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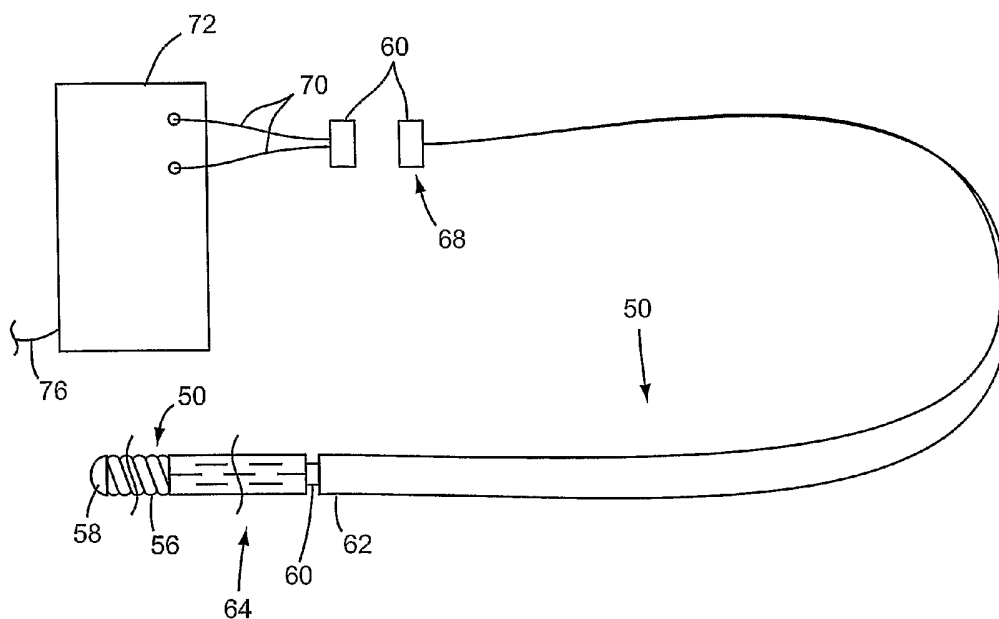
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(54) Title: ELECTROLYTIC STENT DELIVERY SYSTEMS



(57) Abstract: Medical device and methods for delivery or implantation of prostheses within hollow body organs and vessels or other luminal anatomy are disclosed. The subject technologies may be used in the treatment of arteriosclerosis in stenting procedures. For such purposes, a self-expanding stent (10/52) may be deployed in connection with an angioplasty procedure with a bipolar electrolytic joint stent hold-down and detachment system. The electrolytic joint (102/104/106/108/110/120/126/132/134/136) may be solder alone or it may be provided in connection with at least one supplemental restraint.



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ELECTROLYTIC STENT DELIVERY SYSTEMS

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical device and methods. More particularly, it relates to delivery systems for implanting prostheses within hollow body organs and vessels or other luminal anatomy.

BACKGROUND OF THE INVENTION

[0002] Implants such as stents and occlusive coils have been used in patients for a wide variety of reasons. One of the most common "stenting" procedures is carried out in connection with the treatment of atherosclerosis, a disease which result in a narrowing and stenosis of body lumens, such as the coronary arteries. At the site of the narrowing (i.e., the site of a lesion) a balloon is typically dilatated in an angioplasty procedure to open the vessel. A stent is set in apposition to the interior surface of the lumen in order to help maintain an open passageway. This result may be effected by means of scaffolding support alone or by virtue of the presence of one or more drugs carried by the stent aiding in the prevention of restenosis.

[0003] Various stent designs have been developed and used clinically, but self-expandable and balloon-expandable stent systems and their related deployment techniques are now predominant. Examples of self-expandable stents currently in use are the Magic WALLSTENT® stents and Radius stents (Boston Scientific). A commonly used balloon-expandable stent is the Cypher® stent (Cordis Corporation). Additional self-expanding stent background is presented in: "An Overview of Superelastic Stent Design," Min. Invas Ther & Allied Technol 2002: 9(3/4) 235-246, "A Survey of Stent Designs," Min. Invas Ther & Allied Technol 2002: 11(4) 137-147, and "Coronary Artery Stents: Design and Biologic Considerations," Cardiology Special Edition, 2003: 9(2) 9-14, "Clinical and Angiographic Efficacy of a Self-Expanding Stent" Am Heart J 2003: 145(5) 868-874.

[0004] Because self-expanding prosthetic devices need not be set over a balloon (as with balloon-expandable designs), self-expanding stent delivery systems can be designed to a relatively smaller outer diameter than their balloon-expandable counterparts. As such, self-expanding stents may be better suited to reach the smallest vasculature or achieve access in more difficult cases.

[0005] To realize such benefits, however, there continues to be a need in developing improved delivery systems. Problems encountered with known systems include drawbacks ranging from failure to provide means to enable precise placement of the subject prosthetic, to a lack of

space efficiency in delivery system design. Poor placement hampers stent efficacy. Space inefficiency in system design prohibits scaling the systems to sizes as small as necessary to enable difficult access or small-vessel procedures (i.e., in tortuous vasculature or vessels having a diameter less than 3 mm, even less than 2mm).

[0006] U.S. Patent No. 5,873,907 offers a system with a self-expanding stent in which the problem of precise placement is addressed. The system employs the use of circumferential bands, each having an electrolytically erodable joint, where the bands hold a stent in a collapsed configuration until the joints are released. In the case of the monopolar system it describes, it is electrically inefficient. In the case of the bipolar system it describes, it is also space inefficient. Even though the patent purports to offer space-efficiency in avoiding the need for a sheath, improvement is needed in order to provide a system able to reach the smallest vessels.

[0007] U.S. Patent No. 5,980,514 discloses a system in which a self-expanding stent is held onto a wire by electrolytically erodable joints. The system is potentially very compact (as evidenced from the fact that the system is shown involved in the act of treating a cerebral aneurism). However, the system is monopolar in design. Furthermore, the system employs a coil stent - thus presenting placement difficulties due to the degree to which the length of the stent shrinks upon radial expansion from its tightly wound state to a deployed state (a characteristic generically referred to as foreshortening). Thus, improvement is required (even in a space-efficient system) in terms of electrical efficiency and accurate stent placement.

[0008] Accordingly, there exists a need for the present invention in that it may offer improvement in one or more of the noted areas. Those with skill in the art may also appreciate further advantages or benefits of the invention.

SUMMARY OF THE INVENTION

[0009] An implant delivery system is provided in which a stent is attached to a delivery guide member by at least one electrolytic joint. The joint may comprise solder or it may be provided in connection with at least one supplemental restraint. Such restraining members may be one or more circumferential bands with a joint section, or a combined passive mechanical restraint and electrolytic joint system. However they are configured, the electrolytic joints are electrically connected to a power source via at least one inner conductive portion of a guide member over which the stent is secured. This core electrode is overridden by an outer electrode. In a bipolar system, the outer electrode serves as return electrode to the power source. Whether used in this manner or not, the outer electrode is preferably provided by a

tubular body riding over and insulated from contact with the inner, core member and any of the stent-constraining joints.

[0010] This arrangement is highly space efficient in that the core member both serves as an electrode and the support member for the stent at its distal end, while the body of the core member preferably contributes to the structural requirements of the overall delivery system. Likewise, the outer member serves as an electrode and preferably also contributes to the structural requirements of the delivery system proximal of the stent. Together, these members provide a highly space and electrically efficient delivery system, in which both members serve as electrodes (or at least a portion of each one does) and one or the other or both provide for the structural requirements of the delivery system that enable navigation to a delivery site.

[0011] Certainly, the sizing (including the relative sizing) of the electrode elements may be varied. It may be the case that nearly all of the structural requirements of the system are met by one or the other of the core member or tubular outer member along a given length of the delivery guide. In any case, no additional wires for actuation of the joints will be required. Therefore, (accounting for various insulation and gaps/spacing requirements) it may be the case that the body of the guide member consists of no other structure, or that the core member and outer member (however constructed) define the only portions of the body of the inventive delivery guide.

[0012] As for the operation of the subject system, when a distal end of the system including a stent and an end of the return electrode is submersed in an electrolytic solution and a voltage is applied, ions of the joint material transport a charge between the system electrodes from anode to cathode. Because the stent may be small and any erosion thereof detrimental to its performance, it may be preferred that the joint material (in the form of solder joint or secondary means including a joint – such as a restraining band), is selected to have a higher Mendelev number than at least the stent, to ensure that it erodes first.

[0013] Generally, it will be desired to apply a voltage of between about 1.5V and about 12V DC to the system. More preferably, the voltage will be between about 3V to about 9V. In either such case, the positive pole of a power supply is connected to the core electrode, and the negative to the outer electrode. A resulting current flow of about 0.01 ma to about 0.1 ma, or more preferably about 1 ma to about 5 ma, or up to 10 ma will be achieved for the purpose of eroding the joint(s) provided.

[0014] Upon erosion of at least a portion of the restraint (at least enough erosion to weaken the restraint structure to a point so that it breaks), the stent is released from its restrained/collapsed shape and able to assume an expanded shape. Such action is facilitated by constructing the

stent from an elastic or superelastic material. Still, the stent might be made of a heat-activated shape memory alloy. In any case, the stent is a self-expanding stent.

[0015] Regardless of the particular mode of operation of the self-expanding stent, the nature of the subject bipolar electrode system is such that ions from the joint that migrate through solution (blood in a patient's body) upon the application of voltage are deposited on the return electrode, rather than carried off in the blood stream as in a monopolar system. As such, the electrochemical operation of the present invention may offer some relative health benefits to a monopolar system where ions are simply released into a patient's blood stream.

[0016] In addition, the system offers a highly precise manner of implant/stent placement. The system operates without the requirement for a mechanical input which can disturb placement or impart a motive force to the stent during the process of release. Still further, the subject system offers variations in which the implant can be released in a staged or sequential fashion to achieve highly precise control. Such sequential release may be accomplished by means of providing more or less material at a joint location and/or providing additional electrodes such that each of a number of joints provided can be individually actuated (eroded).

[0017] Delivery guides and delivery systems (i.e., a delivery guide member plus one or more stents secured thereto) according to the present invention are amenable to scaling to sizes not previously achieved. Consequently, the systems may be used in lieu of a guidewire, as in a "guidewireless" delivery approach. Alternatively, the delivery guide may be used in a manner similar to a guidewire, as in a "through the lumen" type approach, referenced below. Still further, rather than providing an "over-the-wire" delivery system as is common, the present systems may be regarded as "on-the-wire" delivery systems, since – in effect – delivery is accomplished by a system in which the stent is carried by a delivery guide occupying a catheter lumen that would commonly otherwise be used to accommodate a guidewire.

[0018] Whether used in such a manner or otherwise (such as by configuring the subject systems for treating larger peripheral vessels), the present invention includes systems comprising any combination of the features described herein. Methodology described in association with the devices disclosed also forms part of the invention. Such methodology may include that associated with completing an angioplasty, bridging an aneurysm, deploying radially-expandable anchors for pacing leads or an embolic filter, or placement of a prosthesis within neurovasculature, an organ selected from the kidney and liver, within reproductive anatomy such as selected vasdeferens and fallopian tubes or other applications.

DEFINITIONS

- [0019] The term “stent” as used herein refers to any coronary artery stent, other vascular prosthesis, or other radially expanding or expandable prosthesis or scaffold-type implant suitable for the noted treatments or otherwise. Exemplary structures include wire mesh or lattice patterns and coils, though others may be employed in the present invention.
- [0020] A “self expanding” stent is a scaffold-type structure (serving any of a number of purposes) that expands by its own action from a reduced-diameter configuration to an increased-diameter configuration. The “diameter” need not be circular – it may be of any open configuration. Self-expanding materials may be so by virtue of simple elastic behavior, superelastic behavior, a shape memory effect (i.e., heat-activated transformation from martensite to austenite) or some other manner. Since the stents will remain in the subject’s body, the material should be biocompatible or at least be amenable to biocompatible coating. As such, suitable self expanding stent materials for use in the subject invention include Nickel-Titanium (i.e., NiTi) alloy (e.g., NITINOL) and various other alloys or polymers.
- [0021] A “wire” as used herein generally comprises a common metallic member. However, the wire may be coated or covered by a polymeric material (e.g., with a lubricious material such as TEFLON®) or otherwise. Still further, the “wire” may be a hybrid structure with metal and a polymeric material (e.g. Vectra™, Spectra™, Nylon, etc.) or composite material (e.g., carbon fiber in a polymer matrix). The wire may be a filament, bundle of filaments, cable, ribbon or in some other form. It is generally not hollow.
- [0022] A “core” wire as referred to herein is a member internal to an outer member, such as a tubular member. As a core wire, the member, fills or at least substantially fills all of the interior space of the tubular member.
- [0023] A “hypotube” or “hypotubing” as referred to herein means small diameter tubing in the size range discussed below, generally with a thin wall. The hypotube may specifically be hypodermic needle tubing. Alternatively, it may be wound or braided cable tubing, such as provided by Asahi Intec Co., Ltd or otherwise. As with the “wire” discussed above, the material defining the hypotube may be metallic, polymeric or a hybrid of metallic and polymeric or composite material.
- [0024] A “sleeve” as referred to herein may be made of such hypotubing or otherwise. The sleeve may be a tubular member, or it may have longitudinal opening(s). It is an outer member, able to slidably receive and hold an inner member.
- [0025] An “atraumatic tip” may comprise a plurality of spring coils attached to a tapered wire section. At a distal end the coils typically terminate with a bulb or ball that is often made of

solder. In such a construction, the coils and/or solder is often platinum alloy or another radiopaque material. The coils may also be platinum, or be of another material. In the present invention, the wire section to which the coils are attached may be tapered, but need not be tapered. In addition, alternate structures are possible. For instance, molding or dip-coating with a polymer may be employed. In one example, the atraumatic tip may comprise a molded tantalum-loaded 35 durometer Pebax™ tip. However constructed, the atraumatic tip may be straight or curved, the latter configuration possibly assisting in directing or steering the delivery guide to a desired intravascular location.

[0026] To “connect” or to have or make a “connection” between parts refers to fusing, bonding, welding (by resistance, chemically, ultrasonically, etc), gluing, pinning, crimping, clamping or otherwise mechanically or physically joining, attaching or holding components together (permanently or temporarily).

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Each of the figures diagrammatically illustrates aspects of the invention. Of these: Figure 1 shows a heart in which its vessels may be the subject of one or more angioplasty and stenting procedures; Figure 2 shows an expanded stent cut pattern as may be used in producing a stent for delivery by the subject guide member; Figures 3A-3L illustrate stent deployment methodology to be carried out with the subject delivery member; Figure 4 shows the inventive system including the subject guide member and an electrical box; Figure 5 shows such computer hardware, software and peripheral packaging as may be employed in connection with the present invention; Figure 6 is a side detail view of a distal portion of the delivery member shown in Fig. 4; Figure 7 is an enlarged sectional view taken along line A-A in Fig. 6; Figure 8 shows a stent constrained in a collapsed profile by solder set within its cell geometry; Figures 9A-9E show approaches to stent restraint using external solder, and Figures 10A-10E show optional solder cross-sectional configurations for the solder approaches of figures 9A-9C as indicated by alphabetical characters; Figure 11 shows a stent restraint approach combining a solder joint and end caps;

Figure 12 shows a circumferential stent restraint with a solder joint; and
Figure 13 shows an approach with a plurality of circumferential stent restraint
bands, each having a reduced-section joint.

Variation of the invention from the embodiments pictured is, of course, contemplated.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Before the present invention is described in detail, it is to be understood that this invention is not limited to particular variations set forth and may, of course, vary. 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.

[0029] Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as the recited order of events. Furthermore, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. 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.

[0030] All existing subject matter mentioned herein (*e.g.*, publications, patents, patent applications and hardware) is incorporated by reference herein in its entirety except insofar as the subject matter may conflict with that of the present invention (in which case what is present herein shall prevail). The referenced items are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such material by virtue of prior invention.

[0031] Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said" and "the" include plural referents unless the context clearly dictates otherwise. 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. Unless defined otherwise herein, all technical and

scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

[0032] Turning now to Fig. 1, it shows a heart 2 in which its vessels may be the subject of one or more angioplasty and stenting procedures. To date, however, significant difficulty or impossibility is confronted in reaching smaller coronary arteries 4. If a stent and a delivery system could be provided for accessing such small vessels and other difficult anatomy, an additional 20 to 25% coronary percutaneous procedures could be performed with such a system. Such a potential offers opportunity for huge gains in human healthcare and a concomitant market opportunity in the realm of roughly \$1 billion U.S. dollars – with the further benefit of avoiding loss of income and productivity of those treated.

[0033] Features of the present invention are uniquely suited for a system able to reach small vessels (though use of the subject systems is not limited to such a setting.) By “small” coronary vessels, it is meant vessels having an inside diameter between about 1.5 or 2 and about 3 mm in diameter. These vessels include, but are not limited to, the Posterior Descending Artery (PDA), Obtuse Marginal (OM) and small diagonals. Conditions such as diffuse stenosis and diabetes produce conditions that represent other access and delivery challenges which can be addressed with a delivery system according to the present invention. Other extended treatment areas addressable with the subject systems include vessel bifurcations, chronic total occlusions (CTOs), and prevention procedures (such as in stenting vulnerable plaque).

[0034] Assuming a means of delivering one or more appropriately-sized stents, it may be preferred to use a drug eluting stent in such an application to aid in preventing restenosis. However, bare-metal stents may be employed in the present invention – and even may be preferred or required in connection with certain embodiments as will be apparent to those with skill in the art. The present invention is advantageously employed with self-expanding stents. However, the teachings herein may be adapted for application in the context of balloon-expandable stents.

[0035] In any case, features of the present invention are provided in order to hold an implant (e.g., a stent) to be delivered in an access or deployment configuration, after which, the implant assumes its deployed or expanded configuration. Hold-down features may restrain a stent under compressive forces, whereupon release, the stent “springs” open. Alternatively, the stent (or other implant) may simply be secured to the delivery member, whereupon release, some other mechanism opens the stent (e.g., ceasing a flow of chilled saline, thereby allowing a shape memory device to warm in order that a material phase change from martensite to austenite will cause the stent to open).

[0036] While some might argue that the particular role and optimal usage of self expanding stents has yet to be defined, they offer an inherent advantage over balloon expandable stents. The latter type of devices produce “skid mark” trauma (at least when delivered uncovered upon a balloon) and end dissections during deployment (barotraumas – caused at least in part by high balloon pressures a lack of balloon conformance as is required for deforming a balloon-expandable stent).

[0037] Yet, with an appropriate deployment system, self-expanding stents may offer one or more of the following advantages over balloon-expandable models: 1) greater accessibility to distal, tortuous and small vessel anatomy – by virtue of decreasing crossing diameter and increasing compliance relative to a system requiring a deployment balloon, 2) sequentially controlled or “gentle” device deployment, 3) use with low balloon pre-dilatation (if desirable) to reduce barotraumas, 4) strut thickness reduction in some cases reducing the amount of “foreign body” material in a vessel or other body conduit, 5) opportunity to treat neurovasculature – due to smaller crossing diameters and/or gentle delivery options, 6) the ability to easily scale-up a successful treatment system to treat larger vessels or vice versa, 7) a decrease in system complexity, offering potential advantages both in terms of reliability and system cost, 8) reducing intimal hyperplasia, and 9) conforming to tapering anatomy – without imparting complimentary geometry to the stent (though this option exists as well).

[0038] At least some of these noted advantages may be realized using a stent 10 as shown in Fig. 2 in connection with the subject deployment system described in further detail below. Naturally, other stent configurations might be used instead. However, the one pictured is well suited for use in small vessels. It may be collapsed to an outer diameter of about 0.018 inch (0.46 mm), or even smaller to about 0.014 inch (0.36 mm) -including the restraint/joint used - and expand to a size (fully unrestrained) between about 1.5 mm (0.059 inch) or 2 mm (0.079 inch) or 3 mm (0.12 inch) and about 3.5 mm (0.14 inch). In use, the stent will be sized so that it is not fully expanded within a vessel in order that it will provide a measure of radial force thereto. The force will secure the stent and offer potential benefits in reducing hyperplasia and vessel collapse or even pinning dissected tissue in apposition.

[0039] The stent employed in connection with the subject delivery system preferably comprises NiTi that is superelastic at room temperature and above. Also, it is preferably electropolished. Depending on the nature of the restraint selected drug coating the stent may be desired. Either way, coating may be provided internal to the stent to reduce in-stent restenosis. The drug can be directly applied to the stent surface(s), or introduced into an

appropriate matrix. Of course, restraints in the form of solder set over the stent may preclude drug coating of affected areas.

[0040] In a 0.014 inch delivery system (one in which the maximum nominal outer diameter of the stent/coating and guide member/restraint have a diameter that does not exceed 0.014 inch), the thickness of the NiTi is about 0.0025 inch (0.64 mm) for a stent adapted to expand to 3.5 mm. Such a stent is designed for use in a 3 mm vessel or other body conduit, thereby providing the desired radial force in the manner noted above. Further information regarding radial force parameters in coronary stents may be noted in the article, "Radial Force of Coronary Stents: A Comparative Analysis," *Catheterization and Cardiovascular Interventions* 46: 380-391 (1999), incorporated by reference herein in its entirety.

[0041] As for the stent that may be employed, an optional expanded stent cut pattern 10 is shown in Fig. 2. In one manner of production, the stent is laser (or Electrical Discharge Machining, i.e., EDM) cut from round NiTi tubing, with the flattened-out pattern shown wrapping around the tube as indicated by dashed lines. In such a procedure, the stent is preferably cut in its fully-expanded shape. By initially producing the stent to full size, the approach allows cutting finer details in comparison to simply cutting a smaller tube with slits and then heat-expanding/annealing it into its final (working) diameter. Avoiding post-cutting heat forming also reduces production cost.

[0042] Regarding the finer details of the subject stent, necked down bridge or junction sections 12 are provided between adjacent struts 14, wherein the struts define a lattice of closed cells 16. The ends 18 of the cells are preferably rounded-off so as to be atraumatic. To increase stent conformability to tortuous anatomy, the bridge sections can be strategically separated or opened as indicated by broken line. To facilitate such tuning of the stent, the bridge sections are sufficiently long so that fully rounded ends 18 may be formed internally to the lattice just as shown on the outside of the stent if the connection(s) is/are severed to separate adjacent cells 16.

[0043] The advantage of the double-concave profile of each strut bridge or junction section 12 is that it reduces material width (relative to what would otherwise be presented by a parallel side profile) to improve trackability and conformability of the stent within the subject anatomy while still maintaining the option for separating/breaking the cells apart.

[0044] Further optional features of stent 10 are employed in the cell end regions 18 of the design. Specifically, strut ends 20 increase in width relative to medial strut portions 22. Such a configuration results in a majority of bending (during collapse of the stent) occurring along the length of the struts rather than at the corners of the cells. Longer struts to allow for lower

stresses within the stent (and, hence, possibility for higher compression ratios). Shorter struts allow for greater radial force (and concomitant resistance to a radially applied load) upon deployment.

[0045] In order to provide a stent that collapses as much as possible (to a solid or near-solid structure, such as shown in the fully-loaded systems of the figures) accommodation is made for the stiffer strut ends 20 provided in the design shown in Fig. 2. Namely, the gap 24 between the strut ends 22 is set at a smaller angle as if the stent were already partially collapsed in that area. Thus, the smaller amount of angular deflection that occurs at ends 20 will bring the sections parallel (or nearly so) when the strut medial portions 22 are so-arranged. Radiused sections 26 provide a transition from a medial strut angle α (ranging from about 85 degrees to about 60 degrees) to an end strut angle β (ranging from about 30 to about 0 degrees). In addition, it is noted that gap 24 and angle β may actually be configured to completely close prior to fully collapsing angle α . The value of doing so would be to limit the strains (and hence, stresses) at the strut ends 22 and cell end regions 18 by providing a physical stop to prevent further strain.

[0046] By utilizing a design that minimizes strain, very high compression ratios of the stent may be achieved. Compression ratios (from a fully expanded outside diameter to compressed outside diameter – expressed in those terms used by physicians) of as much as 3.5 mm : 0.014 inch (about 10X) are possible – with or without a drug coating and/or restraint used. Compression ratios of 3.0 mm : 0.014 inch (about 8.5X), 3.5 mm : 0.018 inch (about 7.5X), 3.0 mm : 0.018 inch (about 6.5X), 2.5 mm : 0.014 inch (about 7X), 2.5 mm : 0.018 inch (about 5.5X), 2.0 mm : 0.014 inch (about 5.5X), 2.0 mm : 0.018 inch (about 4.5X) offer utility not heretofore possible with existing systems as well.

[0047] These selected sizings (and expansion ratios) correspond to treating 1.5 to 3.0 mm vessels by way of delivery systems adapted to pass through existing balloon catheter and microcatheter guidewire lumen. In other words, the 0.014 inch and 0.018 inch systems are designed to corresponding common guidewire sizes. The system may also be scaled to other common guidewire sizes (e.g., 0.22 inch / 0.56 mm or 0.025 inch / 0.64 mm) while offering advantages over known systems.

[0048] While designing the delivery systems to have a crossing profile corresponding to common guidewire sizes, especially for full-custom systems, intermediate sizes may be employed. Still further, it is contemplated that the system sizing may be set to correspond to French (FR) sizing. In that case, system sizes contemplated range at least from 1 to 1.5 FR,

whereas the smallest know balloon-expandable stent delivery systems are in the size range of about 3 to about 4 FR.

[0049] At least when produced at the smallest sizes (whether in a even/standard guidewire or FR size, or otherwise), the system enables a substantially new mode of stent deployment in which delivery is achieved through an angioplasty balloon catheter or small microcatheter lumen. Further discussion and details of “through the lumen” delivery is presented in the above-referenced “Balloon Catheter Lumen Based Stent Delivery Systems” patent application.

[0050] In “small vessel” cases or applications (where the vessel to be treated has a diameter up to about 3.0 mm), it may also be advantageous to employ a stent delivery system sized at between about 0.022 to about 0.025 inch in diameter. Such a system can be used with catheters compatible with 0.022 inch diameter guidewires.

[0051] While such a system may not be suitable for reaching the very smallest vessels, in reaching the larger of the small vessels (i.e., those having a diameter of about 2.5 mm or larger), even this variation of the invention is quite advantageous in comparison to known systems. By way of comparison, the smallest known over-the-guidewire delivery system (the “Pixel” system – produced by Guidant) that is adapted to treat vessels between 2 and 2.5 mm has a crossing profile of 0.036 inch (0.91 mm). A system described in U.S. Patent Publication No. 2002/0147491 for treating small vessels is purported to be capable of being made as small as 0.026 inch (0.66 mm) in diameter.

[0052] With respect to the Pixel and ‘491 systems, however, it must be appreciated that a further decrease in stent size may be practically impossible in view of materials limitations and functional parameters of the stent. Instead, the present invention offers a different paradigm for delivery devices and stents that are scalable to the sizes noted herein.

[0053] By virtue of the approaches taught herein, it is feasible to design system diameters to match (or at least nearly match) common guidewire size diameters (i.e., 0.014, 0.018 and 0.022 inch) for small vessel delivery applications. As noted above, doing so facilitates use with compatible catheters and opens the possibility for methodology employing the same as elaborated upon below and in the above-referenced “Balloon Catheter Lumen Based Stent Delivery Systems” patent application.

[0054] Of further note, it may be desired to design a variation of the subject system for use in deploying stents in larger, peripheral vessels, biliary ducts or other hollow body organs. Such applications involve a stent being emplaced in a region having a diameter from about 3.5 to about 13 mm (0.5 inch). In this regard, the scalability of the present system, again, allows for creating a system adapted for such use that is designed around a common wire size. Namely, a

0.035 to 0.039 inch (3 FR) diameter crossing profile system is advantageously provided in which the stent expands (unconstrained) to a size between about roughly 0.5 mm and about 1.0 mm greater than the vessel or hollow body organ to be treated. Sufficient stent expansion is easily achieved with the exemplary stent pattern shown in Fig. 2.

[0055] Again, as a matter of comparison, the smallest delivery systems known to applicants for stent delivery in treating such larger-diameter vessels or biliary ducts is a 6 FR system (nominal 0.084 inch outer diameter), which is suited for use in an 8 FR guiding catheter. Thus, even in the larger sizes, the present invention affords opportunities not heretofore possible in achieving delivery systems in the size range of a commonly used guidewire, with the concomitant advantages discussed herein.

[0056] Several known stent delivery systems are compatible with (i.e., may be delivered over) common-sized guides wires ranging from 0.014 inch to 0.035 inch (0.89 mm). Yet, none of the delivery systems are themselves known to be so-sized.

[0057] As for the manner of using the inventive system as optionally configured, Figs. 3A-3L illustrate an exemplary angioplasty procedure. Still, the delivery systems and stents or implants described herein may be used otherwise – especially as specifically referenced herein.

[0058] As for the manner of using the inventive system as optionally configured, Figs. 3A-3L illustrate an exemplary angioplasty procedure. Still, the delivery systems and stents or implants described herein may be used otherwise – especially as specifically referenced herein.

[0059] Turning to Fig. 3A, it shows a coronary artery 30 that is partially or totally occluded by plaque at a treatment site/lesion 32. Into this vessel, a guidewire 40 is passed distal the treatment site. In Fig. 3B, a balloon catheter 42 with a balloon tip 44 is passed over the guidewire, aligning the balloon portion with the lesion (the balloon catheter shaft proximal to the balloon is shown in cross section with guidewire 40 therein).

[0060] As illustrated in Fig. 3C, balloon 44 is expanded (dilatated or dilated) in performing an angioplasty procedure, compressing lesion 32. The balloon expansion may be regarded as “predilatation” in the sense that it will be followed by stent placement (and optimally) a “postdilatation” balloon expansion procedure.

[0061] Next, the balloon is at least partially deflated passed forward, beyond the dilate segment 32' as shown in Fig. 3D. At this point, guidewire 40 is removed as illustrated in Fig. 3E. It is exchanged for a delivery guide member 50 carrying stent 52 as further described below. This exchange is illustrated in Figs. 3E and 3F.

[0062] However, it should be appreciated that such an exchange need not occur. Rather, the original guidewire device inside the balloon catheter (or any other catheter used) may be that

of item 50, instead of the standard guidewire 40 shown in Fig. 3A. Thus, the steps depicted in Figs. 3E and 3F (hence, the figures also) may be omitted. In addition, there may be no use in performing the step in Fig. 3D of advancing the balloon catheter past the lesion, since such placement is merely for the purpose of avoiding disturbing the site of the lesion by moving a guidewire past the same.

[0063] Fig. 3G illustrates the next act in either case. Particularly, the balloon catheter is withdrawn so that its distal end 46 clears the lesion. Preferably, delivery guide 50 is held stationary, in a stable position. After the balloon is pulled back, so is delivery device 50, positioning stent 52 where desired. Note, however, that simultaneous retraction may be undertaken, combining the acts in Figs. 3G and 3H. Whatever the case, it should also be appreciated that the coordinated movement will typically be achieved by virtue of skilled manipulation by a doctor viewing one or more radiopaque features associated with the stent or delivery system under medical imaging.

[0064] Once placement of the stent across from dilated segment 32' is accomplished, stent deployment commences. The manner of deployment is elaborated upon below. Upon deployment, stent 52 assumes an at least partially expanded shape in apposition to the compressed plaque as shown in Fig. 3I. Next, the aforementioned postdilatation may be effected as shown in Fig. 3J by positioning balloon 44 within stent 52 and expanding both. This procedure may further expand the stent, pushing it into adjacent plaque – helping to secure each.

[0065] Of course, the balloon need not be reintroduced for postdilatation, but it may be preferred. Regardless, once the delivery device 50 and balloon catheter 42 are withdrawn as in Fig. 3K, the angioplasty and stenting procedure in vessel 30 is complete. Fig. 3L shows a detailed view of the emplaced stent and the desired resultant product in the form of a supported, open vessel.

[0066] Of course (as alluded to above), other endpoints may be desired such as implanting an anchoring stent in a hollow tubular body organ, closing off an aneurism, delivering a plurality of stents, etc. In performing any of a variety of these or other procedures, suitable modification will be made in the subject methodology. The procedure shown is depicted merely because it illustrates a preferred mode of practicing the subject invention, despite its potential for broader applicability.

[0067] In the above description, a 300 cm extendable delivery system is envisioned. Alternatively, the system can be 190 cm to accommodate a rapid exchange of monorail type of balloon catheter as is commonly known in the art. Of course, other approaches may be

employed as well. In addition, further details applicable to the procedures of the present invention may be appreciated in the related discussion presented in U.S. Patent Application Atty Docket No. CRMD-007, entitled "Sliding Restraint Stent Delivery Systems" filed on even date herewith and incorporated by reference in its entirety.

[0068] As for the structural details of the present system, these are illustrated in Figs. 4-13. An overview of the system illustrating its more global features is shown in Fig. 4. Here, delivery guide member 50 is shown with a stent 52 attached thereto. The delivery guide is shown with an optional atraumatic distal tip 54 in the form of a plurality of spring coils 56 and hemispherical radiopaque platinum cap 58. Interior to each of the stent 52 and tip 54 is a core member 60. The core member is conductive, and is advantageously provided by a stainless steel, titanium alloy or NiTi wire. A hypotube 62 is set over the core wire 60. Tube 62 may be a stainless steel, titanium alloy or NiTi hypotube or it may comprise cabletube to provide increased flexibility. Of course, as noted above, the core wire or hypotube may be of a hybrid construction. However constructed, the outer tubular member 62 will be conductive - as will be core member 60 so each serve as an electrode. Thus, elements 60 and 62 may be referred to in the alternative as the conductive core member and the conductive outer member, respectively. As for the conductivity, it is not necessary that the entirety of the referenced structures be conductive. Naturally, the all-metal constructions will be so.

[0069] What is required, however, from an electrical perspective is that the conductive core member 60 and hypotube 62 (together defining the body of the delivery guide member 50) provide electrical connectivity to the distal end 64 of the guide member system. By way of fittings 66, a proximal end 68 of guide member 50 is connected to electrical leads 70 to a power supply or source 72 for driving dissolution of the electrolytic joints holding the stent or other implant at the delivery device distal end 64.

[0070] Power source 72 may be a stand-alone unit. Alternatively, it may be controlled by a separate processor such as a general purpose computer as shown in Fig. 5. A control cable 76 may connect the two. Specific programming on computer readable media (e.g., as in CD or DVD 82 or remotely accessible means as in the internet) may be provided to control power source 72 setup and/or function. Such programming may be provided in packaged combination with instructions for system use or the readable medium may also include such instructions for use. Whatever the packaging 86 that might be provided for such support material, other packaging will be provided for the system in the form of a sterile tray kit 88 including at least the delivery guide 50 and, possibly, its instructions for use 84. Tray kit 88 may include one or more of an outer box 90 and one or more inner trays 92, 94 with peel-away

coverings as is customary in packaging of disposables provided for operating room use. In contrast, power source 72 (and any control means – whether integral thereto or as in a separate unit 74), will typically be reusable and suited for such duty irrespective of such peripheral packaging employed.

[0071] Fig. 6 provides a side detail view of the distal portion 64 of the delivery guide member shown in Fig. 4. Fig. 7 shows an enlarged sectional view taken along line A-A in Fig. 6. The figures detail the relation of the aforementioned elements of guide member 50. Specifically, core wire 60 is shown in phantom line within electrode tube 62. Underlying stent 52 and tube 62, the core member 60 is, optionally, straight-gauge wire. It advantageously includes a tapered section 96 distal to the stent to aid in providing an atraumatic tip.

[0072] An air-gap or optional spacer 98 electrically separates stent 52 from tube 62. Further, an insulation layer 100 is provided between guide member body portions 60 and 62. The layer may be Teflon tubing, PET, resin or some other material. The insulation layer may be in the form of a coating or jacket on either one or both of body portions.

[0073] Whatever the case, layer 100 electrically isolates core wire 60 from hypotube 62, each of which are interconnected to separate electrical leads 70 through fittings 66 when ready for use. Stent 52, or at least the joint(s) restraining the stent are in electrically connected to the core member.

[0074] Fig. 8 provides an example of such joint(s) 102 as may be employed in the invention. Joints 102 take the form of solder set within the cells 16 of a stent 52. It may be the case that all of the stent cells are filled (as shown) on only some of them. Regardless, the joints will pin the structure in a collapsed profile. Stent 52 may have a symmetrical pattern as shown, or it may be asymmetrical – especially to compliment a partial joint infill pattern.

[0075] The solder for the joints (these or others in the invention) may comprise silver solder or another suitable material. By virtue of adhesion to the stent, or simply by locking the geometry by way of interference, the joints maintain the stent in a collapsed profile as shown. The joints may be bonded (soldered) to the core member 60 thereby providing stent-to-wire connectivity. Alternatively, the joints may simply be bonded with or within the stent portions, thereby providing stent-to-stent joint attachment points (or regions) to restrain the stent.

[0076] Each of these different modes of connection may be applied to the joints and joint-associated structure described throughout. In every example, however, either by way of the stent or by direct connection with the core member, the joints are electrically connected to the core member.

- [0077] In use, when surrounded by blood (electrolyte) in a vessel and a DC voltage is applied by the power source (with the positive pole connected to the core member 60 and negative connected to tube 62), joints 102 erode as ions from the joint material are transported out of (or in the case of latter joint configurations – off of) the stent and onto the electrically isolated tube 62.
- [0078] While such action holds when applying DC voltage, note that low frequency AC might alternatively be employed. In such instances, the mode of material transport to hypotube 62 will be replaced by one in which the metal ions from the joint may be carried away by patient's bloodstream. Accordingly, a DC system may be preferred for its ability to sequester potentially reactive metal ions.
- [0079] Further variation contemplated for the invention includes the use of a variety of different joint structures. As commented upon above, the approach shown in Fig. 8 involves inset joint material. The joints in Figs. 9A-9D are at least partially or substantially external to the stent pattern. These latter approaches help minimize delivery diameter/crossing profile by allowing maximum compression of the stent (or other implant) so adjacent strut sections 14 are touching or are nearly touching.
- [0080] Of the external or overlaying joint approaches, that shown in Fig 9A is the simplest. Here, a full joint covering 104 of solder material overlays at least a substantial length of stent 52 (the outline of which is shown in broken line). Alternatively, two or more shorter joint coverings may be employed. Generally, the joint sections will wrap around the stent, but they need not be solid as shown. In Fig. 9B, two end-covering joints 106 are provided; in Fig. 9C the end joints 106 are complimented with a medial joint solder covering 108. Figs. 9D shows numerous joint bands 110 of erodable material wrapping around the stent. Such an approach might be used in order to minimize the amount of solder employed, while still holding down the entire length of the stent.
- [0081] It should also be noted that such an arrangement of joint elements is advantageously used where the thickness of the solder from one joint to the next is varied in thickness. With varying thickness, those joint bands 110 that are thinner will erode first. In the case of the embodiment in Fig. 9D, an "unzipping" like release will be achieved. Where thickness of the joint is gradually varied in the embodiment in Fig. 9E, a smooth or continuous "unrolling" or "unraveling" release approach is possible as the single joint erodes around the periphery of stent 52. Such routines may be more "gentle" than simply releasing the entire length of the stent at once, as may occur with a constant wall thickness joint covering.

[0082] Actually, when sequential deployment of portions of the stent is intended, any of a number of joint configurations may be employed. Figures 10A-10E particularly illustrate a number of these. Note, however, that the approaches of Figs. 10C and 10D are applicable to that of Fig. 9D and 9E.

[0083] With particular reference to Fig. 10A, joint 104 is shown having a tapered solder layer. Of course, the scale of the taper is grossly exaggerated to shown this effect. Upon the application of voltage, the thinner joint sections or portions at the distal end 112 of the stent will erode and release before those portion of joint 104 at the proximal end 114 release. Such a distal-to-proximal delivery approach is generally preferred. It can facilitate emergency withdrawal of the delivery guide 50 and stent 52.

[0084] By virtue of the sloped or continuous profile of joint 104 in Fig. 10A, a very smooth deployment performance profile should be achieved. However, for manufacturing purposes or in order to have more discernable deployment “stages”, one might opt for a joint configuration as shown in Fig. 10B with relatively thicker and thinner steps 116 and 118, respectively. The action of stent deployment of such steps will, naturally, be such that thin step 118 releases first. In Fig. 10C, the end or capping joints 106 shown in Fig 9B are likewise provided as different thickness steps. They are also configured for distal-to-proximal stent deployment as joint 106A erodes before joint 106B.

[0085] Yet, in Fig. 10D the thickness of joints 106A and 106B and joint 108 are provided to effect a different deployment routine. Here, medial joint 108 will erode first, followed by joint 106A at distal end 112, and finally joint 106B and the proximal end 114 of stent 52. Such an approach may be desirable for the purpose of anchoring the stent at the center of a lesion as a first act. Fig. 10E shows an approach where the deployment routine of Fig 10D is effected using a full-length joint 104.

[0086] By using variable-thickness joints or joint sections, any desired deployment routine can be achieved by selecting joint placement and/or length – and done so without particular need for specialized electronic control or discrete electrical leads to eclectically isolated joints. Such an approach dramatically reduces system complexity as well as conserves valuable space that is especially critical in reaching smaller crossing profiles.

[0087] While all of these approaches have certain benefits, especially where the use of drug eluting stent is desired, minimizing the solder set upon the stent might be preferred. The embodiments of the invention in Figs. 11-13 may be especially useful in this regard.

[0088] The embodiment in Fig. 11 is a hybrid electrolytic-mechanical restraint system that only requires a medial erodable joint 120 (though a plurality of smaller joint bands 110 as in

Figs 9D or 9E might be used instead). To hold the ends of the stent in place, caps 122 (such as made of PET or another material) are secured to the guide member (e.g., upon the outer tube 62 and/or core member 60). Upon release of joint 120, the stent bulges as indicated in phantom line, pulling its ends inward, freeing them of its end-restraints 122 and thereby deploying stent 52.

[0089] The embodiment of the invention in Fig. 12 can be configured so that no solder is in contact with the stent. (Hence, a supplemental electrical connection – not shown – may be desired for connection between the joint and core member 60.) Instead, a circumferential restraint cover 124 surrounds stent 52. Upon release, the cover 124 (which may comprise a polymer or other material) might be left behind and sandwiched between the stent and lesion. The cover may be drug eluting itself, biodegradable or bioabsorbable.

[0090] However the overall structure is configured, joint 126 comprises electrolytically erodable material. Where a solder joint is provided and circumferential cover 124 is polymeric material, intermediate interface portions or jaws 128 may be desired which can be soldered at the joint 126 and glued or otherwise bonded with cover 124. The stent may provide the electrical connection to the joint by way of the interface portions, the jaws may be soldered to the core member, another connection means may be provided as noted above.

[0091] Finally, Fig. 13 shows the last embodiment of the invention that is pictured. It employs a system like that of the '907 patent referenced above. The delivery system includes bands 130, each having a necked-down joint. In the example shown, joints 132, 134 and 136 increase in thickness – thus increasing their delay before release upon the application of a voltage. Though such a joint approach is taught in the '907 patent, that patent does not disclose the space-efficient and electrically-efficient guide member approach provided herein. As such, according to the present invention, at least the joint approach in Fig. 13 is dependent upon the guide member configuration detailed in Fig. 6 and 7.

[0092] In any case, an optional configuration of the guide member offers an advantageous application to the joint variation in Fig. 13. Specifically, where core member 60 is provided with an internal insulation layer 100' that isolates portions 60' and 60'', the core member may serve to provide a plurality of electrodes or electrical leads. Each one of this plurality may be connected to a single band 130. So long as each band is electrically isolated from stent 52, the joints (132, etc.) can be individually actuated (released by electrolytic action) regardless of whether they have different thicknesses. Of course, the core member may be configured with parallel, electrically isolated members as shown, or the wire may be wrapped like cable or be provided in some other convenient form.

[0093] What is significant is that the core member serves as both an electrode and a structural component of the system extending past the outer electrode to support or carry the stent until release. Of further significance is that the return electrode in the subject system optionally and optimally comprises an outer tube that provides for the structural capacity of the system to serve as a guide member in delivering an implant to a target site. Together, these members provide a highly space and electrically efficient delivery system that offer potential health benefits relative, especially, in its preferred mode of bipolar operation.

[0094] In this arrangement of elements, the core member may be as small as between 0.005 inch (0.13 mm) and about 0.010 inch (0.25 mm), especially when provided as a coaxial core to an outer, tubular conductive member. Sizing of the outer tubular member will depend on the overall size intended of the delivery guide device. For the smallest possible systems, and where a metal hypotube is used, its thickness may be as little as about 0.0015 inch (0.038 mm). A system using a 0.005 inch diameter core wire and 0.0015 inch thick hypotube for the inner and outer conductive members, respectively, can produce a system with as small as about a 0.010 inch (0.25 mm) crossing diameter, taking insulation needs and tolerances into account. More often, hypotube wall thickness will be between about 0.002 (0.051) and about 0.004 inch (0.10 mm) in order to provide delivery systems in the size ranges noted above.

[0095] Certainly, a degree of engineering acumen is advantageously applied in order to balance the dynamic requirements of the system with its electrical needs. Yet, however the relation of these members is optimized given the overall system configuration and desired performance, it may be further desired to coat any portion of the inner member in contact the stent or joint(s) with a conductive but protective layer. By electroplating (or otherwise depositing) a noble metal such as gold or platinum on the conductive core member, it is possible to ensure that when an relatively less expensive wire is used for the bulk of the member that it will not be subject to electrolytic erosion, itself.

[0096] In addition, it is to be understood that various radiopaque markers or features may be employed in the system to 1) locate stent position and length, 2) indicated device actuation and stent delivery and/or 3) locate the distal end of the delivery guide. As such, various platinum (or other radiopaque material) bands or other markers (such as tantalum plugs) may be variously incorporated into the system. Especially where the stent employed may shorten somewhat upon deployment, it may also be desired to align radiopaque features with the expected location (relative to the body of the guide member) of the stent upon deployment.

CLAIMS

[0097] Though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each embodiment or variation of the invention. The breadth of the present invention is to be limited only by the literal or equitable scope of the following claims. That being said, we claim:

1. An stent delivery and deployment system comprising:
a self-expanding stent;
a guide member adapted to access a remote target site via a body lumen, the guide member comprising a conductive inner member and a conductive outer member electrically isolated from one another, the guide member being adapted for connection of the inner member and outer member to a power supply; and
an electrolytically erodable joint in electrical communication with the inner member and maintaining the stent in a collapsed configuration, supported by the inner member at a distal portion of the guide member.
2. The system of claim 1, wherein the inner member and outer member are connected to a power supply.
3. The system of claim 1, wherein the outer member comprises a tube and the inner member is coaxial with the tubular outer member.
4. The system of claim 1, wherein the inner member comprises a plurality of wires.
5. The system of claim 1, wherein a cross-sectional area of each of the inner and outer members are substantially equal to one another.
6. The system of claim 1, wherein the delivery system has a diameter up to about 0.022 inch at, at least, the distal portion.
7. The system of claim 6, wherein the delivery system has a diameter up to about 0.018 inch at, at least, the distal portion.
8. The system of claim 7, wherein the delivery system has a diameter up to about 0.014 inch at, at least, the distal portion.
9. The system of claim 8, wherein at least one of the inner member and outer member is only partially conductive.

10. The system of claim 9, wherein the partially conductive member comprises a hybrid structure.
11. The system of claim 1, wherein the collapsed diameter of the stent is about equal to a diameter of the outer member.
12. The system of claim 1, wherein the joint attaches a portion of the stent to the inner member.
13. The system of claim 1, wherein the joint attaches a portion of the stent to another portion of the stent to maintain the collapsed configuration.
14. The system of claim 1, wherein the joint is provided in a supplemental restraint.
15. The system of claim 14, wherein the supplemental restraint comprises a band.
16. The system of claim 15, wherein the band is attached to the stent and remains with the stent upon deployment.
17. The system of claim 1, wherein a plurality of joints are provided.
18. The system of claim 17, wherein the joints are adapted to erode and release in a sequential fashion.
19. The system of claim 18, wherein the joints have a different thickness to erode and release in a sequential fashion.
20. The system of claim 17, wherein the inner member comprises a plurality of electrically isolated wires, and one of each of the plurality of joints is attached to each of the plurality of wires for individual joint actuation.
21. The system of claim 1, wherein a single joint is provided, the joint having a plurality of different thickness sections to erode differentially to release the stent sequentially.

22. The system of claim 21, wherein the different thickness sections are stepped.
23. The system of claim 21, wherein the different thickness sections are tapered.
24. The system of claim 1, wherein the system is adapted to release a medial portion of the stent first.
25. The system of claim 24, wherein the system is adapted to release a distal end of the stent after release of the medial portion.
26. The system of claim 1, wherein the system is adapted to release a distal end of the stent first.
27. The system of claim 1, further comprising cap portions at proximal and distal ends of the stent, the caps adapted to hold the ends, wherein the joint is provided between the caps and release of the joint allows expansion of a medial portion of the stent, withdrawing the ends from the caps.
28. The system of claim 1, wherein the inner member is between about 0.005 and 0.010 inch in diameter.
29. The system of claim 1, wherein an exposed distal portion of the inner member is coated with platinum or gold.
30. A method of stent delivery, the method comprising:
providing a system according to claim 2,
positioning the stent at a target site, and
applying a voltage to erode the joint and release the stent for deployment.
31. A method of stent delivery, the method comprising:
providing a stent secured to a guide member by an electrolytically erodable joint configured to maintain the stent in a collapsed configuration until release of the stent,
positioning the stent at a target site, and

applying a voltage to a coaxial set of electrodes to erode the joint and release the stent for deployment.

32. The method of claim 30 or 31, wherein the release is from a stent-to-guide member attachment point.

33. The method of claim 30 or 31, wherein the release is from a stent-to-stent portion attachment point.

34. The method of claim 30 or 31, wherein the release is from at least one circumferential restraint that opens at the location of the joint.

35. The method of claim 34, further comprising leaving the at circumferential restraint with the stent upon deployment.

36. The method of claim 30 or 31, wherein a plurality of joints are provided and the joints are eroded to sequentially release the stent.

37. The method of claim 30 or 31, wherein a single joint is provided, the joint having different thickness portions to erode and release the stent in a sequential fashion.

38. The method of claim 30 or 31, wherein the stent is released in a distal-to-proximal fashion.

39. The method of claim 30 or 31, wherein a medial portion of the stent is released first.

40. The method of claim 39, wherein a distal portion of the stent is next released.

41. The method of claim 30 or 31, further comprising dilatating a balloon of a balloon catheter in an angioplasty procedure prior to the releasing of the stent.

42. The method of claim 39, further comprising dilatating the balloon within the stent after deployment of the stent.

43. The method of claim 39, wherein the guide member is passed through a lumen of the balloon catheter to effect the positioning of the stent.
44. The method of claim, wherein only one balloon catheter is employed.

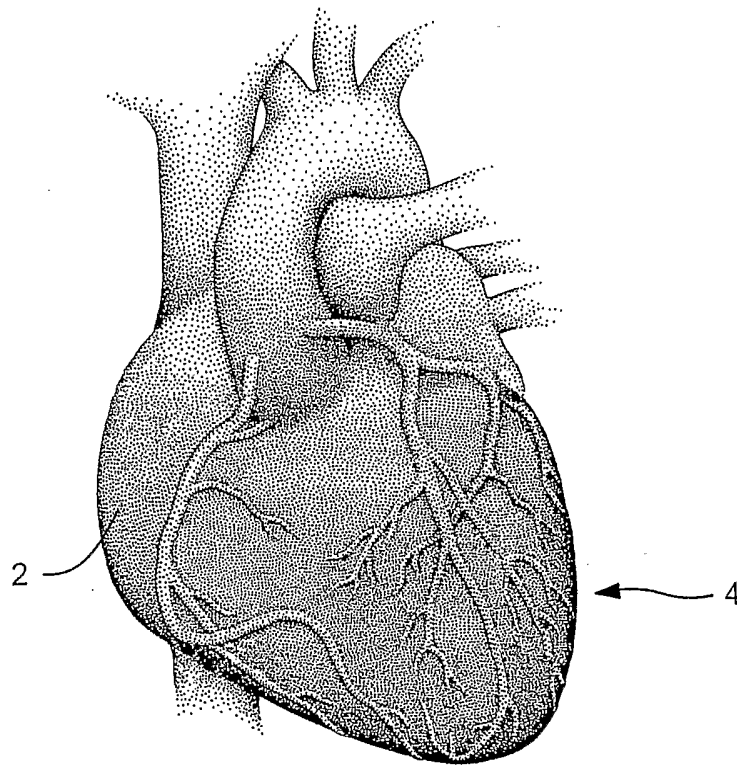


FIG. 1

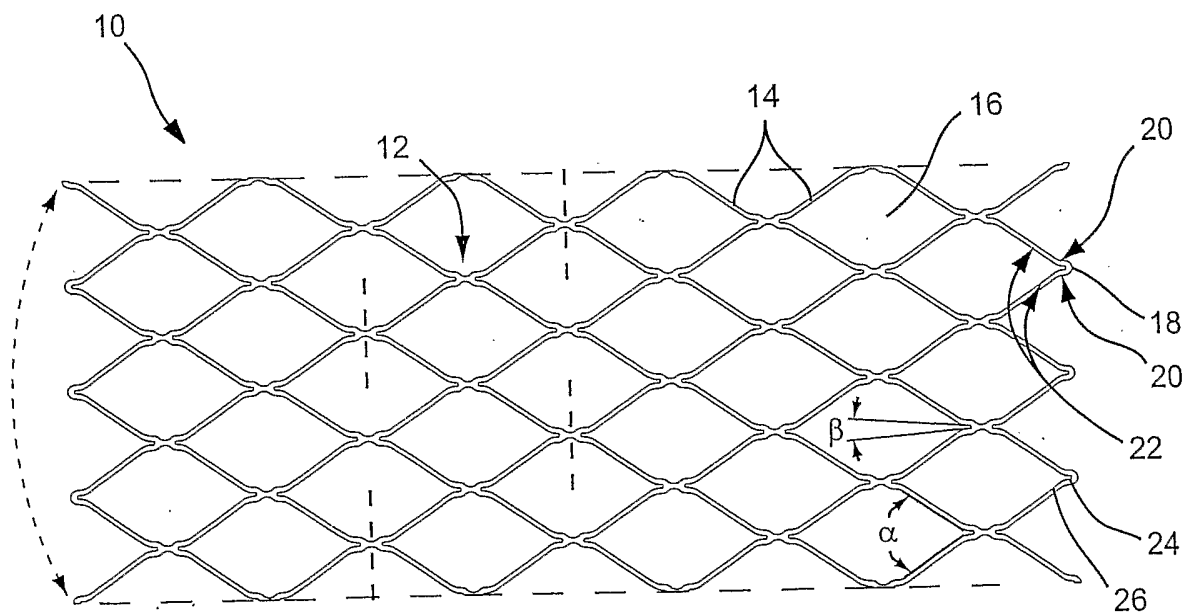


FIG. 2

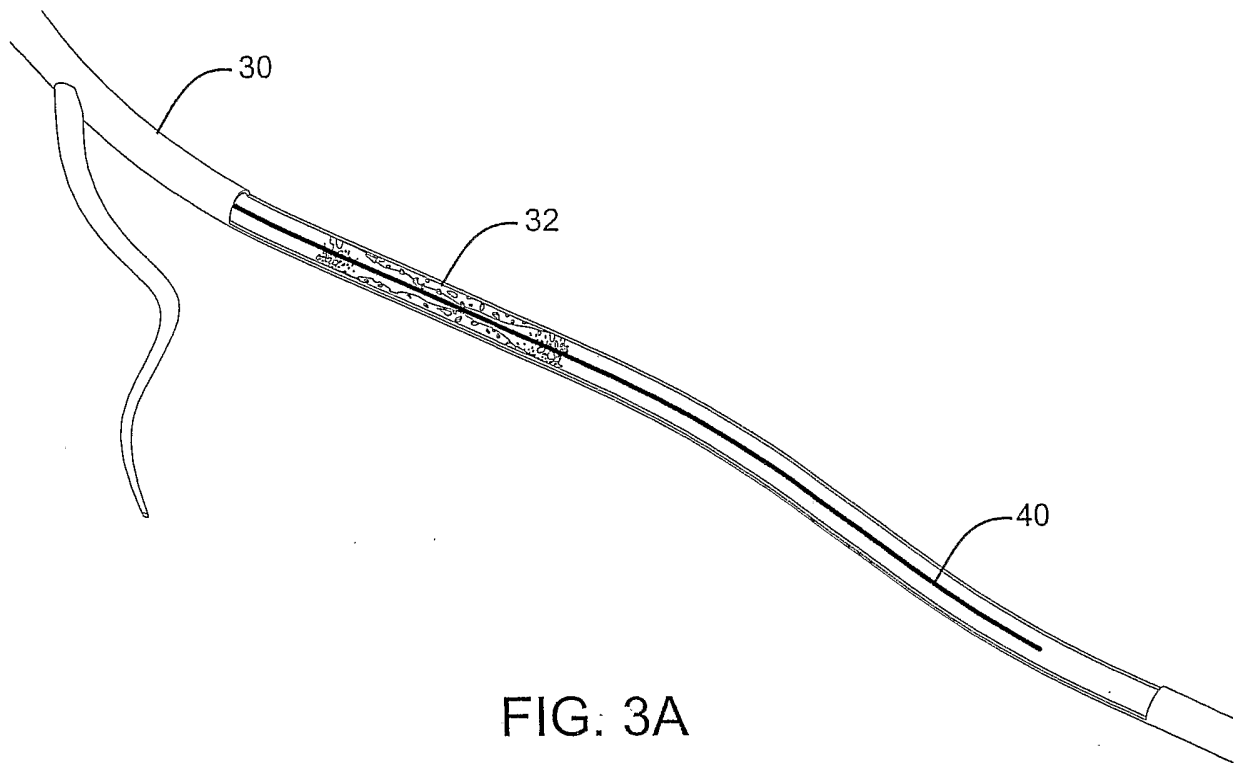


FIG. 3A

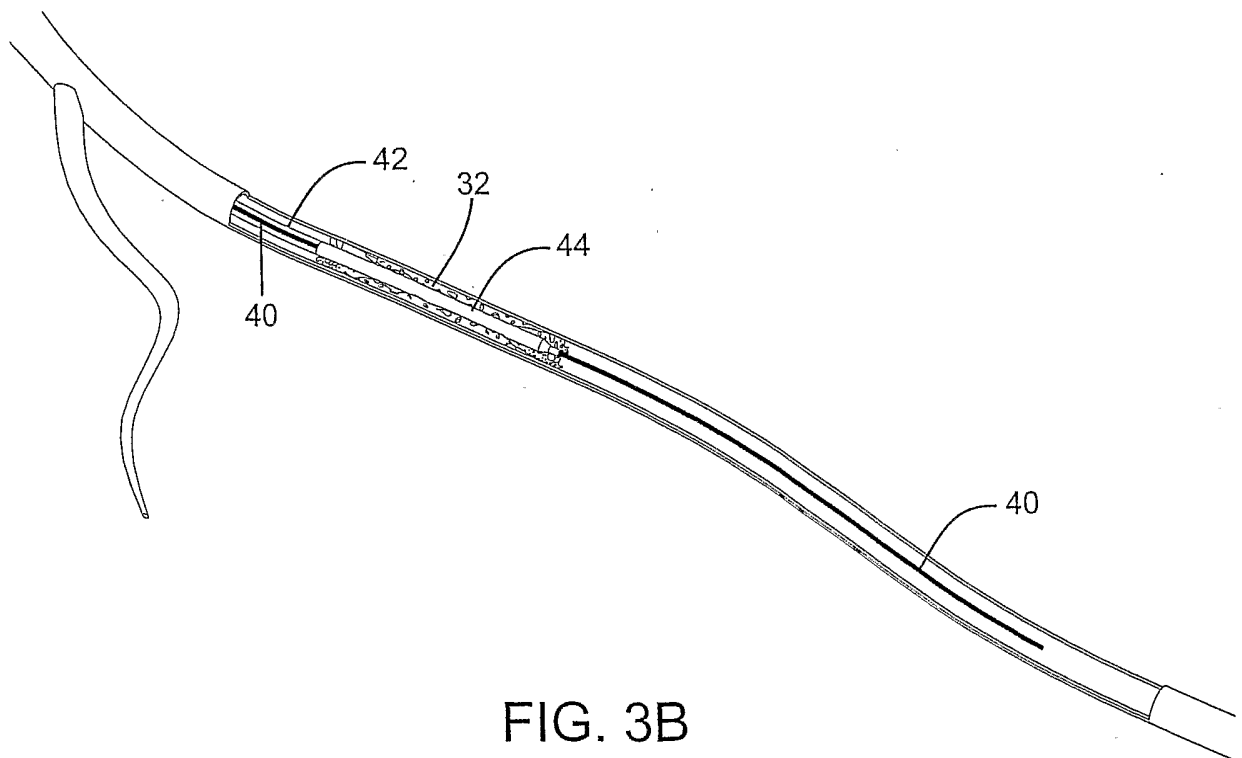
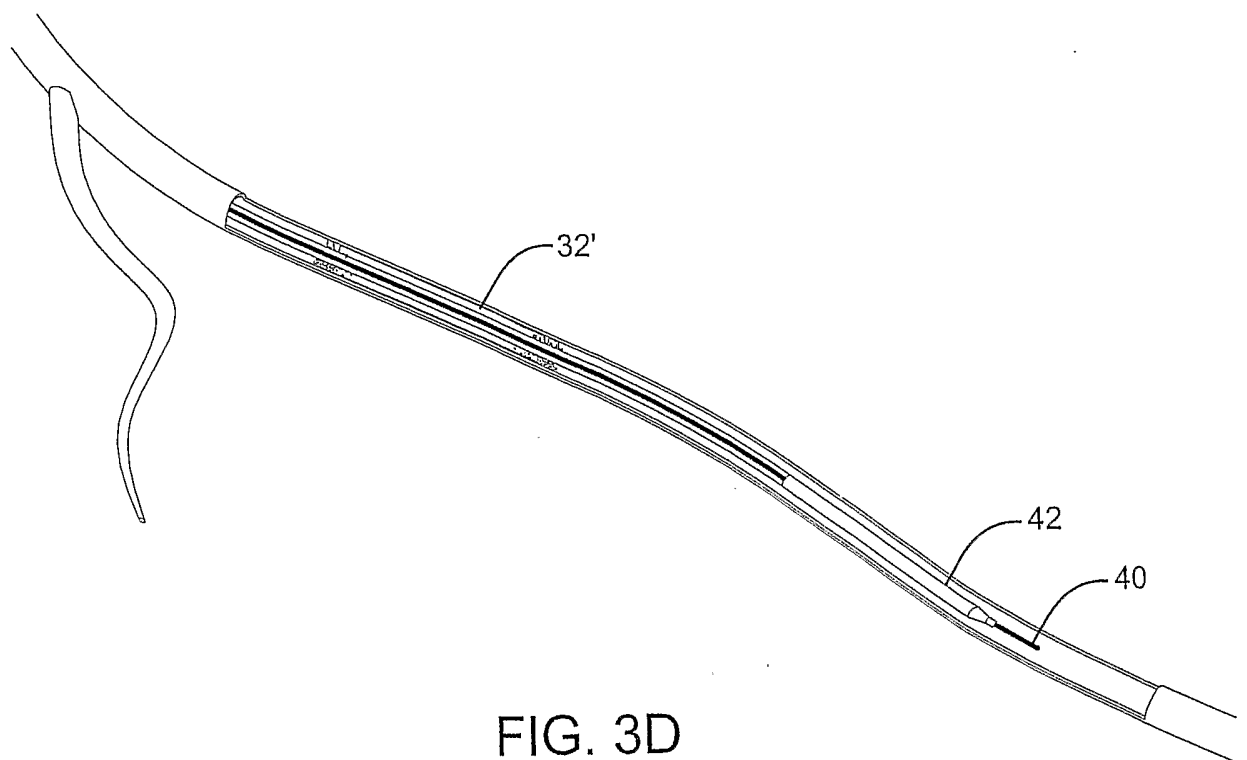
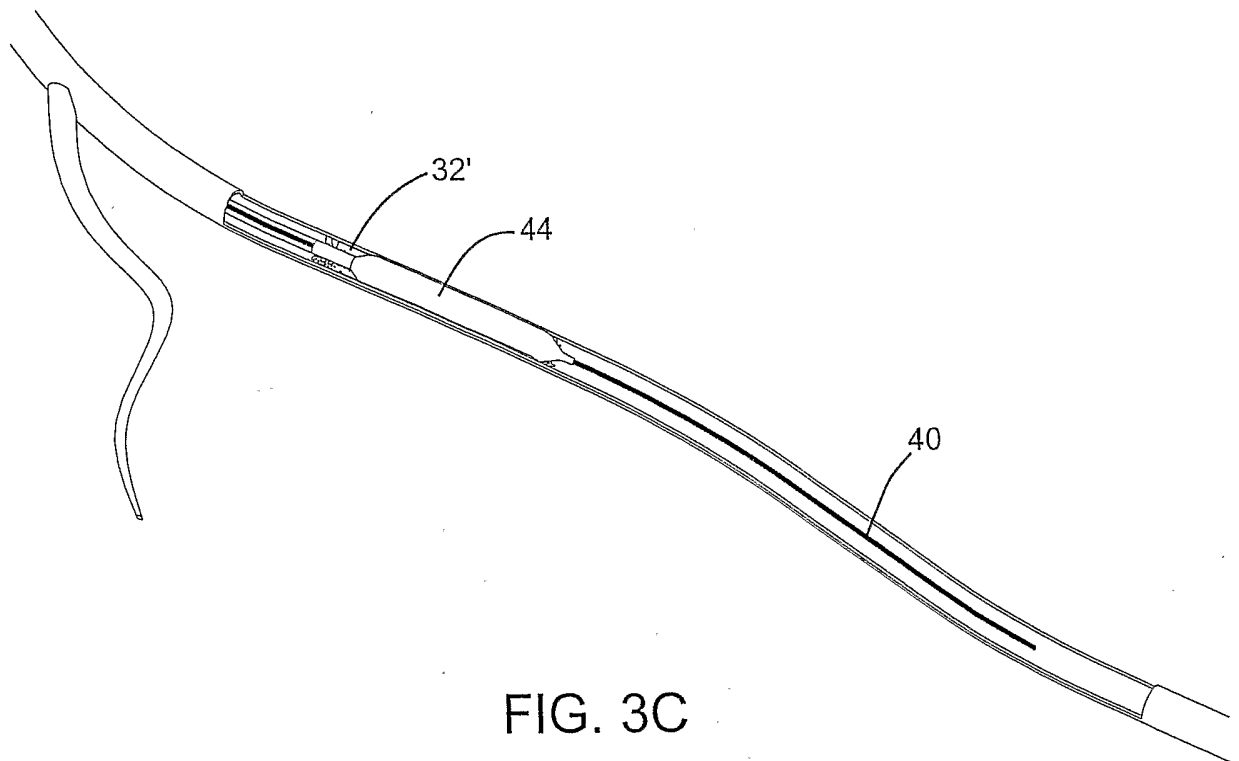
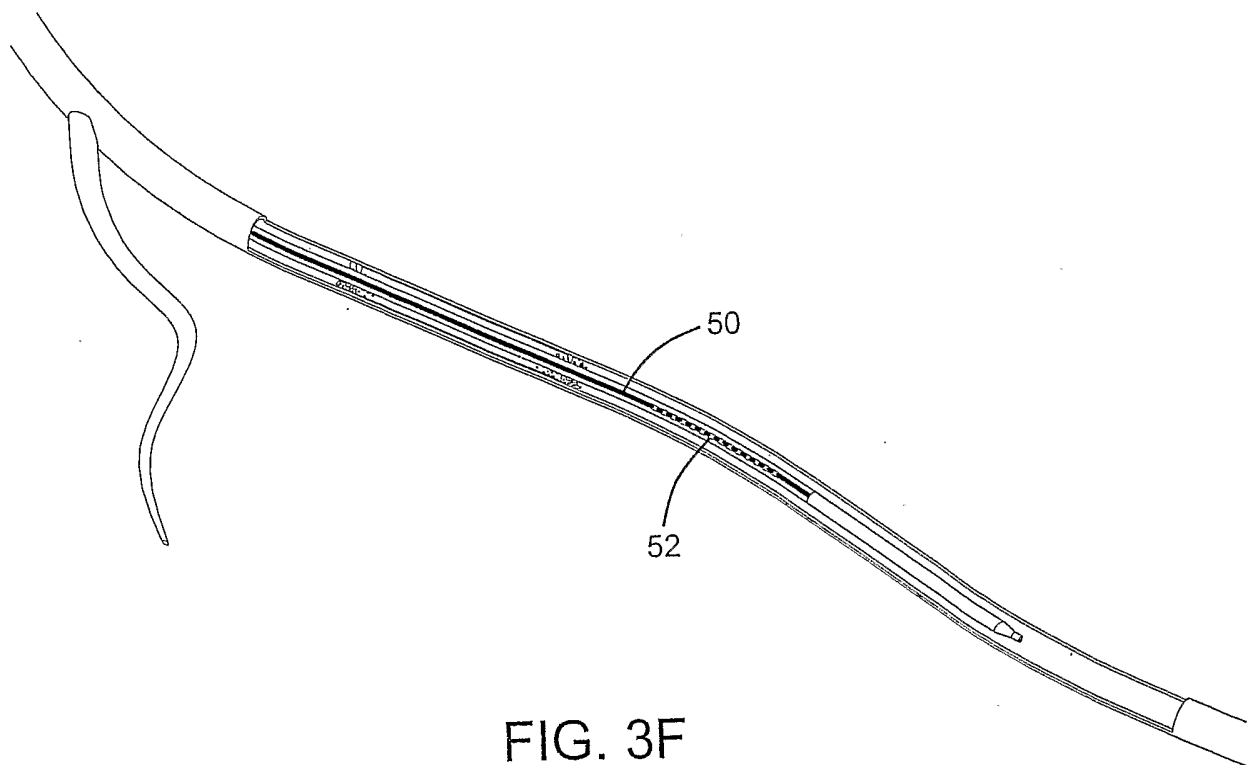
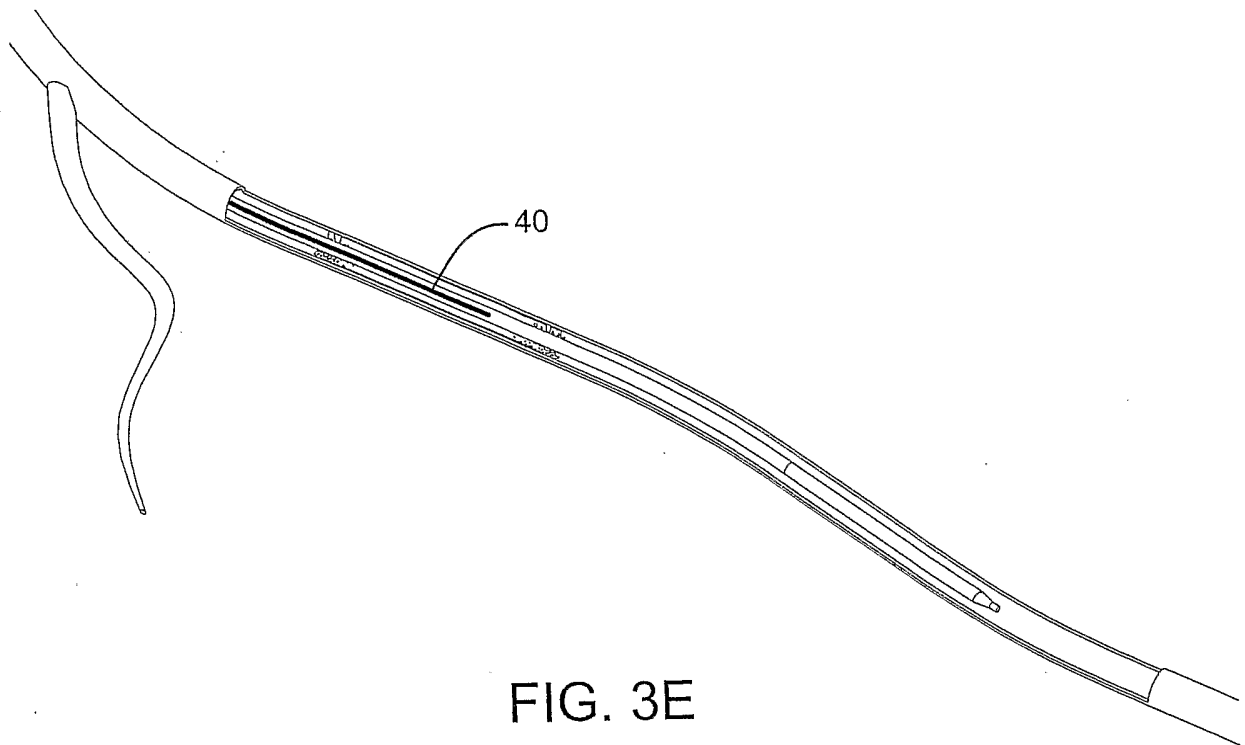


FIG. 3B





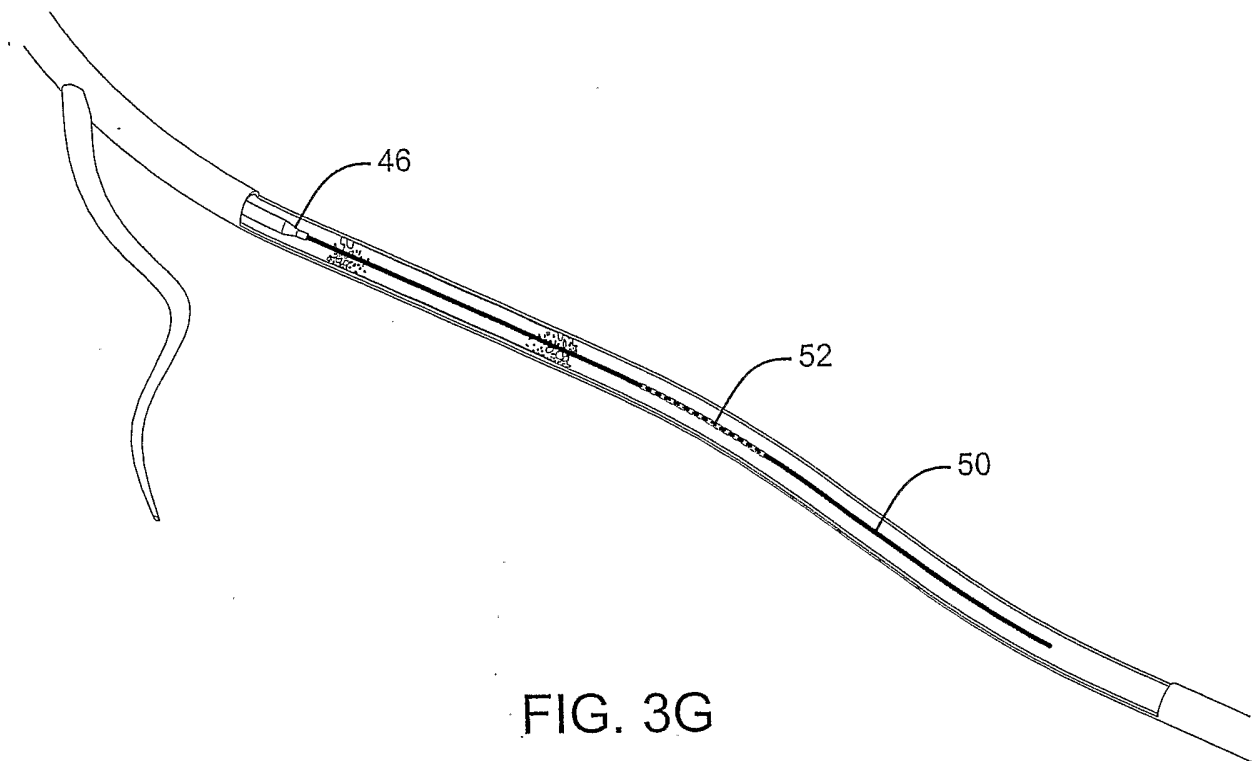


FIG. 3G

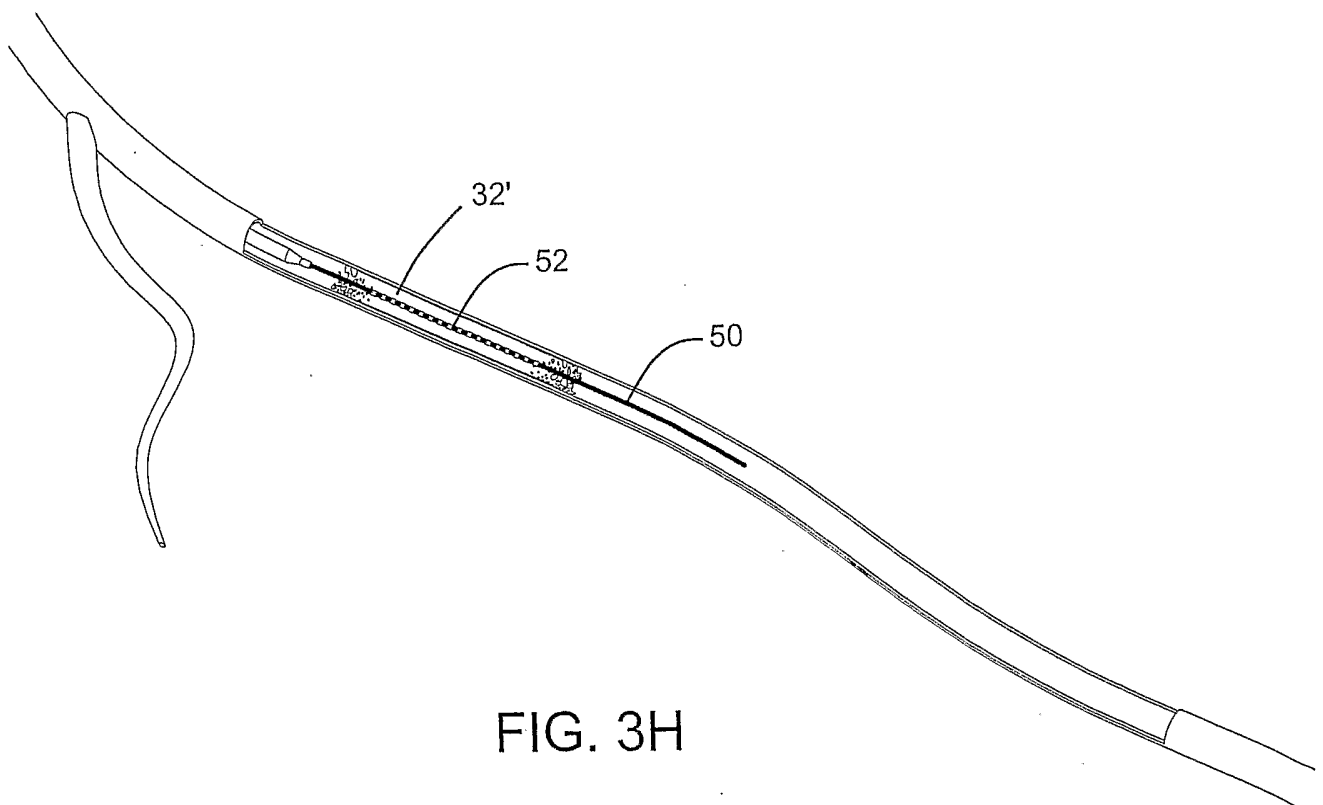


FIG. 3H

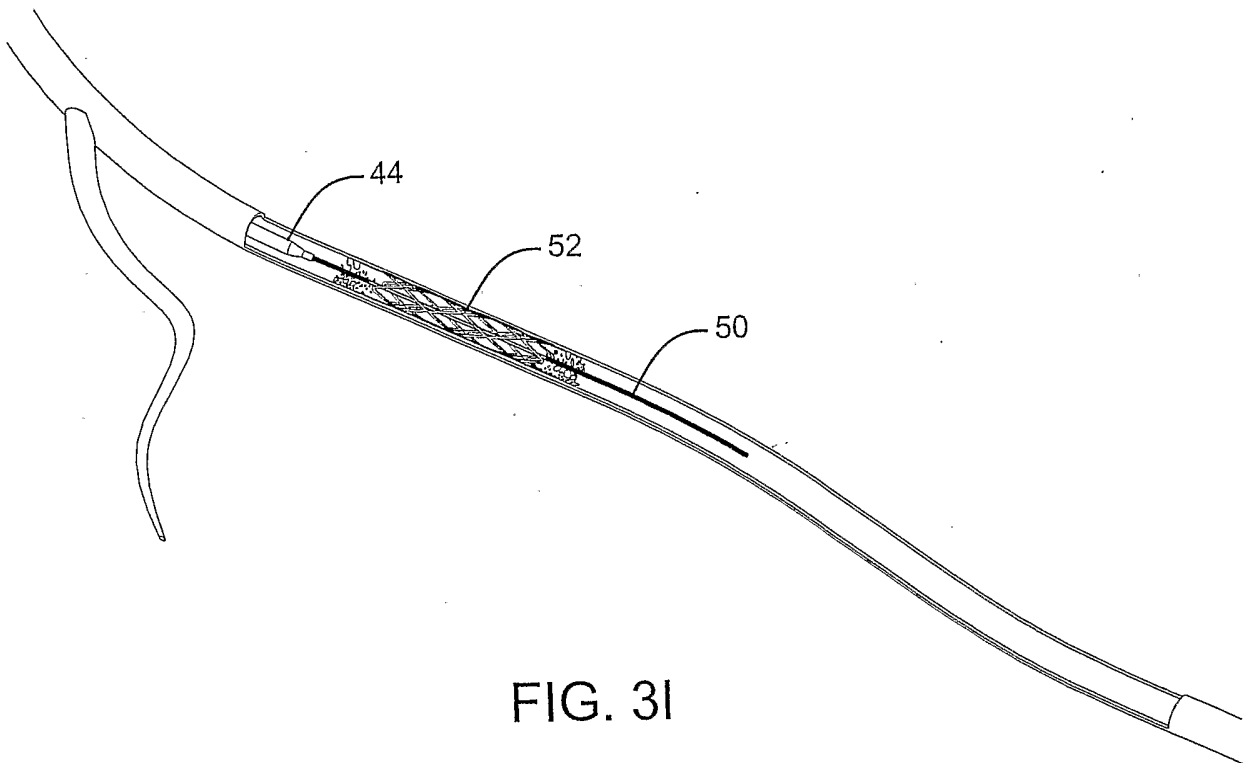


FIG. 3I

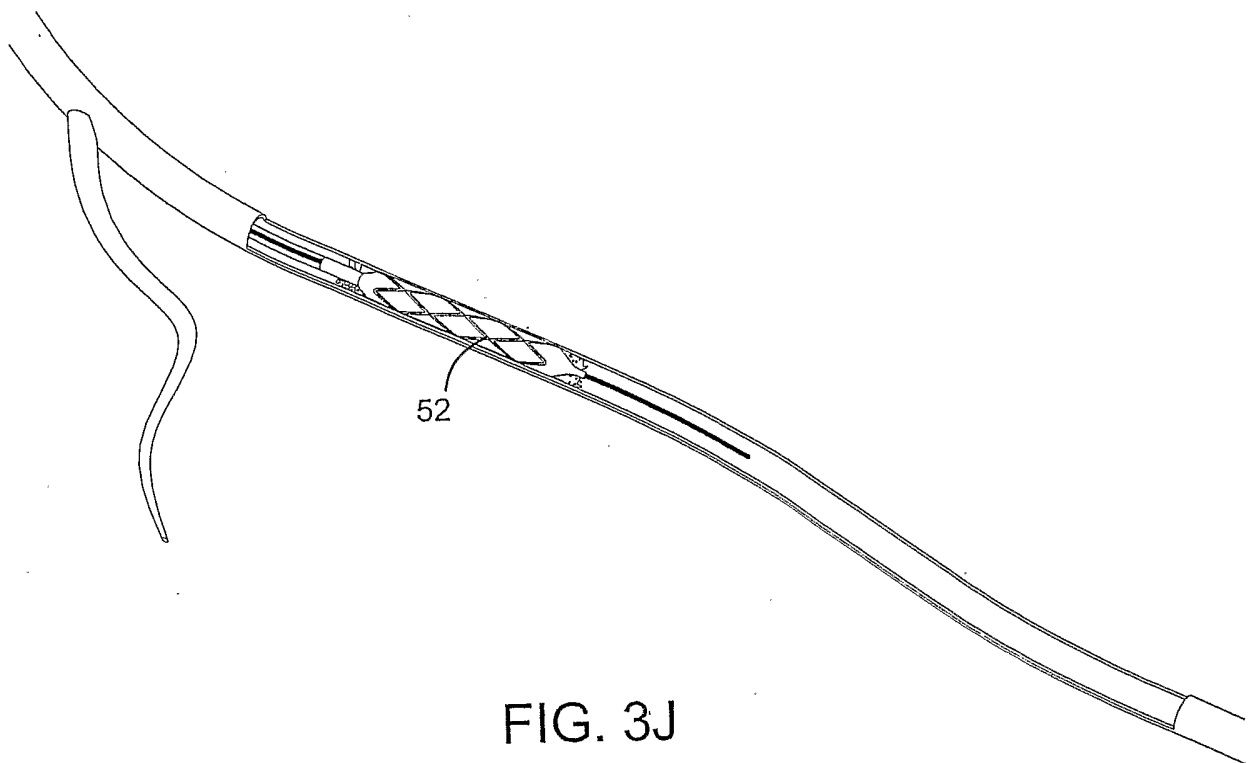


FIG. 3J

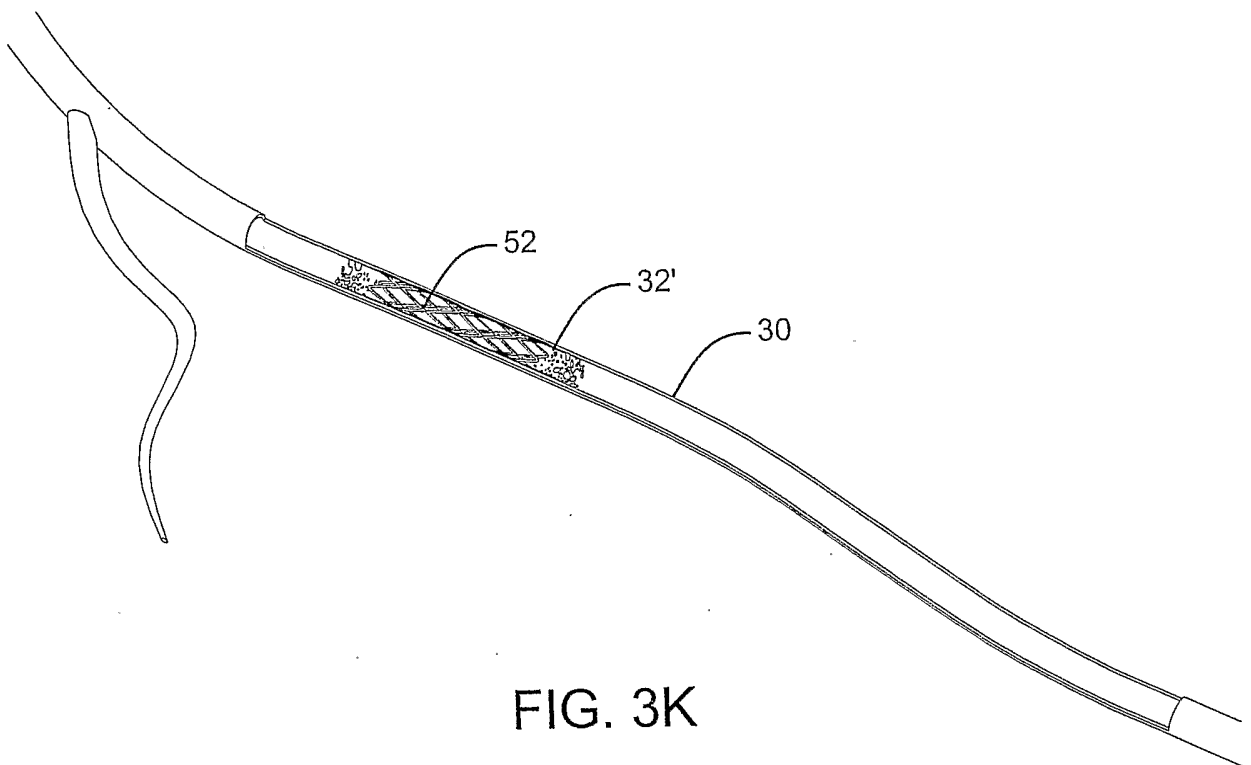


FIG. 3K

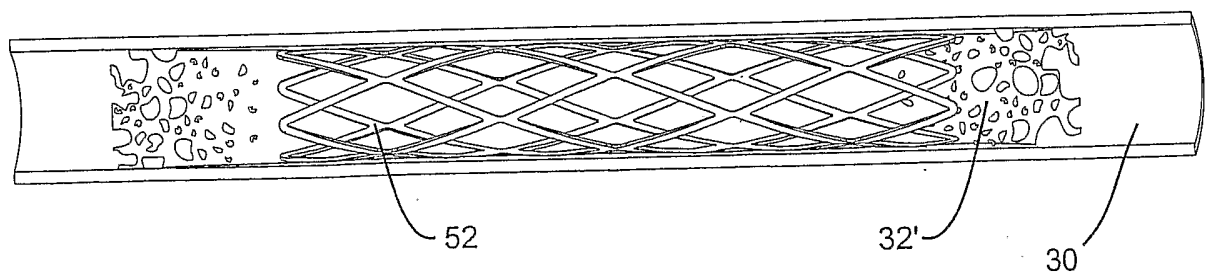
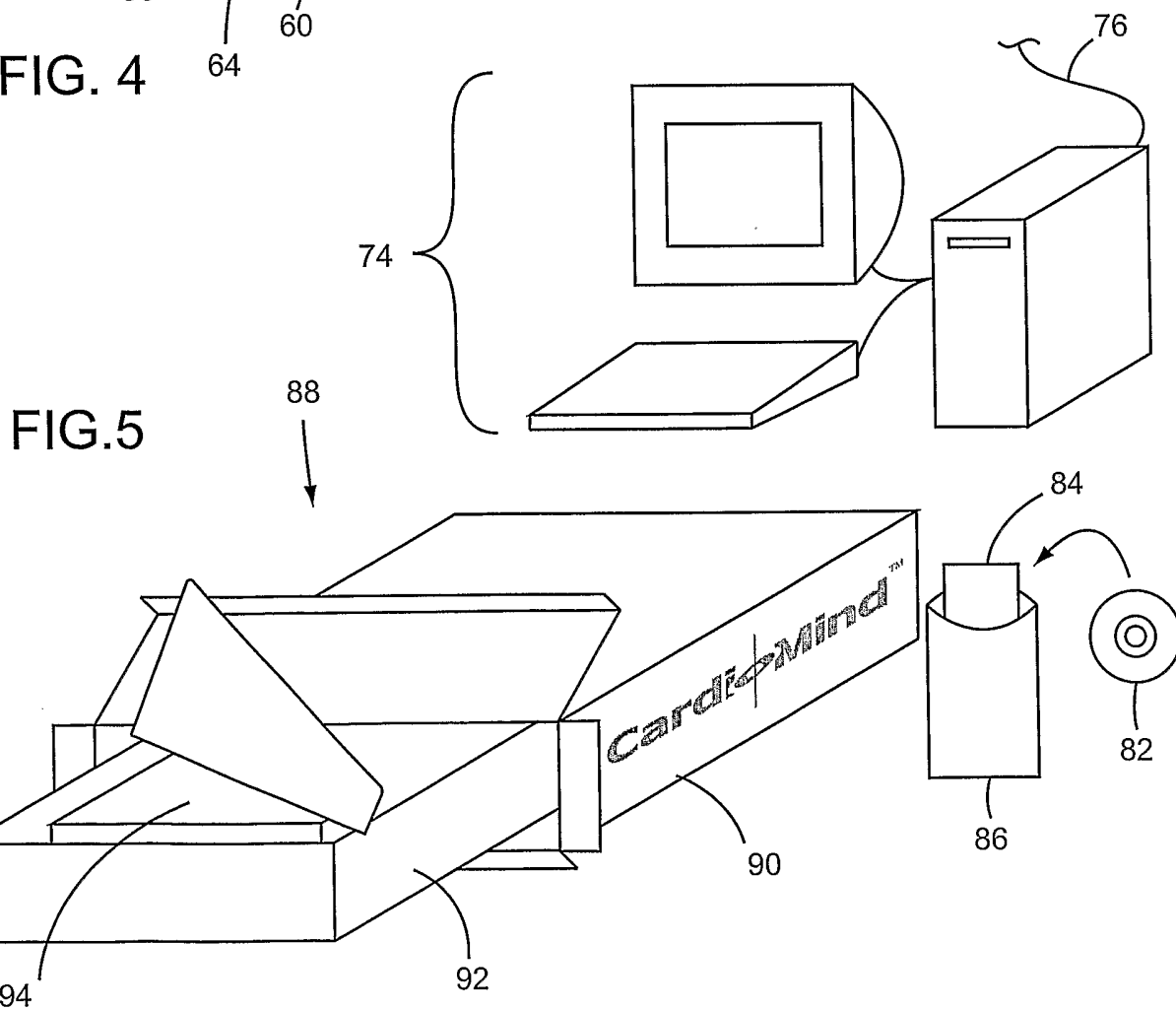
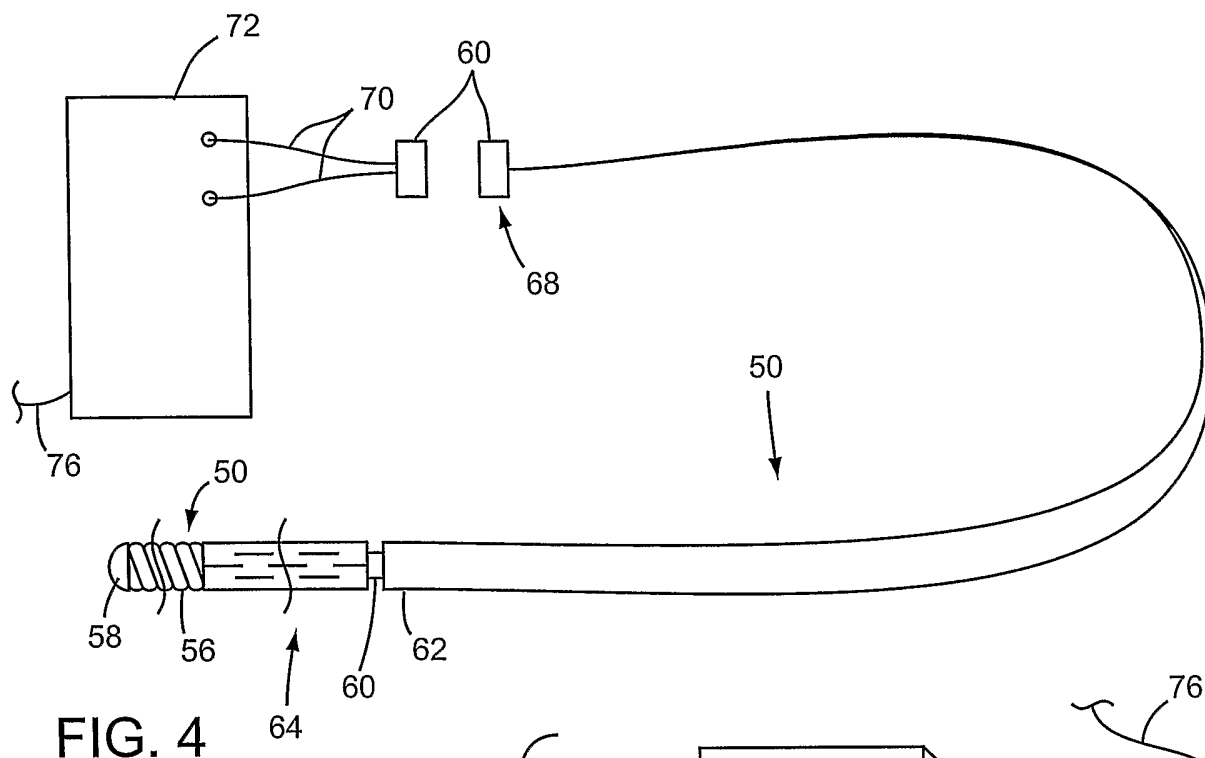


FIG. 3L



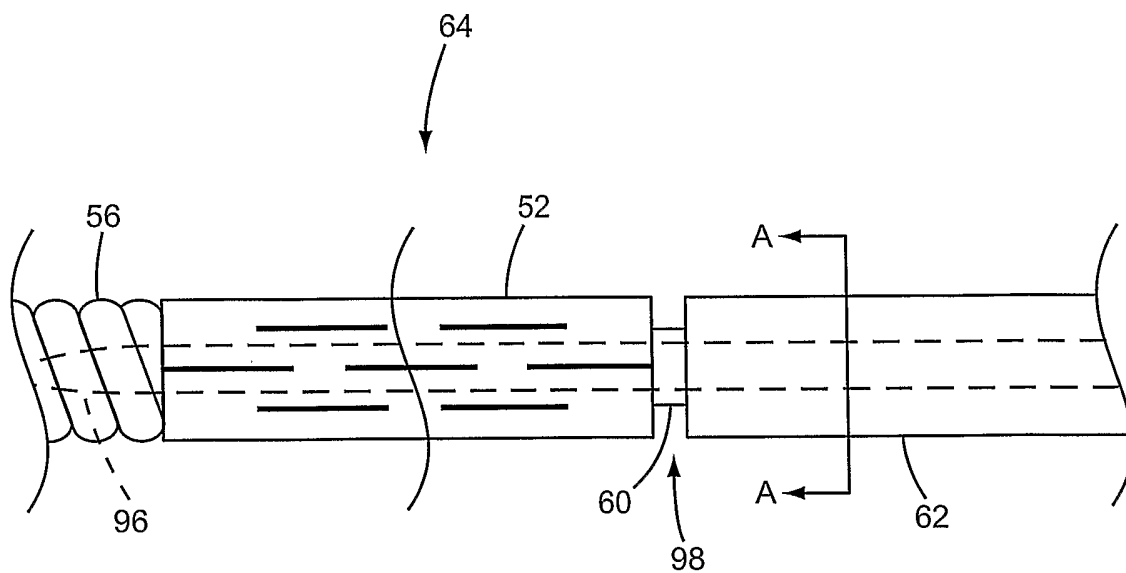


FIG. 6

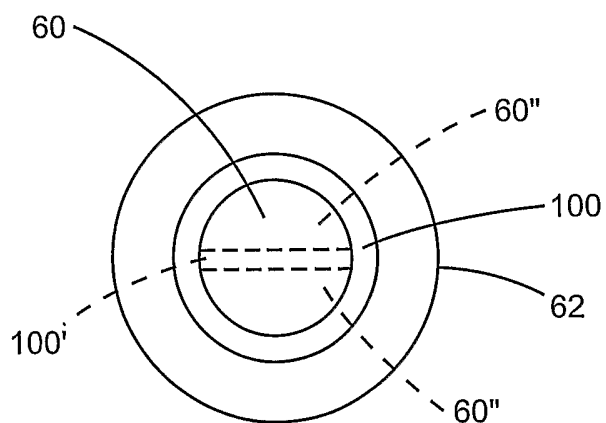


FIG. 7

SECTION A - A

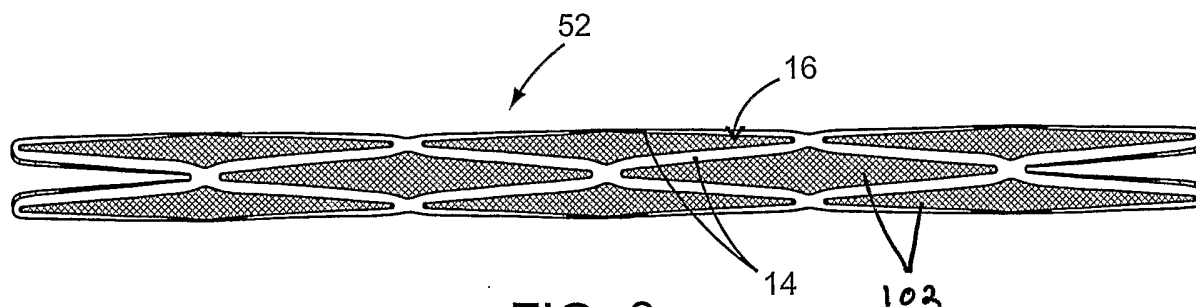


FIG. 8

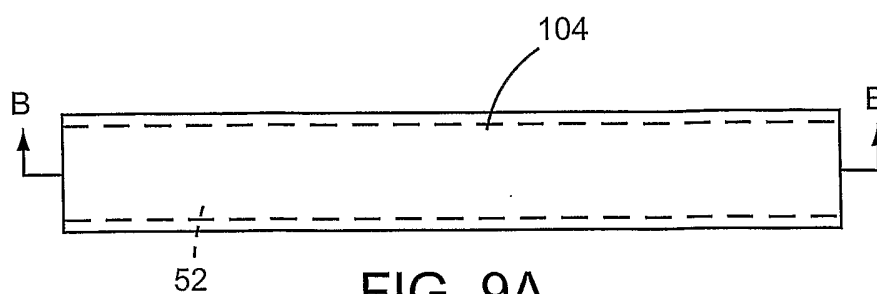


FIG. 9A

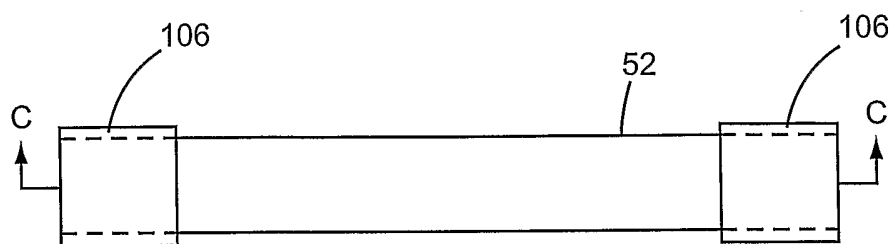


FIG. 9B

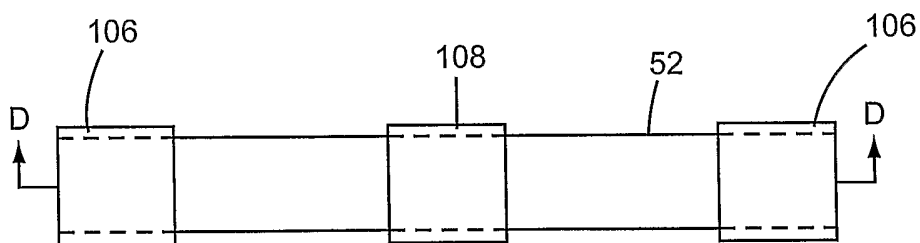


FIG. 9C

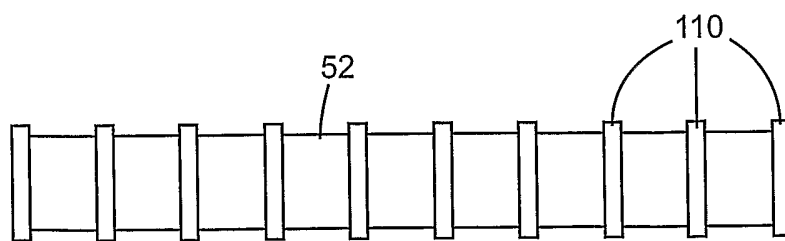


FIG. 9D

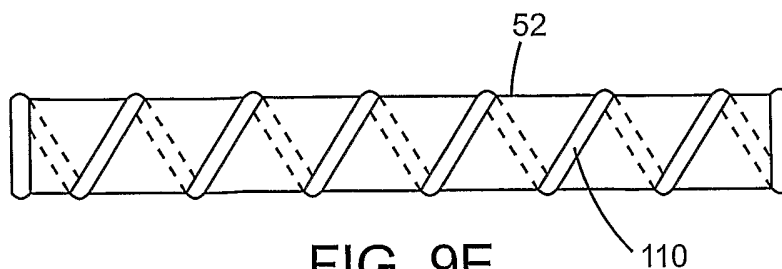
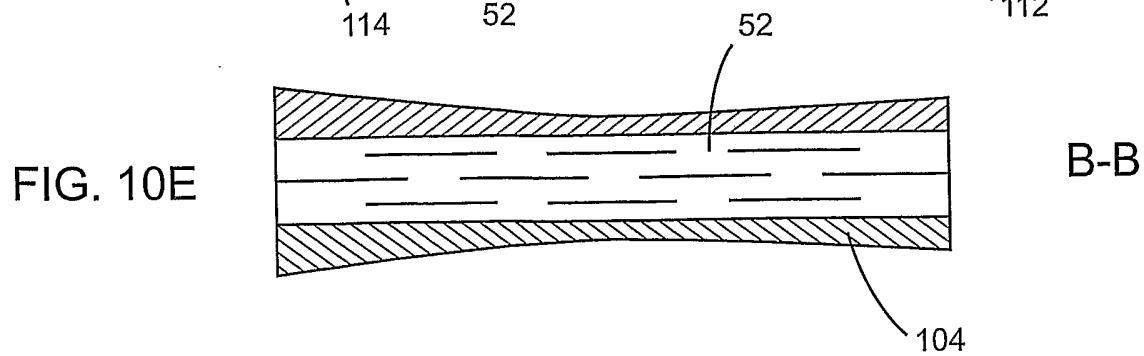
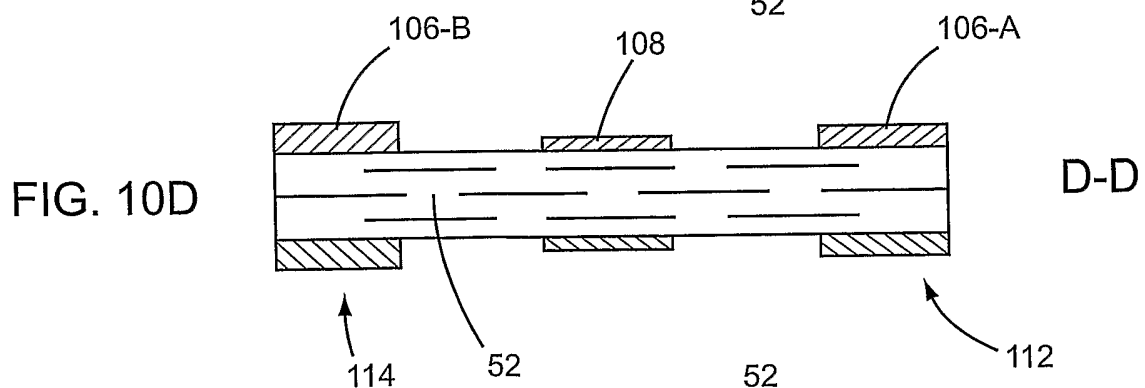
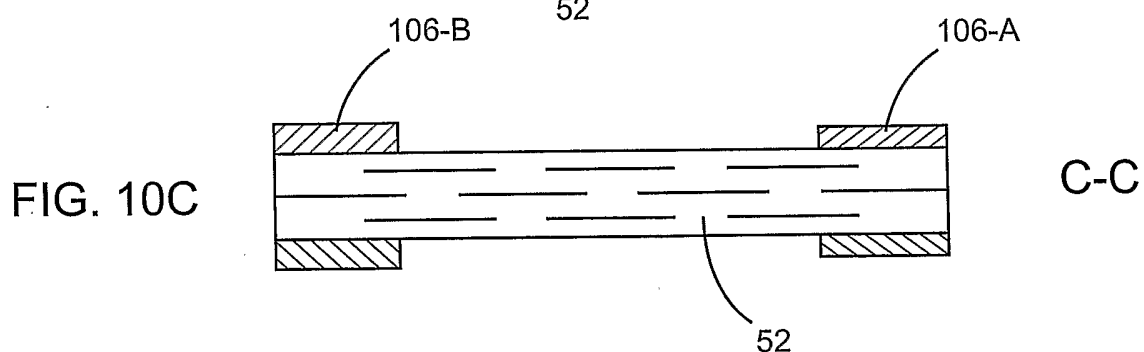
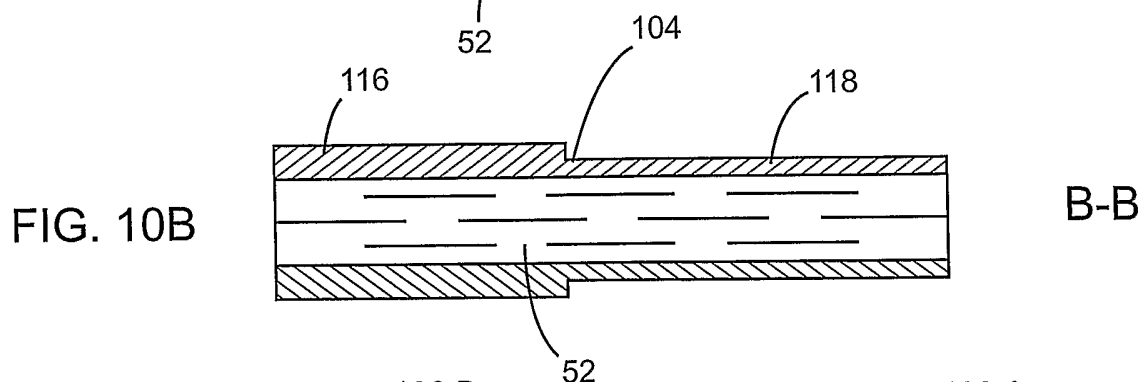
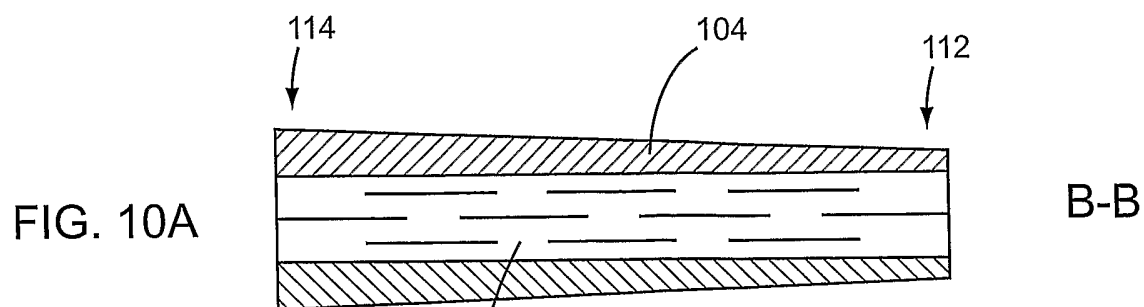


FIG. 9E



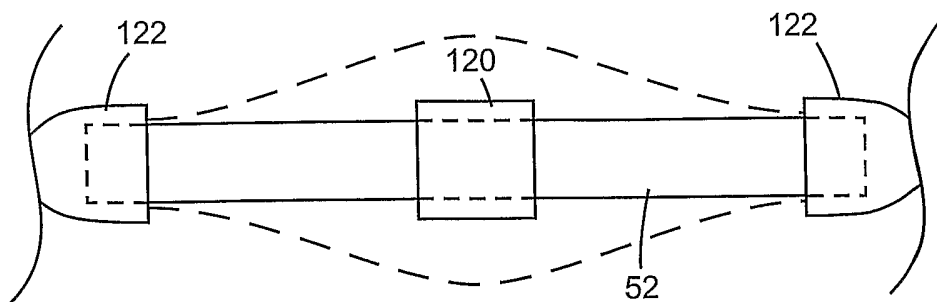


FIG. 11

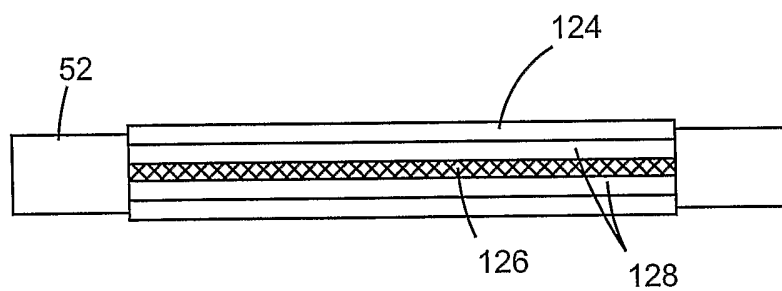


FIG. 12

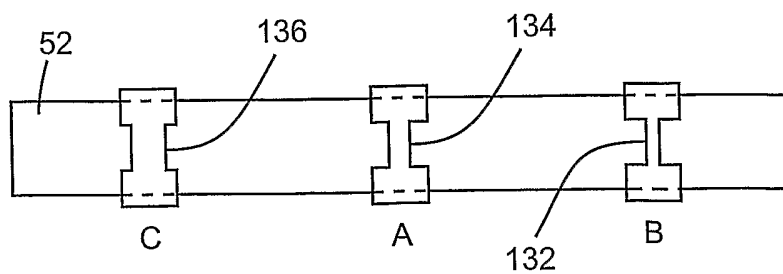


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/06386

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06

US CL : 623/1.11,1.15-1.22; 606/200.

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)

U.S. : 623/1.11,1.15-1.22; 606/200.

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 practicable, search terms used)
East

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,579,308 B1 (Janse et al.) 17 June 2003 (17.06.2003), Figs. 1-4; col. 2, lines 26-48; col. 5, lines 10-16.	1-2, 4-5, 9-12, 14, 17-18, 20, 30-36, 38 ----- 3, 6-8, 13, 15-16, 19, 21-29, 37, 39-44.



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:		"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier application or patent published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search

15 March 2005 (15.03.2005)

Date of mailing of the international search report

05 APR 2005

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