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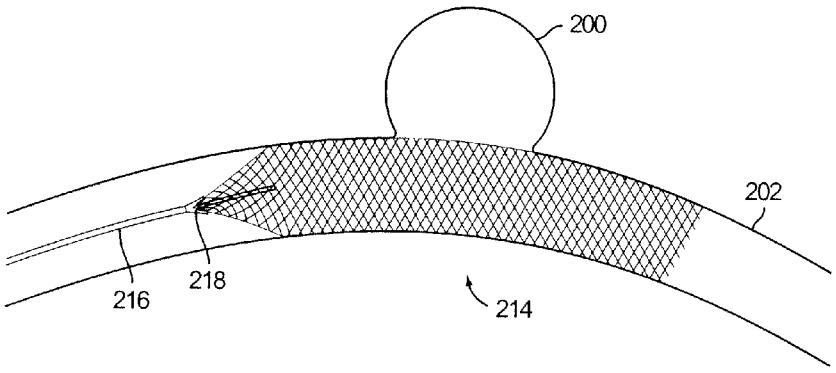

Fig. 12C

(57) Abstract: Embolic implants delivery systems and methods of manufacture and delivery are disclosed. The devices can be used for aneurysm and/or fistula treatment. The designs offer low profile compressibility for delivery to neurovasculature, while maintaining advantageous delivery and implant detachment control features.

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BRAID IMPLANT DELIVERY SYSTEMS

FIELD OF THE INVENTION

[0001] The subject matter described herein relates generally to systems, devices and methods for the delivery of textured (e.g., braided or woven) medical implants.

BACKGROUND

[0001] Mainstream clinical practice in endovascular treatment of intracranial aneurysms has changed little since the 1990's when vasooclusive coil use became widespread. Certainly, improved catheters and other auxiliary devices (e.g., stents) have helped make coiling procedures safer and/or more effective. However, the art in achieving adequate and appropriate aneurysm coil packing is best accomplished by the most highly skilled physicians.

[0002] Where practicable, aneurysm exclusion by cover-type devices (e.g., as described in US Patent Application No. 12/397,123 to the assignee hereof) may be preferred. Certain other groups are attempting to shift the paradigm away from intra-aneurysm coil packing to achieve embolization via deployment of an extra-aneurysm flow disruptor/diverter stent in the parent vessel. These densely braided devices and/or multiple braid devices layered upon one another are placed in the parent vessel across the neck of an aneurysm with the intent to alter hemodynamics so as to effect embolization.

[0003] US Patent Publications 2006/0271149 and 2006/0271153, assigned to Chestnut Medical Technologies, Inc., disclose delivery systems such braid-type stents. In one example system, a coil socket holds the distal end of the implant until this end is released during delivery catheter retraction with grippers holding the proximal end of the implant. These grippers are able to maintain contact with the proximal end of the implant through compression by the delivery catheter sleeve surrounding the grippers. Upon sleeve withdrawal, the grippers release the proximal end of the stent.

[0004] System miniaturization of the referenced system(s) is limited by the gripper configuration. Also, the lack of an active release mechanism for detachment from the distal socket presents issues of inadvertent deployment and/or non-optimal control.

[0005] Accordingly, there remains a need for each of more robust/reliable and/or more compact systems for advanced braid-type implant delivery. The present invention offers such systems with various advantages as presented herein and others as may be apparent to those with skill in the art.

SUMMARY OF THE INVENTION

[0006] The systems, methods and devices described in this section and elsewhere herein are done so by way of exemplary variations or embodiments. These examples are provided to aid in the description of the inventive subject matter and are in no way intended to limit the inventive subject matter beyond the express language of the claims.

[0007] The implant is preferably (i.e., has been selected as but is not necessarily) a stent or stent-like device and is held onto the delivery system by one or more releasable tubular covers. Each such cover is typically limited in length to envelop a relatively short length of the implant. Overlap between the members (i.e., cover and implant) is typically between about 1 mm and about 5 mm. More preferably, the overlap is between about 1.5 mm and about 3 mm. Accordingly, the cover(s) can be characterized as mini-sheath(s).

[0008] Implant release from the delivery system is accomplished by rupturing, tearing or otherwise splitting the mini-sheath cover(s). The cover(s) may be perforated or notched to promote breakage/rupture/tearing upon application of an expansive force.

[0009] Each mini-sheath is opened by expansive mechanical action generated by retraction of a core member. The core member may be user-actuated from a handle, by shape memory alloy (SMA) action upon heat application, or operate otherwise.

[0010] The expansion action is transmitted through the implant to force open the cover. In some examples, a sledge or wedge-type feature is pulled under the implant, thereby expanding it against the cover. In other examples, an expandable body under the implant forces the cover to open. Some examples described herein rely on both types of action.

[0011] The expander (e.g., in the form of a wedge or an expandable body) may contact the implant directly. Alternatively, an intermediate layer of material may be provided. Such a layer can be used to avoid implant damage, where the intermediate layer or member takes any abrasion, etc. along its inner surface – in effect shielding the implant matrix – and expands in unison with the implant to open the cover. The intermediate layer may also, or instead, be selected to provide a surface against which the implant is frictionally locked when constrained by the cover.

[0012] Such a lock relies on a high degree of surface friction between the implant and an underlying surface to resist longitudinal/axial motion of the implant (in its contracted state) along the longitudinal axis of the delivery device or sleeve. Substantial

surface friction between implant and the underlying surface will prevent the implant from sliding relative to the underlying surface, preventing the implant from decreasing in length (i.e., foreshortening) and radially expanding. Although the term "lock" can be used, it should be understood that the implant is not locked from all movement in an absolute sense, as the implant can be forced from the lock should sufficient force be applied to overcome the surface friction. Rather, the implant is preferably locked in place sufficiently to resist the implant's own bias towards expansion (if any), to resist bias applied by a secondary expansion device (if any), to resist forces applied against the implant while maneuvering within the patient's vasculature (e.g., forces applied either by the delivery device or the patient's vasculature or blood flow), and/or to resist forces applied to the implant during any loading, unloading, or deployment procedures. Of course, one of skill in the art will appreciate that the degree of surface friction necessary to achieve the state of frictional lock will depend on the specific delivery device implementation and intended application(s).

[0013] When a frictional lock is relied upon to retain the implant on the delivery system until release, the implant preferably has textured surfaces (which may be continuous or disconnected) where it is intended to be secured to the delivery system by the mini-sheath(s). The surface(s) is/are preferably present about the entire inner periphery of the implant, but can also be located in limited regions generally corresponding to the interface regions of the sleeve.

[0014] In a preferred implementation, both the intermediate body and the implant comprise braid. However, other textured surfaces can be formed on either body by altering its surface to create a textured pattern, e.g., by etching, grinding, sanding, and the like. Still other textured surfaces can be formed by applying a high-friction coating to the body. Of course, any combination of these can also be used (e.g., a braid implant on a patterned underlying surface, etc.). Other optional details and discussion of the frictional interface between the implant and delivery system body may be taken from US Patent Application Serial No. 12/412,731, filed on March 27, 2009 and titled "Friction-release Distal Latch Implant Delivery System and Components," which is incorporated by reference for this purpose.

[0015] In another variation, instead of using a frictional lock generated between the implant and an underlying member to maintain the implant on the delivery system, an interlocking approach with the mini-sheath may be relied upon. In one example, the mini-sheath may comprise heat shrink that is entrained with the implant. Such interlocking may be assisted by vacuum forming while shrinking.

[0016] The interlock may alternatively, or additionally, be improved by including interface features on/in the implant around which the heat shrink forms. In an example where the implant comprises braid, some or all of the ends of the braid may be formed into ball ends (e.g., by laser application to from 0.003-0.005 inch diameter bodies) that the heat shrink can grasp. As a corollary advantage, these bodies may be radiopaque. Alternatively, radiopaque bands or coils that are crimpled, welded, soldered or otherwise affixed the implants ends could serve as retention features for the mini-sheath(s). These may be affixed only at the ends, or at intermediate points (e.g., to indicate a central section of increased density or any included cover).

[0017] In a preferred embodiment, the implant is a braided device with a braided surface about its entire exterior. The implant's number of wires, braid angle, pore size, profile, diameter, etc. may range in size. The braid may be metallic (as in NiTi, St. Steel, CoCr, other Ti and/or Zirconium alloy. etc.), polymeric, of hybrid construction or otherwise. Preferred variations may be formed of Nitinol. The alloy is preferably superelastic at body temperature. The metal may be a binary alloy or a ternary alloy to provide additional radiopacity. Alternatively, platinum or tantalum DFT Nitinol or platinum or tantalum wires may be included in the braid.

[0018] The density of the device is paramount in applications where braid itself is intended to affect blood flow, allowing thrombosis outside the implant to occlude a site. High density braid/mesh is typically required for such applications. Namely, braid having at least about 48 ends, typically set at about 90 degrees or greater, in diameters from about 4 to about 8 mm may be employed. At larger diameters (e.g., about 6mm to 12mm or more), more wire ends (e.g., common braider-size multiples of 64, 72 or 96) may be employed in forming the implants. Still higher typical wire counts may be employed. Moreover, 3-D braiding technology (such services are provided by 3Tex, Inc.) may be employed in forming the implant braid matrix.

[0019] A range of wire sizes or combination of wire sizes may be employed, typically ranging from about 0.0008 to about 0.0015 inch, and up to about 0.003 inches depending on desired delivery profile. A single braid tube may have all wires the same diameter, or may have some wires of a slightly thicker diameter to impart additional strength to the braid layer. The thicker wires impart greater strength to the implant without significantly increasing the device delivery profile, with the thinner wires offering some strength while filling-out the braid matrix density.

[0020] At least when employing Nitinol wire, to improve implant wire corrosion resistance and/or biocompatibility after any heat setting shape, the implants may be etched in "AYA" Sulfamic Acid solution, then passivated in Nitric acid solution. Alternatively or additionally, pre-etched and/or polished wire may be employed in braiding the implant matrix. Shape setting the braid in the implant shape may be performed in an oven/furnace, a fluidized bath or salt pot. All such processing is within the knowledge of those with ordinary skill in the art.

[0021] In some cases, the braid may incorporate polymeric fibers into the braid matrix – biodegradable (e.g., PLA/PGLA) or otherwise. Likewise, while the implants advantageously comprise include polymeric fill fiber, the entire braid may instead comprise polymer – especially high strength biodegradable polymer such as MX-2 (MAX-Prene), synthetic absorbable monofilament (90/10 Glycolide/L-Lactide) and/or G-2 (Glycoprene), synthetic absorbable monofilament (Glycolide (PGA), ε-Caprolactone (PCL), Trimethylene Carbonate (TMC) Copolymer) that is heat set into shape (e.g., at 110 degrees centigrade for an hour).

[0022] Whatever the material, the braid may be uniform, or it may be configured with a higher density center "patch" or circumferential section. If so, such a section will typically be located at the center of the device. Or, it may be offset distally. Moreover, a coating – such as urethane, etc. may be set over the implant in similar fashion. Still further configurations of implants having grafts, coatings (e.g., lubricious, drug-eluting, and the like) or other non-textured surfaces present on the exterior of the implant are possible. See, e.g., USPN 4,416,028 to Eriksson, et al. Coatings, such as those available through NiCast, Inc. (Israel) or Medical Device Works (Belgium), may be used for such purposes, as well as others. Hydrogel coating also offers an appealing option, such as a hydrogel-based polymer network capable of entrapping therapeutic agents as described in USPN 6,905,700 to Won et al.

[0023] The implant may include radiopaque markers as described above, or as described in either of U.S. Patent Application Serial Nos. 12/412,731, filed on March 27, 2009 and titled "Friction-release Distal Latch Implant Delivery System and Components," or 61/177,847, filed on May 13, 2009 and titled "Absorbable Braid Implants and Delivery Systems," each incorporated herein by reference in its entirety.

[0024] The implant is expandable from a contracted state to an expanded state, and preferably self-biased towards the expanded state (i.e., "self-expanding" as understood by those with skill in the art. Generally, expansion results in lengthwise shortening of

the implant. Especially in braid-type implants, holding the end portions of the implant stretched apart from each other (as in at least one exemplary variation herein) can cause the implant to be maintained in a contracted state, without the need to radially restrain the entire implant (such as with a full body sheath).

[0025] Certain variations of the subject invention take advantage of this action. One such example releasably captures both ends of the implant so as to offer potential for independent navigation, especially when an optional atraumatic tip is incorporated in the design. Precision placement of the implant is achieved by predictable mini-sheath release upon rupture by contact with an inner floating wedge. By contracting the system, the floating wedge contacts each mini-sheath region at substantially the same time. However, the mini-sheath regions can be staged to release independently, for example, by using sheaths with varying thicknesses or by other means readily apparent to those of ordinary skill in the art,.

[0026] System flexibility can be optimized by using multi-segment (e.g., rings) wedge members. Alternatively, a selectively slit hypotube (e.g., Nitinol, resembling a segment of a SYNCHRO guidewire) or a coil spring (e.g., stainless steel or Nitinol) may be used. The coil spring can be tightly packed or include gaps that bottom-out upon compression. In any case, the ends of the spring are optionally be held together (e.g., by soldering) or set within jacket(s).

[0027] However constructed, the wedge member(s) may underlie a braid shaft – preferably attached adjacent an atraumatic tip, and running the full length of the delivery system. As discussed above, such a braid shaft offers an advantageous interlock with a braid implant to provide for robust stretch to a reduced diameter profile. Still further, the section of braid under the implant may be used to provide a mechanical expansion "balloon" effect to assist in splitting the mini-sheaths when compressed.

[0028] In an alternative construction, no wedges are provided, but such a braid expander is relied upon alone to open the mini-sheaths. Likewise, other constructions that expand when axially compressed are contemplated for rupturing the implant covers, including: coils, volume-incompressible polymer bodies (e.g. one or more urethane tubes), micro-machined (e.g., etched, EDM or laser-cut) metal lattices, etc.

[0029] Regardless, when deployed – as typical – in a vessel undersized relative to the implant, the system offers the potential for unique operation. In one mode of delivery, the stent is compressed until it reaches the vessel wall. After advancing the

implant to a treatment site, the implant is compressed to achieve tissue apposition. With the body of the implant so-anchored, the end being moved (typically the distal end is retracted and the proximal shaft held stationary) causes the braid to evert and roll inward.

[0030] Upon release, the result is an implant having a substantially predictable (user selected) in-situ length, with a double-layer section of the braid. Such a feature is unique to delivery of braid-type implants because their length is typically dictated by vessel diameter. The current system, instead, allows not only for more precise placement than known delivery systems (typically sheath-based), but also a specified final implant length. In another mode of delivery, sizing may be selected to simply provide one layer. Either way, maximum braid density (e.g., as useful for flow-disruption/occlusion application) is achievable through the compressed delivery of the braid implant.

[0031] In an alternative configuration, the delivery system includes only one implant release latch. Such a device will be used in coordination with a microcatheter.

[0032] The latch may be configured for the proximal end or the distal end of the implant. In any case, precision placement of the implant is once-again achieved by predictable mini-sheath release upon its rupture. The rupture may be driven by a wedge member, an expandable braid or coil section, other means or a combination of such means.

[0033] However configured, to facilitate loading into a microcatheter for navigation to a treatment site and use, a loading sheath may be provided over at least a portion of the implant as typical. To assist in tracking within the catheter, delivery system may include a passive socket in which to receive the distal end of the implant and/or include a floppy tip.

[0034] Some of the delivery system architectures advantageously incorporate a braided tube that runs substantially the length of the system. With a jacket over the proximal portion, the construction provides a stable shaft. The jacket for the braided shaft may simply be an extension of the mini-sheath heat shrink material. At least one distal section of this braid is exposed to serve at least as a frictional interface member with the implant. In one example, it is only the interface. In another example, it provides both the implant interface and one or more expander element(s).

[0035] A jacketed braid shaft can be configured to be highly pushable, torqueable and kink-resistant. Moreover, in a braided configuration, the composite sleeve can

have its PIC (Per Inch Crosses) varied along its length to provide enhanced distal flexibility. In other words, the sleeve may be tuned/modified as a catheter-like subcomponent of the system. In an alternative configuration, an elongate polymeric, metallic or metal alloy shaft can be used with section to interface with the implant.

[0036] Similarly, the core member can also be configured for enhanced flexibility. For example, the core member may have one or more successively tapered regions near or adjacent to its distal end, like a typical guidewire. In some examples, the core member has column strength (i.e., as in a wire) to allow tip extension; in others, it may be a tensile-capable member alone (e.g., as in a fiber or yarn). Both the core member and the sleeve can comprise an elastic or superelastic material such as stainless steel, NiTi, CoCr, other alloys, polymeric materials, and the like.

[0037] The sleeve jacket and/or implant restraint sheaths can, for example, be formed by heat-shrinkable tubing. The heatshrink for the covers, and the jacket described above, may be PE (polyethylene), PET (polyester), or the like. PI (polyamide), FEP, PEEK and other materials may also be advantageously employed in some cases. The mini-sheath/sleeve may be perforated or notched to promote breakage/rupture.

[0038] It is typically thin-walled heat shrink (e.g., about 0.0003 to about 0.0005 inch wall thickness PET). With or without the underlying braid frictional lock "Velcro" effect (and instead using a discrete proximal shaft comprising, e.g., PEEK or Nitinol) the mini-sheaths preferably comprise heat-shrink tubing that recovers to engage the implant. Thin wall (e.g., about 0.001 inch or less) PET is suitable for such retention and release as shown and described. Still, other materials may be used for the mini-sheaths, just as any suitable conventional material may be employed for the core member (e.g., NiTi, stainless steel) and other system components including those referenced above.

[0039] Depending on the device configuration, the delivery system inserted into the patient's vasculature may be directly navigated to a treatment site using conventional techniques just as if it were a guidewire. Alternatively, it may simply be passed through a catheter after exchange with a guidewire. Accordingly, for neurovascular applications, the system is advantageously sized to cross either an 0.021 or 0.027 inch microcatheter. The device is feasibly made with as small as about an 0.018 inches diameter. It may still be useful at larger sizes (especially for other applications - such as in the coronary or peripheral vasculature) as well.

[0040] After advancement to the treatment site, the implant is delivered by releasing or disengaging the implant. The implant may be so-delivered for a number of purposes. With a braided stent, at higher densities, it may be used to disrupt/divert the flow to treat an aneurysm or fistula. The implant may be delivered across a lateral wall aneurysm to effect flow disruption alone or with multiple devices. It may be also be used as a "coil jailer" by first trapping a microcatheter between the stent and a vessel wall and delivering coils into an aneurysm. It could be placed along one branch of a bifurcation to disrupt flow to a bifurcation/trifurcation aneurysm or offer a platform for retaining coils therein. It may be used as a liner, followed by placement of a tube-cut stent within it when stenting diseased saphenous vein grafts.

[0041] Other possibilities exist as well or will be apparent to those of ordinary skill in the art. The inventive subject matter provided herein includes these methods, systems and devices for practicing these methods, and methods of manufacturing those systems and devices.

[0042] The present filing claims the benefit of each of US Patent Application Serial Nos. 61/052,756 filed May 13, 2008 and 61/083,959 filed July 28, 2008 – each of which is incorporated herein by reference in its entirety.

BRIEF DESCRIPTION OF THE FIGURES

[0043] The details of the inventive subject matter set forth herein – both as to structure and operation – may be appreciated, in part, by study of the accompanying figures, in which like reference numerals may refer to like parts. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the subject matter. Moreover, all illustrations are intended to convey concepts, where relative sizes, shapes and other detailed attributes may be illustrated schematically rather than literally or precisely. Variation from the embodiments depicted is, of course, contemplated. Moreover, details commonly understood by those with skill in the art may be omitted as will be understood in review of the figures. Of these:

Figs. 1A and 1B are partial side views depicting an example embodiment of the implant delivery system with an implant attached to and released from the system, respectively; Figs. 2A and 2B are partial side views depicting another example embodiment of the implant delivery system during progressive stages of deployment; Figs. 3A-3C are partial side views depicting yet another example embodiment of the

implant delivery system during progressive stages of deployment; Fig. 4A-4C depict different wedge components as may be employed in the delivery systems, especially that shown in Figs. 3A-3C; Figs. 5A and 5B are detail illustrations of various mini-sheath/cover construction options to facilitate release; Fig. 6 is another delivery system detail illustration which concerns component spacing to ensure cover release from the implant; Fig 7 is a partial side view of a one-sided detachment system related to the double-sided system in Figs. 3A-3C in it use of a wedge member and expandable braid section for cover release; Fig. 8 is a partial side view of another one-sided wedge-plus-braid expander type system; Fig. 9 is a partial side view of a system like that presented in Fig. 7 but without an expansion wedge; Fig. 10 is a partial side view of a system like that presented in Fig. 8 but without an expansion wedge; Figs. 11A and 11B are partial side views depicting an embodiment of the implant delivery system utilizing a compactable coil for cover release with an implant attached to and released from the system, respectively; and Figs. 12A-D are side views depicting an exemplary embodiment of the implant delivery system at different stages of implant deployment in treating an aneurysm.

In these views, elements that are contained within other elements are shown in profile with broken lines. However, though sometimes partially obscured, the implant profile is illustrated using an "x x x x x" pattern for the sake of clarity.

DETAILED DESCRIPTION

[0044] Various exemplary embodiments of the invention are described below. Reference is made to these examples in a non-limiting sense. They are provided to illustrate more broadly applicable aspects of the present invention. Various changes may be made to the invention described and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention. All such modifications are intended to be within the scope of the claims made herein.

[0045] Turning to Fig. 1A, it shows an implant delivery system 10 including an implant 12 comprising braid and having proximal 14 and distal ends 16 and a detachable pusher

20. An elongate sleeve 22 defines the pusher body. A core member 24 within the sleeve is connected to a wedge band 26. It may terminate at the wedge band or extend beyond it as shown. The core member 24 is optionally a wire (e.g., Stainless Steel or Nitinol), with one or more steps or taper as shown to offer graduated flex performance at least toward the distal end of the pusher 22 (up to or past the band 26). The band 26 may be cut from hypotube and be solder, welded or otherwise connected to the wire. It advantageously comprises steel or another hard material to avoid galling from contact with the braid. Alternatively, the "band" may comprise a few turns of a coil affixed to the core wire 24.

[0046] Sleeve (pusher) 22 comprises a liner 28 (e.g. PTFE lined Polyimide), tubular braid 30 (e.g., Stainless steel or Nitinol) and a jacket 32 (e.g., PET shrink tubing). Sleeve braid 30 extends under the implant proximal end 16, optionally, to terminate beyond core member 24 with a polymeric soft tip 34.

[0047] Mini-sheath or cover 36 holds the implant in a state of frictional lock with braid layer 30 along an overlap zone 38. This engagement is maintained until the core member 24 is withdrawn as illustrated in Fig. 1B. This action drives the wedge 26 under the engaged portion of the implant causing it to expand and tear, crack or otherwise rupture cover 36 open. Self-expansion of the implant effects release, and/or the pusher is simply withdrawn, to relieve any further interference. To ensure disengagement before removal, a 90 to 180 degree turn of the system may be advisable because the cover will typically (though not necessarily) split only along one side. Even without the turn, however, the lock holding the implant to the pusher is released allowing withdrawal with the implant in place.

[0048] Because the core member 24 in this variation of the invention is actuated only in tension, it may comprise a polymeric filament of fiber (e.g., Vectran or Spectra fiber), in which case the core member 24 is advantageously knotted to retain band 26, with optional potting with glue (e.g. 4014 LOCTITE). Delivery system flexibility can be maximized in this fashion, with any changes in stiffness developed along the body of the pusher (e.g., by changes to the braid and/or jacketing).

[0049] Figs. 2A and 2B show a variation of the system in Figs. 1A and 1B in which the intermediate braid layer 30 extends to secure a coil tip 40 and a cap or socket 42 for the implant distal end 16. For attachment to the coil tip 40, some of the braid wires may be trimmed-out with the remainder acting as a core to the tip. Such a tip may improve

device tracking in a catheter. Setting the distal end of the implant in a socket may offer similar advantages.

[0050] When inside a catheter 44 (transferred thereto via a loading sheath as conventionally accomplished) the distal end of the implant 12 is protected within the cap 42. Upon exit from the catheter 44, the implant 12 is partially unconstrained and is able to expand so as to pull-out of the socket 42. Because no distal lock is provided in this variation of the invention, the cap 42 may comprise any of PI, PET or other tubing. No shrink onto the implant is necessary or desirable.

[0051] Braid extension 46 is optionally covered by a jacket 48 (e.g., with PTFE or PET shrink tubing or otherwise) to maintain dimensional stability of this body. Extending the jacket 48 underneath the distal end 16 of the implant 12 may also help ensure release as intended and illustrated in Fig. 2B when the implant 12 is free of the catheter 44.

[0052] Figs. 3A-3C are partial side views depicting yet another example embodiment of the implant delivery system during progressive stages of deployment. While the previous examples only held one end of the implant in a locked arrangement, this delivery system 100 releasable captures both ends of the implant.

[0053] In this case, atraumatic tip 102 is connected to core wire, or member, 104 received within sleeve 106. Braid extension section 46 is preferably similarly attached. In this manner, when the core member 104 is withdrawn (compare Fig. 3A and Fig. 3B), the braid extension section 46 expands. This expansion may serve either of one or two purposes. In the variation shown, it may simply provide clearance for the floating expander wedge member(s) 108, allowing them to move into position to force open each of the proximal and distal covers 110, 112 (in a similar fashion to that described in reference to Figs. 1A and 1B. Still further, braid section 46 can itself operate as an expander to open the covers 110, 112.

[0054] In any case, when the compressive action continues (by withdrawal of core member 104 and/or advancement of sleeve/shaft 106), the wedges 108 are driven fully under the covers 110, 112 to break them open and allow implant release. Cover release may occur substantially simultaneously. Alternatively, the action can be staged. In some applications it may be desirable to open the proximal end first; in others the distal first (especially for potential recapture purposes).

[0055] One way in which to accomplish sequential release is to utilize different thickness material, different type of material and/or vary such parameters as discussed

in connection with Figs. 5A and 5B, below, so that one cover is more freeable than the other.

[0056] In any case, it will be appreciated that a unique feature of delivery system 100 is that two release points are actuated by a single user input. This approach allows for minimizing delivery system profile as compared to a system that might include additional concentric layers to achieve similar two-sided functionality.

[0057] Indeed, minimizing the crossing profile for such a system can be especially useful in instances where it is intended to be used as a navigable delivery system in itself, as an interventionalist would employ a guidewire. Either by actively extending the core wire or by originally locking it into such a configuration during manufacturing, a "wire-like" delivery system is offered as shown in Fig. 3A. Given its (optional) tip-to-tail braid construction and the full-length core wire, the system can be optimized for such use. Excellent torquability is possible given that there need be no joints. Nor are their any performance-sapping component crossovers. The system is arranged in a completely concentric fashion in the example shown.

[0058] Fig. 4A-4C depict different wedge components as may be employed in delivery systems 100. Fig. 4A shows multiple bands 114. The bands may be independent (as shown) or interlocked in puzzle-piece fashion. Fig. 4B shows a coil spring 120. Turns 122 of the coil end are stabilized by soldered or welded zones 124. Fig. 4C shows a slit (e.g., by laser cutting or otherwise) hypotube 126. All of these options can provide excellent flexibility, while offering adequate resistance to compression during system actuation in order to work reliably. Moreover, the length of any of these members can be tuned/selected so as to match the implant mounted to the delivery system 100 and coordinate with its intended delivery action (e.g., simple linear deployment vs. the doubling-over approach described above).

[0059] Actually, in one variation, delivery system 100 can be configured to work without the bands at all. Specifically, braid section 46 can be tuned such that it severs as the only cover expander/expansion means necessary to effect release.

[0060] Whatever element(s) define as expansion means, treatment of the cover merits discussion itself. In some cases, the covers may simply be heat-shrunk down to the implant. As shown in Fig. 5A, however, it may be desirable to add perforations 130 (e.g., with a pin, laser or otherwise) to provide a weakened section or section(s) in the cover 36 to promote controlled rupture. In another approach, the cover 36 includes a notch or slit 132 to provide a point from which an intentional tear can propagate as

shown in Fig. 5B. While not shown, the cover could alternatively be scored to a partial depth. Other options are possible as well.

[0061] Fig. 6 illustrates another detail relevant to consistent release performance in wedge-based variations of the subject invention. Namely, a gap "G" is advantageously provided between the proximal end of the implant and any jacket 32 and/or liner 28 that would interfere with wedge member 26 withdrawal past the end of the implant. Allowing the wedge to (at least partially) pass beyond the implant during actuation ensures that cover 36 opens to fully release the implant. The length of the gap will typically be between about 1 mm to about 2 mm to ensure desired action.

[0062] Also important is the amount of expansion that the wedge member(s) provide. Generally, expansion is at least about 0.004 inches but more typically about 0.006 to about 0.012 inches. While more expansion/interference may be desired in some cases, care should be taken not to introduce other system performance issues in maximizing the size of the wedge body (e.g., hindering crossing profile, mechanical advantage in addressing the cover or generating other interference issues).

[0063] Note also, it may be desirable to introduce a chamfer or lead-in to the wedge to assist its introduction under the covered portion of the implant. However, no such feature has been observed as necessary when the components are sized appropriately. It may be preferred (at least in variations of the invention in which a single wedge body is employed) to minimize the wedge member length (e.g., size it to about 0.010 inches or less) to avoid significant effects on system flex performance. In any case, selecting and tuning the size, shape and performance of the constituent parts of the subject systems is within the knowledge of those with skill in the art.

[0064] Beyond such routine development considerations, the present invention includes additional exemplary architectures. Of these, delivery system 140 illustrated in Fig. 7 is essentially a one-sided variation of system 100 illustrated in Figs. 3A-3C. More particularly, it uses a single wedge member 26 and expandable braid section 142 working together to effect cover release. The architecture also closely resembles that of delivery system 10 illustrated in Fig. 1A. However, core member 144 in the case of system 140 in Fig. 7 actually connects to the distal end of the braid. This connection can be made by soldering, welding, gluing, etc.

[0065] Fig. 8 shows another one-sided wedge-plus-braid expander type delivery system. In this configuration, delivery system 150 wedge member 152 is set distal to the braid expander section 154.

[0066] As another option (equally applicable to other systems as described herein), the expander section of braid need not comprise an extension of braid defining shaft 156. Rather, the shaft may comprise a hypotube sleeve 158 and liner 160, with the expander braid captured external thereto by an extension of cover 162 heat-shrink tube. Other attachment approach are possible as well.

[0067] The inclusion of coil 164 (e.g. comprising Stainless Steel or Nitinol ribbon) is also a notable feature. It serves as compressible buttresses to the expander braid layer to in generate a firm lock for the implant between the braid layer and cover.

[0068] In delivery system 150, the wedge 152 may comprise a solder joint attaching the core member to the braid. Alternatively, it may comprise a weld joint between the bodies and/or be supplemented with a band to help define a consistent geometry. In any case, the architecture of system 150 may offer advantages in action by first progressively expanding the cover with the braid and then "finish" by drawing the wedge under the implant to ensure the sheath opens for implant release.

[0069] In lieu of what one could call "belt-and-suspenders" approaches as taught in connection with Figs. 7 and 8, the systems in Figs. 9 and 10 rely only on braid-based expander members. Delivery system 170 illustrated in Fig. 9 is, in essence, a wedgeless version of system 140 illustrated in Fig. 7. As such, release action relies on braid expansion member 142 alone. Likewise, delivery system 180 as shown in Fig. 10 is analogous to delivery system 150 illustrated in Fig. 8, except that the braid and core member termination feature 182 is not sized to provide any wedging action to aid in cover release. In these systems, avoiding the "bump" otherwise present with a wedge member may help achieve more desirable crossing profiles. However, it may require heavier braid construction than embodiments that include one or more wedge features.

[0070] The final delivery system architecture illustrated here is shown in Figs. 11A and 11B. The figures show delivery system 190 before and after implant deployment. In one sense, delivery system 190 operates like braid-expander systems 170 and 180 in that it uses changing angles of a compressed member to drive cover release. However, it is implemented with a compactable coil 192. Advantageously, the coil is isolated from moving across implant 12 by braid layer 32. In use, coil 192 is drawn down by core member 144 so its angle flattens to consequentially expand implant 10 and force cover 26 to open.

[0071] Apart from these various device architectures provided (in part) to enable the full generic scope of any of the appended claims, specific methods are still

contemplated within the invention. An important application of the subject devices is presented in Figs. 12A-12D.

[0072] In these figures, pertinent implant deployment steps are illustrated in connection with treating a cerebral aneurysm. In this case, a sidewall aneurysm 200 has formed off of an artery 202. After removal from sterile packaging (not shown), and loading the delivery system 210 in a microcathter 212 that has accessed a target site, the implant 214 is exposed as illustrated in Fig. 12A. To do so, the implant pusher (hidden in Fig. 12A) is typically held stationary, and the microcathter withdrawn. Microcathter withdrawal is continued until the entire implant 214 is exposed, attached to pusher 216 by cover 218 as shown in Fig. 12B. Then, the core member within the delivery system is withdrawn to rupture the cover as shown in Fig. 12C. After a quarter turn or straight withdrawal, the implant is free of the delivery system and implantation procedure complete as shown in Fig. 12D.

[0073] The subject methods may include each of the physician activities associated with implant positioning and release. As such, methodology implicit to the positioning and deployment of an implant device forms part of the invention. Such methodology may include navigating or tracking an implant through a catheter to a treatment site. In some methods, the various acts of implant introduction adjacent to an aneurysm considered. Other methods concern the manner in which the system is prepared for delivering an implant, for example attaching the implant to the delivery system. Any method herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events, or slight modifications of those events or the event order.

[0074] Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there is a plurality of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said," and "the" include plural referents unless specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[0075] Without the use of such exclusive terminology, the term "comprising" in the claims shall allow for the inclusion of any additional element irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth in the claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

[0076] The breadth of the present invention is not to be limited to the examples provided and/or the subject specification, but rather only by the scope of the claim language. Use of the term "invention" herein is not intended to limit the scope of the claims in any manner. Rather it should be recognized that the "invention" includes the many variations explicitly or implicitly described herein, including those variations that would be obvious to one of ordinary skill in the art upon reading the present specification. Further, it is not intended that any section of this specification (e.g., summary, detailed description, abstract, field of the invention) be accorded special significance in describing the invention relative to another or the claims. All references cited are incorporated by reference in their entirety. Although the foregoing invention has been described in detail for purposes of clarity of understanding, it is contemplated that certain modifications may be practiced within the scope of the appended claims.

CLAIMS

1. An implant delivery system comprising:

a tubular implant having proximal and distal ends;

an elongate sleeve;

an elongate core member received in the sleeve,

at least one end of the implant received between the sleeve and a cover, the cover being openable by movement of an underlying expander,

wherein the expander is movable by withdrawal of the core member.

2. The system of claim 1, wherein in the implant comprises braid.

3. The system of claim 2, wherein at least a section of the sleeve under a covered-portion of the implant comprises braid.

4. The system of claim 1, wherein the cover is adapted to open by tearing.

5. The system of claim 1, wherein the cover is adapted to open by rupturing.

6. The system of claim 1, wherein the expander comprises a wedge body.

7. The system of claim 6, wherein the wedge body comprises a plurality of bands.

8. The system of claim 1, wherein the expander comprises braid.

9. The system of claim 1, wherein the expander comprises braid and a wedge body.

10. The system of claim 1, wherein the expander comprises a coil.

11. The system of claim 1, wherein an atraumatic tip is mounted to the core member.

12. The system of claim 1, wherein the core member comprises a material selected from metal wire and polymeric filament.

13. The system of claim 1, wherein the core member comprises a metal wire, and a coil is affixed thereto under at least a proximal, covered end of the implant.

14. The system of claim 1, wherein each end of the implant is received between the sleeve and a cover.

15. The system of claim 1, wherein only one end of the implant is received between the sleeve and a cover.

16. The system of claim 15, wherein a proximal end of the implant is so-received.

17. A method of implant delivery comprising:

advancing an implant mounted on a delivery system to a target site; and

compressing an implant-bearing region of the delivery system, the compressing first expanding the implant to achieve tissue apposition; and then releasing both the proximal and distal ends of the implant.

18. The method of claim 1, wherein the implant inverts during the compressing to deploy at a user-selected length.

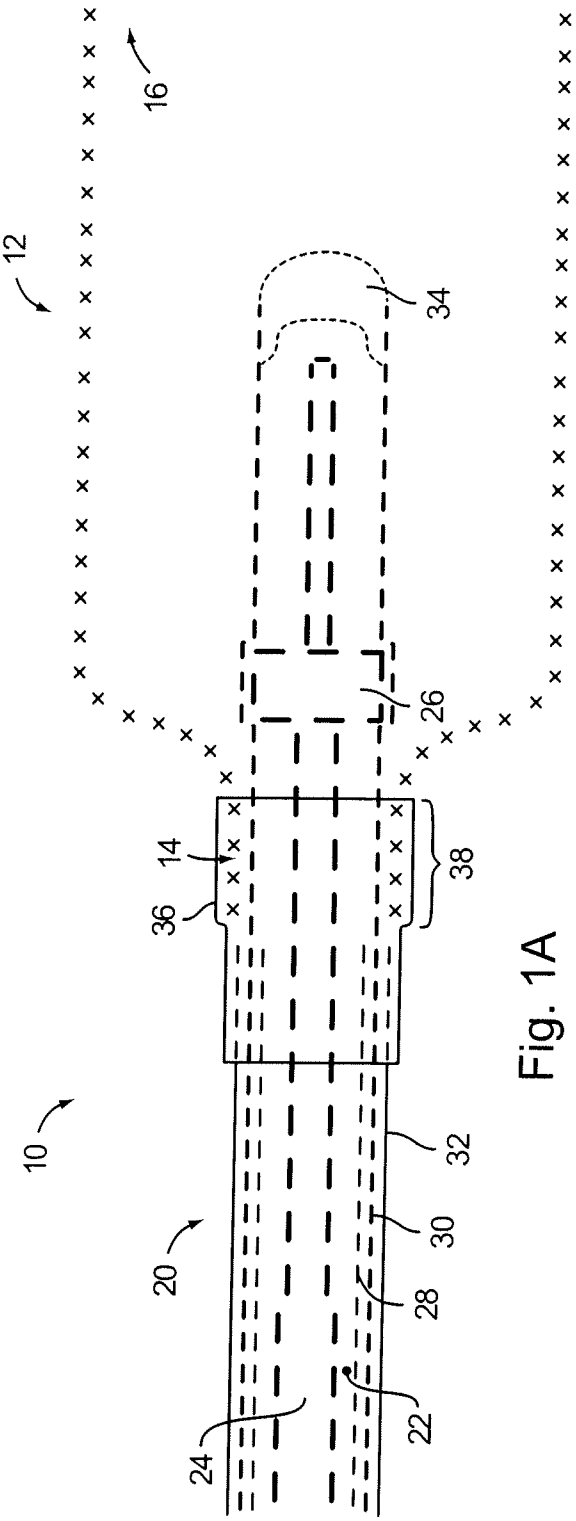

Fig. 1A

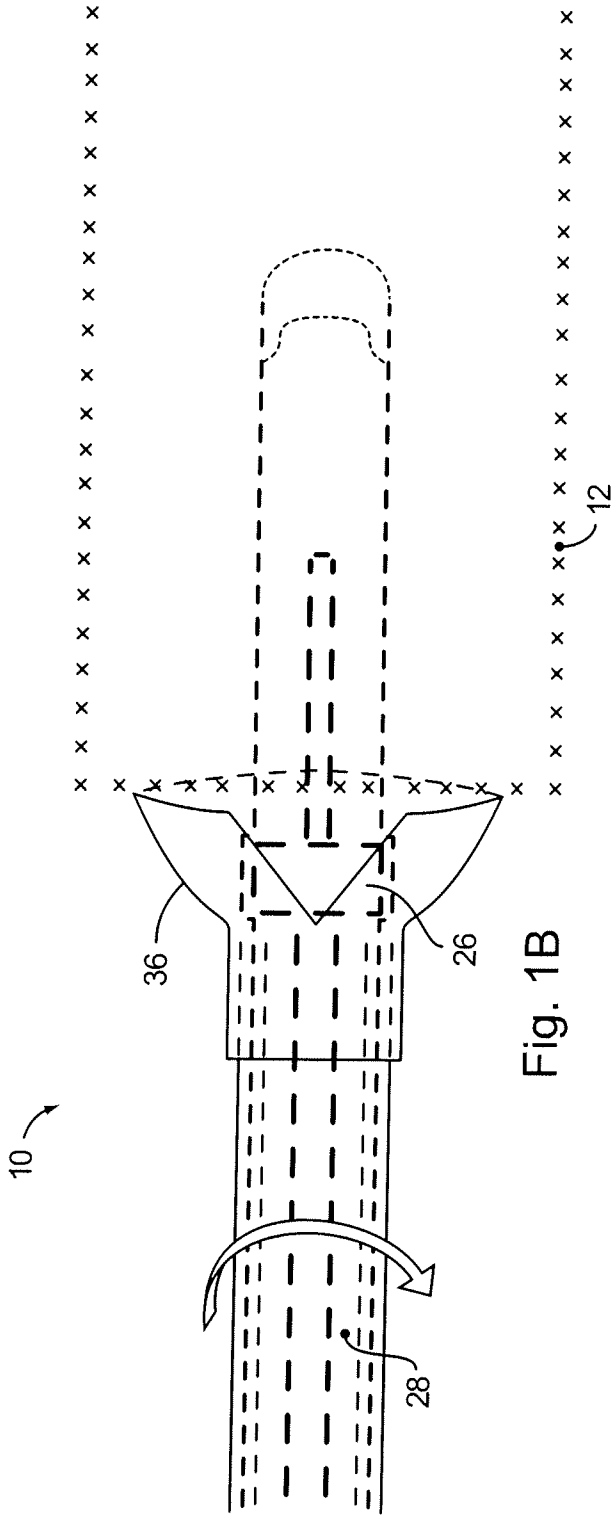

Fig. 1B

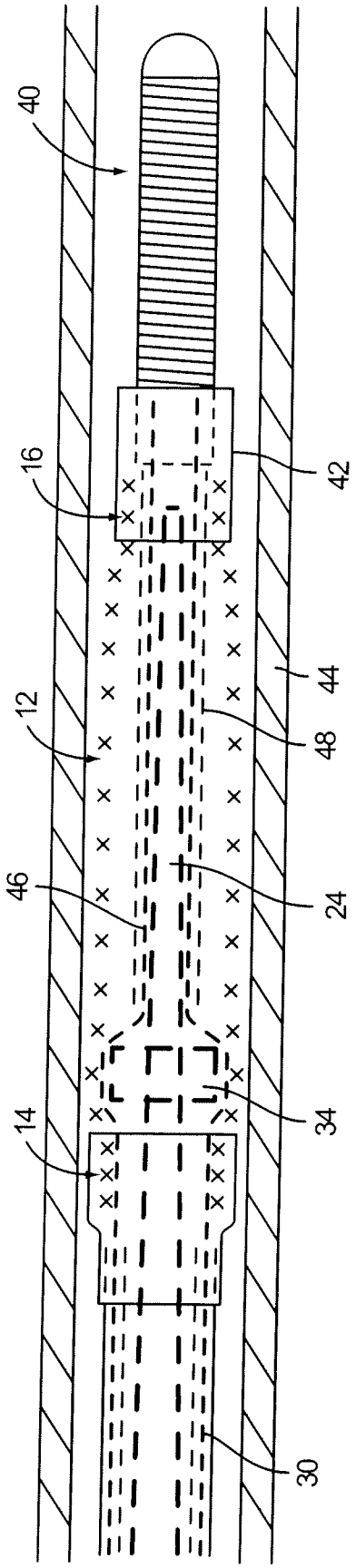

Fig. 2A

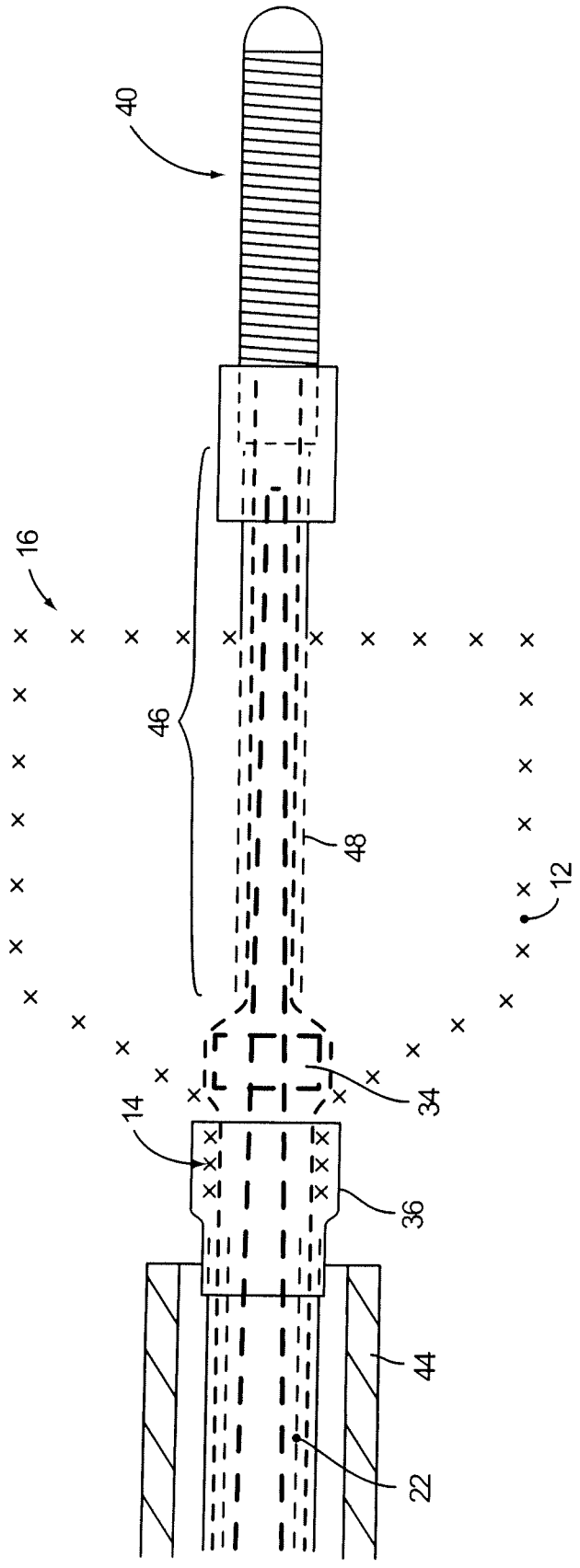

Fig. 2B

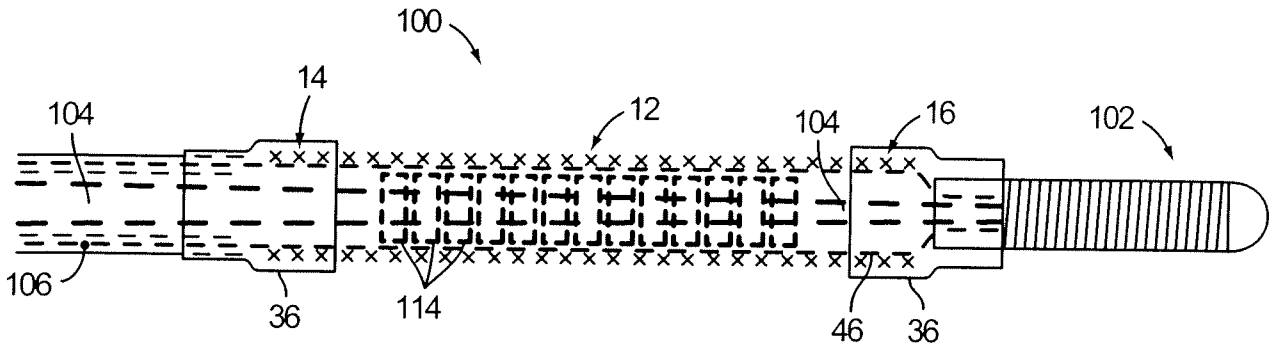

Fig. 3A

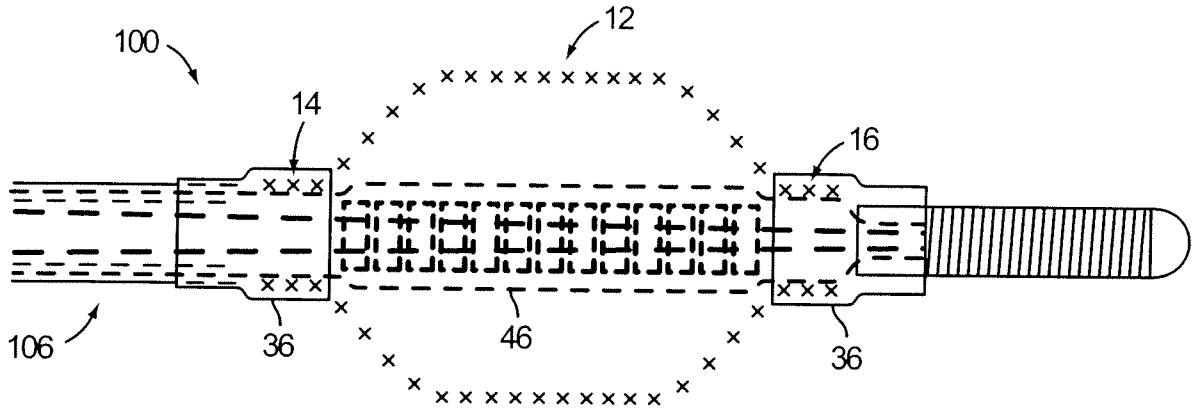

Fig. 3B

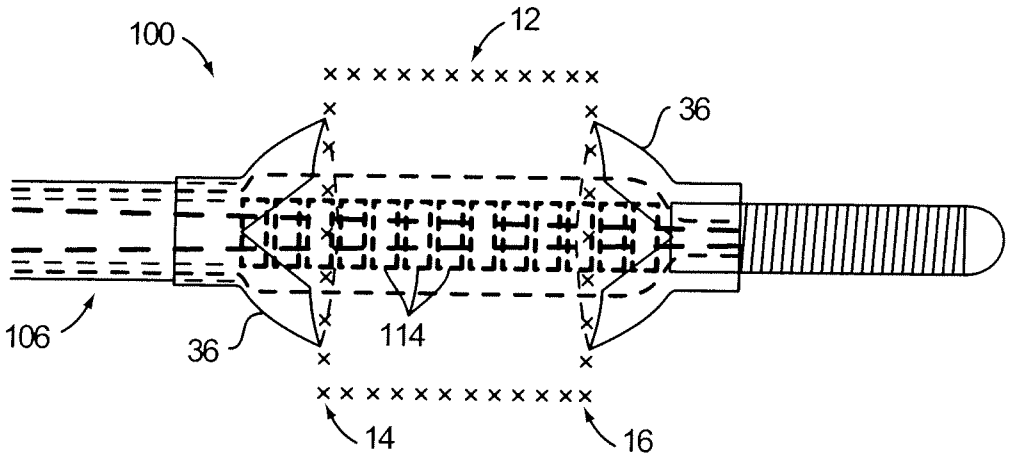

Fig. 3C

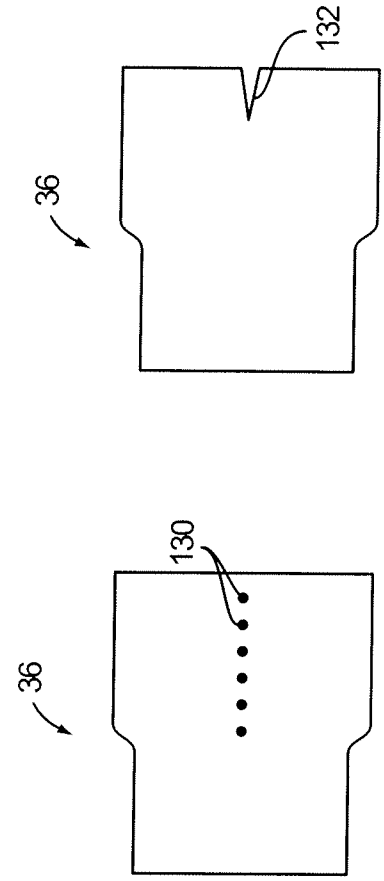

Fig. 5B

Fig. 5A

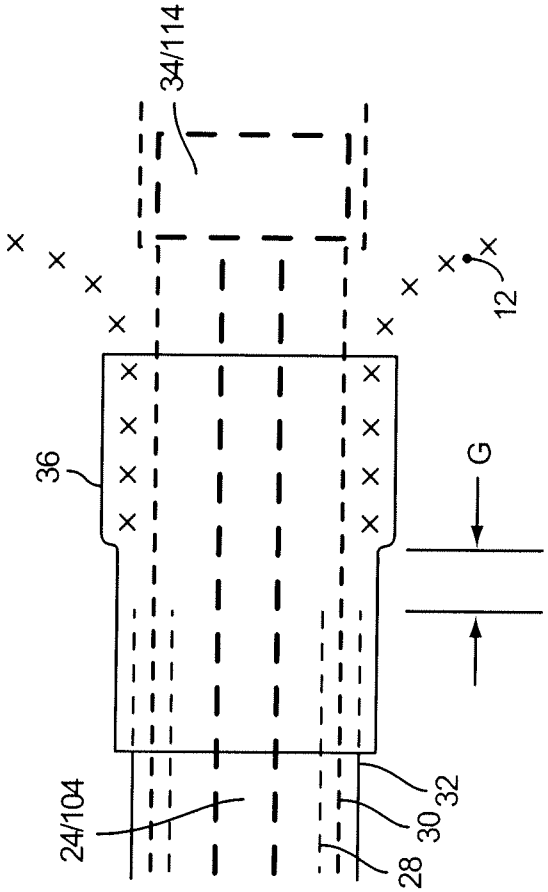

Fig. 6

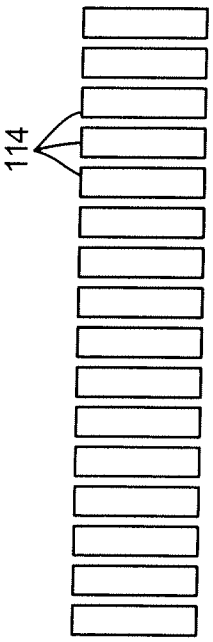

Fig. 4A

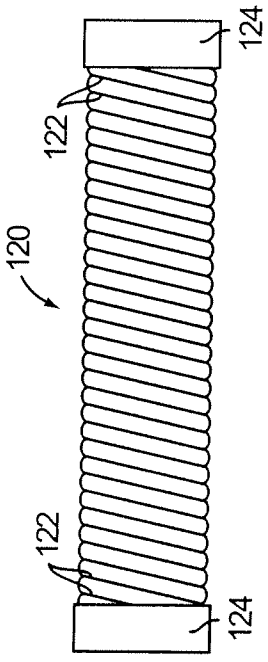

Fig. 4B

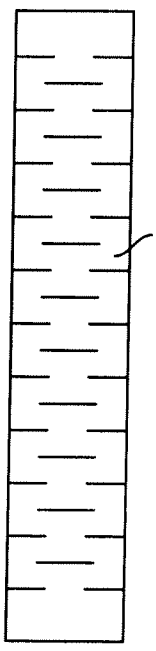

Fig. 4C

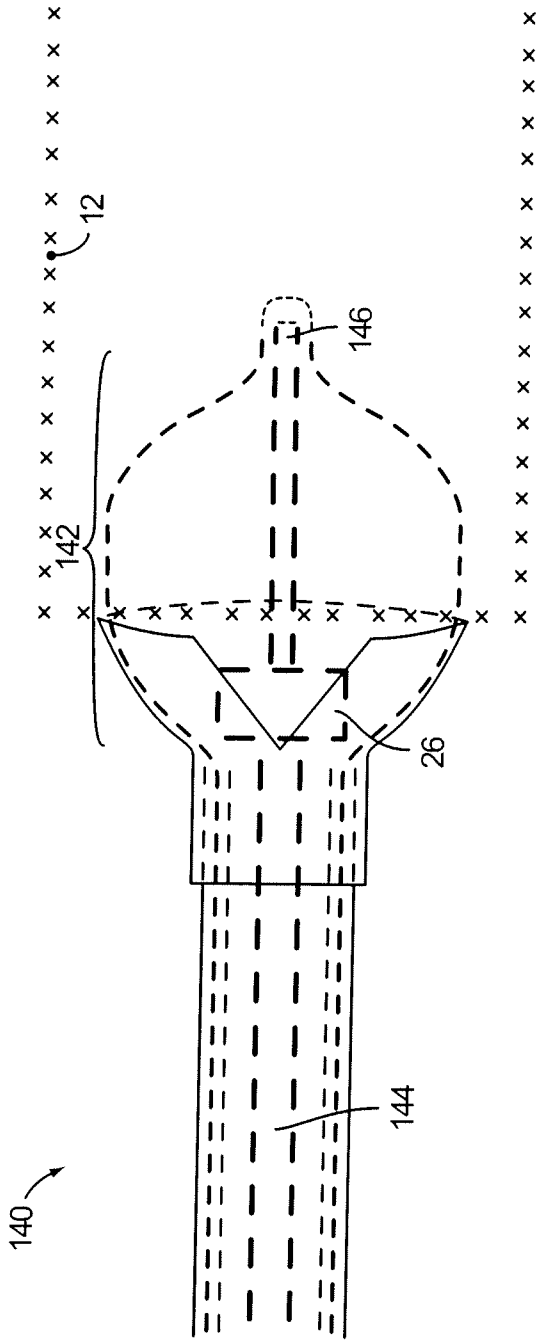

Fig. 7

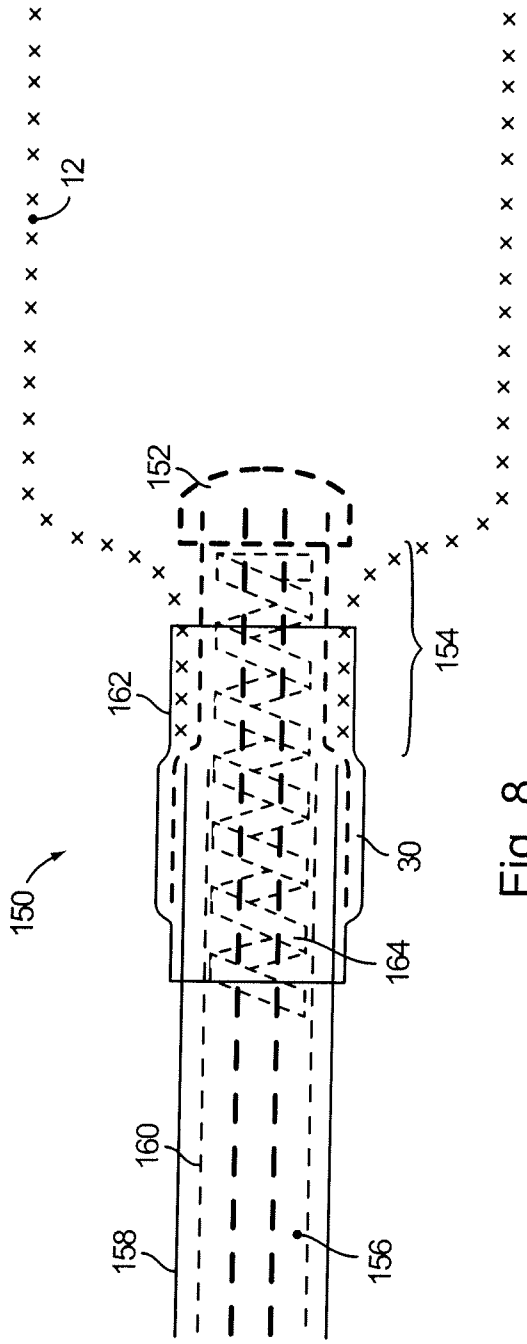

Fig. 8

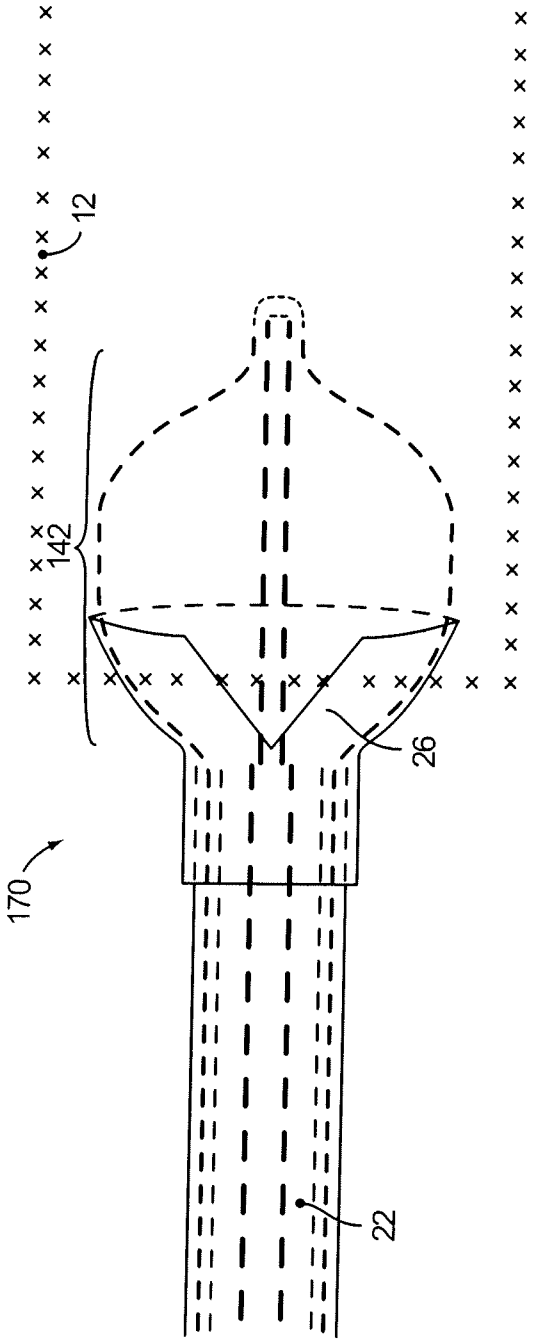

Fig. 9

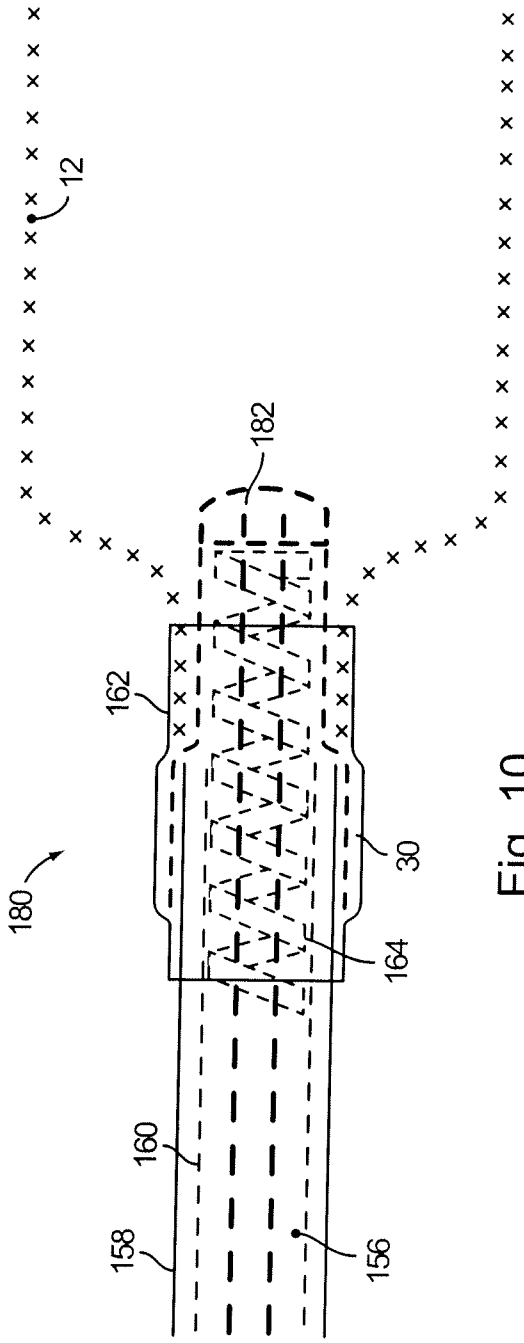

Fig. 10

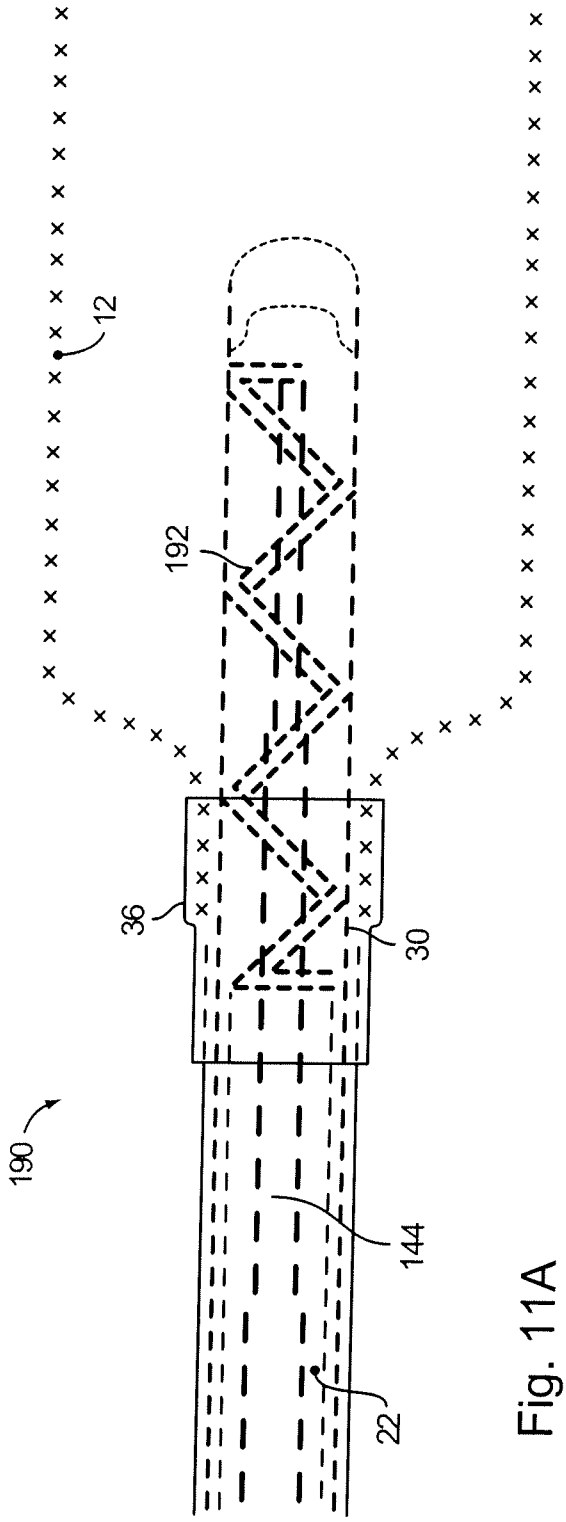

Fig. 11A

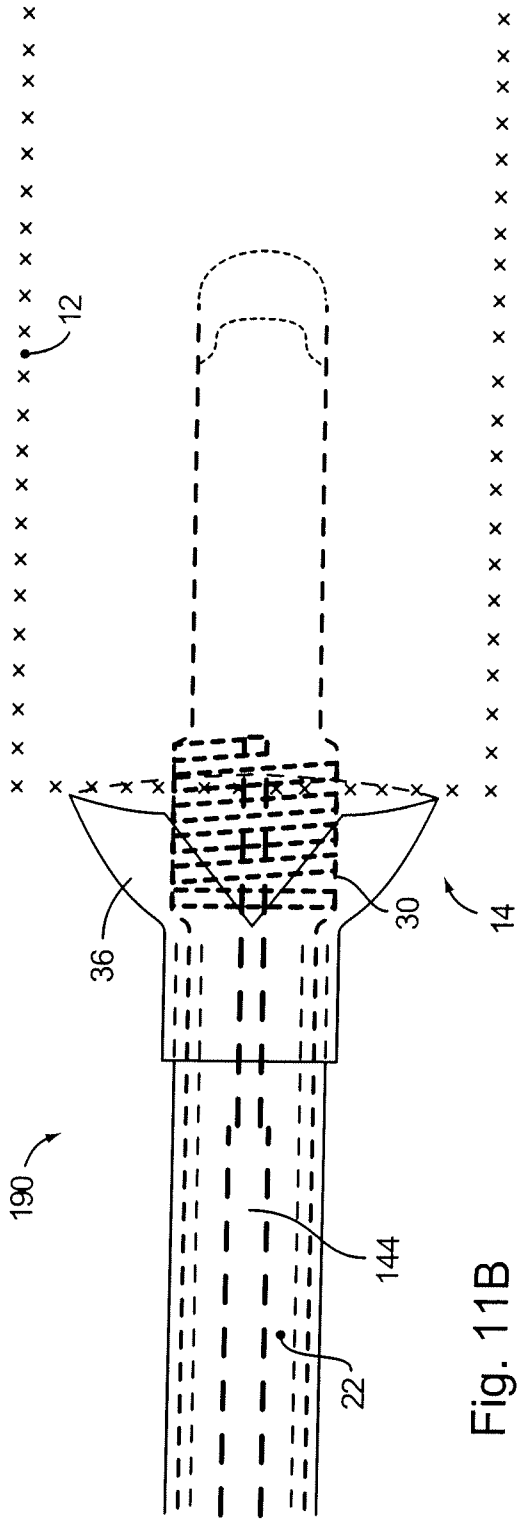

Fig. 11B

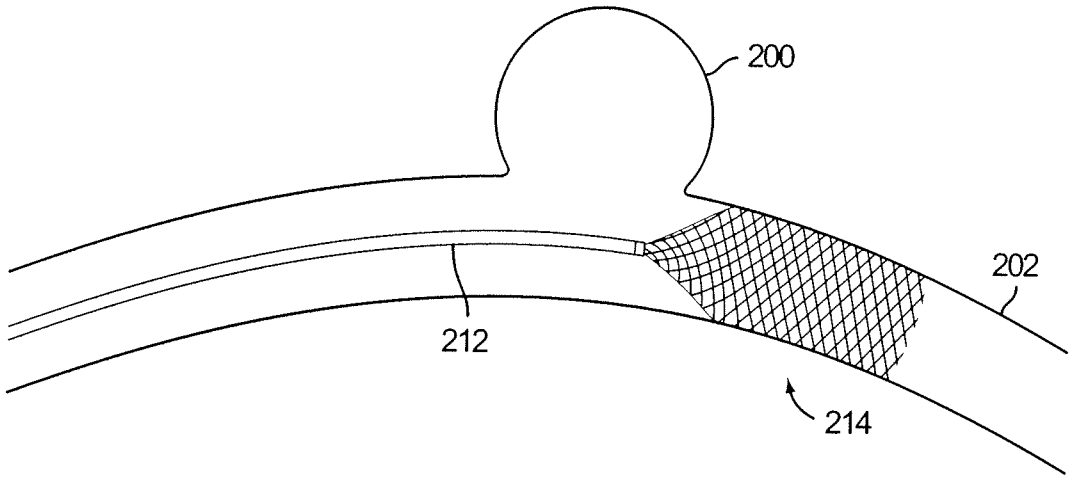

Fig. 12A

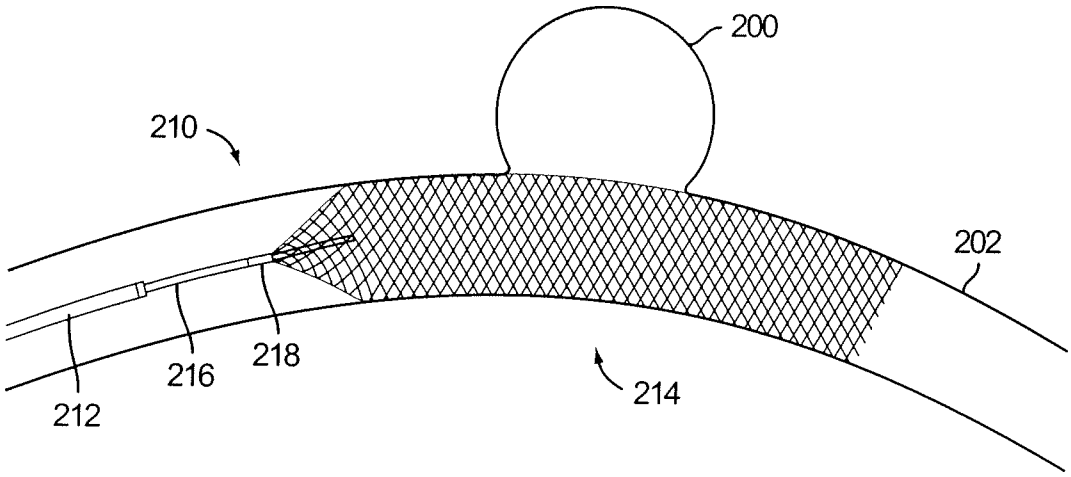

Fig. 12B

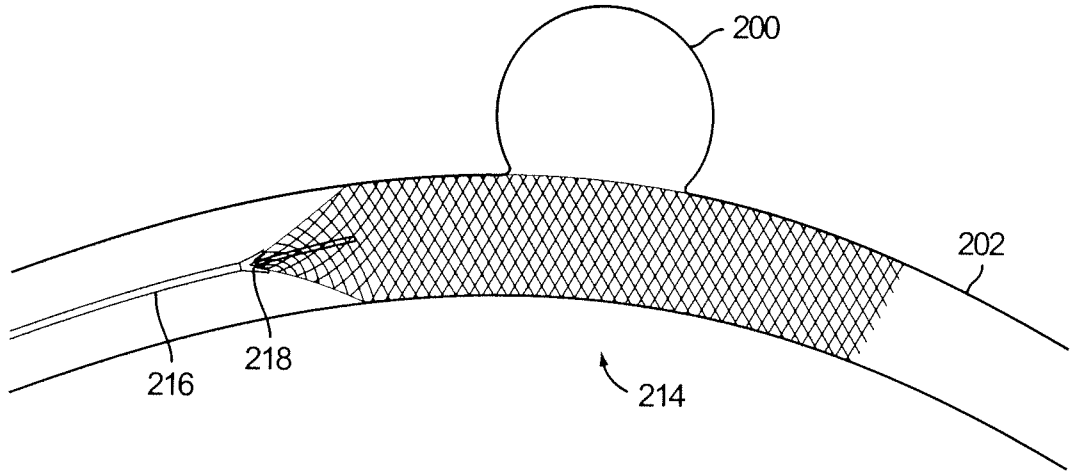

Fig. 12C

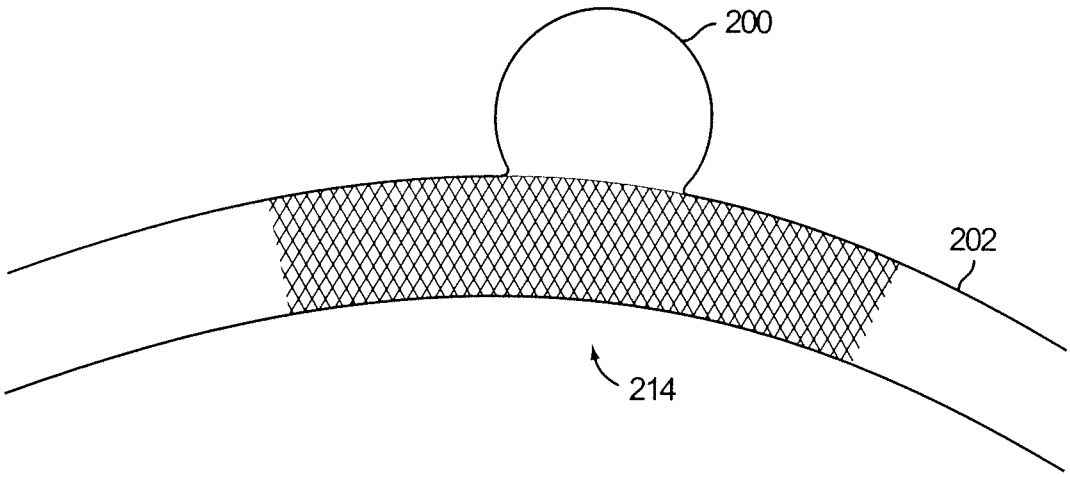

Fig. 12D

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/043858

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/84

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/087006 A (CARDIOMIND INC [US]; NIKOLCHEV JULIAN [US]; TON DAI T [US]; GEORGE WIL) 14 October 2004 (2004-10-14) paragraphs [0041], [0042] figures 3D1-3D3	1-3,6-16
X	WO 02/060345 A (GORE ENTERPRISE HOLDINGS INC [US]) 8 August 2002 (2002-08-08) page 17, line 26 - page 18, line 9 figures 16A,16B	1-6,11, 14-16
X	US 2004/015224 A1 (ARMSTRONG JOSEPH R [US] ET AL) 22 January 2004 (2004-01-22) paragraphs [0043] - [0060], [0065] figures 1-4B,5F	1-6,8-16

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 August 2009	03/09/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Chevalot, Nicolas

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/043858

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2005/018728 A (NMT MEDICAL INC [US]; WRIGHT JOHN A JR [US]; PEAVEY TODD A [US]; KOLBE) 3 March 2005 (2005-03-03) paragraph [0036] figures 5A,5B	1-3
A	WO 2004/066809 A (GORE ENTERPRISE HOLDINGS INC [US]; BRUUN STEVEN R [US]; CULLY EDWARD H) 12 August 2004 (2004-08-12) page 9, line 36 - page 10, line 3 figures 7,7A-7C	1,4,5
A	US 2007/233224 A1 (LEYNOV ALEXANDER [US] ET AL) 4 October 2007 (2007-10-04) paragraphs [0052] - [0054] figures 7,8	1,10,12, 13
A	EP 0 418 677 A (ADVANCED CARDIOVASCULAR SYSTEM [US]) 27 March 1991 (1991-03-27) column 4, line 18 - column 5, line 21 figures 1-3	1,8-12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/043858

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17,18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/043858

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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