. 6A depicts a side elevational view of a catheter according to some embodiments.

[0034] FIG. 6B describes a cross-sectional elevational view taken along the line A-A of FIG. 6A.

[0035] FIG. 6C illustrates a cross-sectional view taken along the line B-B of FIG. 6A.

[0036] FIG. 7A depicts a side elevational view of a catheter according to some embodiments.

[0037] FIG. 7B describes a cross-sectional elevational view taken along the line A-A of FIG. 7A, showing one or more axially extending filaments.

[0038] FIG. 7C illustrates a cross-sectional view taken along the line B-B of FIG. 7A, showing one or more axially extending filaments.

[0039] FIG. 8A illustrates a side elevational view of a progressively enhanced flexibility catheter according to some embodiments.

[0040] FIG. 8B is a proximal end view of the enhanced flexibility catheter of FIG. 8A.

[0041] FIG. 9 illustrates back-up support of the catheter in accordance with some embodiments.

[0042] FIG. 10 depicts a graph of modulus or durometer of the catheter along the length of the catheter, from the proximal end to the distal end.

[0043] FIG. 11 depicts a graph of flexure test profiles of catheters in accordance with some embodiments compared with conventional catheters.

[0044] FIG. 12 shows a side view of a catheter with a distal transition cover according to some embodiments..

[0045] FIG. 13 is a longitudinal cross-sectional view of the catheter wall segment shown in Figure 12.

[0046] FIGS. 14A-14F illustrate cross-sectional elevational views of a catheter wall at a distal transition according to some embodiments.

[0047] FIGS. 15A-15F illustrate cross-sectional elevational views of a catheter wall at a distal transition according to some embodiments, showing one or more axially extending filaments.

[0048] FIGS. 16A-16F illustrate cross-sectional elevational views of a catheter wall at a distal transition with a distal transition cover according to some embodiments.

[0049] FIGS. 17A-17F illustrate cross-sectional elevational views of a catheter wall at a distal transition with a distal transition cover according to some embodiments, showing one or more axially extending filaments.

[0050] FIGS. 18A-18F illustrate cross-sectional elevational views of a catheter wall at a distal transition with a distal transition cover according to some embodiments.

[0051] FIGS. 19A-19F illustrate cross-sectional elevational views of a catheter wall at a distal transition with a distal transition cover according to some embodiments, showing one or more axially extending filaments.

[0052] FIG. 20 shows flexibility of braids of some embodiments according to different annealing processes.

[0053] FIGS. 21A-21B show images of braid microstructure of some embodiments according to different annealing processes.

[0054] FIG. 22A shows plots of the effects of annealing power and time on the flexibility of braids according to some embodiments.

[0055] FIG. 22B shows a plot of braid flexibility versus annealing power for various annealing times according to some embodiments.

[0056] FIG. 23 illustrates a perspective view of a distal transition connector according to some embodiments.

[0057] FIGS. 24A-24B illustrate side views of various configurations of a distal transition connector according to some embodiments.

[0058] FIG. 25 illustrates a side view of a catheter with a distal transition connector according to some embodiments.

DETAILED DESCRIPTION

[0059] Referring to FIG. 1 and FIG. 2, there is disclosed a catheter 10 in accordance with one aspect of present embodiments. Although primarily described in the context of an axially extendable distal segment aspiration catheter with a single central lumen, catheters of present embodiments can readily be modified to incorporate additional structures, such as permanent or removable column strength enhancing mandrels, two or more lumen such as to permit drug, contrast or irrigant infusion or to supply inflation media to one or more inflatable balloons carried by the catheter, or combinations of these features, as will be readily apparent

to one of skill in the art in view of the disclosure herein. In addition, present embodiments will be described primarily in the context of removing obstructive material from remote arteries, veins or vasculature in the brain, but have applicability as access catheters for delivery and removal of any of a variety of diagnostics or therapeutic devices with or without aspiration.

[0060] The catheters disclosed herein may readily be adapted for use throughout the body wherever it may be desirable to distally advance a low profile or small diameter distal catheter segment from a larger diameter proximal segment. For example, axially extendable catheter shafts in accordance with the present embodiments may be dimensioned for use throughout the coronary and peripheral vasculature, the gastrointestinal tract, the urethra, ureters, Fallopian tubes and other lumens and potential lumens, as well. The telescoping structure of the present embodiments may also be used to provide minimally invasive percutaneous tissue access, such as for diagnostic or therapeutic access to a solid tissue target (e.g., breast or liver or brain biopsy or tissue excision), delivery of laparoscopic tools or access to bones such as the spine for delivery of screws, bone cement or other tools or implants.

[0061] The catheter 10 generally comprises an elongate tubular body 16 extending between a proximal end 12 and a distal functional end 14. The length of the tubular body 16 depends upon the desired application. For example, lengths in the area of from about 120 cm to about 140 cm or more are typical for use in femoral access percutaneous transluminal coronary applications. Intracranial or other applications may call for a different catheter shaft length depending upon the vascular access site, as will be understood in the art.

[0062] In the illustrated embodiment, the tubular body 16 is divided into at least a fixed proximal section 33 and an axially extendable and retractable distal section 34 separated at a transition 32. However, the catheter sidewall constructions disclosed herein have applicability in catheters without the use of an extension segment, such as a first single lumen aspiration catheter having a first diameter and optionally a second single lumen aspiration catheter having a second, smaller diameter and greater length than the first catheter so that the second catheter can be advanced through the first catheter.

[0063] Simplified method for aspirating a thrombotic occlusion in accordance with present embodiments is described in connection with FIGS. 3A—3F. The steps for aspirating a thrombotic occlusion make use of a transitional guidewire and a transitional guide sheath. The transitional guidewire has a soft and trackable distal segment that can include a smaller

diameter guidewire than in other situations so that the transitional guidewire may be advanced deeper. In addition, the transitional guide sheath has a soft and trackable distal segment such that the transitional guide sheath may be advanced deeper than previous guide sheaths. Using a transitional guidewire and a transitional guide sheath that can be advanced to an area near the clot eliminates the need to use a second guidewire or a reperfusion catheter to reach the clot.

[0064] Referring to FIG. 3A, an introducer sheath 1220 is introduced at the femoral artery 1218. The outer diameter of the introducer sheath 1220 may be equal to or less than about 12F, 11F, 10F, 9F, 8F, 7F, or 6F. Then, a transitional guide sheath 1222 such as the combination access and aspiration catheter discussed in greater detail below is inserted through the introducer sheath 1220 at the femoral artery 1218. The outer diameter of the guide sheath 1222 may be equal to or less than about 9F, 8F, 7F, 6F, 5F, 4F, or 3F. Referring to FIG. 3B, an insert catheter 1224 is inserted through the transitional guide sheath 1222. The outer diameter of the insert catheter 1224 may be less than about 9F, 8F, 7F, 6F, 5F, 4F, or 3F, and the inner diameter of the transitional guide sheath 1222 may be greater than the outer diameter of the insert catheter 1224. In some cases, a first guidewire may be introduced through the insert catheter 1224 (not shown in FIG. 3B). The diameter of the proximal section of the first guidewire may be equal to or less than about 0.079", about 0.066", about 0.053", about 0.038", about 0.035", about 0.030", or about 0.013".

[0065] The transitional guide sheath 1222, the insert catheter 1224, and optionally the first guidewire are tracked up to the aortic arch 1214. See FIG. 3B. The insert catheter 1224 may be used to select the origin of a vessel. In FIG. 3B, the insert catheter 1224 engages the origin 1216 of the brachiocephalic artery 82. An angiographic run may be performed by injecting contrast media through the insert catheter 1224. In the cases where the first guidewire is used before the angiographic run, the first guidewire may be removed prior to injecting the contrast media.

[0066] Referring to FIG. 3C, the transitional guidewire 1226 is inserted through the lumen of the insert catheter 1224 or guide sheath 1222. The diameter of at least a portion of the transitional guidewire 1226 (e.g., proximal diameter) is substantially similar to that of the first guidewire 1126. The diameter of at least a portion of the transitional guidewire 1226 (e.g., distal diameter) may be smaller than that of the first guidewire 1126 and may have a diameter

along a proximal segment of at least about 0.030" and in some embodiments about 0.038". A transition begins within the range of from about 15 cm to 30 cm from the distal end, and typically no more than about 20 cm or 25 cm from the distal end, distally of which the diameter tapers down to no more than about 0.018" and in some embodiments about 0.016". Referring to FIG. 3D, if utilized, the insert catheter 1224 may be removed because it may be too stiff to be advanced to the MCA 1204. In some embodiments, the transitional guidewire 1226 provides sufficient back up support that the combination access and aspiration catheter 1224 may be advanced directly over the transitional guidewire without any intervening devices. Then, the transitional guidewire 1226 is advanced to the MCA 1204. The transitional guidewire 1226 has a distal segment that has a smaller diameter than that of the first guidewire 1126 described in FIG. 9C. The distal segment of the transitional guidewire 1226 comprises a soft and atraumatic tip and can be tracked to the remote neurovasculature such as the MCA 1204, which is distal to the petrous segment 1212 of the ICA 1206.

[0067] Referring to FIG. 3E, the transitional guide sheath 1222 is advanced to or beyond the cavernous segment 1210 or the cerebral 1208 segment of the ICA 1206. Unlike the guide sheath 1122 described in FIG. 9D, the transitional guide sheath 1222 may be advanced to the cavernous segment 1210 or the cerebral 1208 segment of the ICA 1206 beyond the petrous segment 1212 because the transitional guide sheath 1222 has a soft yet trackable distal segment described in further detail below, for example in connection with Figure 14. The larger proximal diameter and stiffer body of the transitional guidewire 1226 may provide better support for the transitional guide sheath 1222 to track through the vasculature.

[0068] Referring to FIG. 3F, after the transitional guide sheath 1222 is advanced to the cerebral segment 1208 of the ICA 1206, the transitional guidewire 1226 is removed. Then, a vacuum pressure is applied at the proximal end of the transitional guide sheath 1222 to aspirate the occlusion 1202 through the central lumen of the transitional guide sheath 1222. The inner diameter of the transitional guide sheath 1222 may be equal to about or greater than about 0.100", about 0.088", about 0.080", about 0.070", or about 0.060". The inner diameter of the transitional guide sheath 1222 is larger than prior aspiration catheters, which translates to more effective aspiration. The cross-sectional area of the central lumen of the transitional guide sheath 1222 may be almost twice as large as that of the largest aspiration catheter 1128 currently available.

[0069] If the guide sheath 1222 is not able to track deep enough into the distal vasculature to reach the occlusion or other desired target site, a telescopic extension segment as discussed elsewhere herein may be introduced into the proximal end of sheath 1222 and advanced distally to extend beyond the distal end of the sheath 1222 and thereby extend the reach of the aspiration system. In some embodiments, the extension segment has an ID of about 0.070".

[0070] If thrombotic material is not able to be drawn into the sheath 1222 or extension segment under constant vacuum, pulsatile vacuum may be applied as discussed below. If pulsatile vacuum does not satisfactorily capture the occlusion, an agitator may be advanced through the sheath 1222 and extension segment to facilitate drawing the clot into the central lumen. Additional details of the agitator and its use are disclosed below.

[0071] A pulsatile vacuum pressure aspirator may be used in order to improve effectiveness of aspiration for vascular thrombectomy and to improve catheter trackability through tortuous vasculatures. In some embodiments, a pulsatile vacuum pressure aspirator may apply intermittent or pulsatile vacuum to lumen 40 or a lumen of the various embodiments described herein. A pulsatile vacuum pressure aspirator can be in fluid connection with the proximal end 12 of the catheter 10 and comprises one or more of vacuum generator, vacuum chamber, collection canister, solenoid valve, frequency modulator, valve controller, or remote controller.

[0072] In some embodiments, referring to FIG. 4, the catheter 3000 may have an effective length from the manifold to distal tip from about 70cm to about 150cm, from about 80cm to about 140cm, from about 90cm to about 130cm, from about 100cm to about 120cm, or from about 105cm to about 115cm. The outer diameter of the catheter 3000 may be from about 0.07 inches to about 0.15 inches, from about 0.08 inches to about 0.14 inches, from about 0.09 inches to about 0.13 inches, from about 0.1 inches to about 0.12 inches, or from about 0.105 inches to about 0.115 inches, and may be less in a distal segment than in a proximal segment. The inner diameter 3108 of the catheter 3000 in a single central lumen embodiment may be greater than or equal to about 0.11 inches, greater than or equal to about 0.1 inches, greater than or equal to about 0.09 inches, greater than or equal to about 0.088 inches, greater than or equal to about 0.08 inches, greater than or equal to about 0.07 inches, greater than or equal to about 0.06 inches, or greater than or equal to about 0.05 inches. The inner diameter

3108 of the catheter 3000 in a single central lumen embodiment may be less than or equal to about 0.11 inches, less than or equal to about 0.1 inches, less than or equal to about 0.09 inches, less than or equal to about 0.088 inches, less than or equal to about 0.08 inches, less than or equal to about 0.07 inches, less than or equal to about 0.06 inches, or less than or equal to about 0.05 inches. Referring to FIG. 4, an inner liner 3014 may be formed by dip coating a mandrel (not shown) to provide a thin walled tubular inside layer of the catheter body 3000. The dip coating may be produced by coating a wire such as a silver coated copper wire in PTFE. The mandrel may thereafter be axially elongated to reduce its diameter, and removed to leave the tubular inner liner. The outside surface of the tubular inner liner 3014 may thereafter be coated with a soft tie layer 3012 such as polyurethane (e.g., TecoflexTM), to produce a layer having a thickness of no more than about 0.005 inches, and in some implementations approximately 0.001 inches. The tie layer 3012 will generally extend along at least about the most distal 10 cm or 20 cm of the catheter 3000, generally less than about 50 cm and may in some embodiments extend approximately the distal 30 cm of the catheter 3000.

[0073] A braid such as a 75 ppi stainless steel braid 3010 may thereafter be wrapped around the inner liner 3014 through a proximal zone up to a distal transition 3011. From the distal transition 3011 to the distal end of the catheter 3000, a coil 3024 comprising a shape memory material such as a Nitinol alloy may thereafter be wrapped around the inner liner 3014. In some embodiments, the Nitinol coil has a transition temperature below body temperature so that the Nitinol resides in the austenite (springy/super elastic) state at body temperature. Adjacent loops or filars of the coil may be closely tightly wound in a proximal zone with a distal section having looser spacing between adjacent loops. In embodiments having a coil section 3024 with an axial length of between about 20% and 30% of the overall catheter length, (e.g., 28 cm coil length in a 110 cm catheter 3000), at least the distal 1 or 2 or 3 or 4 cm of the coil will have a spacing that is at least about 130%, and in some implementations at least about 150% or more than the spacing in the proximal coil section. In a 110 cm catheter 3000 having a Nitinol coil the spacing in the proximal coil may be about 0.004 inches and in the distal section may be at least about 0.006 inches or 0.007 inches or more.

[0074] The distal end of the coil 3024 may be spaced proximally from the distal end of the inner liner 3014 to provide room for an annular radiopaque marker 3040. In some

embodiments, the distal end of the catheter 3000 is provided with a beveled distal surface 3006 residing on a plane having an angle of at least about 10° or 20° and in some embodiments about 30° with respect to a longitudinal axis of the catheter 3000. The radiopaque marker 3040 may reside in a plane that is transverse to the longitudinal axis. Alternatively, at least the distally facing edge of the annular radiopaque (RO) marker 3040 may be an ellipse, residing on a plane which is inclined with respect to the longitudinal axis to complement the bevel angle of the distal surface 3006.

[0075] After applying the proximal braid 3010, the distal coil 3024 and the RO marker 3040, an outer sleeve or jacket 3020 may be applied such as a shrink wrap tube to enclose the body of catheter 3000. The outer shrink-wrapped sleeve 3020 may comprise any of a variety of materials, such as polyethylene, polyurethane, PEBAX, nylon or others known in the art. In some embodiments, the outer shrink-wrapped sleeve or jacket 3020 may comprise a hydrophilic material. Sufficient heat is applied to cause the polymer to flow into and embed the proximal braid and distal coil.

[0076] In some embodiments, the outer shrink wrap jacket 3020 is formed by sequentially advancing a plurality of short tubular segments 3022, 3026, 3028, 3030, 3032, 3034, 3036, 3038 concentrically over the catheter shaft subassembly, and applying heat to shrink the sections on to the catheter 3000 and provide a smooth continuous outer tubular body. The foregoing construction may extend along at least the most distal 10 cm, and in some embodiments at least about the most distal 20 or 25 cm of the catheter 3000.

[0077] The durometer of the outer wall segments may decrease in a distal direction. For example, proximal segments such as 3022 and 3026 may have a durometer of at least about 60 or 70D, with gradual decrease in durometer of successive segments in a distal direction to a durometer of no more than about 35D or 25D or lower. A 25 cm section may have at least about 3 or 5 or 7 or more segments and the catheter 3000 overall may have at least about 6 or 8 or 10 or more distinct flexibility zones. The distal 1 or 2 or 4 or more segments 3036, 3038, may have a smaller OD following shrinking than the more proximal segments 3022-3034 to produce a step down in OD for the finished body of catheter 3000. The length of the smaller OD section 3004 may be within the range of from about 3 cm to about 15 cm and in some embodiments is within the range of from about 5 cm to about 10 cm such as about 7 cm or 8

cm, and may be accomplished by providing the distal segments 3036, 3038 with a smaller wall thickness.

[0078] Referring to FIGS. 5A-5C, the catheter may further comprise a tension support for increasing the tension resistance in the distal zone. The tension support may comprise a filament and, more specifically, may comprise one or more axially extending filaments 3042. The one or more axially extending filaments 3042 may be axially placed inside the catheter wall near the distal end of the catheter. The one or more axially extending filaments 3042 serve as a tension support and resist elongation of the catheter wall under tension (e.g., when the catheter is being proximally retracted through tortuous vasculature). At least one of the one or more axially extending filaments 3042 may proximally extend along the length of the catheter wall from near the distal end of the catheter to less than about 5cm from the distal end of the catheter, less than about 10cm from the distal end of the catheter, less than about 15cm from the distal end of the catheter, less than about 20cm from the distal end of the catheter, less than about 25cm from the distal end of the catheter, less than about 30cm from the distal end of the catheter, less than about 35cm from the distal end of the catheter, less than about 40cm from the distal end of the catheter, or less than about 50cm from the distal end of the catheter. The one or more axially extending filaments 3042 may have a length greater than or equal to about 50cm, greater than or equal to about 40cm, greater than or equal to about 35cm, greater than or equal to about 30cm, greater than or equal to about 25cm, greater than or equal to about 20cm, greater than or equal to about 15cm, greater than or equal to about 10cm, or greater than or equal to about 5cm. At least one of the one or more axially extending filaments 3042 may have a length less than or equal to about 50cm, less than or equal to about 40cm, less than or equal to about 35cm, less than or equal to about 30cm, less than or equal to about 25cm, less than or equal to about 20cm, less than or equal to about 15cm, less than or equal to about 10cm, or less than or equal to about 5cm. At least one of the one or more axially extending filaments 3042 may extend at least about the most distal 50 cm of the length of the catheter, at least about the most distal 40 cm of the length of the catheter, at least about the most distal 35 cm of the length of the catheter, at least about the most distal 30 cm of the length of the catheter, at least about the most distal 25 cm of the length of the catheter, at least about the most distal 20 cm of the length of the catheter, at least about the most distal

15 cm of the length of the catheter, at least about the most distal 10 cm of the length of the catheter, or at least about the most distal 5 cm of the length of the catheter.

[0079] The one or more axially extending filaments 3042 may be placed near or radially outside the tie layer 3012 or the inner liner 3014. The one or more axially extending filaments 3042 may be placed near or radially inside the braid 3010 and/or the coil 3024. The one or more axially extending filaments 3042 may be carried between the inner liner 3014 and the helical coil 3024.

[0080] When more than one axially extending filaments 3042 are placed in the catheter wall, the axially extending filaments 3042 may be placed in a radially symmetrical manner. For example, the angle between the two axially extending filaments 3042 with respect to the radial center of the catheter may be about 180 degree. Alternatively, depending on desired clinical performances (e.g., flexibility, trackability), the axially extending filaments 3042 may be placed in a radially asymmetrical manner. The angle between any two axially extending filaments 3042 with respect to the radial center of the catheter may be less than about 180 degree, less than or equal to about 165 degree, less than or equal to about 150 degree, less than or equal to about 135 degree, less than or equal to about 120 degree, less than or equal to about 105 degree, less than or equal to about 90 degree, less than or equal to about 75 degree, less than or equal to about 60 degree, less than or equal to about 45 degree, less than or equal to about 30 degree, less than or equal to about 15 degree, less than or equal to about 10 degree, or less than or equal to about 5 degree.

[0081] The one or more axially extending filaments 3042 may be made of materials such as Kevlar, Polyester, Meta-Para-Aramide, or any combinations thereof. At least one of the one or more axially extending filaments 3042 may comprise a single fiber or a multi-fiber bundle, and the fiber or bundle may have a round, rectangular, or other cross-sectional shape. The terms fiber or filament do not convey composition, and they may comprise any of a variety of high tensile strength polymers, metals or alloys depending upon design considerations such as the desired tensile failure limit and wall thickness. The cross-sectional dimension of the one or more axially extending filaments 3042, as measured in the radial direction, may be no more than about 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 11%, 12%, 13%, 14%, 15%, 20%, 25%, or 30% of that of the catheter 3000. The cross-sectional dimension of the one or more axially extending filaments 3042, as measured in the radial direction, may be no more

than about 0.001 inches, about 0.002 inches, about 0.003 inches, about 0.004 inches, about 0.005 inches, about 0.006 inches, about 0.007 inches, about 0.008 inches, about 0.009 inches, about 0.010 inches, about 0.015 inches, about 0.020 inches, about 0.025 inches, or about 0.030 inches.

[0082] The one or more axially extending filaments 3042 may increase the tensile strength of the distal zone of the catheter to at least about 1 pound, at least about 2 pounds, at least about 3 pounds, at least about 4 pounds, at least about 5 pounds, at least about 6 pounds, at least about 7 pounds, at least about 8 pounds, or at least about 10 pounds or more.

[0083] Referring to FIGS. 6A-6C, depending on whether the catheter 3000 is able to navigate sufficiently distally to reach the target site, an intraluminal catheter 3200 such as a telescopic extension segment having a proximally extending control wire as has been described elsewhere herein may be inserted through the catheter 3000 from the proximal end of the catheter 3000. The intraluminal catheter 3200 is inserted such that the distal end of the intraluminal catheter 3200 reaches further distally beyond the distal end of the catheter 3000. The outer diameter of the intraluminal catheter 3200 is smaller than the inner diameter of the catheter 3000. This way, the intraluminal catheter 3200 can slide inside the lumen of the catheter 3000.

[0084] The intraluminal catheter 3200 incorporates characteristics of the side wall construction of the catheter 3000 described herein. The axial length of the tubular extension segment may be less than about 50% and typically less than about 25% of the length of the catheter 3000. The axial length of the tubular extension segment will generally be at least about 10 cm or 15 cm or 20 cm or 25 cm or more but generally no more than about 70 cm or 50 cm or 30 cm.

[0085] Referring to FIGS. 7A-7C, the intraluminal catheter 3200 may have one or more axially extending filaments 3242. The one or more axially extending filaments 3242 incorporate characteristics of the one or more axially extending filaments 3042 of the catheter 3000, except the cross-sectional dimension as measured in the radial direction of the one or more axially extending filaments 3242 of the intraluminal catheter 3200 may be less than the corresponding dimension of the filament 3042 in the catheter 3000.

[0086] Referring to FIGS. 8A-8B, there is illustrated one example of an outer jacket segment stacking pattern for a progressive flexibility catheter of the type discussed in

connection with FIG. 4. A distal segment 3038 may have a length within the range of about 1 – 3 cm, and a durometer of less than about 35D or 30D. An adjacent proximal segment 3036 may have a length within the range of about 4 – 6 cm, and a durometer of less than about 35D or 30D. An adjacent proximal segment 3034 may have a length within the range of about 4 – 6 cm, and a durometer of about 35D or less. An adjacent proximal segment 3032 may have a length within the range of about 1 – 3 cm, and a durometer within the range of from about 35D to about 45D (e.g., 40D). An adjacent proximal segment 3030 may have a length within the range of about 1 – 3 cm, and a durometer within the range of from about 50D to about 60D (e.g., about 55D). An adjacent proximal segment 3028 may have a length within the range of about 1 – 3 cm, and a durometer within the range of from about 35D to about 50D to about 60D (e.g., about 55D). An adjacent proximal segment 3026 may have a length within the range of about 1 – 3 cm, and a durometer of at least about 60D and typically less than about 75D. More proximal segments may have a durometer of at least about 65D or 70D. The distal most two or three segments may comprise a material such as Tecothane, and more proximal segments may comprise PEBAX or other catheter jacket materials known in the art. At least three or five or seven or nine or more discrete segments may be utilized, having a change in durometer between highest and lowest along the length of the catheter shaft of at least about 10D, preferably at least about 20D and in some implementations at least about 30D or 40D or more.

[0087] Performance metrics of a catheter include back-up support, trackability, pushability, and kink resistance. Back-up support means ability of the catheter to remain in position within anatomy and provide a stable platform through which endoluminal devices may advance. Referring to FIG. 9, when the devices are pushed through the catheter 3202, if there is not enough back-up support in the catheter 3202, the distal portion 3204 of the catheter 3202 may prolapse, pull out, or back out of a vessel 3206 that branches out of a main blood vessel (e.g., brachiocephalic artery 82, common carotid artery 80, or subclavian artery 84). Back-up support for the catheter 3202 may be improved by providing a proximal region with high durometer or modulus and a distal region with low durometer or modulus. Durometer or modulus of the proximal region of the catheter 3202 may be improved by braid reinforcement. The region of the catheter at which durometer or modulus is strengthened may be placed near branching points at which the aortic arch 1114, 1214 branches into brachiocephalic artery 82,

common carotid artery 80, or subclavian artery 84 or near other anatomical structures (i.e., branching points) at which a main vessel branches into one or more smaller vessels, providing an opportunity for a catheter with poor back-up support to prolapse. For example, the region of the catheter at which durometer or modulus is strengthened may be placed within about 0.5cm, about 1cm, about 2cm, about 3cm, about 4cm, about 5cm, or about 6cm from a branching point at which a main vessel branches into one or more smaller vessels.

[0088] Trackability means ability of the catheter to track further distally than other catheters (e.g., to M1). For example, a catheter that can reach a cerebral segment of the internal carotid artery (ICA) has better trackability than a catheter that can reach a cavernous or petrous segment of the ICA. Trackability of the catheter may be improved by using a catheter wall with low durometer or modulus or by adding a coating (e.g., a hydrophilic coating) on at least a portion of the catheter wall. In some embodiments, the hydrophilic coating may be placed along the distal most region of the catheter. The hydrophilic coating on the catheter may extend to about 1cm, about 5cm, about 10cm, about 15cm, or about 20cm from the distal end of the catheter. The region with lower durometer or modulus may locate at the distal most region of the catheter. The region with lower durometer or modulus may extend to about 1cm, about 5cm, about 10cm, about 15cm, or about 20cm from the distal end of the catheter.

[0089] Pushability means rigidity of the catheter sufficient to push through anatomy without “buckling”. Pushability of the catheter may be improved by increasing its durometer or modulus. Pushability of the catheter may also be improved by providing a proximal region with high durometer or modulus and a distal region with low durometer or modulus. A transition region of the catheter in which durometer or modulus changes along its longitudinal length (e.g., decreasing durometer or modulus from the proximal end to the distal end) may begin at about 50%, 60%, 70%, 75%, 80%, or more of the length of the catheter from its proximal end.

[0090] Kink resistance means resistance of the catheter to kinking. In addition, if the catheter does kink, kink resistance of the catheter helps it return to its original shape. Kink resistance is important in the distal segment of the catheter, which is more prone to kinking than the proximal segment. Kink resistance of the catheter may be improved by adding one or more NiTi coils (or a coil at least a portion of which is Nitinol) to the catheter wall.

[0091] FIG. 10 describes a graph of durometer or modulus of a catheter in accordance with the embodiments herein along the length of the catheter, from the proximal end ($x = 0$) to the distal end ($x = 1$). The catheter according to some embodiments may have a decreasing durometer or modulus (E) approaching its distal end. The proximal end of the catheter has higher durometer or modulus than that of the distal end of the catheter. High durometer or modulus near the proximal end provides superior back-up support of the catheter. Durometer or modulus of the catheter is substantially constant along its length near the proximal end 3302 of the catheter. Then, durometer or modulus of the catheter decreases near the distal end 3304 of the catheter. Durometer or modulus of the catheter may begin to decrease (i.e., transition region) at about 50%, 70%, 75%, 80%, or 90% of the length of the catheter from its proximal end. The catheter may have successively decreasing durometer or modulus near its distal end by using materials with less durometer or modulus, having a thinner catheter wall near the distal end, or both. Decreased durometer or modulus near the distal end provides superior trackability of the catheter.

[0092] FIG. 11 describes flexibility test profiles of catheters in accordance with the embodiments herein compared with conventional catheters. Flexibility of a catheter was measured by the three point flexural test with a span of one inch and a displacement of 2mm. In other words, FIG. 11 describes a force (i.e., flexural load) necessary to vertically displace a one-inch-long catheter segment by 2mm with respect to distance from strain relief (i.e., proximal end of the catheter) to the point of force application. All catheters tested in FIG 21 show modulus or flexibility profiles similar to the one shown in FIG. 10. Modulus of the catheters stays substantially constant along its length near the proximal end and then gradually decreases near the distal end.

[0093] Catheters according to some embodiments herein may have a flexural load that is substantially constant along the longitudinal length near the proximal end and a rapidly decreasing flexural load near the distal end. In a catheter having a length of about 125 cm, the catheters may have a flexural load greater than or equal to about 1.0 lbF, about 1.5 lbF, about 2.0 lbF, about 2.5 lbF, about 3.0 lbF, or about 3.5 lbF at about 85 cm from the proximal end. The catheters may have a flexural load less than or equal to about 2.5 lbF, about 2.0 lbF, about 1.5 lbF, about 1.0 lbF, or about 0.5 lbF at about 95 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.5 lbF, about 1.0 lbF, about 0.75 lbF,

about 0.5 lbF, about 0.25 lbF, or about 0.1 lbF at about 105 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.4 lbF, about 0.3 lbF, about 0.2 lbF, or about 0.1 lbF at about 115 cm from the proximal end. For catheters having different lengths, the foregoing dimensions can be scaled from the distal end of the catheter as a percentage of catheter length.

[0094] In some embodiments constructed in accordance with FIG. 4, the flexural load may be less than about 3.0 or 3.25 lbF at 65 cm from the proximal end and greater than about 2.25 or 2.5 lbF on average from 65 cm to 85 cm from the proximal end. Flexural load may drop to no more than about 1.0 and preferably no more than about 0.5 lbF at about 95 cm from the proximal end. This provides enhanced backup support in the aorta while maintaining enhanced trackability into the distal vasculature.

[0095] In some embodiments, the catheters may have a flexural load greater than or equal to about 1.0 lbF, about 1.5 lbF, about 2.0 lbF, about 2.5 lbF, about 3.0 lbF, or about 3.5 lbF at about 60 cm from the proximal end. The catheters may have a flexural load less than or equal to about 2.0 lbF, about 1.5 lbF, about 1.0 lbF, or about 0.5 lbF at about 70 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.4 lbF, about 0.3 lbF, about 0.2 lbF, or about 0.1 lbF at about 80 cm from the proximal end. The catheters may have a flexural load less than or equal to about 1.0 lbF, about 0.75 lbF, about 0.5 lbF, about 0.4 lbF, about 0.3 lbF, about 0.2 lbF, or about 0.1 lbF at about 90 cm from the proximal end.

[0096] The catheters may have a transition region, in which its flexural load changes by greater than or equal to about 1.0 lbF, about 1.5 lbF, about 2.0 lbF, about 2.5 lbF, about 3.0 lbF, or about 3.5 lbF. The longitudinal length of the transition region may be less than or equal to about 20cm, about 15cm, about 10cm, about 5 cm, about 3cm, or about 1cm.

[0097] Compared to Neuron Max (Penumbra, Inc.) 3402, catheters according to some of the embodiments described herein (e.g., 3404, 3406, 3408, 3410) have comparable modulus near their proximal end. This way, the catheters according to some embodiments provide back-up support comparable to that of Neuron Max 3402. In addition, the catheters may have modulus that decrease more rapidly near the transition region (between the proximal end and the distal end) than that of Neuron Max.

[0098] Compared to Ace 68 catheter (Penumbra) 3412, Ace 64 catheter (Penumbra) 3414, Benchmark 71 catheter (Penumbra) 3416, and Sofia Plus (MicroVention) 3418, the catheters according to some embodiments herein have greater modulus near their proximal end and comparable modulus near their distal end. This way, the catheters according to some embodiments herein provide superior back-up support with comparable trackability compared to conventional catheters. The catheters according to some embodiments herein may achieve this modulus profile even when their inner diameters (and thus lumen volumes) are greater than or equal to those of Ace 68, Ace 64, Benchmark 71, and Sofia Plus, which range from 0.064 inch to 0.071 inch.

[0099] Many of the catheters in accordance with the present invention include a side wall junction such as transition 3011 in Figure 4, between a proximal tubular support structure such as a braid 3010 and an axially adjacent different tubular support structure such as coil 3024. A variety of structural features may be included to distribute force and improve the bending characteristics across the transition, as illustrated in Figures 12 – 25.

[0100] The location of the junction along the axial length of the catheter may be varied depending upon the desired performance. In some implementations, the catheter segment distal of the junction will have a length within the range of from about 12 cm to about 20 cm or within the range of from about 14 cm and 18 cm, in a catheter having an overall length within the range of from about 80 cm to about 110 cm. In other implementations, the catheter segment distal of the junction will have a length within the range of from about 35 cm to about 45 cm or within the range of from about 38 cm to about 42 cm, in a catheter having an overall length within the range of from about 150 cm to about 170 cm or within the range of from about 155 cm to about 161 cm.

[0101] Referring to FIGS. 12 and 13, shown is a side view and longitudinal cross section of an example catheter with a force dissipation support or cover 3060 embedded in the side wall and spanning the junction between a proximal braid 3010 and a distal coil 3024. The support may be a tubular segment such as a stent. In this embodiment, the stent was made by laser cutting a section of thin-walled Nitinol tubing followed by electro polishing the stent, creating, as shown, a stent with struts oriented in a predominantly circumferential direction with a strut thickness of about 0.0015". The stent may have an axial length of at least about 2

cm or at least about 3 cm or at least about 5 cm but generally no more than about 20 cm or 15 cm or less.

[0102] The stent may be loaded on the catheter comprising a proximal zone comprising a braid 3010 and a distal zone comprising a coil 3024 at a distal transition 3011 by loading it onto a mandrel before assembly. Further as shown in this example, a distal transition cover jacket 3070 overlays the stent and comprises a thin-walled PET sleeve of about 0.00025" thickness that was heat shrunk over the stent.

[0103] The stent thus spans the junction between the distal end of the braid 3010 and the proximal end of the coil 3024. An optional proximal coil 3023 may extend distally along the braid such as from the hub and across the junction, thus axially overlapping with the distal coil 3024 along an intertwined zone in which the two coils are intertwined. The intertwined zone may have an axial length within the range of from about 5mm to about 10mm or may extend up to a length of 5cm or 10 cm or more depending upon desired performance characteristics.

[0104] The proximal coil 3023 may extend distally across the intertwined zone to end within the axial length of the support. In the illustrated implementation, the distal end of the coil 3023 is approximately adjacent the proximal end of the axially extending filament 3242. The proximal coil may be formed from stainless steel wire, having a larger diameter than the distal coil 3024 which may be formed from NiTi wire. SS has a significantly higher modulus than NiTi, so reducing the relative diameter of the SS coil is useful to keep the transition from one to the other 'smooth' in terms of stiffness.

[0105] Also as shown in this example, the braid 3010 of the proximal zone comprises a zone of reduced thickness 3050 leading up to the junction in distal transition 3011. In particular, the zone of reduced thickness 3050 was created by etching about 2 cm of axial length of the braid 3010, which comprises stainless steel ribbon with a thickness of about 0.0015" and a width of about 0.004", down to a ribbon thickness of about 0.0012"; since the braid as shown in this example comprises two interwoven stainless steel ribbons, the etching process reduced the overall braid outer diameter from about 0.0030" down to about 0.0024", which closely matches the about 0.0025" outer diameter of the coil 3024 comprising Nitinol. Catheters made with this configuration kinked in the U-bend kink test as described herein over a pin with a 24 mm diameter (this diameter is slightly smaller than the typical inner diameter

of the aortic arch), which would allow such a catheter to prolapse inside an aortic arch of a human without kinking.

[0106] In another example, a distal transition cover 3060 comprising a Nitinol braid made with 0.001" outer diameter wire was placed over a proximal zone and a distal zone of a catheter as described herein. In this example, the catheter comprised a stainless steel braid with a wire ribbon of 0.0015" thickness and 0.004" width that was etched 2 cm at its distal end to reduce its overall thickness to 0.0024" (the stainless steel braid comprised two wire ribbons, with each ribbon being reduced in thickness from the etching process to 0.0012" thickness). This created a thickness of the stainless steel braid of the proximal zone (0.0024") that closely matched a thickness of a Nitinol coil of a distal zone (0.0025"). Catheters made with this configuration kinked in the U-bend kink test as described herein over a pin with a 24 mm diameter (this diameter is slightly smaller than the typical inner diameter of the aortic arch), which would allow such a catheter to prolapse inside an aortic arch of a human without kinking.

[0107] In another example, a distal transition cover 3060 comprising the liquid crystal polymer Vectran was placed over a proximal zone and a distal zone of a catheter as described herein. In this example, the Vectran was laminated with a thin layer of Vestamid over a mandrel before assembly onto the catheter. Further in this example, fibers of the Vectran were oriented about the longitudinal axis of the catheter to increase the tensile strength of the catheter in its location (i.e., not braided in order to minimize the overall thickness of this distal transition cover embodiment). In another example, fibers of the Vectran were oriented at about 45 degrees to the longitudinal axis of the catheter.

[0108] Referring to FIGS. 14A-14F and FIGS. 15A-15F, catheters of the various embodiments described herein may comprise a distal transition 3011. FIGS. 14A-14F and FIGS. 15A-15F illustrate cross-sectional elevational views of a catheter wall with various embodiments of the distal transition 3011 wherein a proximal braid 3010 has a zone of reduced thickness 3050 at the distal transition 3011.

[0109] In some embodiments, a zone 3050 of increased flexibility (e.g., reduced thickness) may comprise a length of about 0.5 cm, about 1.0 cm, about 1.5 cm, about 2.0 cm, about 2.5 cm, about 3.0 cm and about 3.5 cm. In some embodiments, a zone of reduced thickness 3050 may comprise a length of at least about 0.5 cm. In some embodiments, a zone of reduced thickness 3050 may comprise a length of less than about 3.0 cm. In some

embodiments, a zone of reduced thickness 3050 may comprise a length of about 1.5 cm to about 2.5 cm. In some embodiments, a zone of reduced thickness 3050 may comprise a braid of a proximal zone of a catheter as described herein with a reduced thickness. In some embodiments, a zone of reduced thickness 3050 may comprise a braid of a proximal zone of a catheter as described herein with a reduced outer diameter. In some embodiments, a zone of reduced thickness 3050 may comprise a braid of a proximal zone of a catheter as described herein with an enlarged inner diameter. In some embodiments, a zone of reduced thickness 3050 may comprise a braid of a proximal zone of a catheter as described herein with a reduced outer diameter and an enlarged inner diameter. In some embodiments, a zone of reduced thickness 3050 may comprise a smooth, a curved, a curvilinear, a linear, and a stepped transition in thickness. In some embodiments, a zone of reduced thickness 3050 may comprise a smooth, a curved, a curvilinear, a linear, and a stepped transition in catheter stiffness between a proximal zone and a distal zone of the catheter and provide superior kink resistance. In some embodiments, a zone of reduced thickness 3050 may create a transition in catheter stiffness between a proximal zone and a distal zone of the catheter and provide superior kink resistance. In some embodiments, a zone of reduced thickness 3050 may reduce a stiffness of a proximal zone of a catheter and provide superior kink resistance. In some embodiments, a zone of reduced thickness 3050 may reduce a stiffness of a braid of a proximal zone of a catheter and provide superior kink resistance.

[0110] A reduced thickness of a proximal braid 3010 at a distal transition 3011 may be accomplished by etching the braid at its distal end where it meets distal transition 3011. The etching may be performed prior to annealing. The etching may be performed after annealing. The etching may be performed prior to application of an inner liner 3014 and a tie layer 3012. The etching may be performed after application of an inner liner 3014 and a tie layer 3012. The etching may be applied to an outer surface of a proximal braid 3010, thus creating a proximal braid with a reduced outer diameter at a distal transition 3011. The etching may be applied to an inner surface of a proximal braid 3010, thus creating a proximal braid with an enlarged inner diameter at a distal transition 3011. The etching may be applied to an outer surface and an inner surface of a proximal braid 3010, thus creating a proximal braid with a reduced outer diameter and an enlarged inner diameter at a distal transition 3011. The etching may be performed to create about the same (e.g., $\pm 10\%$) or different thickness profiles

between an inner surface and an outer surface of a proximal braid 3010 at a distal transition 3011. Alternatively, a reduced thickness of a proximal braid 3010 at a distal transition 3011 may be accomplished by utilizing a braid with a thinner thickness where it meets distal transition 3011, such as by extrusion of a ribbon comprising the braid.

[0111] In one non-limiting example, etching a distal 2 cm of a stainless steel braid comprising stainless steel ribbon with a thickness of 0.0015" reduced the thickness of the braid to 0.0011". When catheters comprising this etched stainless steel braid were laminated with 0.0035" wall thickness Vestamid, the resulting etched catheters were found to be able to resist kinking in a U-bend kink test (i.e., bending an unsupported shaft of a catheter 180 degrees around a pin starting with a pin of a relatively large outer diameter and progressively testing on smaller diameter pins) until wrapped around a pin with an outer diameter of 18 mm. In practice, this enables a catheter of this embodiment to prolapse within an aortic arch of a human without kinking.

[0112] Referring to FIG. 14A, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. In this embodiment, the zone of reduced thickness 3050 may allow for a reduced outer diameter of catheter 3000 in the distal direction, while the inner diameter of catheter 3000 may remain about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and a sleeve 3020 as described elsewhere herein.

[0113] Referring to FIG. 14B, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter that is smaller than an outer diameter of a coil 3024 of a distal zone, and an inner diameter that is about the same (e.g., $\pm 10\%$) as an inner diameter of the coil 3024 of the distal zone at a distal transition 3011. In this embodiment, the outer diameter and inner diameter of catheter 3000 may be about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and a sleeve 3020 as described elsewhere herein.

[0114] Referring to FIG. 14C, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an inner diameter that is about the same (e.g., $\pm 10\%$) as

an inner diameter of a coil 3024 of a distal zone, and an outer diameter that is about the same (e.g., $\pm 10\%$) as the outer diameter of the coil 3024 at a distal transition 3011. In this embodiment, the zone of reduced thickness 3050 may allow for an enlarged inner diameter of catheter 3000 in the distal direction, while the outer diameter of catheter 3000 may remain about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and a sleeve 3020 as described elsewhere herein.

[0115] Referring to FIG. 14D, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an inner diameter that is larger than an inner diameter of a coil 3024 of a distal zone, and an outer diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter of the coil 3024 of the distal zone at a distal transition 3011. In this embodiment, the outer and inner diameter of catheter 3000 may be about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and a sleeve 3020 as described elsewhere herein.

[0116] Referring to FIG. 14E, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter that is smaller than an outer diameter of a coil 3024 of a distal zone at a distal transition 3011, and an inner diameter that is larger than an inner diameter of the coil 3024 of the distal zone at the distal transition 3011. In this embodiment, the outer and inner diameter of catheter 3000 may be about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and a sleeve 3020 as described herein.

[0117] Referring to FIG. 14F, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter of a coil 3024 of a distal zone at a distal transition 3011, and an inner diameter that is about the same (e.g., $\pm 10\%$) as an inner diameter of the coil 3024 of the distal zone at the distal transition 3011. In this embodiment, the zone of reduced thickness 3050 may allow for a reduced outer diameter and an enlarged inner diameter of catheter 3000 in the distal direction between the proximal and distal zones at distal transition 3011. Also as shown, this

embodiment may comprise an inner liner 3014, a tie layer 3012, and a sleeve 3020 as described herein.

[0118] Referring to FIG. 15A, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. In this embodiment, the zone of reduced thickness 3050 may allow for a reduced outer diameter of catheter 3000 in the distal direction, while the inner diameter of catheter 3000 may remain about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, an axially extending filament 3042, and a sleeve 3020 as described elsewhere herein.

[0119] Referring to FIG. 15B, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter that is smaller than an outer diameter of a coil 3024 of a distal zone, and an inner diameter that is about the same (e.g., $\pm 10\%$) as an inner diameter of the coil 3024 of the distal zone at a distal transition 3011. In this embodiment, the outer diameter and inner diameter of catheter 3000 may be about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, an axially extending filament 3042, and a sleeve 3020 as described elsewhere herein.

[0120] Referring to FIG. 15C, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an inner diameter that is about the same (e.g., $\pm 10\%$) as an inner diameter of a coil 3024 of a distal zone, and an outer diameter that is about the same (e.g., $\pm 10\%$) as the outer diameter of the coil 3024 at a distal transition 3011. In this embodiment, the zone of reduced thickness 3050 may allow for an enlarged inner diameter of catheter 3000 in the distal direction, while the outer diameter of catheter 3000 may remain about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, an axially extending filament 3042, and a sleeve 3020 as described elsewhere herein.

[0121] Referring to FIG. 15D, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an inner diameter that is larger than an inner diameter of a coil 3024 of a distal zone, and an outer diameter that is about the same (e.g., $\pm 10\%$) as an

outer diameter of the coil 3024 of the distal zone at a distal transition 3011. In this embodiment, the outer and inner diameter of catheter 3000 may be about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, an axially extending filament 3042, and a sleeve 3020 as described elsewhere herein.

[0122] Referring to FIG. 15E, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter that is smaller than an outer diameter of a coil 3024 of a distal zone at a distal transition 3011, and an inner diameter that is larger than an inner diameter of the coil 3024 of the distal zone at the distal transition 3011. In this embodiment, the outer and inner diameter of catheter 3000 may be about the same (e.g., $\pm 10\%$) between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, an axially extending filament 3042, and a sleeve 3020 as described elsewhere herein.

[0123] Referring to FIG. 15F, shown is a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. In this embodiment, the zone of reduced thickness 3050 may allow for a reduced outer diameter and an enlarged inner diameter of catheter 3000 in the distal direction between the proximal and distal zones at distal transition 3011. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, an axially extending filament 3042, and a sleeve 3020 as described elsewhere herein.

[0124] Referring to FIGS. 16A-16F, FIGS. 17A-17F, FIGS. 18A-18F, FIGS. 19A-19F, and FIG. 20, catheters of the various embodiments described herein may comprise a distal transition 3011 with a distal transition cover 3060. Also shown in FIG. 16C, FIG. 16F, FIG. 17C, FIG. 17F, FIG. 18B, FIG. 18E, FIG. 19B, FIG. 19E, and FIG. 20, catheters of the various embodiments described herein may comprise a distal transition 3011 with a distal transition cover 3060 and a distal transition cover sleeve 3070. Note that FIGS. 16A-16F, FIGS. 17A-17F, FIGS. 18A-18F, and FIGS. 19A-19F illustrate cross-sectional elevational views of a catheter wall according to some of these various embodiments.

[0125] In some embodiments, a distal transition cover 3060 may comprise a braid (e.g., a wire braid, a stainless steel wire braid, a stainless steel ribbon braid, a shape-memory

or superelastic wire braid, a shape-memory or superelastic ribbon braid, a Nitinol wire braid, a Nitinol ribbon braid, a polymer braid, a nylon braid, a polypropylene braid, a polyester braid), a stent (e.g., a stainless steel stent, a shape-memory or superelastic stent, a Nitinol stent, a polymer stent, a nylon stent, a polypropylene stent, a polyester stent), a coil (e.g., a stainless steel coil, a shape-memory or superelastic coil, a polymer coil, a nylon coil, a polypropylene coil), a liquid crystal polymer (e.g., PET copolyester, copolyimide, polyester-amide, Vectran), a shrink-wrap or heat-shrink tubing, and a composite material. In some embodiments, a distal transition cover 3060 may extend about a distal transition 3011 in about equal lengths distally and proximally. In some embodiments, a distal transition cover 3060 may extend about a distal transition 3011 more in the proximal direction than in the distal direction (e.g., to cover more of the catheter's proximal zone than its distal zone). In some embodiments, a distal transition cover 3060 may extend about a distal transition 3011 more in the distal direction than in the proximal direction (e.g., to cover more of the catheter's distal zone than its proximal zone). In some embodiments, a distal transition cover 3060 may cover a catheter comprising a proximal zone comprising a braid and a distal zone comprising a coil. Parameters of braid, stent, coil, liquid crystal polymer, shrink-wrap or heat-shrink tubing, and composite materials that comprise a distal transition cover 3060 may be modified to tune the stiffness and flexibility of a catheter (e.g., braid wire thickness, braid wire width, stent strut orientation, stent window size, stent thickness, liquid crystal polymer orientation about the catheter axis, shrink-wrap or heat-shrink tubing thickness and composition).

[0126] In some embodiments, a catheter with a distal transition cover 3060 may comprise a distal transition cover sleeve 3070 that covers the distal transition cover 3060. In some embodiments, a distal transition cover sleeve 3070 may comprise a shrink-wrap or heat-shrink tubing, a polymer, and/or a composite material. An example of a distal transition cover sleeve material includes thin-walled PET. In some embodiments, a distal transition cover sleeve 3070 may extend beyond a distal transition cover 3060 and cover a proximal zone and a distal zone of a catheter 3000. In some embodiments, a distal transition cover sleeve 3070 may cover a distal transition cover 3060 and cover a proximal zone and a distal zone of a catheter 3000 in variable lengths.

[0127] In some embodiments, a distal transition cover 3060 may provide a transition in catheter stiffness between a proximal zone and a distal zone of the catheter and

provide superior kink resistance. In some embodiments, a distal transition cover 3060 and a distal transition cover sleeve 3070 may provide a transition in catheter stiffness between a proximal zone and a distal zone of the catheter and provide superior kink resistance.

[0128] In some embodiments, a distal transition cover 3060 may be placed over a mandrel before assembly onto a catheter as described herein. In some embodiments, a distal transition cover sleeve may be assembled over a distal transition cover 3060 (e.g., a thin wall PET sleeve of about 0.00025" heat shrunk over the distal transition cover).

[0129] Referring to FIG. 16A, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material that directly abuts an underlying braid 3010 of a proximal zone and an underlying coil 3024 of a distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described herein. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0130] Referring to FIG. 16B, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060 (i.e., cover sleeve 3020 is formed under distal transition cover 3060). Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0131] Referring to FIG. 16C, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0132] Referring to FIG. 16D, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a coil that directly abuts an underlying

braid 3010 of a proximal zone and an underlying coil 3024 of a distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described herein. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0133] Referring to FIG. 16E, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0134] Referring to FIG. 16F, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0135] Referring to FIG. 17A, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material that directly abuts an underlying braid 3010 of a proximal zone and an underlying coil 3024 of a distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described herein. Also as shown, this embodiment may comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0136] Referring to FIG. 17B, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and a composite material. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0137] Referring to FIG. 17C, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and a composite material. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0138] Referring to FIG. 17D, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a coil that directly abuts an underlying braid 3010 of a proximal zone and an underlying coil 3024 of a distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described herein. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0139] Referring to FIG. 17E, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0140] Referring to FIG. 17F, shown is a catheter with a distal transition 3011 covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates a braid 3010 of a proximal zone and a coil 3024 of a distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0141] In some embodiments, a catheter 3000 may combine multiple aspects of the various distal transitions described herein. Referring to FIG. 18A, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner

diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and a composite material that directly abuts the underlying braid 3010 of the proximal zone and the underlying coil 3024 of the distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described herein. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0142] Referring to FIG. 18B, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0143] Referring to FIG. 18C, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0144] Referring to FIG. 18D, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition

cover 3060 comprising a coil that directly abuts the underlying braid 3010 of the proximal zone and the underlying coil 3024 of the distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described herein. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0145] Referring to FIG. 18E, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0146] Referring to FIG. 18F, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014 and a tie layer 3012 as described elsewhere herein.

[0147] Referring to FIG. 19A, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material that directly abuts the underlying braid 3010 of the proximal zone and the underlying coil 3024 of the distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal

zone as described herein. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0148] Referring to FIG. 19B, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example, extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0149] Referring to FIG. 19C, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a braid, a stent, a liquid crystal polymer, a shrink-wrap or heat-shrink tubing, and/or a composite material. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Also as shown, this embodiment may comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0150] Referring to FIG. 19D, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a coil that directly abuts the underlying braid 3010 of the proximal zone and the underlying coil 3024 of the distal zone. Further as shown, distal transition cover 3060 may be covered by sleeve 3020 that covers at least a portion of the distal zone as described

herein. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0151] Referring to FIG. 19E, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Further as shown, distal transition cover 3060 may be covered by a distal transition cover sleeve 3070, which in this example, extends proximally and distally beyond the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0152] Referring to FIG. 19F, shown is a catheter with a braid 3010 of a proximal zone with a zone of reduced thickness 3050 with an outer diameter and an inner diameter that is about the same (e.g., $\pm 10\%$) as an outer diameter and an inner diameter of a coil 3024 of a distal zone at a distal transition 3011. The distal transition 3011 is covered by a distal transition cover 3060 comprising a coil. A cover sleeve 3020 separates the braid 3010 of the proximal zone and the coil 3024 of the distal zone from the distal transition cover 3060. Also as shown, this embodiment may optionally comprise an inner liner 3014, a tie layer 3012, and an axially extending filament 3042 as described elsewhere herein.

[0153] Referring to FIG. 20, FIGS. 21A-21B, and FIGS. 22A-22B, catheters may be annealed to advantageously tune the stiffness, flexibility, and/or durometer of one or more portion of the catheters. While the annealing process in connection with FIGS. 20-22B may be discussed in connection with a catheter of one or more various embodiments described herein, it will be understood by one having ordinary skill in the art that one or more steps of the annealing process discussed herein may be used on any suitable catheter in an effort to advantageously tune one or more properties of the catheter.

[0154] With reference to the figures, catheters of the various embodiments described herein may comprise a proximal zone comprising a braid that is annealed at a distal transition 3011 to tune the stiffness, flexibility, and/or durometer of the braid. In some embodiments, annealing of the braid may be used to advantageously tune at least one of the

stiffness, flexibility, and/or durometer of the braid. Annealing, in some instances, may allow for a smooth transition in catheter stiffness, flexibility, and/or durometer from the proximal zone to the distal zone and/or provide for a catheter with superior kink resistance. In some embodiments, annealing of the braid to tune the stiffness, flexibility, and/or durometer of the braid allows for a smooth transition in catheter stiffness, flexibility, and/or durometer from the proximal zone to the distal zone comprising a coil and provide for a catheter with superior kink resistance.

[0155] A catheter with a proximal zone comprising a braid may be annealed by any suitable heating process. In some embodiments, the heating process may include an induction heating process. The induction heating process may be performed by placing at least a portion of the braid over a mandrel. Some examples of a mandrel may include any one of a ferritic stainless steel mandrel, a martensitic stainless steel mandrel, and a duplex stainless steel mandrel. The induction heating process, in some instance, may include placing the braid and mandrel in a coil of an induction heater (e.g., an RDO induction heater). Induction heat generated in the mandrel may be transferred into the braid. In some instance, transfer of induction heat into the braid may perform the annealing.

[0156] The induction heating process may advantageously permit control of various parameters, such as induction power and time. Control of one or more of the parameters may, in some instances, may permit variation in the amount of heat transferred from the mandrel to the braid and may further permit variation in the amount of annealing performed.

[0157] In some embodiments, the amount of braid annealing may be assessed by a visible parameter change in the wires comprising the braid. A visible parameter change may include at least one of a change in color, size, shape, or other physical property. For example, wires comprising the braid being annealed may change in color during the annealing process. FIGS. 21A and 21B illustrate an exemplary embodiment where the braid being annealed changes from silver, to blue, and then to yellow with increased annealing. In some situations, excessive annealing may cause the surface of the braid to oxidize and/or to potentially adhere to the mandrel that is being used to heat it. The ability to visually identify a parameter change in the anneal process may advantageously facilitate control of the annealing process in an effort to avoid excessive annealing.

[0158] Annealing a braid as described herein may advantageously produce a braid with increased flexibility, decreased stiffness, and decreased durometer when compared to previous annealing processes. For example, a prior annealing process may have created a stress-relieved braid such that upon cutting the braid it would not fray. As shown in FIG. 21, the flexibility of braids according to braids of example catheters that underwent different annealing processes (i.e., a non-annealed braid (left bar), a braid annealed according to the prior process (middle bar), and a braid annealed according to a new process that created a fully annealed braid (right bar)) was tested using an Instron (e.g., TM00075) cantilever bending test. As seen in FIG. 20, increased annealing led to less grams-force (gf) being required to be applied to a braid to achieve the same amount of bending (as shown: about 97 gf required for a non-annealed braid, about 80 gf required for a braid annealed according to the old process, and about 34 gf required for a braid annealed according to the new process). In terms of percentages, this initial experimentation was found to increase braid flexibility by about 18% for the old annealing process, and by about 65% for the new annealing process. In some instances, an amount of spring back that occurs after a catheter has been crushed may advantageously decrease as a result of increasing annealing.

[0159] Referring to FIGS. 21A-21B, micrographs of a section of braids after annealing are shown according to the old annealing process (FIG. 21A) and the fully annealed process (FIG. 21B) as described herein and corresponding to FIG. 20.

[0160] Referring to FIGS. 22A-22B, plots of the effects of annealing on braids are shown found through experimentation wherein annealing power and time were varied as inputs and braid wire color and braid flexibility were measured as outputs. Through this experimentation, parameters were found that produced braids with a flexibility of about 30 gf as measured per the Instron cantilever bending test described herein. Also found through experimentation, as annealing time increased, oxidation of annealed braids increased.

[0161] In some embodiments, annealing power may be increased to mitigate braid oxidation and/or to allow for decreased annealing time. The functional impact of braid annealing may be evaluated by kink testing. For example, braids annealed according to the fully annealed process described herein showed an improvement in kink resistance over samples processed according to the old annealing process. In production, the annealing process

may be monitored and controlled by visually inspecting the color of the braid and measuring the amount of braid springback after crushing.

[0162] Referring to FIG. 23, FIGS. 24A-24B, and FIG. 25, in some embodiments, catheters as described herein may comprise a distal transition 3011 comprising a distal transition connector 3080. In some embodiments, the distal transition connector 3080 may comprise a connector, a stepped connector, a marker band, a stepped marker band, a stent, or a stepped stent. In some embodiments, the distal transition connector 3080 may comprise a weld, a braze, a solder, or an epoxy. In some embodiments, a weld, a braze, a solder, or an epoxy may be circumferential between a proximal zone and a distal zone of a catheter as described herein. In some embodiments, a weld, a braze, a solder, or an epoxy may be applied irregularly spaced or regularly spaced around a circumference between a proximal zone and a distal zone (e.g., spaced tack welds) of a catheter as described herein. In some embodiments, the distal transition connector 3080 may comprise a distal facing surface that matches at least a portion of a proximal facing surface of a distal zone. In some embodiments, a braid of a proximal zone of a catheter as described herein may comprise a step that matches at least a portion of a proximal facing surface of a coil of a distal zone. In some embodiments, a distal transition connector 3080 may comprise a proximal facing surface that is planar and a distal facing surface comprising a step. In some embodiments, a distal transition connector 3080 may comprise a proximal facing surface that is planar and a distal facing surface comprising a step created by removing a pitch from the distal facing surface. In some embodiments, a distal transition connector 3080 may comprise a distal facing surface that mirrors a proximal facing surface of a distal zone of a catheter as described herein so that a uniform or near uniform gap is created when the distal facing surface of the distal transition connector 3080 abuts the proximal facing surface of the distal zone. In some embodiments, a distal transition connector 3080 may comprise a distal facing surface that mirrors a proximal facing surface of a coil of a distal zone of a catheter as described herein so that a uniform or near uniform gap is created when the distal facing surface of the distal transition connector 3080 abuts the proximal facing surface of the coil of the distal zone. In some embodiments, a distal transition connector 3080 may comprise a distal facing surface with at least a portion of the surface that mirrors at least a portion of a proximal facing surface of a distal zone of a catheter as described herein so that a uniform or near uniform gap is created when the at least a portion of the distal facing surface

of the distal transition connector 3080 abuts the at least a portion of the proximal facing surface of the distal zone. In some embodiments, a distal transition connector 3080 may comprise a distal facing surface with at least a portion of the surface that mirrors at least a portion of a proximal facing surface of a coil of a distal zone of a catheter as described herein so that a uniform or near uniform gap is created when the at least a portion of the distal facing surface of the distal transition connector 3080 abuts the at least a portion of the proximal facing surface of the coil of the distal zone.

[0163] Referring to FIG. 23, shown is a distal transition connector 3080 according to some embodiments. Distal transition connector 3080 may comprise a distal end 3081, a proximal end 3082, an outer diameter 3084, an inner diameter 3085, a proximal surface 3086, and a distal surface 3087. In some embodiments and as shown in FIG. 23, the distal surface 3087 of the distal transition connector 3080 may comprise a step creating a tangential surface 3088. In some embodiments, the step in the distal surface 3087 allows for a proximal end of a coil of a distal zone of a catheter as described herein to form a uniform or near uniform gap between the distal surface 3087 and the proximal end of the coil of the distal zone when the tangential surface 3088 abuts an end of the coil. In some embodiments, proximal surface 3086 of the distal transition connector 3080 is planar to form a uniform or near uniform gap between the proximal surface 3086 and a distal end of a braid of a proximal zone of a catheter as described herein. In some embodiments, the inner diameter 3085 of the distal transition connector 3080 creates an interior lumen in fluid communication with an interior lumen of a proximal zone and an interior lumen of a distal zone of a catheter as described herein.

[0164] Referring to FIGS. 24A-24B, in some embodiments of a catheter as described herein, a distal transition connector 3080 may comprise a proximal end 3082 with a profile that is about perpendicular in angle to a side wall of the distal transition connector and a distal end 3081 with a profile comprised of a step cut out of the distal end 3081 to create a tangential surface 3088 in the distal end. In some embodiments of a catheter as described herein, a distal transition connector 3080 may comprise a proximal end 3082 with a profile that is about perpendicular in angle to a side wall of the distal transition connector and a distal end 3081 with a profile comprised of a step cut out of the distal end 3081 to create a near tangential surface 3088 in the distal end (e.g., the surface 3088 is at an angle relative to the surface 3087 of about 85 degrees, about 86 degrees, about 87 degrees, about 88 degrees, about 89 degrees,

about 90 degrees, about 91 degrees, about 92 degrees, about 93 degrees, about 94 degrees, about 95 degrees, at least about 80 degrees, at most about 95 degrees, between about 85 degrees and about 95 degrees, between about 88 degrees and 91 degrees, between about 89 degrees and 90 degrees). In some embodiments, the step cut out of distal end 3081 of the distal transition connector 3080 comprises an about 5/1000 pitch, an about 4/1000 pitch, an about 3/1000 pitch, an about 6/1000 pitch, an about 7/1000 pitch, at least an about 3/1000 pitch, less than an about 7/1000 pitch, between an about 3/1000 pitch and an about 7/1000 pitch, and between an about 4/1000 pitch and an about 6/1000 pitch removed from the distal end 3081. In some embodiments, a step in the distal end 3081 of distal transition connector 3080 allows a coil 3024 of a distal zone of a catheter as described herein to join flush to the distal surface 3087 of the distal transition connector 3080. In some embodiments, a step in the distal end 3081 of distal transition connector 3080 allows a coil 3024 of a distal zone of a catheter as described herein to join flush to the distal surface 3087 of the distal transition connector 3080 and produce a uniform or near uniform gap between the distal transition connector 3080 and the coil 3024 to facilitate joining the components via a procedure comprising welding, brazing, and/or epoxying. In some embodiments, a step in the distal end 3081 of distal transition connector 3080 allows a coil 3024 of a distal zone of a catheter as described herein to join flush to the distal surface 3087 of the distal transition connector 3080 and produce a uniform or near uniform gap between the distal transition connector 3080 and the coil 3024 to facilitate joining the components via a procedure comprising welding, brazing, and/or epoxying that prevents damage to an underlying liner (e.g., tie layer 3012, inner liner 3014).

[0165] Referring to FIG. 25, illustrated is a side view of a catheter with a distal transition connector according to some embodiments. As shown in FIG. 25, the catheter of this embodiment comprises a proximal zone comprising a braid 3010, a distal transition connector 3080 according to FIG. 23, and a distal zone comprising a helical coil 3024, wherein the proximal surface 3086 of the distal transition connector joins to a distal end of the braid 3010, and wherein the distal surface 3087 and tangential surface 3088 of the distal transition connector join to a proximal end of the helical coil 3024. In this embodiment, the joining of the proximal end of the distal transition connector 3080 to the braid 3010 may comprise a weld, a braze, and/or a solder. In this embodiment, the joining of the distal end of the distal transition connector 3080 to the coil 3024 may comprise a weld, a braze, and/or a solder.

[0166] In some embodiments, a distal transition connector 3080 may comprise a material that facilitates welding, brazing, and/or soldering of a stainless steel braid 3010 of a proximal zone to a proximal end 3082 of the distal transition connector 3080 and welding, brazing, and/or soldering of a Nitinol coil 3024 of a distal zone to the distal end 3081 of the distal transition connector 3080. In some embodiments, the distal transition connector comprises Platinum, a Platinum alloy (e.g., 90% Platinum and 10% Iridium), Nickel, a Nickel alloy, Gold, or a Gold alloy (e.g., Au-22Ni-8Pd, Au-20Cu). In some embodiments, the distal transition connector 3080 may be comprised of a material that allows for a transition in catheter flexibility, durometer, and/or stiffness between a proximal zone and a distal zone of the catheter. In some embodiments, the distal transition connector 3080 may be comprised of a material that allows for a smooth, a curved, a curvilinear, a linear, and/or a stepped transition in catheter flexibility, durometer, and/or stiffness between a proximal zone and a distal zone of the catheter.

[0167] In some embodiments, a distal transition connector 3080 may comprise an inner diameter 3085 and an outer diameter 3084 that are consistent across a length of the distal transition connector. In some embodiments, a distal transition connector 3080 may comprise an inner diameter 3085 and an outer diameter 3084 that are different across a length of the distal transition connector. In some embodiments, a distal transition connector 3080 may comprise an inner diameter 3085 and an outer diameter 3084 that taper across a length of the distal transition connector. In some embodiments, a distal transition connector 3080 may comprise an inner diameter 3085 and an outer diameter 3084 that match at its proximal end 3082 an inner and outer diameter of a braid of a proximal zone of a catheter as described herein. In some embodiments, a distal transition connector 3080 may comprise an inner diameter 3085 and an outer diameter 3084 that match at its distal end 3081 an inner and outer diameter of a coil of a distal zone of a catheter as described herein.

[0168] In some embodiments, a distal transition connector 3080 may be rolled over a pin gauge to open its inside diameter 3085 and allow it to be added over an inner liner of a catheter as described herein. In some embodiments, a distal transition connector 3080 may be rolled over a pin gauge to open its inside diameter 3085 and allow it to be added over an inner liner of a catheter as described herein to prevent damage to the inner liner.

[0169] In an example, catheters according to the embodiment shown in FIG. 25 with a 5/1000 pitch removed from the distal end 3081 of the distal transition connector 3080 made of a 90% Platinum 10% Iridium alloy, welded at its proximal end 3082 to a stainless steel braid 3010, and welded at its distal end 3081 to a Nitinol helical coil 3024 kinked in the U-bend kink test as described herein over a pin with a 24 mm diameter (this diameter is slightly smaller than the typical inner diameter of the aortic arch), which would allow such a catheter to prolapse inside an aortic arch of a human without kinking.

[0170] In some embodiments of the catheters described herein, distal coil 3024 may be comprised of a wire with a variable thickness, cross-sectional diameter, and/or cross-sectional area. In some embodiments, distal coil 3024 may be comprised of a wire with a thickness, cross-sectional diameter, and/or cross-sectional area that decreases in the distal direction. In some embodiments, the distal coil 3024 may be comprised of a wire with a thickness, cross-sectional diameter, and/or cross-sectional area that decreases in the distal direction to provide for a catheter with increasing flexibility in the distal direction. In some embodiments, the distal coil 3024 may be comprised of a wire with a thickness, cross-sectional diameter, and/or cross-sectional area that decreases in the distal direction to provide for a catheter with decreasing durometer in the distal direction. In some embodiments, the distal coil 3024 may be comprised of a wire with a thickness, cross-sectional diameter, and/or cross-sectional area that decreases in the distal direction to provide for a catheter that has a durometer more closely matched to a durometer of a proximal braid 3010 at its proximal end, and with a decreasing durometer in the distal direction to provide for a catheter with increased distal flexibility. In some embodiments, the distal coil 3024 may be comprised of a wire with a thickness, cross-sectional diameter, and/or cross-sectional area that decreases in the distal direction to provide for a catheter that has a durometer more closely matched to a durometer of a distal transition connector 3080 at its proximal end, and with a decreasing durometer in the distal direction to provide for a catheter with increased distal flexibility. In some embodiments, a catheter as described herein may have a durometer that decreases in the distal direction, such that the decrease in durometer is smooth and without significant steps in durometer change. In some embodiments, a catheter as described herein may have a durometer that decreases in the distal direction, such that the decrease in durometer is smooth and without significant steps in durometer change to produce a catheter having superior kink resistance.

[0171] Although the present embodiments have been described in terms of certain preferred embodiments, they may be incorporated into other embodiments by persons of skill in the art in view of the disclosure herein. The scope of the embodiments are therefore not intended to be limited by the specific embodiments disclosed herein, but are intended to be defined by the full scope of the following claims.

Example Embodiments

[0172] An enhanced flexibility catheter comprising one or more of the following:

[0173] an elongate flexible body having a proximal end, a distal end, and a side wall defining a central lumen,

[0174] wherein the side wall comprises:

[0175] a proximal zone comprising a tubular braid and a first helical coil;

[0176] a distal zone comprising a second helical coil, and

[0177] a transition between the distal zone and the proximal zone,

[0178] wherein the transition comprises a distal end of the tubular braid within 1 cm of a proximal end of the second helical coil, and the first helical coil extends distally beyond the transition.

[0179] An enhanced flexibility catheter of any embodiment disclosed herein, wherein distal end of the tubular braid is within 5 mm of the proximal end of the second helical coil.

[0180] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the first helical coil is formed from a wire having a first diameter, and the second helical coil is formed from a wire having a second, larger diameter.

[0181] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the first helical coil comprises stainless steel.

[0182] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the second helical coil comprises Nitinol.

[0183] An enhanced flexibility catheter of any embodiment disclosed herein, wherein a distal section of the braid has been heat annealed

[0184] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the first and second helical coils are intertwined over a length of at least about 5mm.

[0185] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the side wall further comprises a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the second helical coil of the distal zone is adjacent the tie layer and the braid of the proximal zone is adjacent the tie layer.

[0186] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the elongate flexible body further comprises an outer jacket formed from a plurality of axially adjacent tubular segments wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

[0187] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the elongate flexible body further comprises an axially extending filament within the side wall.

[0188] An enhanced flexibility catheter of any embodiment disclosed herein, further comprising a tubular support having a proximal end surrounding a distal portion of the braid and a distal end surrounding a proximal portion of the second coil.

[0189] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the tubular support comprises a slotted metal tube.

[0190] An enhanced flexibility catheter comprising one or more of the following:

[0191] an elongate flexible body having a proximal end, a distal end, and a side wall defining a central lumen,

[0192] wherein the side wall comprises:

[0193] a proximal tubular braid having a distal end adjacent a proximal end of a helical coil to form a junction,

[0194] a tubular metal support spanning the junction; and

[0195] an outer jacket surrounding the tubular support.

[0196] An enhanced flexibility catheter of any embodiment disclosed herein, further comprising an axial filament extending distally from beneath the tubular support.

[0197] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the side wall further comprises a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the helical coil of the distal zone surrounds the tie layer and the braid of the proximal zone surrounds the tie layer.

[0198] An enhanced flexibility catheter of any embodiment disclosed herein, wherein the elongate flexible body further comprises an outer jacket formed from a plurality of axially adjacent tubular segments extending coaxially about the helical coil, wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

[0199] A method of making an enhanced flexibility catheter, the method comprising one or more of the following:

[0200] forming a catheter comprising a braid in a proximal zone of the catheter;

[0201] placing at least a portion of the braid of the catheter over a mandrel;

[0202] annealing a distal section of the braid comprising induction heating the braid and mandrel in a coil; and

[0203] visibly monitoring a parameter change of the braid.

[0204] A method of making an enhanced flexibility catheter as disclosed in any embodiment herein. wherein induction heating the braid comprises placing the braid and mandrel within an ERDO induction heater.

[0205] A method of making an enhanced flexibility catheter as disclosed in any embodiment herein. wherein the parameter change comprises a color change of the braid.

[0206] A method of making an enhanced flexibility catheter as disclosed in any embodiment herein, wherein the distal section has an axial length of no more than about 2 cm.

WHAT IS CLAIMED IS:

1. An enhanced flexibility catheter, comprising:
an elongate flexible body having a proximal end, a distal end, and a side wall defining a central lumen,
wherein the side wall comprises:
a proximal zone comprising a tubular braid and a first helical coil;
a distal zone comprising a second helical coil, and
a transition between the distal zone and the proximal zone,
wherein the transition comprises a distal end of the tubular braid within 1 cm of a proximal end of the second helical coil, and the first helical coil extends distally beyond the transition.
2. An enhanced flexibility catheter as in claim 1, wherein distal end of the tubular braid is within 5 mm of the proximal end of the second helical coil.
3. An enhanced flexibility catheter as in claim 1, wherein the first helical coil is formed from a wire having a first diameter, and the second helical coil is formed from a wire having a second, larger diameter.
4. An enhanced flexibility catheter as in claim 3, wherein the first helical coil comprises stainless steel.
5. An enhanced flexibility catheter as in claim 3, wherein the second helical coil comprises Nitinol.
6. An enhanced flexibility catheter as in claim 1, wherein a distal section of the braid has been heat annealed
7. An enhanced flexibility catheter as in claim 5, wherein the first and second helical coils are intertwined over a length of at least about 5mm.
8. An enhanced flexibility catheter as in claim 9, wherein the side wall further comprises a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the second helical coil of the distal zone is adjacent the tie layer and the braid of the proximal zone is adjacent the tie layer.
9. An enhanced flexibility catheter as in claim 1, wherein the elongate flexible body further comprises an outer jacket formed from a plurality of axially adjacent tubular

segments wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

10. An enhanced flexibility catheter as in claim 9, wherein the elongate flexible body further comprises an axially extending filament within the side wall.

11. An enhanced flexibility catheter as in claim 1, further comprising a tubular support having a proximal end surrounding a distal portion of the braid and a distal end surrounding a proximal portion of the second coil.

12. An enhanced flexibility catheter as in claim 11, wherein the tubular support comprises a slotted metal tube.

13. An enhanced flexibility catheter, comprising:

an elongate flexible body having a proximal end, a distal end, and a side wall defining a central lumen,

wherein the side wall comprises:

a proximal tubular braid having a distal end adjacent a proximal end of a helical coil to form a junction,

a tubular metal support spanning the junction; and

an outer jacket surrounding the tubular support.

14. An enhanced flexibility catheter as in claim 13, further comprising an axial filament extending distally from beneath the tubular support.

15. An enhanced flexibility catheter as in claim 13, wherein the side wall further comprises a tubular inner liner and a tie layer separated from the lumen by the inner liner, wherein the helical coil of the distal zone surrounds the tie layer and the braid of the proximal zone surrounds the tie layer.

16. An enhanced flexibility catheter as in claim 13, wherein the elongate flexible body further comprises an outer jacket formed from a plurality of axially adjacent tubular segments extending coaxially about the helical coil, wherein a proximal one of the tubular segments has a durometer of at least about 60D and a distal one of the tubular segments has a durometer of no more than about 35D.

17. A method of making an enhanced flexibility catheter, the method comprising:
forming a catheter comprising a braid in a proximal zone of the catheter;
placing at least a portion of the braid of the catheter over a mandrel;

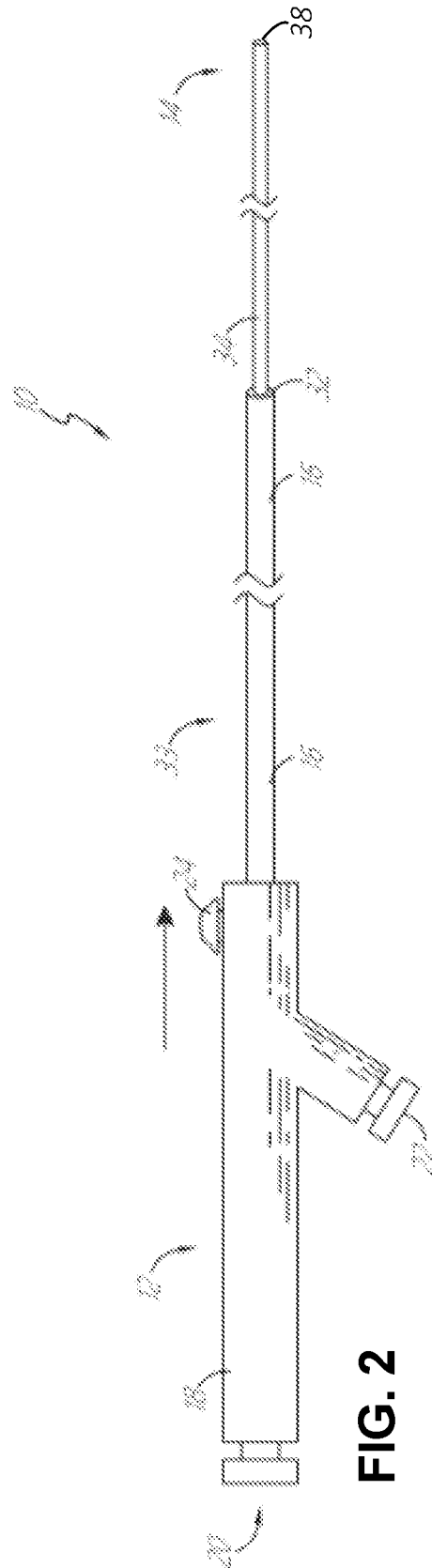
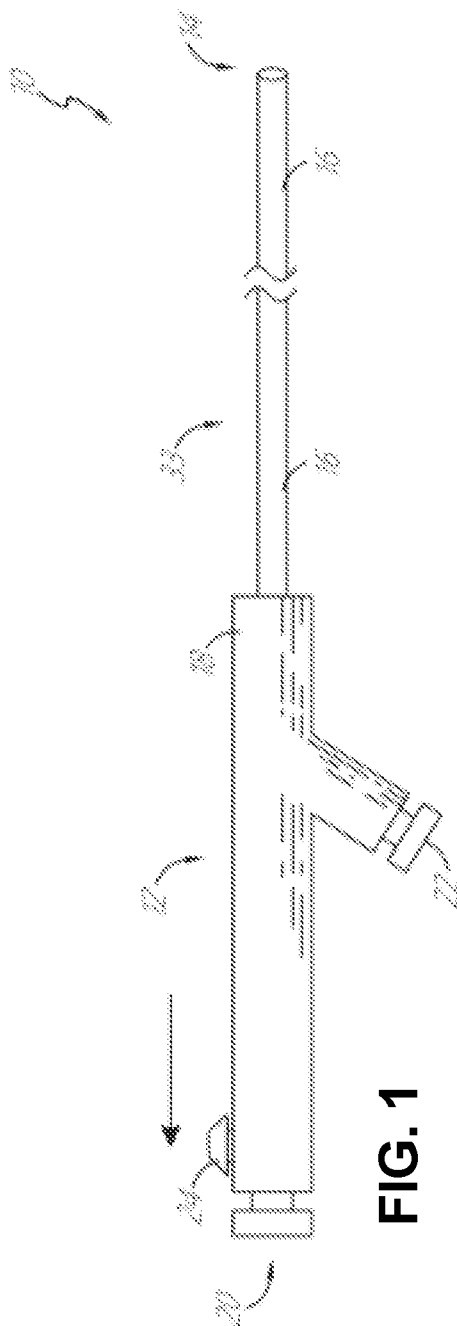
annealing a distal section of the braid comprising induction heating the braid and mandrel in a coil; and

visibly monitoring a parameter change of the braid.

18. The method of claim 17, wherein induction heating the braid comprises placing the braid and mandrel within an ERDO induction heater.

19. The method of claim 18, wherein the parameter change comprises a color change of the braid.

20. The method of claim 17, wherein the distal section has an axial length of no more than about 2 cm.



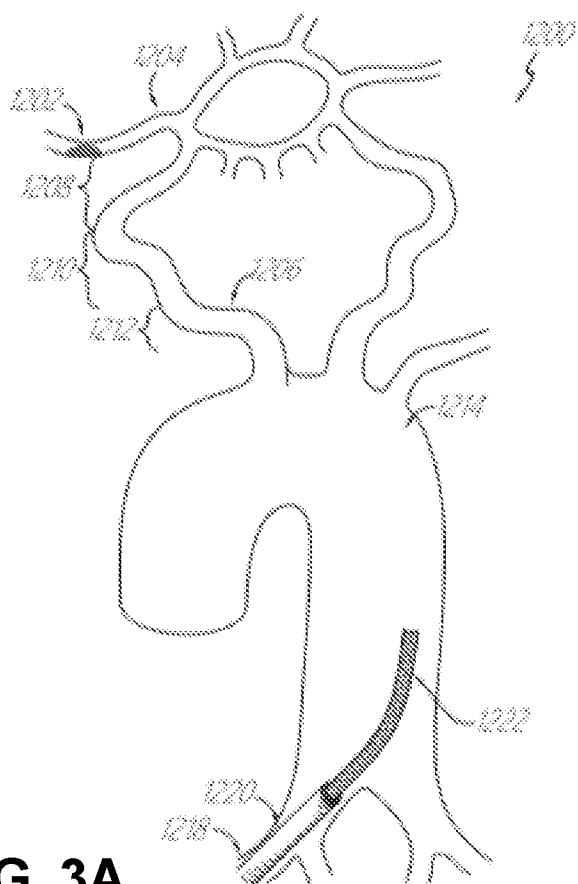


FIG. 3A

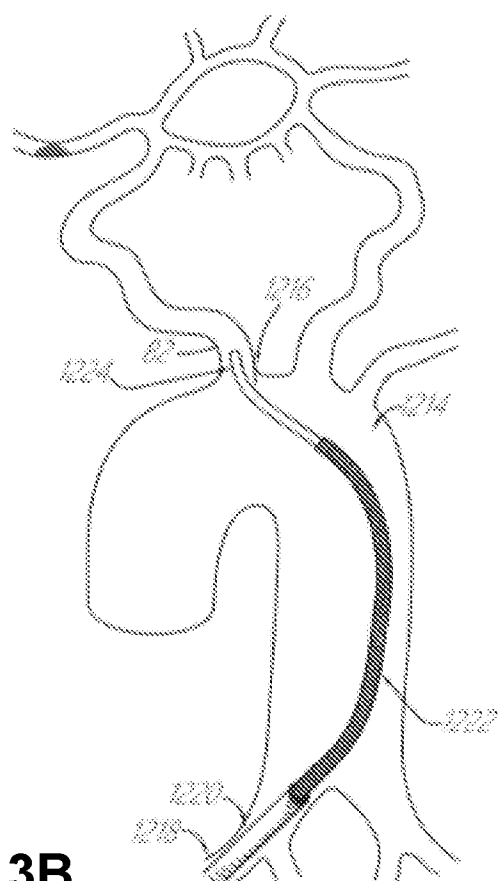


FIG. 3B

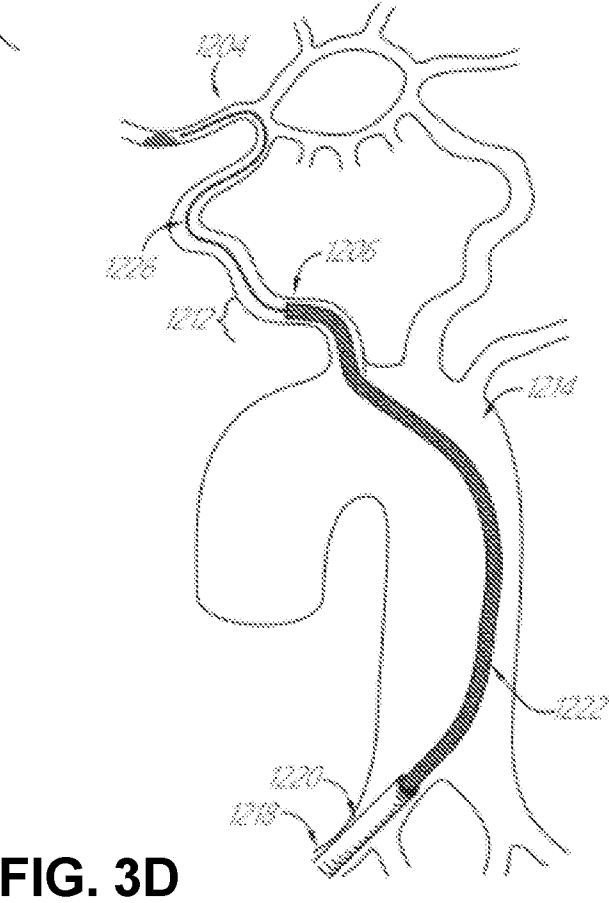
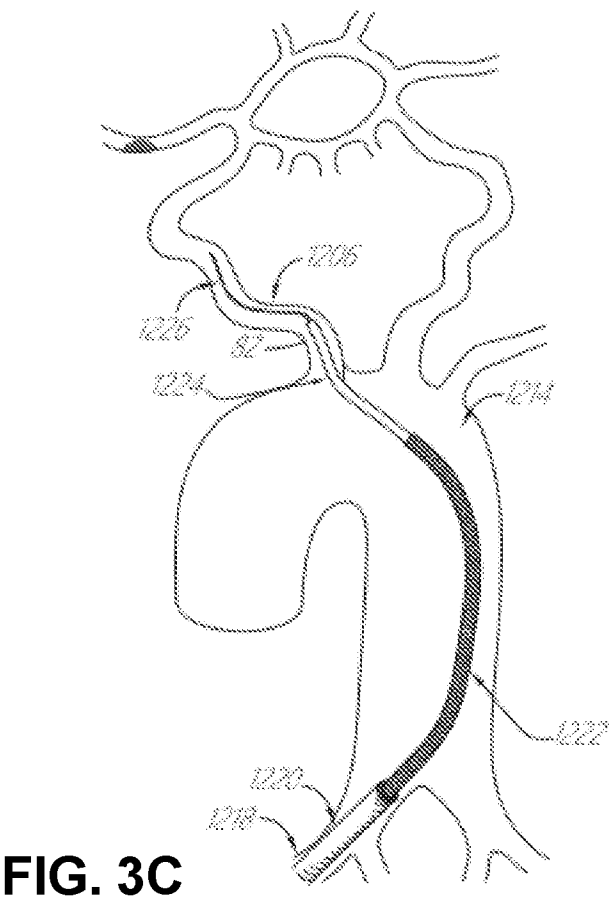


FIG. 3E

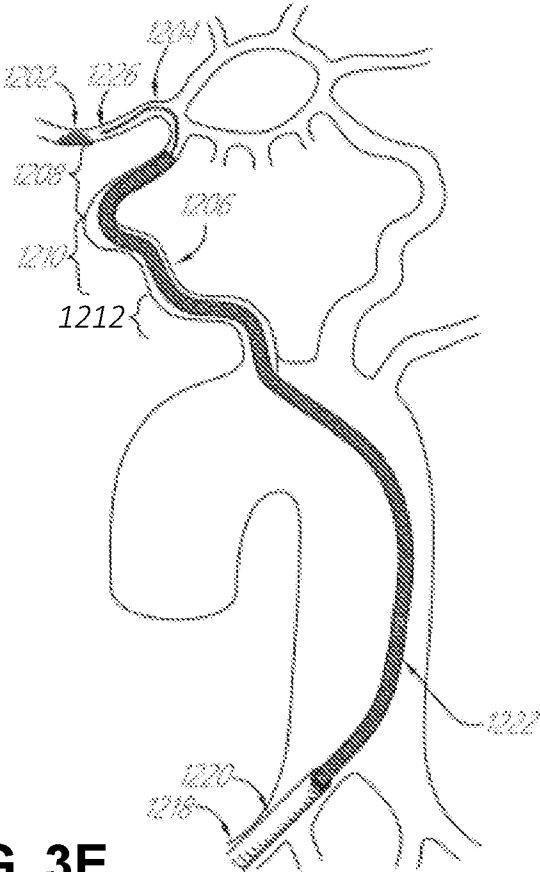
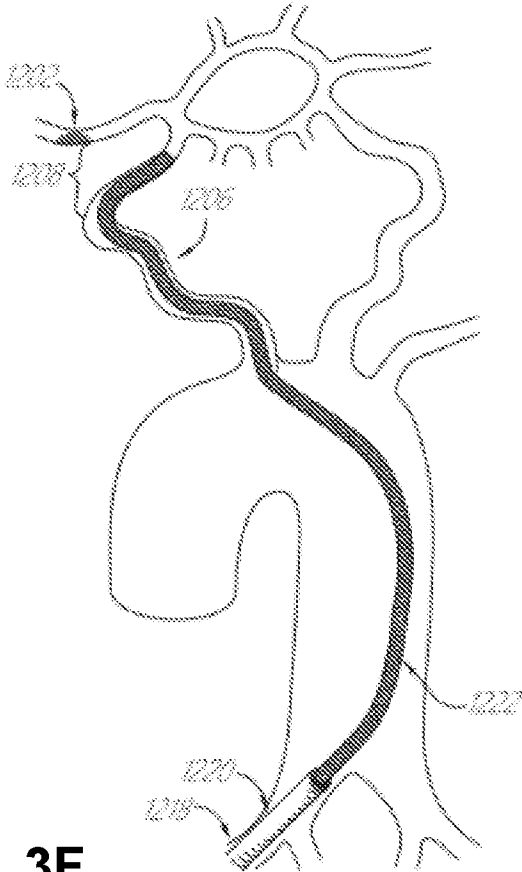


FIG. 3F



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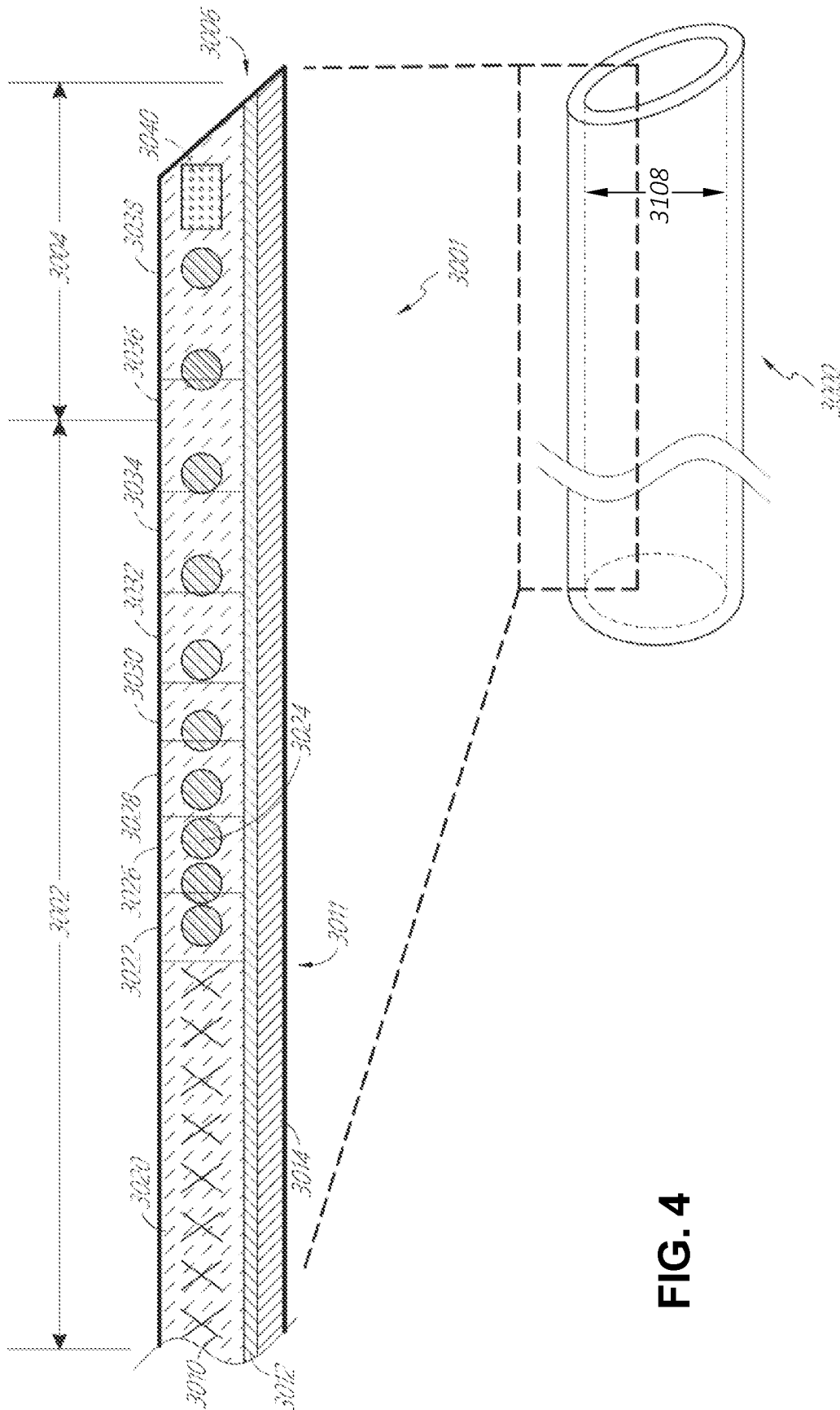


FIG. 4

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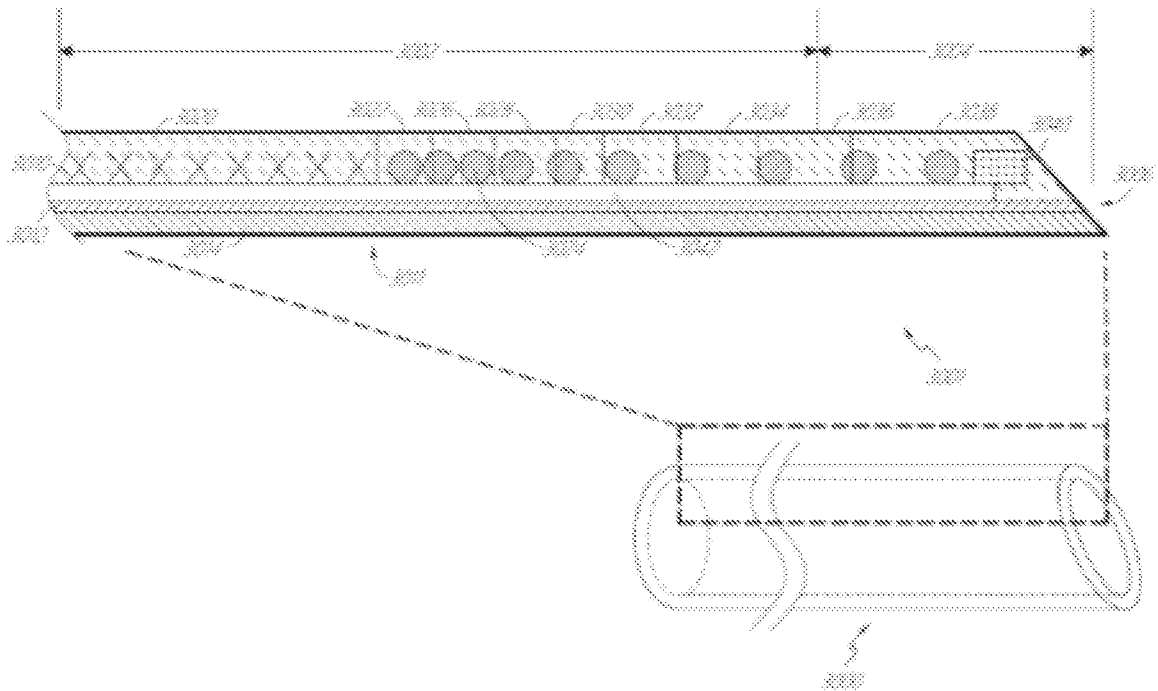


FIG. 5A

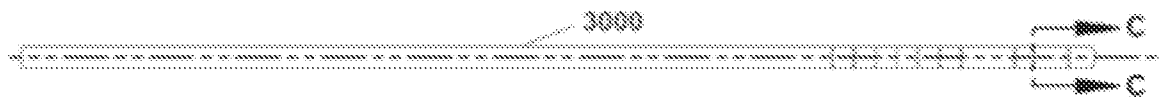


FIG. 5B

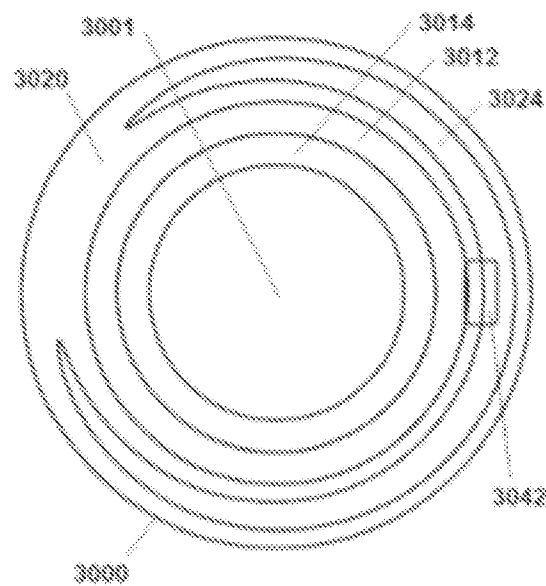


FIG. 5C

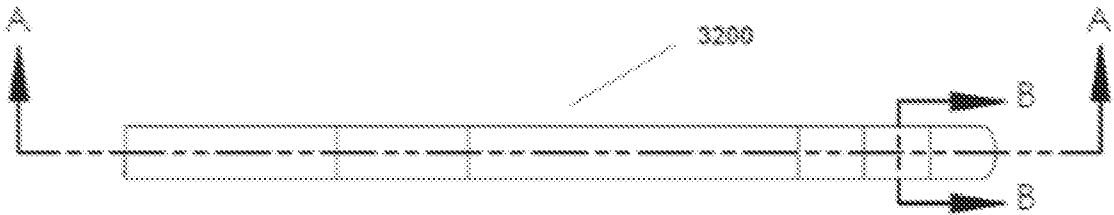


FIG. 6A

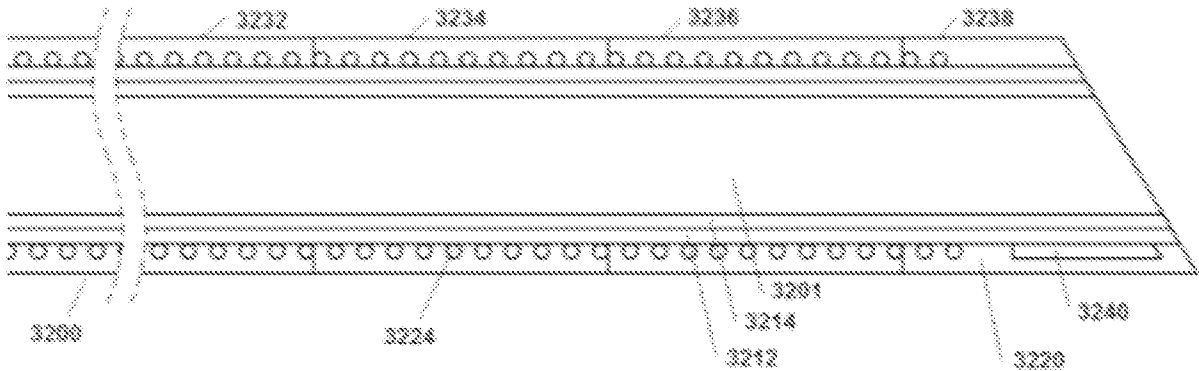


FIG. 6B

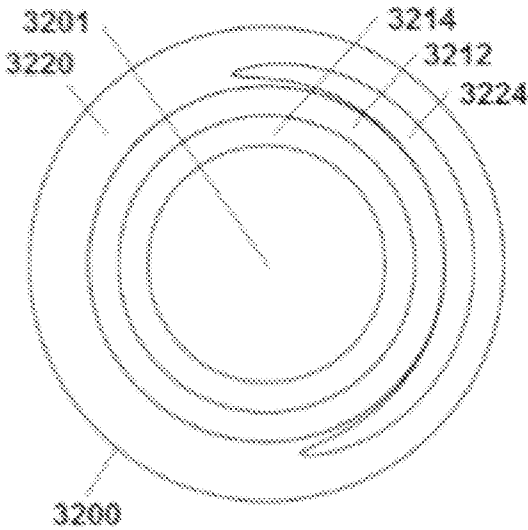


FIG. 6C

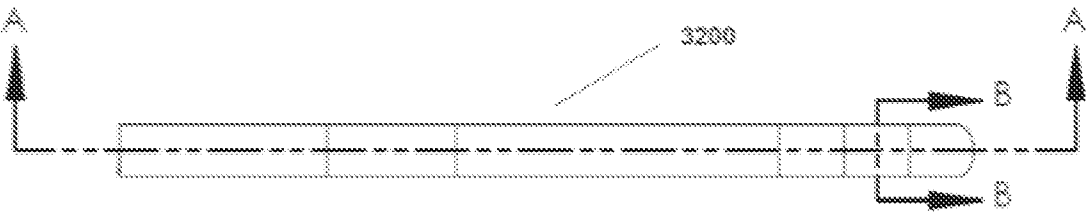


FIG. 7A

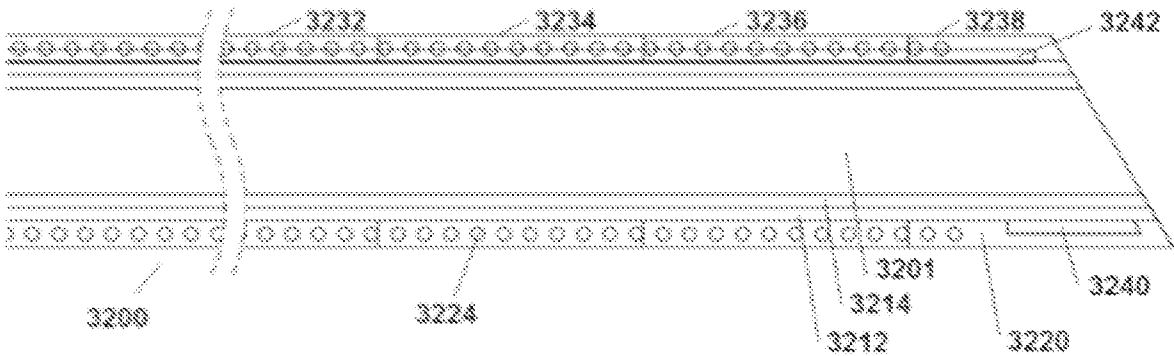


FIG. 7B

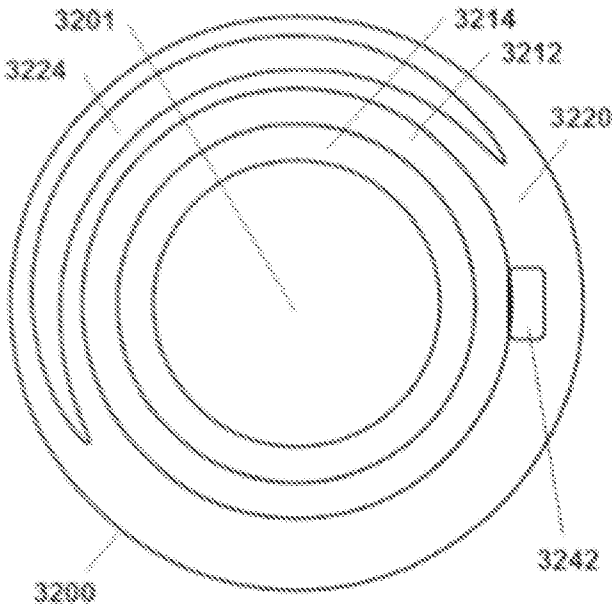


FIG. 7C

FIG. 8A

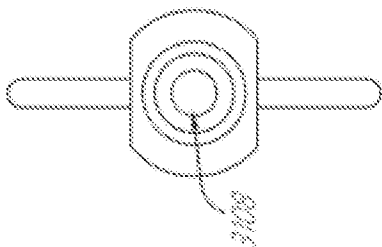
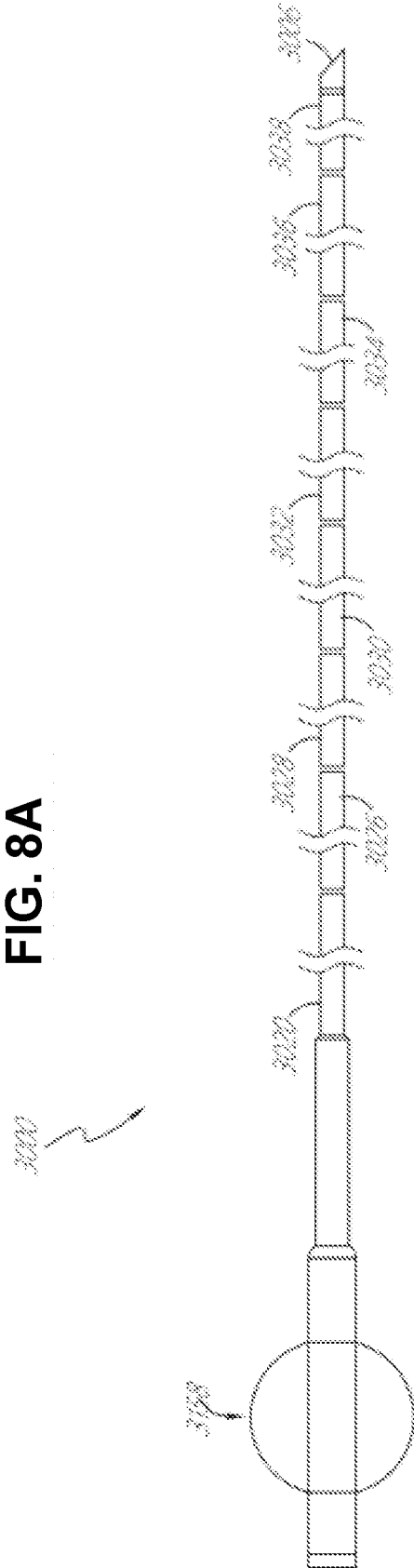


FIG. 8B

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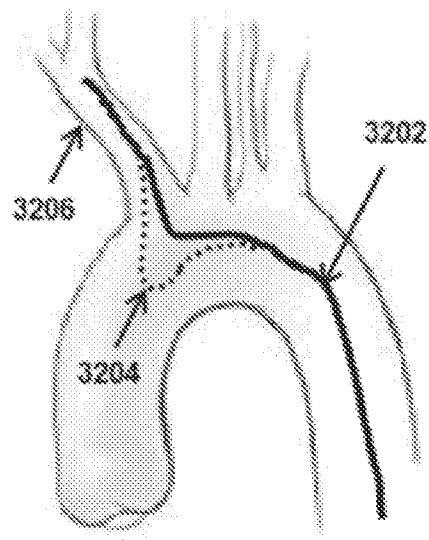


FIG. 9

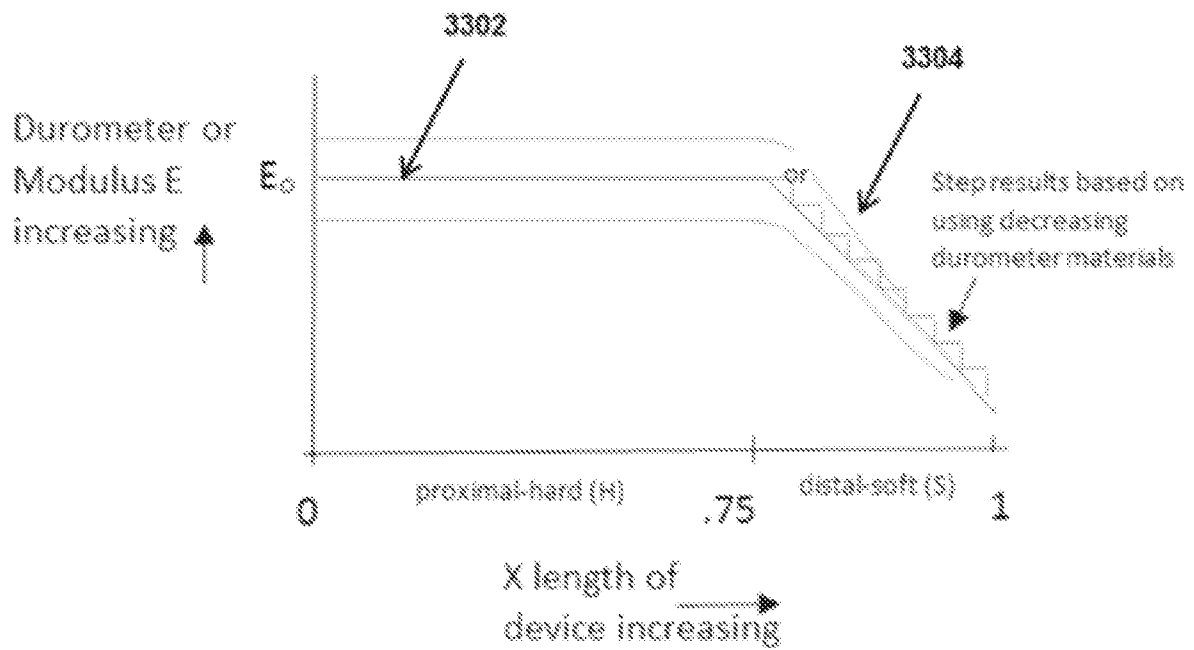
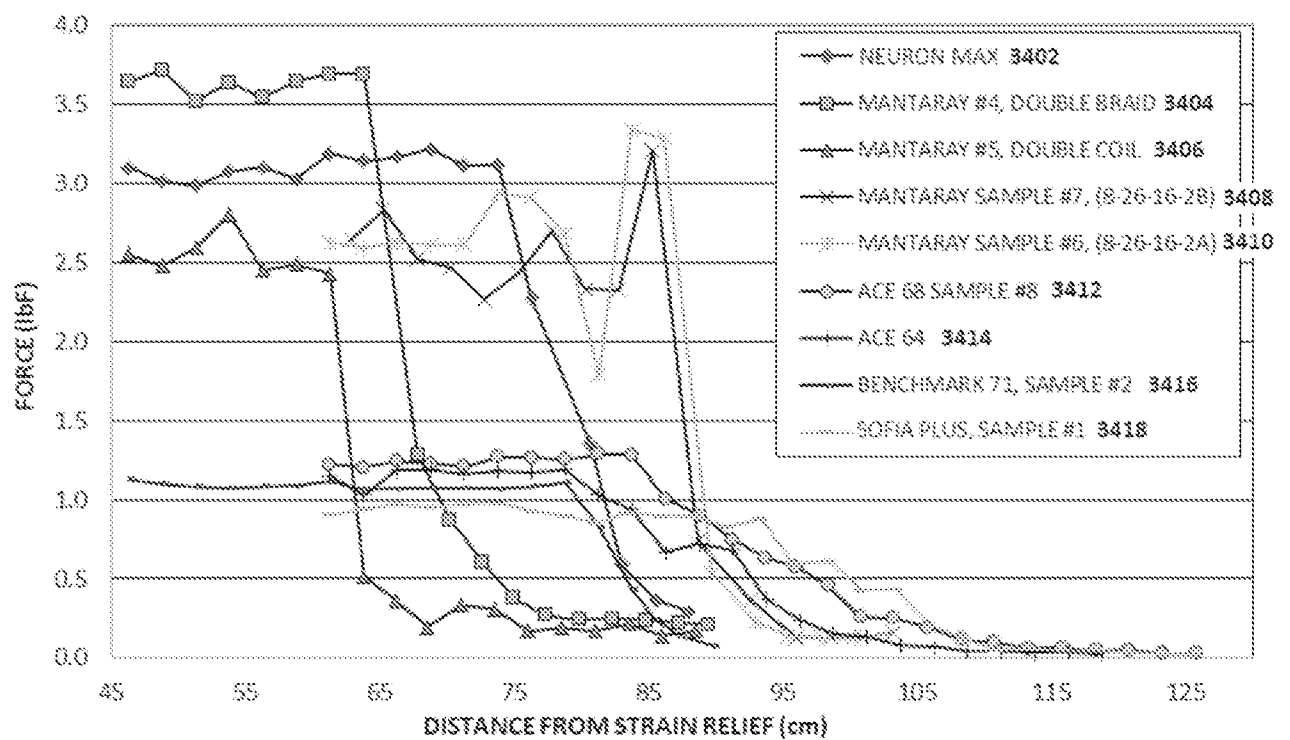


FIG. 10

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**FIG. 11**

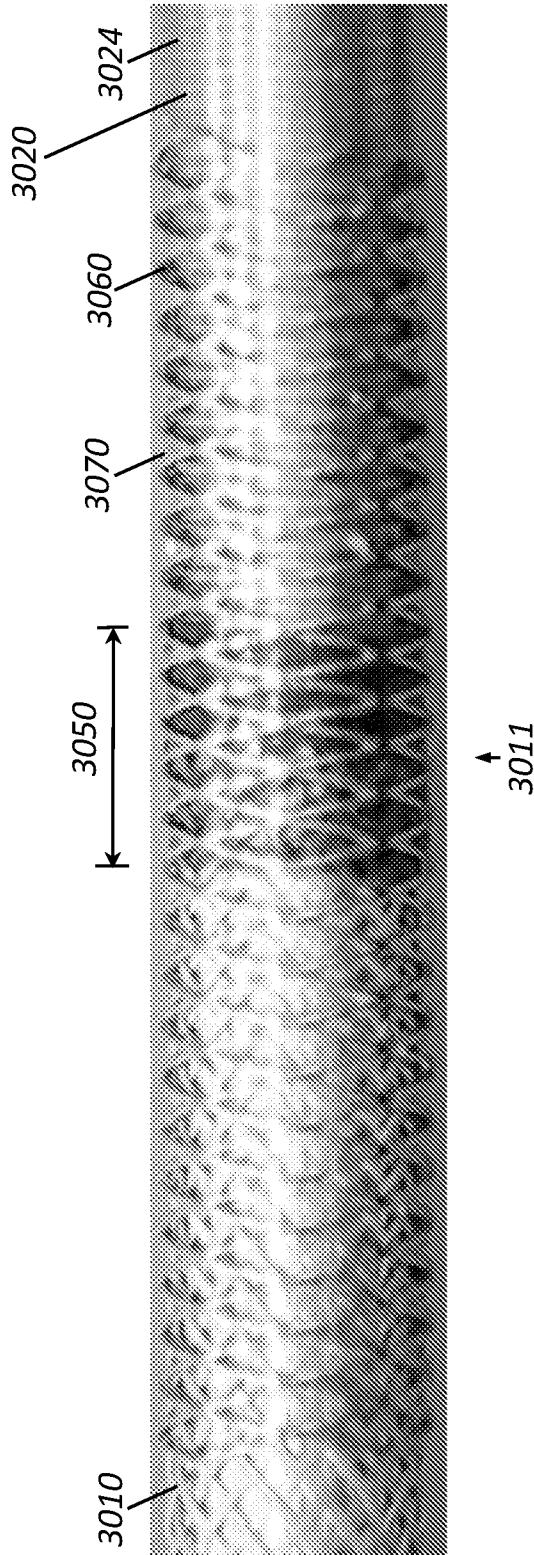


FIG. 12

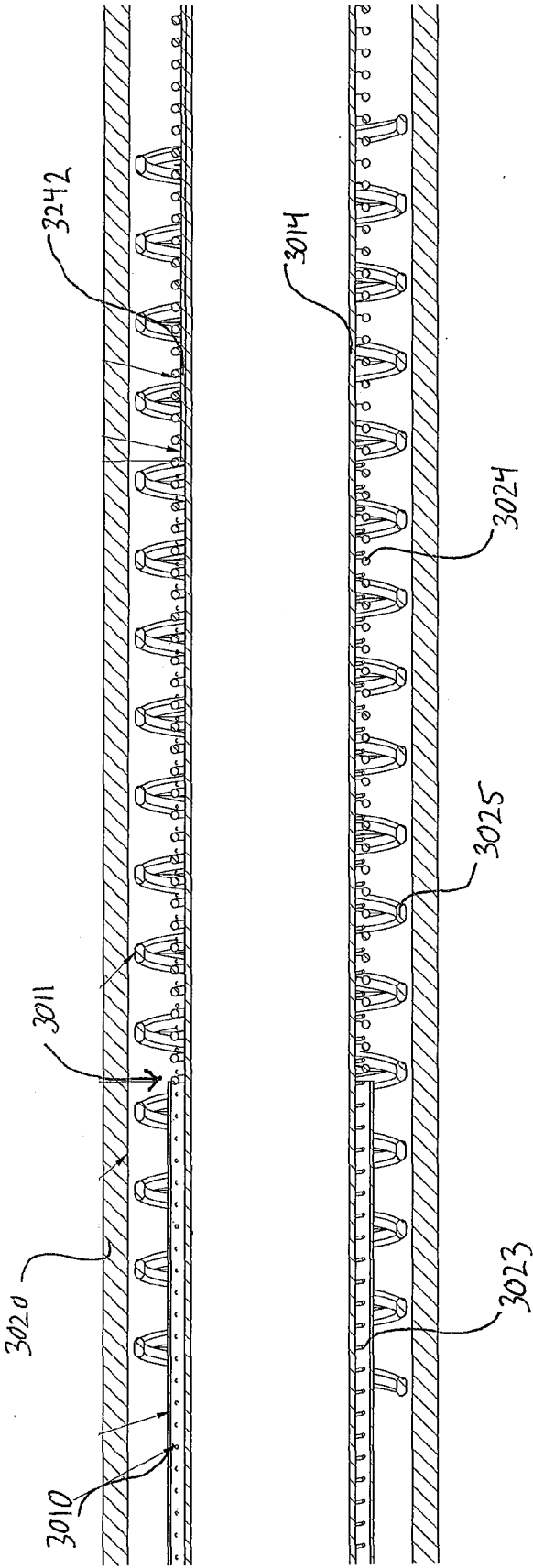


FIG. 13

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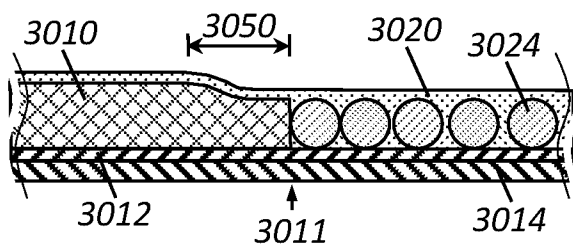


FIG. 14A

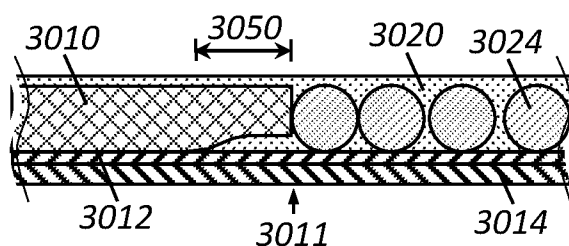


FIG. 14D

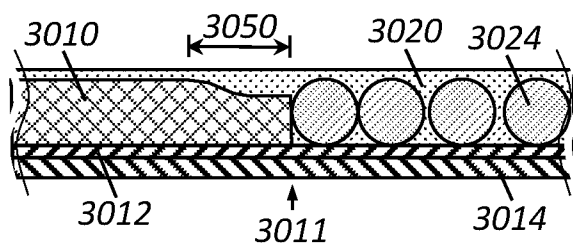


FIG. 14B

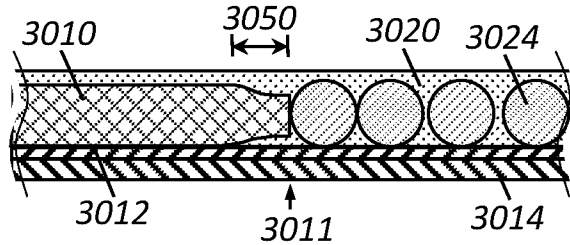


FIG. 14E

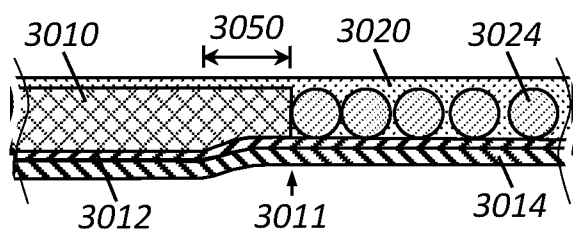


FIG. 14C

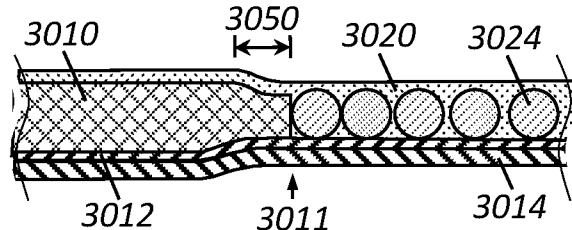
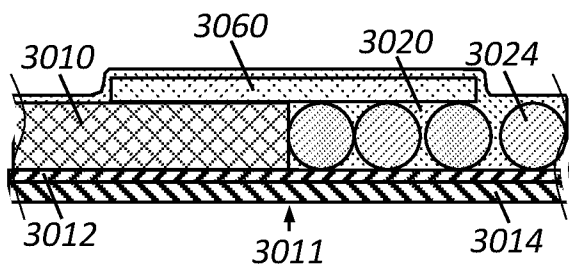
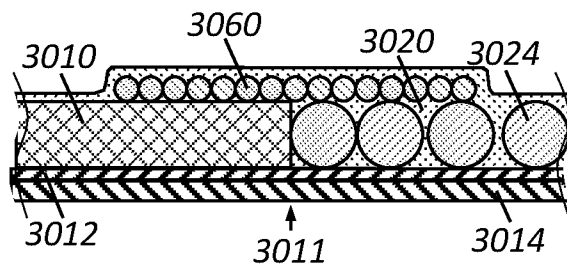
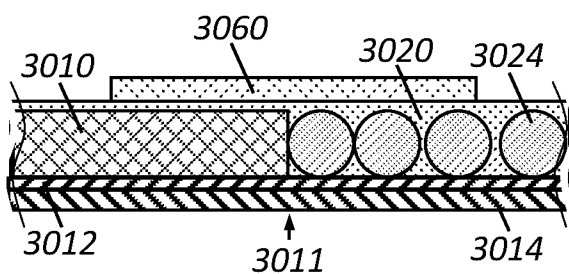
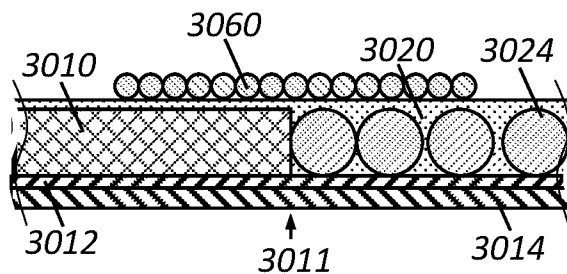
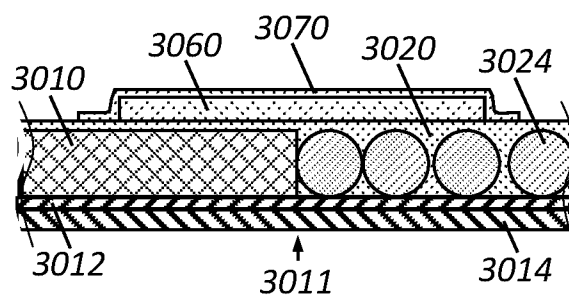
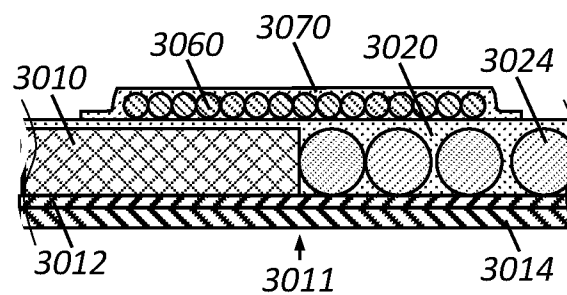


FIG. 14F

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**FIG. 16A****FIG. 16D****FIG. 16B****FIG. 16E****FIG. 16C****FIG. 16F**

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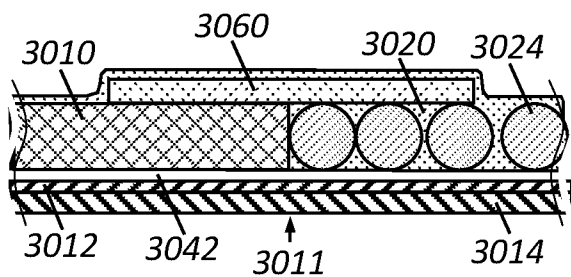


FIG. 17A

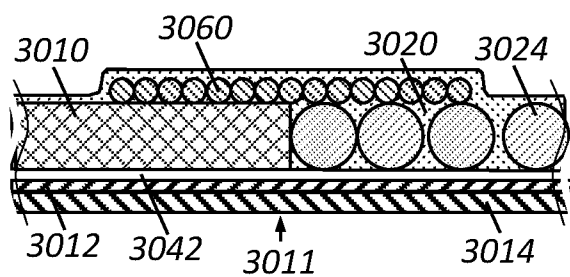


FIG. 17D

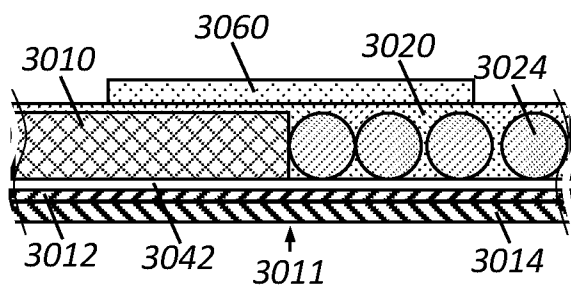


FIG. 17B

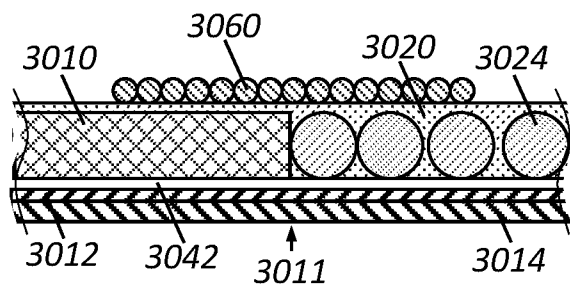


FIG. 17E

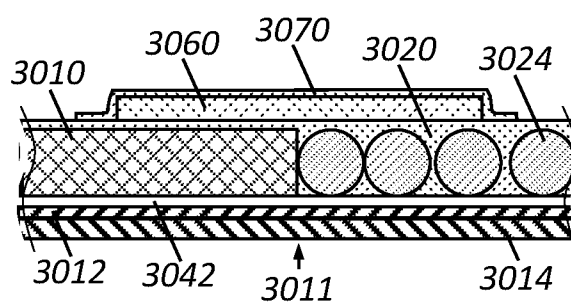


FIG. 17C

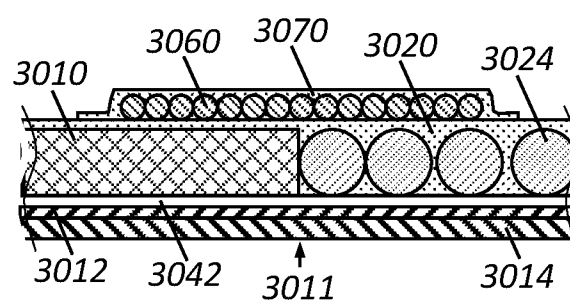


FIG. 17F

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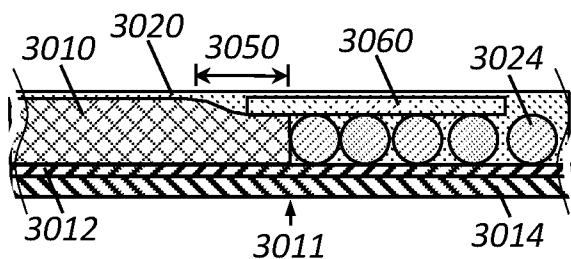


FIG. 18A

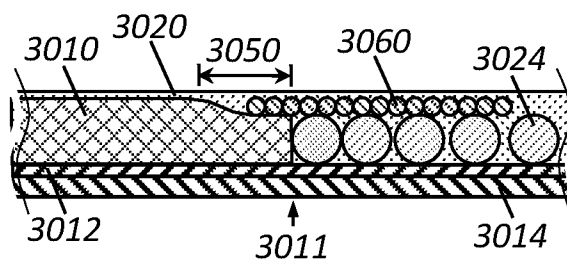


FIG. 18D

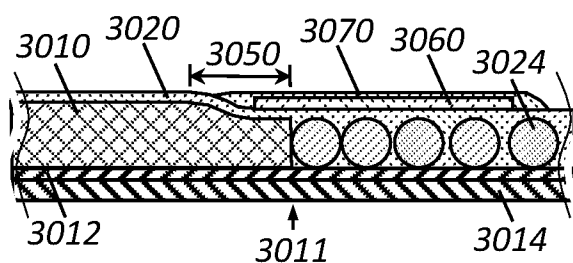


FIG. 18B

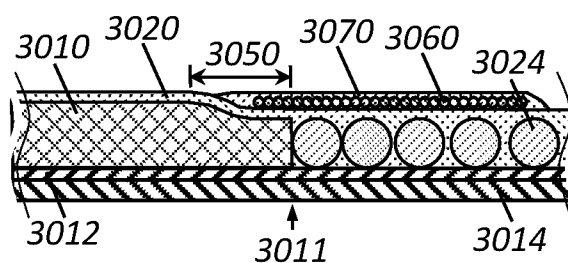


FIG. 18E

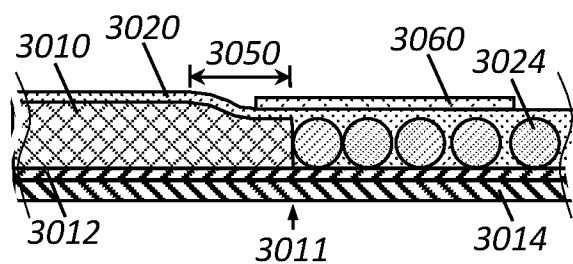


FIG. 18C

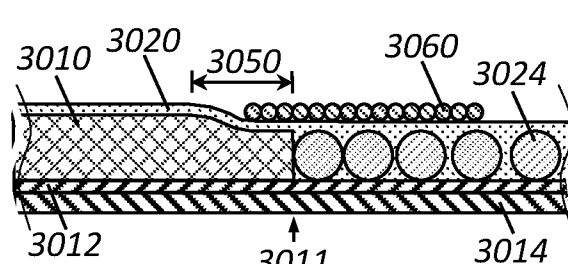
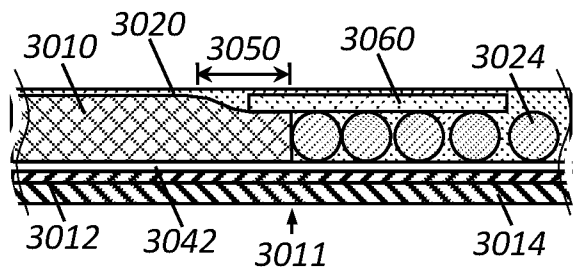
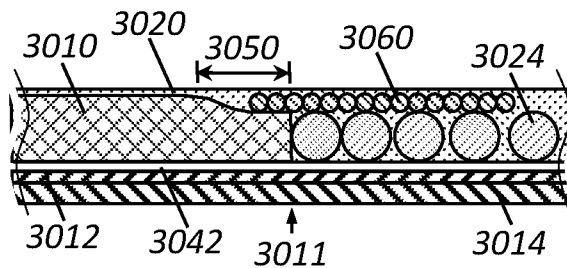
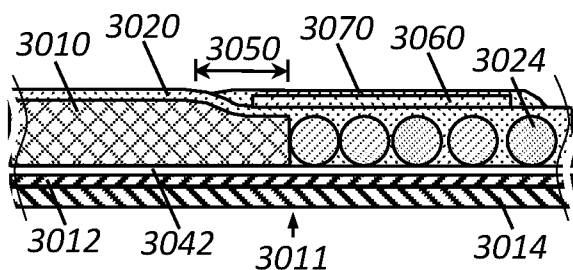
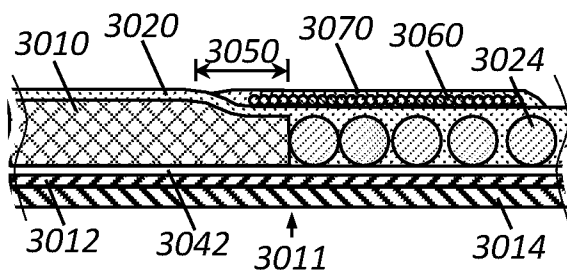
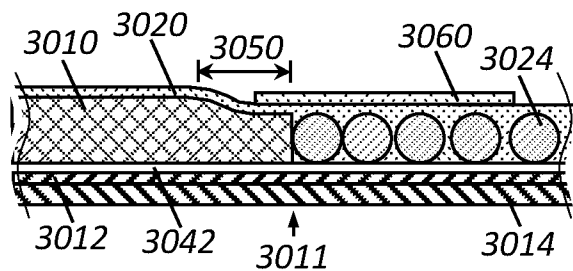
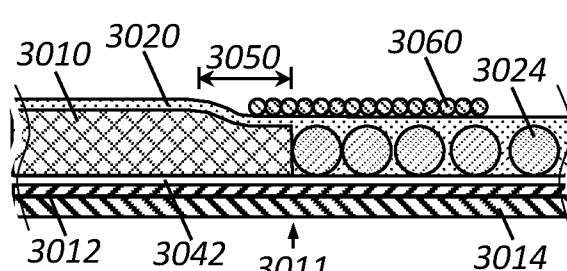
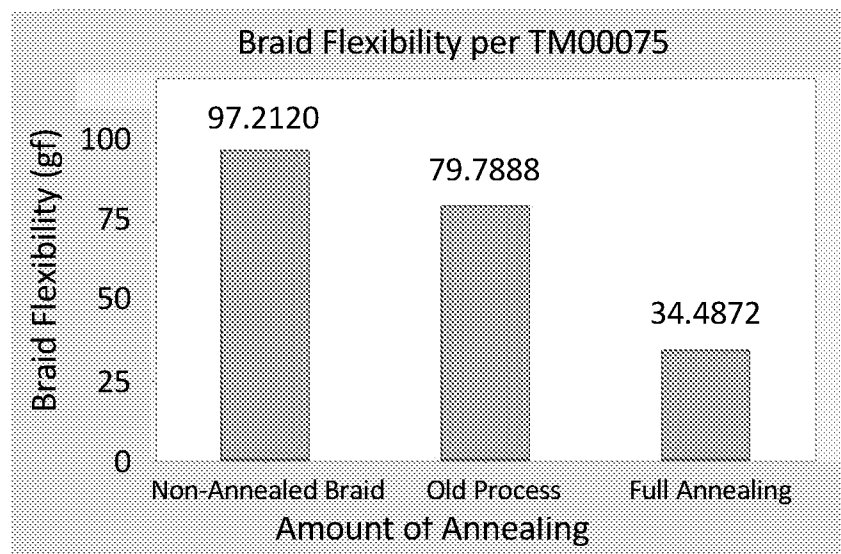
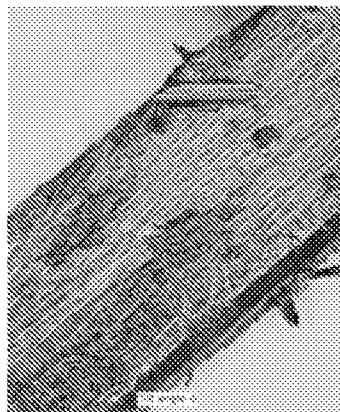


FIG. 18F

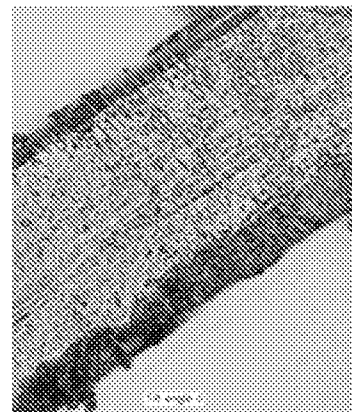
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**FIG. 19A****FIG. 19D****FIG. 19B****FIG. 19E****FIG. 19C****FIG. 19F**

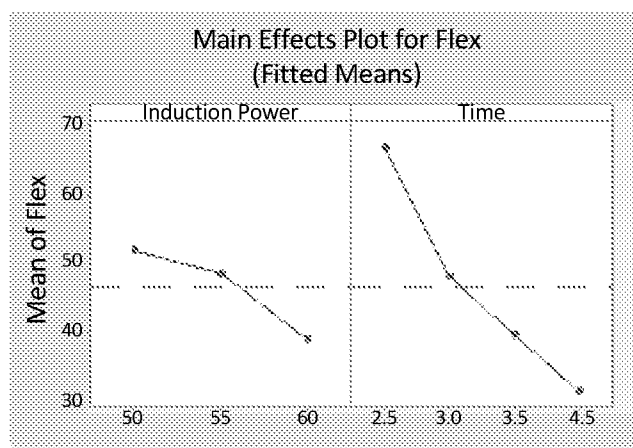
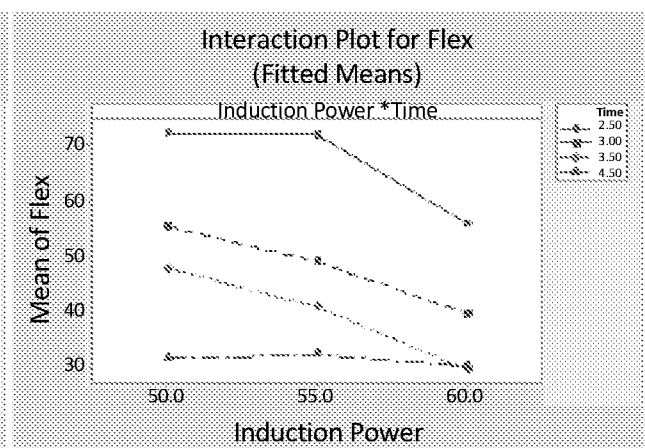
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**FIG. 20**

Old Process

FIG. 21A

Full Annealing

FIG. 21B**FIG. 22A****FIG. 22B**

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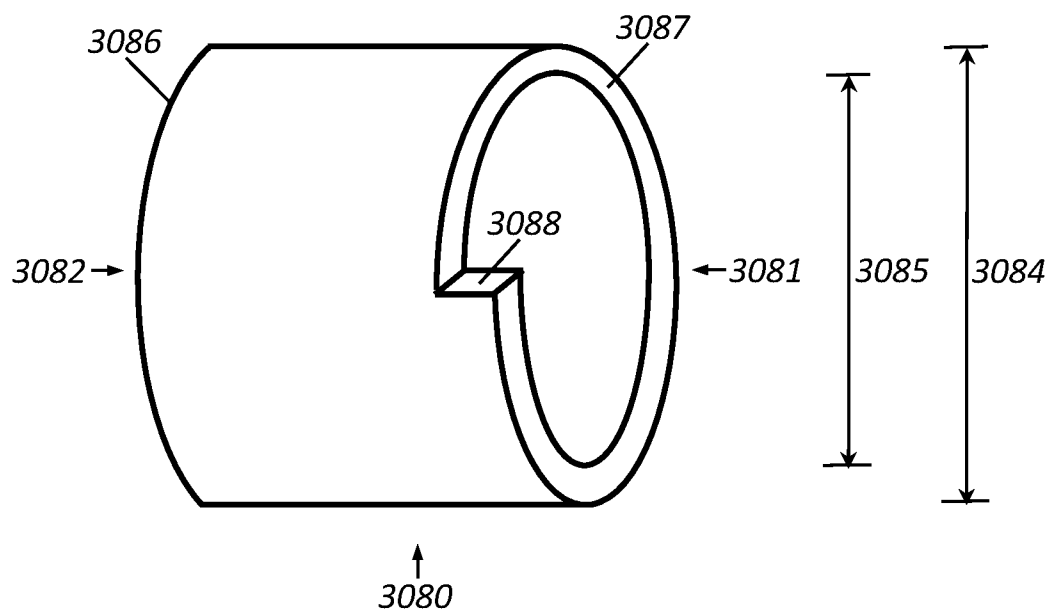


FIG. 23

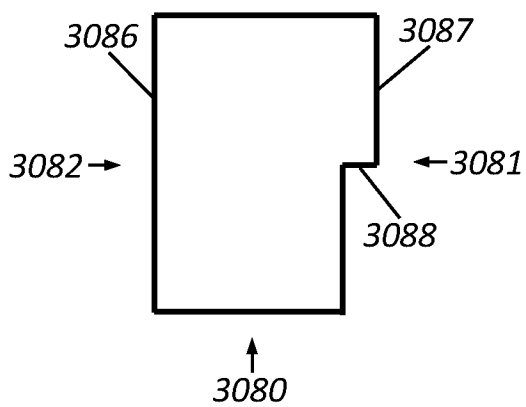


FIG. 24A

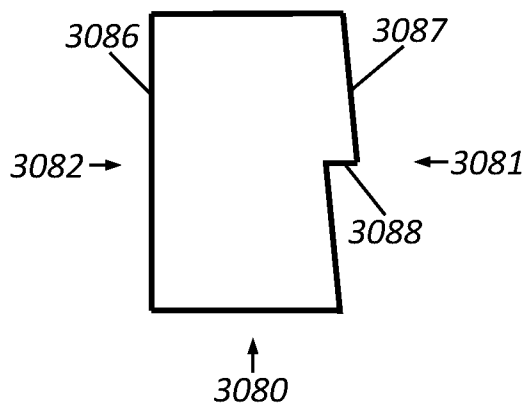


FIG. 24B

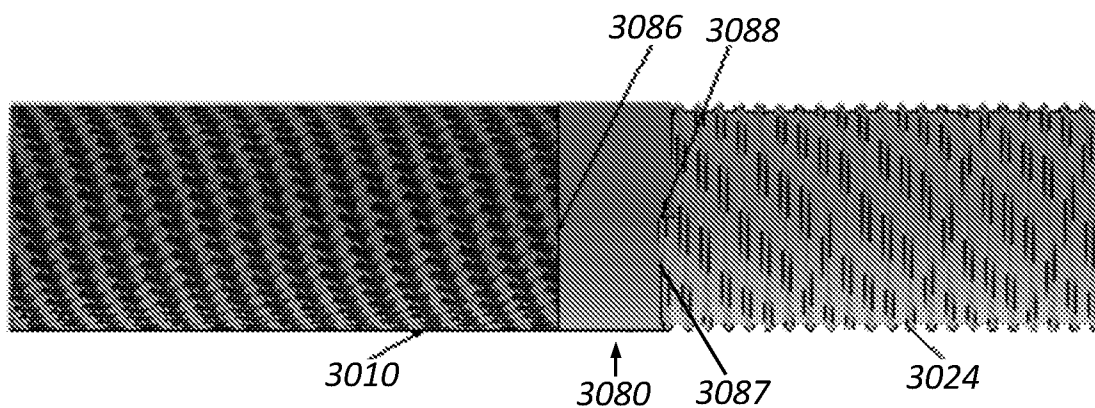


FIG. 25